Comparative Effectiveness Review
Number 183

Tonsillectomy for Obstructive Sleep-Disordered Breathing or Recurrent Throat Infection in Children

AHRQ
Agency for Healthcare Research and Quality

Effective Health Care Program

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Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 290-2015-00003-I

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AHRQ Publication No. 16(17)-EHC042-EF
January 2017

This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00003-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Suggested citation: Francis DO, Chinnadurai S, Sathe NA, Morad A, Jordan AK, Krishnaswami S, Fonnesbeck C, McPheeters ML. Tonsillectomy for Obstructive Sleep-Disordered Breathing or Recurrent Throat Infection in Children. Comparative Effectiveness Review No. 183. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2015-00003-I.) AHRQ Publication No. 16(17)-EHC042-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2017. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officers named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Ms. Jessica Kimber was an invaluable resource for assistance with data extraction and checking, and helped to locate studies and track data. Ms. Katie Worley assisted with data extraction and developing tables, and Ms. Sanura Latham helped with data entry and extraction. Drs. Mamata Raj and Jeff Andrews assisted with screening studies and risk of bias assessment. We sincerely appreciate their dedicated work and the input of our Task Order Officers and Associate Editor, Key Informants, and Technical Experts.

Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who provided input to this report follows:

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Tonsillectomy for Obstructive Sleep-Disordered Breathing or Recurrent Throat Infection in Children

Structured Abstract

Objectives. To systematically review evidence addressing tonsillectomy in children with obstructive sleep-disordered breathing (OSDB) or recurrent throat infections.

Data sources. Multiple databases from January 1980 through June 2016.

Review methods. We included comparative studies of tonsillectomy, perioperative medications to improve outcomes, and postoperative medications for pain. We also included case series and database studies with ≥1,000 children to address harms. Two investigators independently screened studies and rated risk of bias. We extracted and summarized data qualitatively and quantitatively via Bayesian meta-analyses. We also assessed strength of the evidence (SOE).

Results. We identified 218 unique studies (141 randomized controlled trials [RCTs], 12 nonrandomized trials, 7 prospective and 5 retrospective cohort studies, and 53 database or registry studies or case series [67 low, 110 moderate, and 41 high risk of bias]). Populations; surgical approaches; anesthetic, analgesic, and antiemetic regimens varied across studies. For children with OSDB, most studies reported better sleep-related outcomes in those who had a tonsillectomy versus no surgery. For children with recurrent throat infections, tonsillectomy improved the number of infections, associated utilization (clinician visits), and work/school absences in the first postsurgical year. These benefits did not persist over time, however, and longer term outcomes are limited. Partial tonsillectomy was associated with faster return to normal diet or activity versus total tonsillectomy but also with a risk of tonsillar regrowth requiring reoperation. Commonly used "hot" techniques were generally associated with faster return to normal diet and activity than was cold dissection. In meta-analyses, frequency of post-tonsillectomy hemorrhage (PTH) was less than 4 percent, and frequency of bleeding-associated revisits or reoperations was less than 8 percent. Meta-analysis of nine RCTs reporting bleeding associated with perioperative dexamethasone compared with placebo did not indicate a significantly increased risk of bleeding with steroids, although confidence bounds were wide. Studies of perioperative medications were heterogeneous, but dexamethasone was consistently associated with less need for rescue analgesia than placebo. Preemptive perioperative 5-hydroxytryptamine (5-HT) antiemetics were associated with less need for postoperative antiemetics than placebo. Few studies of postoperative medications addressed the same agents or outcomes.

Conclusions. Tonsillectomy can produce short-term improvement in sleep outcomes compared with no surgery in children with OSDB (moderate SOE). In children with recurrent throat infections undergoing tonsillectomy, number of throat infections (moderate SOE) and associated health care utilization and work/school absences (low SOE) improved in the first postsurgical year. These benefits did not persist, and data on longer term results are lacking. Short-term improvements must be weighed against the risk of PTH (high SOE for low frequency of PTH). Surgical technique had little bearing on return to normal diet or activity (low SOE). Perioperative

dexamethasone and pre-emptive 5-HT receptor antagonist antiemetics reduced the need for additional analgesics or antiemetics (low SOE). Dexamethasone did not increase risk of PTH compared with placebo, but estimates had wide confidence bounds (low SOE). Little evidence addressed the use of postoperative medications for pain-related outcomes (insufficient SOE).

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Executive Summary

Introduction

Tonsillectomy or adenotonsillectomy ("tonsillectomy") represent more than 15 percent of all surgical procedures in children under the age of 15 years.[1, 2] The primary indication for tonsillectomy has shifted over the last 20 years from recurrent throat infections to obstructive sleep-disordered breathing (OSDB) and obstructive sleep apnea (OSA).[3, 4] Widely variable national and small area tonsillectomy rates are well-documented. In their seminal study, Wennberg and Gittlesohn found rates of tonsillectomy varied almost 12-fold across adjacent counties in rural Vermont with similar populations.[5] Variation in rates continue despite improved evidence and dissemination about indications.[1]

Indications for Tonsillectomy

Tonsillectomy has two primary indications: recurrent tonsillitis and OSDB recurrent or severe tonsillitis has been defined as seven or more episodes of sore throat in the preceding year OR five or more episodes in the each of the preceding 2 years OR 3 or more episodes in each of the preceding 3 years.[6] No gold standard diagnostic test exists to etiologically implicate or predictably attribute symptoms to tonsillitis. In fact, consensus is lacking on what symptoms attributable to tonsillitis are considered "disabling." Surrogates often used for tonsillitis include sore throat and pharyngitis. However, the degree to which either of these terms reflects true tonsillitis is not known. Bacterial pharyngitis can be diagnosed via rapid testing or culture. It is not possible, however, to determine whether the tonsil represents the infectious nidus or whether the suspected pathogen represents normal bacterial flora for a particular child's pharynx.

Currently, the most common indication for tonsillectomy is OSDB (i.e., breathing difficulties during sleep including OSA and upper airway resistance syndrome [UARS]). OSDB results from obstruction from or dynamic collapse due to upper airway soft tissue during sleep resulting in snoring, hypopnea, apnea, and restless sleep. Adenotonsillar hypertrophy can cause oropharyngeal crowding, thereby increasing the likelihood of symptomatic airway collapse during sleep. OSDB includes disorders ranging from simple snoring to OSA and can result in significant effects on quality of life and health consequences. It has been associated with a five-point decrease in IQ, hypersomnolence, emotional lability, decreased attention, small stature, enuresis, cardiopulmonary morbidity, and missed school.[7] Evidence of the relationship is reinforced by the effectiveness of OSDB treatment in improving behavior, attention, quality of life, neurocognitive functioning, enuresis, parasomnias, and restless sleep, and reversal of associated cardiovascular sequelae.[8, 9] Moreover, OSDB occurs at especially high rates in subsets of children with developmental disorders and craniofacial syndromes, including Down syndrome.

Key Decisional Dilemmas

Tonsillectomy is painful and is associated with odynophagia (painful swallowing) and dysphagia (difficulty swallowing) that can make it difficult to return to normal diet or stay hydrated, and can be associated with postoperative hemorrhage, nausea and vomiting. To help

minimize these concerns, clinicians may use perioperative antibiotics, steroids, antiemetics, and pain medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] and other analgesics).

Clinicians and parents need to know three key things: 1) what is the likelihood that the surgery (compared with watchful waiting with supportive care) will improve clinical outcomes around recurrent throat infections and sleep disorders; 2) what is the risk that the child will experience a harm, primarily post-tonsillectomy hemorrhage (PTH), with the surgery; and 3) if surgery is indicated, what approach, in terms of both surgical technique and perioperative medical care, has been demonstrated to optimize effectiveness and minimize harms? We address these questions by reviewing the comparative data for effectiveness on a specific set of outcomes and also searching a broader set of studies for harms data in order to estimate the frequency of the most common and most severe harms, namely PTH, readmission, and reoperation. The results from this report will be widely applicable; however, lack of consistently reported modifier data (e.g., body mass index [BMI], surgical indications) may limit its generalizability to every child.

Scope and Key Questions

Scope and Uses of the Review

The current review addresses the comparative effectiveness and harms of tonsillectomy in children with the most common indications for the procedure, namely, OSDB and recurrent throat infections. We targeted the review on these two key indications in order to maximize its utility for a broad population while maintaining a scope of work feasible for the systematic review. The review, nominated by the American Academy of Otolaryngology - Head & Neck Surgery Foundation, addresses key decisional dilemmas identified by stakeholders and through our preliminary scan of the literature in a comprehensive manner. The review also includes Key Questions (KQs) to improve understanding of outcomes in subgroups such as very young children (1-2 years old), children with Down syndrome, and those who are overweight or obese.

We anticipate this report will be of primary value to organizations that develop guidelines for tonsillectomy, to clinicians who provide care for children with indications for tonsillectomy, and for families making treatment decisions. Children who are candidates for tonsillectomy may be treated by clinicians including pediatricians, otolaryngologists, family physicians, nurses, nurse-practitioners, and physician assistants. This report supplies practitioners and researchers up-to-date information about the current state of evidence, and assesses the quality of studies that aim to determine the outcomes and safety of tonsillectomy.

Key Questions

We developed KQs in consultation with Key Informants and the Task Order Officer. KQs were posted for review to the Agency for Healthcare Research and Quality Effective Health Care Web site. We note that OSDB includes breathing difficulties during sleep as operationalized in each study, including OSA and UARS. As noted, tonsillectomy includes tonsillectomy, partial tonsillectomy, and adenotonsillectomy. We also note that comparative effectiveness includes both the benefits and harms of interventions.

Questions were as follows:

KQ1. In children with OSDB, what is the comparative effectiveness of tonsillectomy compared with continuous positive airway pressure (CPAP) or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1a. In children with OSDB and neuromuscular or craniofacial abnormalities, what is the comparative effectiveness of tonsillectomy compared with CPAP or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1b. In children with OSDB under age 3 years, what is the comparative effectiveness of tonsillectomy compared with watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1c. In children with OSDB and Down syndrome, what is the comparative effectiveness of tonsillectomy compared with CPAP or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1d. In children with OSDB who are overweight or obese, what is the comparative effectiveness of tonsillectomy compared with CPAP, weight loss, or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ2. Among children with recurrent throat infections, what is the comparative effectiveness, including harms, of tonsillectomy compared with watchful waiting with supportive care (including pharmacologic—antibiotic or non-antibiotic—treatments) on the number and severity of throat infections, quality of life, and health care utilization?

KQ3. Do benefits and harms differ between partial tonsillectomy and total tonsillectomy?

KQ4. Do benefits and harms differ by surgical technique (e.g., cautery, coblation)?

KQ5. What are the benefits and harms of adjunctive perioperative (i.e., preoperative, intraoperative, or in postanesthesia care) pharmacologic agents intended to improve outcomes?

KQ6. What are the benefits and harms of postoperative (i.e., after discharge from postanesthesia care and up to 10 days postsurgery) pharmacologic agents intended to reduce pain-related outcomes?

Analytic Framework

The analytic frameworks illustrate the population, interventions, and outcomes that guided the literature search and synthesis (Appendix A of the main report). The frameworks depict the KQs within the context of population, intervention, comparator, outcomes, timing, and setting (PICOTS) parameters. In general, the figures illustrate how tonsillectomy may result in outcomes such as changes in sleep parameters, numbers of throat infections, quality of life, or health care utilization.

Methods

Literature Search Strategy

To ensure comprehensive retrieval of relevant studies of therapies for children undergoing tonsillectomy, we used three key databases: the MEDLINE® medical literature database via the PubMed® interface; EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid® interface; and the Cochrane Library. Search strategies for KQs applied a combination of controlled vocabulary (Medical Subject Headings [MeSH] and Emtree headings) to focus specifically on tonsillectomy and harms of interventions. We restricted literature searches for KQs to studies published from January 1980 to June 2016 to reflect current techniques for tonsillectomy and perioperative or postoperative medications.

We carried out hand searches of the reference lists of recent systematic reviews or meta-analyses of studies addressing pediatric tonsillectomy. The investigative team also scanned the reference lists of studies included after the full-text review phase for additional studies that potentially could meet our inclusion criteria.

Inclusion and Exclusion Criteria

Table A lists the inclusion/exclusion criteria we used based on our understanding of the literature, key informant and public comment during the topic refinement phase, input from the Technical Expert Panel, and established principles of systematic review methods. We used a best evidence approach to determine final inclusion of studies. That is, if evidence from randomized studies or those with low risk of bias was insufficient to address a KQ or specific outcomes, we considered evidence from observational literature as well as factors related to the relevance of studies to determine if the inclusion of additional studies was warranted.[10]

Table A. Inclusion criteria for studies of tonsillectomy

Category	Criteria
Population	• Children with OSDB age 3-18 years, inclusive (KQ1) • Children with neuromuscular or craniofacial abnormalities and OSDB age 3-18 years, inclusive (KQ1a) • Children under age 3 years with OSDB (KQ1b) • Children with Down syndrome OSDB age 3-18 years, inclusive (KQ1c) • Children with obesity or overweight and OSDB age 3-18 years, inclusive (KQ1d) • Children with recurrent throat infection age 3-18 years, inclusive (KQ2) • Children with OSDB or recurrent throat infection undergoing tonsillectomy age 3-18 years, inclusive (KQ 4-6)
Intervention	• Tonsillectomy, adenotonsillectomy, or tonsillotomy (partial removal of tonsil) using any surgical approach (e.g., coblation, laser, cold dissection) (KQ 1-6) • Perioperative (preoperative, intraoperative, and immediate postoperative [postanesthesia care] periods) NSAIDs, steroids, or antiemetics (KQ5) • Any postoperative (discharge from postanesthesia care to up to 10 days postsurgery) agent for pain (KQ6)
Design	• Effectiveness outcomes: Comparative studies (RCTs, prospective or retrospective cohort studies with comparison groups, nonrandomized trials, case-control studies) (KQ1-6) • Harms: Comparative studies (RCTs, prospective or retrospective cohort studies with comparison groups, nonrandomized trials, case-control studies), database or registry studies (harms of tonsillectomy), case series with at least 1000 participants (harms of tonsillectomy)
Other	• Original research (KQ1-6) • Publication language: English (KQ1-6) • Publication year: January 1980-June 2016 (KQ1-2) or January 2000-June 2016 (KQ3-6) • Reports one or more of the outcomes of interest • Sufficiently detailed methods and results to enable data extraction (KQ1-6) • Reports outcome data by target population or intervention (KQ1-KQ6)

Abbreviations: KQ = Key Question; NSAID = non-steroidal anti-inflammatory drug; OSDB = obstructive sleep-disordered breathing; RCT = randomized controlled trial

Study Selection

Two reviewers independently assessed each abstract. If one reviewer concluded that the article could be eligible to address a KQ based on the abstract, we retained it for review of the full text. Two reviewers independently assessed the full text of each included study potentially addressing a KQ, with any disagreements adjudicated by a senior reviewer.

Data Extraction and Synthesis

We extracted data from included studies into templates that recorded study design, descriptions of the study population (for applicability), description of the interventions, and baseline and outcome data on constructs of interest. Data were initially extracted by one team member and reviewed for accuracy by a second. Extracted data for KQs are available in the Systematic Review Data Repository (srdr.ahrq.gov).

We summarized data for KQs qualitatively using summary tables where meta-analyses were not possible. We used a best evidence approach and focused on lower risk of bias studies where they provided sufficient data to address a KQ.[10]

We identified sufficient data to address PTH and PTH-related readmissions or clinician visits using quantitative meta-analysis methods. We implemented a mixed-effects, arm-based meta-analysis to assess the influence of different surgical procedures as well as the effect of partial compared with total tonsillectomy on the occurrence of PTH outcomes following surgery. We

also conducted analyses to estimate the effects of including high risk of bias studies in the analyses. These analyses suggested no systematic effects of these studies; thus, we retained them. Appendix E of the main report contains a full description of the meta-analytic methods.

Risk-of-Bias Assessment of Individual Studies

We used separate tools appropriate for specific study designs to assess quality of individual studies meeting eligibility criteria for our KQs. We used prespecified questions (Table 4 in *Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions*[11]) appropriate to each study design to assess risk of bias of randomized controlled trials (RCTs) and observational studies and a tool adapted from questions outlined in the McMaster McHarms tool to assess reporting of harms.[12]

Two team members independently assessed each included study, with discrepancies resolved through discussion to reach consensus and/or adjudication by a senior reviewer. We then translated these ratings into standards for low, moderate, or high risk of bias, as described in the full report. Risk-of-bias ratings for each study are in Appendix F of the full report.

Strength of the Body of Evidence

Two senior investigators graded the strength of the evidence (SOE) for key intervention/outcome pairs using methods based on the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[13] We assessed the domains of study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown), directness (direct, indirect), precision (precise, imprecise), and reporting bias (detected, unsuspected). The full team reviewed the final strength of evidence designations. The possible grades were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.[14]

Applicability

We assessed the applicability of findings reported in the included literature addressing KQs to the general population of children who are candidates for tonsillectomy because of OSDB or recurrent throat infection by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include the indication for tonsillectomy, age at treatment, surgical technique, and population characteristics such as BMI, Down syndrome, or craniofacial abnormalities. Applicability tables for each intervention are in Appendix G of the full report.

Results

We identified 9608 nonduplicative titles or abstracts with potential relevance, with 1966 proceeding to full text review. We excluded 1725 studies at full text review. We included 218 unique studies (241 publications) in the review (see main report for all references). These 218 studies (reported in multiple publications) included 165 comparative studies (comprising 141 RCTs, 12 nonrandomized trials, seven prospective and five retrospective cohort studies) and 53 database or registry studies or case series with at least 1000 children. We used database and registry studies and case series for harms data only. We considered 67 studies to have low risk of bias, 110 to have moderate risk, and 41 to have high risk. We did not retain high risk of bias studies as part of the evidence for any KQ, except for in meta-analyses after sensitivity analyses showed that they had no systematic effects on outcomes.

KQ1. Effectiveness of Tonsillectomy Versus No Surgery for OSDB

We identified 13 unique studies addressing tonsillectomy in children with OSDB. Three RCTs, one nonrandomized trial, and four cohort studies had moderate risk of bias. Five cohort studies had high risk. Given the relatively few studies addressing this question, we retained retrospective studies as part of the evidence base.

Two RCTs, two prospective, and two retrospective cohort studies (all with moderate risk of bias) all reported improvement in the Apnea Hypopnea Index (AHI) in children after tonsillectomy compared with watchful waiting (without intervention or with supportive/medical management, excluding CPAP). Differences in AHI between tonsillectomy and watchful waiting groups were statistically significant in three studies and not significant in two. This benefit was consistent across age ranges (1-18 years), though data were most frequently available on children ages 4 to 12. Benefits seemed durable, with followup ranging from 6 months to 4 years. The watchful waiting groups also improved from baseline in three studies and worsened in two cohort studies.

We combined three studies reporting AHI outcomes in a fixed effects meta-analysis. We found a mean effect size of -4.81 (95% credible interval: -6.5 to -3.1), indicating an approximately 5-point improvement in obstructive symptoms in children receiving tonsillectomy compared with those not undergoing surgery. The clinical significance of this improvement is likely influenced by baseline disease severity and may be most obvious in children with mild or moderate OSDB (i.e., AHI scores of 1 to 10). Two RCTs, one nonrandomized trial, and one retrospective cohort (all with moderate risk of bias) used several different parent-reported quality measures to assess sleep quality outcomes, limiting the ability to compare effectiveness directly across studies, although better outcomes were consistently associated with tonsillectomy. In one RCT and one prospective and one retrospective cohort study (moderate risk of bias) evaluating behavioral outcomes (emotional lability, attention, aggression) again using different measures, outcomes were consistently better among children receiving tonsillectomy; in all studies reporting baseline data, scores on behavioral measures were not indicative of clinical concern. While children's behaviors improved in these studies, the clinical significance and magnitude of the improvement is not clear. Executive function measures did not differ among children receiving tonsillectomy or no surgery in one RCT and one prospective cohort study, both with moderate risk of bias. In studies reporting baseline scores, sleep quality and behavioral outcomes for children in the no surgery groups also moderately improved from baseline, with greater improvement in children who had tonsillectomy. Studies rarely reported other outcomes (e.g.,

utilization, cognitive outcomes).

One moderate risk of bias RCT compared tonsillectomy and CPAP. Children had concomitant Down syndrome or mucopolysaccharidoses. Children receiving tonsillectomy had improved AHI scores compared with children receiving CPAP, but group differences were not significant in this small study.

KQ1a. Effectiveness of Tonsillectomy for Children With OSDB and Neuromuscular or Craniofacial Abnormalities

One RCT (moderate risk of bias) compared the efficacy of tonsillectomy to immediate initiation of CPAP in children with Down syndrome and mucopolysaccharidoses who were diagnosed with obstructive sleep apnea by polysomnogram. As discussed above, both groups showed improvement in AHI at 6-month followup, with maintenance at 12-month followup (no significant group differences). One retrospective cohort study including 15 children with syndromic comorbidities reported no significant group differences in improvements in AHI in children with syndromic conditions.

KQ1b. Effectiveness of Tonsillectomy for Children With OSDB Under 3 Years of Age

Although several studies included children under 3, these data were not extractable from the aggregate data of the entire study population. We did not identify studies explicitly addressing this question.

KQ1c. Effectiveness of Tonsillectomy for Children With OSDB and Down Syndrome

As noted, few studies specifically reported analyses of children with Down syndrome. These studies are discussed in detail under KQ1a.

KQ1d. Effectiveness of Tonsillectomy for Children With OSDB and Obesity

One retrospective cohort study, including a mostly overweight/obese population with OSDB, reported a significant improvement in AHI in children who received tonsillectomy compared with those who did not; however, data were insufficient to suggest effect modification by obesity/overweight status in this single, small study. In another retrospective cohort including children with mild OSA, analysis of subgroups of obese children and those with syndromic comorbidities showed no significant benefit between groups in these populations.

KQ2. Effectiveness of Tonsillectomy Versus No Surgery for Recurrent Throat Infection

We identified ten unique studies addressing tonsillectomy specifically for recurrent throat infections. Four RCTs, one nonrandomized trial, and two retrospective cohort studies had moderate risk of bias, and one RCT and one prospective cohort study and nonrandomized trial had high risk of bias. Given the relatively few studies addressing this question, we retained retrospective studies as part of the evidence base. In all studies reporting baseline data, the

number of subsequent infections decreased from baseline in both groups, with significantly greater decreases in children who received tonsillectomy vs. no surgery/watchful waiting with supportive care in the short term (< 12 months).

Children who received tonsillectomy missed fewer days of school in the short-term compared to the non-surgery control group but differences diminished over time in two moderate risk of bias RCTs; no difference in school absences between groups was reported from a third moderate risk of bias trial. Three studies (two RCTs and one nonrandomized trial, all with moderate risk of bias) collected quality of life data, which were not markedly different between any of the study arms at the 24-month time point. Overall, comparative effectiveness assessment of tonsillectomy vs. no surgery to improve number of throat infections, associated health care utilization, and days of work/school missed shows a benefit in the first postsurgical year; benefits did not persist over time, and quality of life improved in both groups.

KQ3. Effectiveness of Partial Versus Total Tonsillectomy

We identified 22 unique studies (20 RCTs—5 with low, 11 with moderate, and 4 with high risk of bias—and 2 nonrandomized trials with high risk of bias) addressing partial tonsillectomy compared with total tonsillectomy. In addition to comparing partial with total tonsil removal, most studies (n=16) also compared surgical techniques including microdebrider, laser, coblation, and electrocautery partial tonsillectomy and cold dissection, coblation, and electrocautery total tonsillectomy. In studies comparing both extent of surgery and surgical techniques (e.g., partial coblation vs. total electrocautery), it is not possible to determine whether effects can be attributed to the technique or to the amount of tissue removed. Thus, except for studies that compared partial or total removal of the tonsils using the same technique (e.g., partial cold dissection vs. total cold dissection), we considered the comparison of interest broadly as partial vs. total tonsil removal. Studies defined "partial" tonsillectomy in varied ways or not explicitly.

Few studies reported the same outcomes, and few reported significant differences in any outcome between partial or total tonsil removal. Two RCTs (low and moderate risk of bias) that compare total and partial cold dissection found that children receiving partial tonsillectomy had significantly faster return to normal diet (~4 days earlier). Two small RCTs with low and moderate risk of bias addressed outcomes following partial vs. total coblation or electrocautery and reported only on return to usual diet or activity. In the coblation study, children in the partial tonsillectomy arm consumed a significantly greater percentage of normal diet and were engaged in a greater portion of normal activity than were children in the total tonsillectomy arm at all time points assessed. In the study of electrocautery tonsillectomy, differences in return to normal activity were not statistically significantly different between groups.

Eight studies with low or moderate risk of bias addressed partial vs. total tonsillectomy using different surgical techniques. In two studies, obstructive symptoms including snoring worsened in the short term in the partial tonsillectomy arm compared with total tonsillectomy, but differences between groups were not significant at longer-term followup (12 to 24 months) post-tonsillectomy. In a third RCT, no children in either group had snoring or apnea at 1 and 3 years postoperatively. In all six studies addressing return to normal diet, children receiving partial tonsillectomy had more favorable outcomes compared with those receiving total tonsillectomy; studies reported different measures to assess this outcome. As with diet, in five RCTs children undergoing partial tonsillectomy had a more favorable return to normal activity (roughly 1 to 4 days faster) than did children who had total tonsillectomy in (significant differences in two). In three of the four studies addressing throat infection, children who had partial tonsillectomy had

more throat infections (1 to 7 more infections, depending on time period) than did those in the total tonsillectomy arms, though differences were not statistically significant in three studies. Three studies addressed quality of life or behavioral outcomes with no significant group differences. Across all studies, 10 of an estimated 166 children (6%) had tonsillar regrowth after partial tonsillectomy. Of these, five ultimately underwent completion of total tonsillectomy as a revision surgery.

KQ4. Effectiveness of Surgical Techniques

We identified 59 unique studies (54 RCTs, 4 nonrandomized trials, and 1 prospective cohort study) comparing surgical techniques for tonsillectomy. Eighteen studies had low risk of bias, 28 had moderate risk, and 13 had high risk. Most studies reported harms data (see Harms of Tonsillectomy section below). Nineteen studies (17 RCTs and 2 nonrandomized trials)—eight with low and 11 with moderate risk of bias—reported on return to normal diet or activity, the only usable effectiveness outcomes reported. Five RCTs and one nonrandomized trial compared coblation and cold dissection tonsillectomy. Across these small, short-term studies, coblation tonsillectomy was generally associated with faster return to normal diet or activity (roughly 1 to 4 days). Four studies reported on return to normal diet, with faster return associated with coblation in two studies and no significant group differences in two studies. Return to normal activity occurred significantly earlier after coblation in three low risk of bias studies.

Electrocautery was generally associated with more favorable results in three small RCTs comparing it with cold dissection. Two studies reported more favorable results associated with electrocautery, whereas results did not differ in the third. Return to activity was significantly faster in the electrocautery arm in one study, but no different in two others.

Four RCTs with moderate risk of bias compared coblation and electrocautery tonsillectomy with mixed results. Children undergoing coblation returned to normal diet more quickly than children undergoing electrocautery tonsillectomy in two studies, but recovery time did not differ significantly between groups in two other trials. Children undergoing coblation also returned to normal activity roughly 2 days more quickly than those receiving electrocautery in two studies.

Three RCTs with moderate risk of bias evaluated tonsillectomy with a harmonic scalpel (which uses ultrasonic frequency to cut and cauterize tissue) compared with electrocautery, coblation, or cold dissection. Studies compared different measures of recovery, thus limiting our ability to draw conclusions about differences in effectiveness, though patients treated with harmonic scalpel recovered more quickly in all studies. Only two small RCTs addressed laser tonsillectomy or thermal welding tonsillectomy and did not provide sufficient data to draw conclusions about effectiveness compared with more standard techniques.

Harms of Tonsillectomy

To account fully for potential harms of tonsillectomy, primarily PTH and readmission and reoperation, we compiled all comparative studies and examined frequency of harms by arm, then reviewed additional case series and database studies not included in the effectiveness analysis. We considered PTH to comprise any report of post-tonsillectomy bleeding, including the entire range of bleeding as reported in each study, from bloody sputum to frank bleeding requiring readmission or reoperation. We did not assess harms separately by indication because there is no reason to expect that they would differ; therefore, we do not separate them into the KQ1 through KQ4 results sections but combine surgical harms here.

We present the data obtained from comparative studies that had low or moderate risk of bias followed by that of the case series and database studies and comment on their consistency. Finally, we conducted a Bayesian meta-analysis to estimate predicted frequency of primary PTH, secondary PTH, reoperation and readmission by partial and total tonsillectomy, and by surgical approach.

Unadjusted frequency of harms reported in comparative studies. One-hundred and four comparative studies of low or moderate risk of bias reported harms data. The 6299 children across studies who were treated with total tonsillectomy experienced 265 episodes (4.2%) of PTH. Sixty-eight children required reoperation to control PTH (2.2%), and 80 had nonoperative revisits or readmissions for PTH (3.0%) Children undergoing tonsillectomy with harmonic scalpel had the highest frequency of PTH (11.3%), although few children underwent this procedure (n=397). Few children also had laser tonsillectomy (n=189), with 5.3 percent experiencing PTH. Frequencies were similar among techniques that are more commonly used: cold dissection=3.8 percent; electrocautery=4.9 percent; and coblation=3.3 percent. Frequency of revisits and reoperations overall were typically less than 6 percent. Frequency of revisits or readmissions for postoperative nausea and vomiting, pain, or dehydration ranged from 0 to 17 percent across techniques used for total tonsillectomy; laser tonsillectomy was associated with the highest frequencies.

PTH did not exceed 5 percent among the 18 study arms contributing data to asses bleeding in partial tonsillectomy. The frequency was highest for coblation partial tonsillectomy (4.2%). No PTH was associated with laser approaches, but few studies assessed this modality. Frequency of readmissions/revisits or reoperation were 1.8 percent and 0.64 percent across all types of techniques. Only three studies of partial tonsillectomy reported revisits for pain, dehydration, or postoperative nausea and vomiting. No children required readmission for dehydration in a single coblation study while 2.5 percent of children in studies of microdebrider had revisits for dehydration. No children in these microdebrider studies had revisits for pain.

Other harms reported in studies of total or partial tonsillectomy were largely minor and included burns or unspecified breathing complications. No comparative study reported deaths.

Meta-analysis of PTH-related data. Seventy studies evaluating partial or total tonsillectomy contributed data to the meta-analysis (63 RCTs, 6 nonrandomized trials, and 1 prospective cohort study). Twenty-two studies had low risk of bias; 36 had moderate risk; and 12 had high risk. In sensitivity analyses, high risk of bias studies did not affect findings, so we included them in final analyses (Table B). Frequency of primary PTH associated with total tonsillectomy in the meta-analyses were consistently at or below 5 percent and with overlapping confidence bounds. Electrocautery and harmonic scalpel were associated with the highest frequencies of secondary PTH (occurring >24 hours postprocedure), with estimates of 4.2 to 4.3 percent and wide 95% Bayesian credible intervals. Frequency of readmission related to PTH ranged from 0.2 percent to 6 percent. Although laser tonsillectomy was associated with the highest estimated risk of readmission, the confidence bounds were very wide. Primary PTH associated with partial tonsillectomy was predicted to be below 4 percent regardless of technique, and secondary PTH below 3 percent. Data on PTH-related readmissions and reoperations were sparse; thus confidence bounds are wide, and it is difficult to predict frequency with any certainty.

Table B. Frequency of PTH and PTH-associated readmissions or revisits after tonsillectomy: percent (95% BCI)

	Technique	Primary PTH	Secondary PTH	Nonoperative Readmission	Reoperation
Total Tonsillectomy	Cold	0.7 (0.1 to 1.5)	3.3 (1.9 to 5.3)	2.7 (0.7 to 4.9)	1.3 (0.5 to 2.1)
	Electrocautery	0.6 (0 to 1.5)	4.2 (2.4 to 6.5)	2.9 (0.7 to 5.3)	1.2 (0.5 to 1.9)
	Coblation	1.1 (0 to 3.0)	2.3 (0.7 to 4.4)	1.4 (0.1 to 3.3)	1.2 (0.3 to 2.4)
	Harmonic Scalpel	1.0 (0 to 3.3)	4.3 (1.8 to 7)	1.5 (0.2 to 3.1)	3.9 (1.6 to 6.9)
	Laser	2.2 (1.0 to 5.8)	1.2 (0 to 3.4)	5.7 (0.7 to 12.6)	5.2 (0.2 to 13.7)
	Molecular Resonance	0.6 (0 to 2.5)	1.1 (0.2 to 2.4)	0.2 (0 to 0.6)	0.2 (0 to 0.5)
	Thermal Welding	0.5 (0 to 2.1)	3.6 (0.5 to 7.5)	2.7 (0 to 12.7)	0.8 (0 to 2.4)
Partial Tonsillectomy	Cold	1.5 (0 to 4.7)	2.3 (1 to 5.9)	3.7 (0.1 to 10.3)	0.5 (0 to 1.3)
	Electrocautery	1.5 (0 to 5.3)	3 (0.2 to 8)	4 (0.2 to 12.3)	0.4 (0 to 1.2)
	Coblation	1.5 (0.1 to 4.2)	1.4 (1 to 3.5)	1.4 (0.1 to 3.1)	0.4 (0 to 1.1)
	Harmonic Scalpel	2.2 (0 to 8.3)	3 (1 to 7.9)	2.1 (0 to 6.3)	1.4 (0 to 3.9)
	Laser	3.9 (0 to 12.9)	0.7 (0 to 2.4)	7.3 (0.2 to 20.7)	1.8 (0 to 5.4)
	Molecular Resonance	1.4 (0 to 6)	0.8 (0 to 2.3)	0.3 (0 to 1)	0.1 (0 to 2)
	Thermal Welding	1 (0 to 4.5)	2.6 (0 to 7.7)	3.4 (0 to 17)	0.3 (0 to 1)

BCI = Bayesian credible interval; PTH = post-tonsillectomy hemorrhage

Unadjusted frequency of harms in case series and database studies. Fifty-three studies addressed harms (19 low risk of bias, 27 moderate, and 7 high [not included in analyses]). Overall, 2.1 percent of children in case series experienced a PTH episode. Few children required readmission or reoperation for PTH (0.41% to 0.72%). Few cases of revisits for pain, dehydration, or postoperative nausea and vomiting (frequency ranging from 1% to 7%) were reported in the 11 studies reporting these data.

At least four deaths were reported across four case series or database studies reporting mortality. Deaths, when cause was reported, were attributed to continued bleeding and suspected ventricular fibrillation. One study compared tonsillectomy complications occurring in different hospital types (teaching or non-teaching children's hospitals, nonteaching hospitals); in each hospital type ≤10 deaths occurred, but the study did not report specific numbers. Another study reported two deaths (out of 36,221 tonsillectomies, 0.006%) but did not report cause of death. Other harms reported in these studies were disparate and typically not clinically significant.

KQ5. Effectiveness of Perioperative Medications To Improve Outcomes

Forty-nine studies (48 RCTs—23 low, 21 moderate, and 4 high risk of bias—and one nonrandomized trial with high risk of bias) evaluated the use of perioperative NSAIDs, steroids, or antiemetics. Most studies reported on time to resume normal diet or activity or need for

rescue medications, which we defined as the need for additional or higher doses of pain medications or antiemetics beyond those given as part of the standard surgical protocol. Doses, routes of administration, combinations of agents, and comparators differed across studies. Followup was limited to <7 days postprocedure, with most studies reporting outcomes in the immediate postoperative period (postanaesthesia care unit and up to 24 hours).

NSAIDs. Fourteen RCTs evaluated NSAIDs. In two studies of diclofenac, postoperative consumption of opioids was significantly lower in diclofenac groups compared with placebo, but analgesics typically did not differ between groups in three trials comparing diclofenac and other analgesics or diclofenac in combination with other agents and placebo. Analgesic needs typically did not differ by group in three studies comparing perioperative ibuprofen (with or without other agents) and placebo or other analgesics. In two studies comparing ketoprofen and including a placebo arm, results were mixed, with significantly lower analgesic needs associated with ketoprofen in one and no group differences in another. Lornoxicam and ketorolac, each addressed in a single study, both reported no differences in analgesic use between these agents and comparators (placebo, fentanyl).

A single moderate risk of bias study evaluating effectiveness of peritonsillar bupivacaine infiltration vs. diclofenac suppository reported no difference in antiemetic rescue use between arms. In two RCTs comparing diclofenac with or without other analgesics to lidocaine or placebo, time to normal activity or diet did not differ significantly between groups.

Six studies of NSAIDs reported six episodes of PTH in 277 treated children (2.2%). Three cases of PTH were associated with diclofenac, two with ibuprofen, and one with ketorolac. Two studies (one of ketorolac and one of lornoxicam) reported no cases of PTH.

Steroids. Eighteen RCTs and one nonrandomized trial evaluated steroids. Three of four trials of dexamethasone at escalating doses, or comparing escalating doses with placebo, or doses of dexamethasone compared with ondansetron or placebo showed no differences in postoperative analgesic requirements by dose. In one placebo controlled trial children who received dexamethasone required significantly less analgesia. Five of eight studies comparing intravenous (IV) dexamethasone and placebo found steroid treatment reduced postoperative analgesic requirements significantly. In four RCTs comparing IV dexamethasone and either IV methylprednisolone, oral gabapentin, IV acetaminophen, or IV ketamine, results varied. Two studies reported less use of analgesia associated with dexamethasone arms; one reported no differences between dexamethasone and methylprednisolone; and one reported no differences between dexamethasone and acetaminophen. Two studies comparing IV and infiltrated dexamethasone both found infiltrated dexamethasone reduced postoperative analgesic requirements significantly. Another study comparing dexamethasone infiltration, levobupivacaine infiltration, and placebo reported lower analgesic use in the dexamethasone arm compared with the other groups.

Two dose-escalation trials reported significantly reduced antiemetic use in groups treated with dexamethasone vs. placebo, and two of five RCTS comparing IV dexamethasone and placebo reported significantly reduced antiemetic use in children treated with dexamethasone. Other studies reported lower use of antiemetics associated with dexamethasone vs. analgesic infiltration; no differences noted comparing dexamethasone and methylprednisolone; and less need for antiemetics with combination dexamethasone and ketamine or dexamethasone alone than placebo. A single RCT comparing IV vs. infiltrated dexamethasone vs. placebo reported

significantly lower rescue antiemetic use in both steroid groups compared with placebo and no differences between active groups.

Two RCTs assessed whether steroids affected time to return to normal diet with favorable effects associated with steroids in one and no group differences in another. In one RCT, time to normal activity was improved in children treated with IV dexamethasone vs. no steroid.

Ten studies reported PTH or PTH-associated utilization (9 study arms addressing dexamethasone and one addressing methylprednisolone). Three steroid studies explicitly noted no PTH. In a meta-analysis of studies comparing dexamethasone and placebo, PTH and PTH-associated reoperation or readmission were each nominally ≥ 1, with wide 95% credible intervals. The wide intervals prohibit firm conclusions about the effects of dexamethasone on PTH. The overall frequency of PTH associated with steroids was 4.7 percent, with frequencies of revisits/readmissions or reoperation for hemostasis below 2 percent. Few studies evaluating perioperative agents reported any revisits for non-PTH indications.

Antiemetics. Six RCTs evaluated the effect of perioperative antiemetic use on post-tonsillectomy analgesic requirements. All studies evaluated 5-hydroxytryptamine (5-HT) receptor antagonists including ramosetron, granisetron, ondansetron, and dolasetron. Antiemetic medications did not have any effect on pain control in any trial. Pre-emptive use of 5-HT receptor antagonists reduced the need for immediate postoperative antiemetic use compared with placebo in three RCTs.

KQ6. Effectiveness of Postoperative Medications To Reduce Pain-Related Outcomes After Tonsillectomy

Thirteen studies addressed postoperative medications for pain-related outcomes including 12 RCTs and 1 nonrandomized trial (4 studies with low, 6 with moderate, and 3 with high risk of bias). Study drugs included steroids (prednisolone), NSAIDs (diclofenac, ibuprofen, celecoxib, aspirin), non-NSAID analgesics (acetaminophen) and antibiotics (amoxicillin). Four trials reported effectiveness outcomes. In the trials comparing analgesics (celecoxib, acetaminophen with or without ibuprofen, ibuprofen, diclofenac), the need for rescue medications typically did not differ among study groups; all trials assessing analgesia outcomes had short-term followup (24 to 48 hours postoperatively). Time to return to normal diet was significantly better for children receiving acetaminophen compared with diclofenac reported in one study, but no time differences were noted for children receiving acetaminophen with morphine or with ibuprofen in another study. Two studies of steroids reported no differences in return to normal diet and activity associated with steroid vs. no steroid over longer-term followup (≥5 days).

Discussion

Key Findings and Strength of Evidence

KQ1. Effectiveness of Tonsillectomy Versus No Surgery for OSDB

Relative to no intervention, most studies reported better sleep-related outcomes in children who had a tonsillectomy. In five studies that included children whose OSDB was confirmed with polysomnography, AHI scores were more improved in children receiving tonsillectomy than in those with no surgery (significant group differences in 3 studies). Meta-analysis of three studies

showed a 5-point improvement in AHI in children who underwent tonsillectomy compared with no surgery. Sleep-related quality of life and reduction in negative behaviors (e.g., anxiety, emotional lability) also improved more among children who had tonsillectomy, but the clinical significance of these changes is not clear. Changes in executive function were not significantly different. We did not find tonsillectomy to be superior to CPAP in the one RCT addressing this comparison, which included children with significant comorbidities.

Our confidence in these conclusions of greater improvement in AHI and negative behaviors with tonsillectomy vs. watchful waiting is low (low strength of evidence). We also found consistently greater improvement in sleep-related quality of life with tonsillectomy vs. watchful waiting and have greater confidence in this conclusion (moderate strength of evidence). We could not make conclusions about effects on executive function or IQ (insufficient strength of evidence). We could not make conclusions about outcomes following tonsillectomy compared with CPAP and in studies assessing outcomes in sub-populations such as children with Down syndrome (KQ1a-d) (insufficient strength of evidence).

KQ1a-d. Effectiveness of Tonsillectomy for Subpopulations of Children With OSDB

While studies may have included some children with craniofacial abnormalities, only a single, small RCT compared tonsillectomy with immediate initiation of CPAP in children with OSDB and concurrent Down syndrome or mucopolysaccharidoses and reported no significant group differences in AHI at 12 months. Another study reported no significant group differences in outcomes in analyses of a subset of children with syndromic comorbidities receiving tonsillectomy or watchful waiting. Two retrospective cohorts specifically evaluated overweight/obese populations with OSDB. One reported a significant decrease in AHI in children who received tonsillectomy compared with those who did not. The other study including children with mild OSA reported no significant differences in subgroup analysis of obese children. Similarly, while several studies included some children less than 3 years old, these data were not extractable from the aggregate study population data. We did not identify studies explicitly addressing this question.

We could not make conclusions about outcomes following tonsillectomy compared with CPAP and in studies assessing outcomes in sub-populations such as children with Down syndrome (insufficient strength of evidence). Table C outlines these findings.

Table C. Summary of evidence in studies addressing effectiveness of tonsillectomy in children with OSDB

Intervention and Comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence Grade	Findings
Tonsillectomy vs. no surgery in children with OSDB	Meta-analysis 2 RCT (456) 1 Prospective cohort (38) 2 Retrospective cohort (94)	Apnea Hypopnea Index	Low for greater improvement of Apnea Hypopnea Index with tonsillectomy compared with no surgery	Significant improvement in tonsillectomy vs. no surgery groups in 1 RCT and 2 retrospective cohort studies; no significant group differences in 1 RCT and 1 prospective cohort. In 3 studies, children in control arms improved from baseline. 4.8-point improvement in AHI in tonsillectomy arms in meta-analysis.
	2 RCT (456) 1 Retrospective cohort (32)	Sleep-related quality of life	Moderate SOE for modest improvement in sleep-related quality of life after tonsillectomy vs. no surgery	Significant improvements in tonsillectomy vs. no tonsillectomy groups on measures of sleep-related quality of life in 2 RCTs and 1 cohort study in the short term
	1 RCT (397) 1 Prospective cohort (38) 1 Retrospective cohort (32)	Behavioral outcomes	Low SOE for improvements in negative behaviors after tonsillectomy vs. no surgery	Significant improvements in tonsillectomy vs. no surgery in 1 RCT and 1 retrospective cohort; no significant differences in 1 prospective cohort; differences in measurement time frames across studies (7 months-4 years) and unclear clinical significance of changes
	1 Prospective cohort (38)	Cognitive changes (IQ)	Insufficient SOE	Insufficient evidence in one small study
	1 RCT (397) 1 Prospective cohort (38)	Executive function	Insufficient SOE	Differences in followup time and medium study limitations preclude conclusions
	1 RCT (397)	Cardiometabolic outcomes	Insufficient SOE	Insufficient evidence in only one RCT
Tonsillectomy vs. CPAP in children with OSDB	1 RCT (73)	Apnea Hypopnea Index, sleep-related quality of life	Insufficient SOE	Insufficient evidence in small study
Tonsillectomy vs. CPAP or watchful waiting in children with OSDB and craniofacial abnormalities	1 RCT (73)	Apnea Hypopnea Index, sleep-related quality of life	Insufficient SOE	Insufficient evidence in small study

Table C. Summary of evidence in studies addressing effectiveness of tonsillectomy in children with OSDB, continued

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
Tonsillectomy vs. CPAP or watchful waiting in children with OSDB & DS	1 RCT (73)	Apnea Hypopnea Index, sleep-related quality of life	Insufficient SOE	Insufficient evidence in small study
Tonsillectomy vs. no surgery in children with OSDB and obesity	1 Retrospective cohort (33)	Apnea Hypopnea Index	Insufficient SOE	Insufficient evidence in small study

CPAP = continuous positive airway pressure; DS = Down syndrome; Non-RCT = nonrandomized trial; OSDB = obstructive sleep-disordered breathing; SOE = strength of the evidence; RCT = randomized controlled trial

KQ2. Effectiveness of Tonsillectomy for Recurrent Throat Infection

Although studies assessed numbers of infections and several utilization measures, such as missed school in the short term, longer term results were rarely reported; studies that did report longer-term results suffered from high attrition and incomplete data. In addition, "throat infection" was not defined consistently across studies and rarely was bacterial infection confirmed. Overall, children undergoing tonsillectomy to improve number of throat infections, associated health care utilization (clinician visits or contacts), and days of work/school missed had improvements in these outcomes in the first postsurgical year compared with children not receiving surgery. These benefits did not persist over time, however, and data on the longer-term outcomes are limited. Quality of life outcomes improved regardless of surgery.

We have moderate confidence in the conclusion that tonsillectomy reduces throat infections or streptococcal infections in the short term (≤12 months) compared with no surgery (moderate strength of evidence). Compared with no surgery, tonsillectomy reduced utilization (clinician contacts), and missed school/work in the short term. We have low confidence in this conclusion (low strength of evidence). In the longer term (>12 months) we found no difference between groups in reduction in streptococcal infections. We have low confidence in this conclusion (low strength of evidence). We found no differences between groups in missed school/work or quality of life in the long term (>12 months) and have low confidence in this conclusion (low strength of evidence). We could not make a conclusion about effects of tonsillectomy on throat infections in the long term (>12 months) (insufficient strength of evidence). Only one study included children with less than 3 episodes of throat infection in the year prior to surgery; we could not make conclusions about outcomes (utilization) reported in this single study (insufficient strength of evidence). Table D outlines strength of evidence findings.

Table D. Summary of evidence in studies addressing effectiveness of tonsillectomy in children with recurrent throat infections

Intervention and Comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence Grade	Findings
Tonsillectomy vs. no surgery in children with ≥ 3 throat infections in year prior to study	4 RCT (761) 1 Non-RCT (303) 1 Retrospective cohort (290)	Throat infection	Moderate SOE for modest reduction in throat infection after tonsillectomy vs. no treatment in short-term (12 months)	Fewer throat infections in tonsillectomy arms in short-term
	3 RCT (260) 1 Non-RCT (138)	Throat infection	Insufficient SOE for reduction following tonsillectomy vs. no surgery over longer term (>12 months)	Insufficient data based on lack of long-term data and high attrition rates in studies
	2 RCT (273) 1 Retrospective cohort (290)	Streptococcal infection	Moderate SOE for reduction in streptococcal infection after tonsillectomy vs. no tonsillectomy in short term (≤12 months)	Fewer streptococcal infections in tonsillectomy arms in short-term
	2 RCT (203) 1 Retrospective cohort (290)	Streptococcal infection	Low SOE for no difference in reduction in streptococcal infection after tonsillectomy vs.no surgery over longer term (2-3 years)	Similar proportion of infections in retrospective cohort and significantly more infections in nonsurgical groups in 2 RCTs
	1 Retrospective cohort (290)	Streptococcal infection	Insufficient SOE for no difference in effects after 4 years of followup	Insufficient evidence in one study
	1 RCT (231) 1 Non-RCT (303)	Utilization (clinician visits or contacts)	Low SOE for reduction in clinician visits or contacts after tonsillectomy vs. no surgery in short term (<12 months)	Fewer consultations in tonsillectomy arms vs. no surgery, but high loss to followup and differences in outcome assessment
	2 RCT (373) 1 Non-RCT (123)	Quality of life	Low SOE for no difference in quality of life after tonsillectomy vs. no tonsillectomy	Improvements in quality of life in both groups; high attrition in both studies
	3 RCT (503)	Missed school or work	Low SOE for greater improvements in missed school after tonsillectomy vs. no surgery in short term (≤ 12 months)	Significantly fewer missed days in tonsillectomy arms vs. no surgery in 2 RCTs with medium study limitations at 12 month followup; no differences in third RCT
	3 RCT (245)	Missed school or work	Low SOE for no difference in effects between in longer term (>12 months)	No significant differences between groups in all studies at longer-term followup; medium study limitations
Tonsillectomy vs. no surgery in children with < 3 throat infections in year prior to study	1 Retrospective cohort (13892)	Utilization	Insufficient SOE	Insufficient evidence in one study with medium limitations

Non-RCT = nonrandomized trial; RCT = randomized controlled trial; SOE = strength of the evidence

KQ3. Effectiveness of Partial Versus Total Tonsillectomy

Twenty-two studies compared partial to total tonsillectomy, but few compared partial and total using the same surgical technique. Three studies compared partial with total cold dissection and reported no differences other than a faster return to normal diet for partial tonsillectomy. Among those comparing partial and total coblation or partial and total electrocautery, return to normal diet and activity were more favorable in children undergoing partial coblation tonsillectomy compared with total. Group differences were not statistically significant in the electrocautery study.

Most studies evaluated partial vs. total tonsillectomy using differing surgical techniques. Our comparison of interest was "partial vs. total," although we cannot be certain that effects can confidently be attributed to the surgical technique rather than the amount of tissue removed. Differences between partial and total tonsillectomy were generally not significant for outcomes related to OSDB persistence, quality of life, or behavior in these studies.

In six studies, children in the partial tonsillectomy arms had faster resumption of normal diet and normal activity compared with those in the total tonsillectomy groups; however, these effects may be due to confounding by indication as surgical indication varied across studies. Across all studies, 10 of an estimated 166 children (6%) had tonsillar regrowth after partial tonsillectomy.

In studies comparing partial and total cold dissection tonsillectomy, return to normal diet was faster in children undergoing partial tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). We could not make conclusions about effects on return to normal activity, throat infections, or OSDB persistence in these studies (insufficient strength of evidence). In studies comparing either partial and total coblation tonsillectomy or partial and total electrocautery tonsillectomy, we could not make conclusions about effects on return to normal diet or activity (insufficient strength of evidence).

In studies comparing mixed techniques for partial or total tonsillectomy, return to normal diet and activity was more favorable in children undergoing partial versus total tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). These effects may be due to confounding by indication as indication varied across studies. We found no difference in effects on long-term (>12 months) persistence of OSDB symptoms, quality of life, behavioral outcomes, or throat infections between partial and total tonsillectomy. Our confidence in these conclusions is low (low strength of evidence). Table E outlines findings.

KQ4. Effectiveness of Surgical Techniques for Tonsillectomy

Only 19 studies identified for this KQ reported return to normal activity and/or diet outcomes. Commonly used "hot" techniques such as coblation and electrocautery were generally associated with faster return to normal diet or activity than was cold dissection (roughly 1 to 3 days). Few studies, typically addressing different measures and using different comparison techniques, addressed newer techniques such as thermal welding, laser, or harmonic scalpel, thus limiting our ability to draw conclusions about these approaches.

We found a speedier return to regular diet with coblation or electrocautery tonsillectomy compared with cold dissection and have low confidence in these conclusions (low strength of evidence). We could not make conclusions about effects associated with other techniques (insufficient strength of evidence). Table E outlines these findings.

Harms of Surgical Techniques

In meta-analyses, the frequency of primary and secondary PTH associated with total and partial tonsillectomy was below 4 percent for any technique and with overlapping confidence bounds. Pooled frequencies (without adjustment) of PTH were less than 5 percent overall (4.2% for total tonsillectomy; 1.5% for partial tonsillectomy) in comparative studies. Unadjusted frequencies of revisits for pain, dehydration, or postoperative nausea and vomiting were less than 5 percent overall. Other harms were disparate and generally not clinically significant (e.g., thermal burn from a cautery apparatus). No comparative studies reported deaths. The frequency of harms in case series and database or registry studies generally aligned with that in comparative studies. At least four deaths were reported in case series including 1,778,342 children.

We found a low frequency of PTH and utilization harms across surgical techniques and have confidence in these findings (high strength of evidence) (Table E). We found a low frequency of revisits or readmission for dehydration associated with partial tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). We have greater confidence in a low frequency of non-bleeding readmissions/revisits associated with total tonsillectomy (moderate strength of evidence). We could not draw conclusions about effects on admissions or revisits for pain or postoperative nausea and vomiting (PONV) associated with partial tonsillectomy given the few comparative studies addressing the outcome (insufficient strength of evidence).

Table E. Summary of evidence in studies addressing effectiveness and harms of tonsillectomy techniques

Intervention and Comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence Grade	Findings
Total vs. partial cold dissection tonsillectomy	2 RCT (131)	Return to normal diet	Low SOE for faster return to normal diet after partial vs. total tonsillectomy	Children undergoing partial tonsillectomy returned to normal diet approximately 4 days sooner than children undergoing total tonsillectomy according to parent report
	1 RCT (101)	Throat infection, OSDB persistence	Insufficient SOE	Insufficient data to assess effects on throat infections given single, small study
Partial vs. total coblation tonsillectomy	1 RCT (69)	Return to normal diet or activity	Insufficient SOE	Insufficient data to assess effects on return to normal diet or activity given single, small study
Partial vs. total electrocautery tonsillectomy	1 RCT (40)	Return to normal activity	Insufficient SOE	Insufficient data to assess effects on return to normal diet or activity given single, small study

Table E. Summary of evidence in studies addressing effectiveness and harms of tonsillectomy techniques, continued

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
Total vs. partial tonsillectomy (mixed techniques)	6 RCT (620)	Return to normal diet or activity	Low SOE for more favorable return to normal diet and activity in children undergoing partial vs. total tonsillectomy	Children undergoing partial vs. total tonsillectomy had consistently more favorable outcomes but unit of measure varied across studies (e.g., mean days, N children)
	3 RCT (214)	OSDB persistence	Low SOE for no difference in effects on long-term persistence of OSDB symptoms between partial and total tonsillectomy	More children undergoing partial vs. total tonsillectomy had short-term snoring or obstructive symptoms in 2 studies but no group differences in longer term in any study
	2 RCT (159)	Quality of Life (≥12 months post-tonsillectomy)	Low SOE for no long-term differences in quality of life after partial vs. total tonsillectomy	Improvements from baseline in both groups in 2 small studies, but no significant group differences in quality of life in either study
	2 RCT (159)	Behavioral Outcomes (≥12 months post-tonsillectomy)	Low SOE for no long-term differences in behavioral outcomes after partial vs. total tonsillectomy	Improvements from baseline in both groups on the Child Behavior Checklist in 2 small studies, but no significant group differences in either study
	4 RCT (296)	Throat Infections (≥12 months post-tonsillectomy)	Low SOE for no effect on throat infections following partial vs. total tonsillectomy	More throat infections or sore throats following partial vs. total tonsillectomy in 3 of 4 RCTs but no significant group differences
Total coblation vs. total cold dissection tonsillectomy	6 RCT (276)	Return to normal activity	Low SOE for faster return with coblation	Coblation, compared with cold dissection, associated with moderately faster return to normal activity in 4 small studies
	4 RCT (255)	Return to normal diet	Insufficient SOE	Insufficient data in small studies with medium limitations
Total electrocautery vs. total cold dissection tonsillectomy	3 RCT (254)	Return to normal diet	Low SOE for faster return with electrocautery	Electrocautery, compared with cold dissection, associated with faster return to normal diet in 2 studies and not significantly faster in a third
Other techniques for total tonsillectomy (laser, thermal welding, harmonic scalpel) vs. other technique	10 RCT (906) 1 Non-RCT (305)	Return to normal diet or activity	Insufficient SOE	Insufficient data in heterogenous, small studies evaluating different techniques and outcome measures

Table E. Summary of evidence in studies addressing effectiveness and harms of tonsillectomy techniques, continued

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
Partial tonsillectomy	Meta-analysis 16 RCT (1234)	PTH and PTH-associated utilization	High SOE for low frequency of PTH associated with partial tonsillectomy	Frequency did not exceed 4% for PTH; fewer data available to assess associated utilization, but rates are likely low given the low frequency of PTH
	3 RCT (221)	Readmissions/ revisits for dehydration	Low SOE for low frequency of dehydration revisits/readmissions associated with partial tonsillectomy	5 readmissions reported across 3 study arms
	3 RCT (221)	Readmissions for postoperative nausea and vomiting or pain	Insufficient SOE	Insufficient data in few studies
Total tonsillectomy	Meta-analysis 52 RCT (6293) 4 Non-RCT (478) 2 Cohort studies (350)	PTH and PTH-associated utilization	High SOE for low frequency associated with total tonsillectomy	Frequency of <5% of PTH and PTH-associated utilization in both meta-analysis and unadjusted analyses associated with commonly used techniques
	17 RCT (2269) 1 Prospective cohort (29) 1 Retrospective cohort (145)	Readmissions for pain, postoperative nausea and vomiting, dehydration	Moderate SOE for low frequency of non-PTH readmissions/revisits associated with total tonsillectomy	In 37 study arms, overall frequency of non-PTH revisits/readmissions was below 2%

Non-RCT = nonrandomized trial; OSDB = obstructive sleep-disordered breathing; PTH = post-tonsillectomy hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence

KQ5. Effectiveness of Adjunctive Perioperative Medications To Improve Outcomes After Tonsillectomy

Studies addressing this KQ were heterogeneous, addressing multiple agents, combinations of agents, routes of administration and dosage, timing of agents, and rescue medications provided. This heterogeneity limits our ability to draw conclusions about perioperative medications. We considered the strength of the evidence for the subset of studies with placebo comparisons. We considered the drug class (instead of individual agent such as diclofenac) in assessing strength of evidence for NSAIDs and antiemetics (Table F). All steroid studies addressed dexamethasone.

NSAIDs. We found a reduced need for analgesia with NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence). We found no difference in effects on return to normal diet or activity with perioperative NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence). We found a frequency of PTH of less than 6% and low associated utilization with perioperative NSAIDs. Our confidence

in this conclusion is low (low strength of evidence). We could not make conclusions about non-PTH related readmissions or revisits following NSAID use as few studies addressed these outcomes (insufficient strength of evidence).

Steroids. We found a reduced need for analgesics or antiemetics associated with steroids (IV or infiltrated dexamethasone) compared with placebo. Our confidence in this conclusion is low (low strength of evidence). Studies of steroids reported few cases of PTH and PTH-related utilization. We have moderate confidence that steroids are associated with a low frequency of PTH (moderate strength of evidence).

Meta-analysis of nine studies comparing steroids and placebo did not indicate a significantly increased risk of PTH with steroids vs. placebo; confidence bounds were wide for all estimates, and we have low confidence in this conclusion (low strength of evidence). We could not make conclusions about the effects of steroids on time to resume normal diet or activity, as the two small studies addressing the outcome reported inconsistent results, or on non-PTH-related readmissions or revisits as few studies reported these outcomes (insufficient strength of evidence).

Antiemetics. Data were consistent in terms of antiemetic medications. We found a reduced need for postoperative antiemetics in studies of perioperative antiemetics; our confidence in this conclusion is low (low strength of evidence). We found no effect of 5-HT perioperative antiemetics on postoperative analgesia requirements. We have moderate confidence in this conclusion (moderate strength of evidence).

KQ6. Effectiveness of Postoperative Medications for Pain After Tonsillectomy

Few studies addressed the same interventions and comparisons, and studies typically reported on need for rescue pain medication, PTH, and time to resume normal diet or activity as outcomes. Data on the effects of NSAIDs on need for rescue pain medication in the first 24 to 48 hours after surgery are conflicting, and no long-term data are available. Two studies compared prednisolone and placebo and found no effect on return to normal diet or activity.

PTH frequency overall was less than 10 percent. PTH in steroid and placebo arms in the two studies addressing that comparison were similar. The frequency of PTH in studies comparing NSAIDs (celecoxib, ibuprofen) and non-NSAID analgesics to placebo or other medications was also similar. In three study arms reporting use of NSAIDs, PTH occurred in 4.7 percent of children (n=32/679).

In studies of postoperative NSAIDs, we found a low frequency of PTH. Our confidence in this estimate is low (low strength of evidence). We could not make conclusions about the effects of postoperative analgesics on need for rescue medications; return to normal diet or activity; or PTH (insufficient strength of evidence).

In studies of postoperative steroids, we found no difference in effects on return to normal diet or activity between steroids and placebo. Our confidence in this conclusion is low (low strength of evidence). We also found no difference in effects on bleeding between postoperative steroids and placebo or no treatment. Our confidence in this conclusion is low (low strength of evidence). Table F outlines these findings.

Table F. Summary of evidence in studies addressing effectiveness and harms of perioperative or postoperative medications

Intervention and Comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence Grade	Findings
Perioperative NSAID vs. Placebo	2 RCT (180)	Return to normal diet and activity	Low SOE for no difference in return to normal diet or activity with NSAIDs vs. placebo	No significant group differences in 2 small studies with medium study limitations
	5 RCT (345)	Need for analgesics	Low SOE for reduced need for rescue analgesia with NSAIDs vs. placebo	Significantly less need in 4 small studies, no group differences in a 5th study
Perioperative NSAIDs	6 RCT (277)	PTH and PTH related admissions or revisits	Low SOE for low frequency of PTH or PTH-related revisits/readmissions associated with perioperative dexamethasone	Frequency of PTH or associated utilization <3% (unadjusted analyses) in 277 children receiving NSAIDs
	1 RCT (20)	Non-PTH readmissions or revisits	Insufficient SOE	Insufficient data in one small study
Perioperative dexamethasone vs. Placebo	10 RCT (979)	Need for rescue analgesic	Low SOE for reduction in analgesic need with dexamethasone vs. placebo	Significantly less need for analgesics after dexamethasone (IV or infiltration) vs. placebo in 7 small studies; no significant differences in 3 studies; inconsistency precludes higher SOE
	8 RCT (812)	Need for rescue antiemetic	Low SOE for reduction in antiemetic need with dexamethasone vs. placebo	Significantly less need for antiemetics after dexamethasone vs. placebo in 5 small studies; no significant differences in 3 studies; inconsistency precludes higher SOE
	2 RCT (354)	Return to normal diet or activity	Insufficient SOE	Insufficient data in 2 studies
	Meta-analysis	PTH and PTH-related revisits or reoperations	Low SOE for no increased risk of PTH with dexamethasone compared with placebo	Odds ratios ≥1 with wide credible intervals. SOE is low given imprecision of estimates
Perioperative dexamethasone	9 RCT (811)	PTH and PTH-related readmissions or revisits	Moderate SOE for low frequency of PTH or PTH-related revisits/readmissions associated with perioperative dexamethasone	Frequency of PTH or associated utilization <5% in 811 children receiving steroids
	4 RCT (279)	Non-PTH readmissions or revisits	Insufficient SOE	Few studies reported outcome

Table F. Summary of evidence in studies addressing effectiveness and harms of perioperative or postoperative medications, continued

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
Perioperative antiemetics	5 RCT (964)	Need for rescue analgesic	Moderate SOE for no effect of antiemetics (5-HT receptor antagonists)	No significant group differences in 5 RCTs comparing 5-HT antagonists with other antiemetics, other 5-HT antagonists, or placebo
	3 RCT (303)	Need for postoperative rescue antiemetic	Low SOE for reduced need for postoperative antiemetics with perioperative 5-HT antiemetics vs. placebo	Significantly less need for postoperative antiemetics in 3 small RCTs comparing 5-HT antagonists and placebo; imprecision precludes higher SOE
Postoperative prednisolone vs. Placebo	2 RCT (331)	Return to normal diet or activity in longer term (≥5 days)	Low SOE for no difference in effects of prednisolone vs. placebo on return to normal diet or activity	Number of children consuming normal diet or engaging in normal activity did not differ at 14 days post-tonsillectomy in one study; time to return to normal diet or activity did not differ in second small RCT
	2 RCT (331)	PTH	Low SOE for no difference in PTH associated with steroids vs. placebo/no treatment	Numbers of PTH in steroid and placebo arms were similar in 2 studies (13 PTH in steroid arms vs. 15 in placebo/no treatment)
Postoperative NSAIDs	2 RCT (564) 1 Non-RCT (115)	PTH	Low SOE for low frequency of PTH	Unadjusted frequency of 0-6% in 3 studies; higher frequency associated with celecoxib
Postoperative analgesics (NSAIDs, non-NSAID analgesics)	2 RCT (157)	Return to normal diet or activity	Insufficient SOE	Outcomes defined differently in 2 small studies
	3 RCT (500)	Need for rescue analgesics	Insufficient SOE	Studies compared different analgesics and different rescue medications

5-HT = 5- hydroxytryptamine; non-RCT = nonrandomized trial; NSAID = non-steroidal anti-inflammatory drug; PTH = post-tonsillectomy hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence

Applicability

Studies included in this review typically did not describe severity of indications of tonsillectomy and comorbidities for populations adequately, which makes applicability difficult to assess. As would be expected, studies addressing KQ1 (tonsillectomy in children with OSDB) and KQ2 (tonsillectomy in children with recurrent throat infection) specified surgical indication and generally provided greater characterization of study participants. Baseline severity of OSDB or throat infection varied across these studies as did definitions of "cure" or resolution of symptoms. Of note, the largest U.S.-based RCT addressing tonsillectomy vs. no surgery for children with OSDB included a majority African-American and majority overweight or obese population as did two additional studies addressing this comparison. Two other studies

addressing this comparison included a majority of children with Down syndrome or mucopolysaccharidoses or children under 2 years of age. RCTs addressing tonsillectomy vs. no surgery for recurrent throat infection explicitly included children with mild to moderate baseline symptoms, and definitions of "throat infection" varied across studies. Two larger studies that addressed this comparison included majority white populations.

Studies addressing surgical approaches and peri- or post- operative medications typically did not specify surgical indications or included both children with OSDB or recurrent throat infections without stratifying analyses. Roughly one-third of studies were conducted in less developed countries in which surgical techniques and procedures may differ from those used in the United States. Regardless of the country in which studies were performed, anesthetic approaches, analgesic agents and dosing, surgical expertise, and surgical and hemostatic techniques (including definitions of "partial tonsillectomy") varied widely across studies. Studies reporting weight or BMI typically did not address whether children were under- or over- weight for age at baseline, and few studies reported baseline comorbidities such as asthma or Down syndrome; thus assessing applicability to these sub-populations is challenging. Most studies used subjective outcome measures or relied on caregiver- or child-completed diaries to assess longer-term outcomes. Objective measures such as the Apnea Hypopnea Index or other polysomnography parameters may not accurately reflect effects on the totality of symptoms associated with OSDB (e.g., behavioral issues, sleepiness, overall quality of life). We also included only studies addressing tonsillectomy for the two most common indications for the surgery: OSDB and recurrent throat infection; thus, individuals seeking information about tonsillectomy for Periodic Fever, Aphthous Stomatitis, Pharyngitis, Cervical Adenitis (PFAPA) or other indications will not find applicable studies in the current review.

Despite these limitations to generalizability, findings reported here are likely widely applicable given the heterogeneous population of children without comorbidities who undergo tonsillectomy for OSDB or recurrent throat infections. Applicability of findings to children with Down syndrome, craniofacial abnormalities, obesity, or under age 2 is limited. Although studies included some children with these comorbidities or in the younger age range, few provided explicit analyses of these subgroups. Appendix G of the full report includes applicability tables for each KQ.

Limitations of the Comparative Effectiveness Review Process

We included studies published in English only; as few non-English studies would have met criteria based on our scan of a random sample of these studies, we believe their exclusion does not introduce significant bias into the review. We also included only studies of perioperative NSAID, steroids, and antiemetics to address KQ5. Although this focus means that some medications are not included in this review, the drug classes addressed in the review comprise key agents frequently used in the perioperative period. We also did not include studies addressing adenoidectomy alone or studies comparing tonsillectomy with adenoidectomy as the choice of procedure is likely driven by the indication for surgery; thus, comparing these approaches would not be appropriate. Given heterogeneity in anesthetic regimens, surgical techniques, postoperative analgesia and medications, and patient populations themselves, we were limited in our ability to stratify findings or identify potential subgroups that may respond more favorably to tonsillectomy or to supportive care.

Limitations of the Evidence Base

A relatively large number of studies have been published on tonsillectomy, including for OSDB and throat infections, but risk of bias is mixed, with fewer studies (31%) having low risk of bias than moderate or high risk. Furthermore, most available studies provided little to no long-term clinical outcome data, focusing instead on intermediate outcomes and harms. In addition, few studies addressed questions about the need for tonsillectomy compared with a non-surgical treatment. Patient populations were generally poorly characterized, and little information was available on first-line treatment attempts before surgery. Very few studies focused on high risk or other special populations.

Particularly in studies intended to assess effects of tonsillectomy on throat infections, parents of severely affected children were noted to refuse randomization and cross over to surgery at high rates. Long-term effects are limited in the literature base, particularly regarding outcomes that include growth and development, sleep quality, and behavior for children with OSDB. Exploration of demographics of patient populations more likely to be refractory to initial management strategies is also limited. It appears clear that throat infections decline in children over time regardless of treatment group, but with high loss to followup, the relative contribution of this decline to apparent effectiveness is unknown.

A particular problem in the literature is a lack of full characterization of the patient population, particularly the clinically documented severity of both sleep-disordered breathing and throat infections. Understanding of "obstructive sleep-disordered breathing" varied from study to study as did degree of hypertrophy and number and severity of throat infections or sore throats. In the context of general lay expectations of the benefit of tonsillectomy, and common opinion that tonsillectomy is a "minor" surgery, patients undergoing tonsillectomy may vary widely in the severity of their clinical states. Among those studies focused on throat infection that did characterize patients, most had low numbers of reported infections, and few reported culture-confirmed bacterial infections.

Of particular importance for this surgical topic is a complete assessment of potential harms, particularly frequency of PTH, including PTH that leads to further intervention. However, the degree, number of repeat episodes, and timing of PTH were rarely defined or measured; thus outcomes can be broadly defined only in terms of primary versus secondary PTH, readmissions, and reoperations, where reported. Our estimates include PTH as reported in eligible studies, which could have ranged from parent-reported bleeding that did not require a clinician visit to PTH requiring surgical hemostasis.

Few studies of postoperative medications for pain met our inclusion criteria; thus, evidence in the current review is inadequate to draw firm conclusions about PTH associated with postoperative NSAIDs. In attempting to assess partial versus total tonsillectomy we note that partial tonsillectomy was rarely precisely specified. These studies also most often used different techniques for the partial and total tonsillectomy, thus introducing confounding that cannot be disentangled.

Implications for Clinical and Policy Decisionmaking

This review provides evidence for decisionmaking in the care of children who are potential candidates for tonsillectomy. Despite the large body of literature, most evidence addresses effects in the short term. The literature reports short-term improvements in obstructive symptoms and throat infections following tonsillectomy compared with no surgery. Evidence about long-

term benefits of tonsillectomy either for OSDB or throat infection is limited. Thus, individual decisionmaking needs to balance needs for relief of illness-related outcomes (including missing school and work) with the risks associated with surgery. Caregivers and providers may wish to consider the potential benefits and drawbacks of attempting to manage children's illnesses for a period of time to see if they outgrow the propensity for infection and may be able to avoid surgery. That said, shared decisionmaking rests in the hands of families and their clinicians, and decisions should be made on an individual basis. Harms are rare and generally minor, and clinicians have information from this review with which to counsel their patients and families.

In cases where families are considering surgery or CPAP for OSDB, comparative evidence is currently inconclusive to inform decisionmaking. Families with children in special subgroups, including those with Down syndrome, similarly cannot rely solely on currently available scientific evidence for their decision as few studies address these populations explicitly. Benefits of specific approaches to tonsillectomy (either partial versus total or by surgical technique) provide little clear guidance for clinicians. Some evidence suggests that partial removal may speed time to return to normal diet or activity relative to total removal; however, we found a roughly 6 percent rate of regrowth with partial tonsillectomy.

PTH typically occurred in less than 4 percent of children across all surgical techniques, and no clear evidence exists for a superior approach. Familiarity with a technique and surgical skill may both have a role in driving outcomes, as has been demonstrated in other fields.[15-17]

Decisional dilemmas still exist regarding the perioperative use of medications and whether they speed postoperative return to normal diet and activity and reduce the need for post-tonsillectomy analgesia and rescue anti-emetic use. Clinical care would be improved by optimizing perioperative use of medication to improve outcomes. The literature base on this topic was insufficient to provide guidance on whether any perioperative medications affect time to resume normal diet or activity. Low strength of evidence suggested that a single dose of IV dexamethasone intraoperatively reduces analgesic requirement in the postanesthesia care unit and up to 24 hours postoperatively. Evidence is mixed as to whether dexamethasone reduces the need for postoperative rescue antiemetics. In contrast, clinicians can have some confidence that pre-emptive 5-HT receptor antagonists given intra-operatively do reduce the need for rescue antiemetics post-tonsillectomy.

Research Gaps and Areas for Future Research

Tonsillectomy is heavily researched, with far more data available to assess safety than efficacy. Despite substantial research, the literature is largely silent on the natural history of OSDB or throat infections that would provide a basis for the need for tonsillectomy in the long term. Many young patients may outgrow the need for intervention, but more data are needed to describe the potential to outgrow these indications to parents and to discern population factors that may predict resolution.[18-20] Indeed, in many studies, outcomes for children in nonsurgical groups also improved, though improvements were generally greater in children receiving tonsillectomy. Long-term data are needed in order to enable caregivers to weigh the benefits of surgery versus the reality of managing their child's condition as they wait for it to resolve; obtaining longer-term data, however, is difficult, as evidenced by the high rate of attrition in most studies with more than 6 months followup included in this review.

Future studies should take more care to characterize patient populations completely—including severity of OSDB or throat infections—such that applicability can be much more specifically described and potential candidates for surgery or watchful waiting identified. Indeed

the literature lacks a consistent, consensus definition of infection; defining infection consistently is critical for promoting synthesis of research in the area. Tonsillitis or "sore throat" may also include cases of entities such as PFAPA; clear characterization of children in studies is necessary for understanding effects on subpopulations.

Similarly, studies also typically did not clearly characterize severity of PTH, and many did not clearly specify timing or number of repeat episodes. Severity of bleeding or repeat episodes may be more predictive of serious morbidity than simple frequency; however, our ability to assess this association was limited. Improved characterization could allow analyses to inform our understanding of factors that may contribute to revisits or readmissions and outcomes such as mortality.

As new technologies for tonsillectomy continue to emerge, as they continuously have over the past few decades, high quality research will be needed to evaluate these technologies, in terms of both efficacy and safety. As we learn more about the deleterious effects of sleep apnea and detection rates increase, more refined and specific treatment algorithms will be in demand. Related to this issue, more data are needed on the use of CPAP in children as an initial modality; such data should address compliance and duration of use.

Future research should also address the current lack of data regarding treatment in special populations including very young children and children with comorbidities such as obesity and neuromuscular disease. Further, concerns about perioperative and postoperative management persist, including over-narcotization and potential respiratory suppression. Better data regarding optimal medication regimens are essential, both in terms of symptomatic relief and minimizing iatrogenic harm.

Measures commonly used to assess objective improvements in obstructed breathing, such as the AHI, are not patient-centered and may not reflect subjective reports of improvements or worsening of outcomes experienced by patients. Future research exploring the alignment of the AHI with patient-reported outcomes such as quality of life would help to gauge effects of tonsillectomy more precisely. Additionally, standardized measures of sleep outcomes are lacking.

Finally, relatively little data exist regarding predictable factors contributing to recurrence of symptoms of failure of OSDB and throat infections following tonsillectomy for primary management. A better understanding of these factors would allow for more specific patient selection.

Conclusions

Tonsillectomy can produce short-term improvement in sleep outcomes and reduction in throat infections compared with no surgery in children with OSDB or recurrent throat infections. Relative to no intervention, most studies reported better sleep-related outcomes in children with OSDB who had a tonsillectomy, but longer term data on durability of outcomes are limited. Children undergoing tonsillectomy to improve number of throat infections, associated health care utilization (clinician visits), and work/school absences had improvements in these outcomes in the first postsurgical year compared with children not receiving surgery. These benefits did not persist over time, and data on longer-term results are lacking. This short-term improvement must be weighed against a roughly 4 percent frequency of PTH. Surgical technique had little bearing on either time to return to normal diet or activity or PTH frequency. Perioperative dexamethasone improved pain and pre-emptive 5-HT receptor antagonist antiemetics reduced antiemetic use in the immediate postoperative period. Dexamethasone did not increase risk of

PTH compared with placebo, but estimates had wide confidence bounds. Little evidence addressed the use of postoperative medications for pain-related outcomes.

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Introduction

Background

Tonsillectomy or adenotonsillectomy ("tonsillectomy") are commonly performed in the United States and represent more than 15 percent of all surgical procedures in children under the age of 15 years.[1, 2] The primary indication for tonsillectomy has shifted over the last 20 years from recurrent throat infections to obstructive sleep-disordered breathing (OSDB) and obstructive sleep apnea (OSA).[3, 4] Widely variable national and small area tonsillectomy rates are well documented. In their seminal study, Wennberg and Gittlesohn found that rates of tonsillectomy varied almost 12-fold across adjacent counties in rural Vermont with similar populations.[5] Variation in rates continues despite improved evidence and dissemination about indications.[1]

Surgical Techniques

Table 1 categorizes common surgical techniques used for tonsillectomy. Choice of technique depends on patient factors including the surgical indication (e.g., recurrent infection, OSDB) and clinician practice patterns. All procedures are performed under general anesthesia. Hereafter, we use the term tonsillectomy to refer to removal of the tonsils alone, removal of tonsils and adenoids (adenotonsillectomy), and partial removal of the tonsils (tonsillotomy, partial tonsillectomy) using any surgical technique or approach.

Table 1. Commonly used surgical techniques or tools for tonsillectomy

Surgical Technique or Tool	Description
Cold dissection	Palatine tonsils dissected and removed from oropharynx using a scalpel, scissors or other nonpowered means.
Electrocautery	Palatine tonsils dissected and removed from oropharynx using electrocautery (i.e., monopolar cautery, bipolar cautery).
Harmonic scalpel	Palatine tonsils dissected and removed from oropharynx using ultrasonic energized instrumentation.
Microdebridement	Palatine tonsils removed from oropharynx using a microdebrider, which suctions tonsillar tissue into a rotary blade, which morselizes and removes tissue. All or part of the tonsil can be removed with this technique.
Laser ablation	Palatine tonsils removed from oropharynx with handheld laser.
Coblation	Palatine tonsils dissected and removed from oropharynx using low-temperature irrigation radio frequency energy device.

Indications for Tonsillectomy

Tonsillectomy has two primary indications: recurrent tonsillitis and obstructive sleep-disordered breathing (OSDB). Recurrent or severe tonsillitis has been defined as seven or more episodes of sore throat in the preceding year OR five or more episodes in the each of the preceding 2 years OR 3 or more episodes in each of the preceding 3 years.[6] No gold standard diagnostic test exists to implicate etiologically or predictably attribute symptoms to tonsillitis. In fact, consensus is lacking on what symptoms attributable to tonsillitis are considered "disabling." Surrogates often used for tonsillitis include sore throat and pharyngitis. However, the degree to which either of these terms reflects true tonsillitis is not known. Bacterial pharyngitis can be diagnosed via rapid testing or culture. It is not possible, however, to determine whether the tonsil represents the infectious nidus or if the suspected pathogen represents normal bacterial flora for a particular child's pharynx.

Despite evidence to the contrary, clinicians sometimes treat sore throat empirically with antibiotics without objective testing.[7] Sore throat or pharyngitis may or may not have a tonsillar origin, and it is possible that many cases have alternative explanations. Nonetheless, many cases are termed "tonsillitis" without supportive documentation.[8] Frequency of infections is a metric of severity used to determine eligibility for tonsillectomy.[6, 9, 10] This criterion is fraught with complexity related to diagnostic variability and to incomplete and inconsistent medical documentation. Thus, heterogeneity in diagnostic accuracy, establishment of severity, and frequency of infections complicates treatment decisions regarding tonsillectomy and the performance of comparative effectiveness of its treatments.[6, 9-11]

Currently, the most common indication for tonsillectomy is OSDB (i.e., breathing difficulties during sleep including OSA, which has been defined as "a disorder in which a person frequently stops breathing during his or her sleep," and may be diagnosed based on the frequency of cessation of airflow [apnea] or reduction in airflow with desaturation [hypopnea],[12] and upper airway resistance syndrome [UARS]). OSDB results from obstruction from or dynamic collapse due to upper airway soft tissue during sleep resulting in snoring, hypopnea, apnea, and restless sleep. Adenotonsillar hypertrophy can cause oropharyngeal crowding, thereby increasing the likelihood of symptomatic airway collapse during sleep. OSDB includes disorders ranging from simple snoring to OSA and can result in significant declines in quality of life and negative health consequences. It has been associated with a five-point decrease in intelligence quotient (IQ), hypersomnolence, emotional lability, decreased attention, small stature, enuresis, cardiopulmonary morbidity, and missed school.[13] Evidence of the relationship is reinforced by the effectiveness of OSDB treatment in improving behavior, attention, quality of life, neurocognitive functioning, enuresis, parasomnias, and restless sleep, and reversal of associated cardiovascular sequelae.[14, 15] Moreover, OSDB occurs at especially high rates in subsets of children with developmental disorders and craniofacial syndromes, including Down syndrome.

As in adults, the gold standard diagnostic test for OSA in children is polysomnography (PSG), which physiologically tests sleep architecture and efficiency. Treatment involves alleviating the inciting upper airway soft tissue obstruction or collapse. One method of primary treatment is continuous positive airway pressure (CPAP), which is a device worn over a child's nose and/or mouth that delivers continuous high pressure flow to the lungs, acting as a pneumatic stent to maintain upper airway patency during sleep. CPAP compliance is highly variable in children.[16-20] Therefore, other treatment approaches include weight loss in overweight children, orthodontic devices to expand the palate, and allergy or anti-inflammatory medications. However, since the most common culprit in children is tonsillar hypertrophy-related oropharyngeal obstruction, tonsillectomy is often used to establish an adequate airway.

Regardless of indication, age may affect tonsillectomy outcomes. In general, younger children tend to tolerate surgery better than older children and adults,[21, 22] but risk is increased with surgery in very young children (< 2 years) compared with older children. Tonsillectomy is not commonly performed in this very young age group. To date, little guidance regarding the comparative effectiveness of treating recurrent infection or OSDB in children less than 2 years of age exists. Furthermore, obesity may differentially affect OSDB, which may alter expectations and treatment efficacy and outcomes.

Tonsillectomy is painful and is associated with odynophagia (painful swallowing) and dysphagia (difficulty swallowing) that can make it difficult to return to normal diet or stay hydrated, and can be associated with postoperative hemorrhage, nausea and vomiting. To help minimize these concerns, clinicians may use perioperative antibiotics, steroids, antiemetics, and

pain medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs] and other analgesics). A 2012 Cochrane review examining the effect of perioperative systemic antibiotics on post-tonsillectomy morbidity (pain, consumption of pain medications, secondary hemorrhage, fever, and return to normal diet) failed to find any clinically important impact of antibiotics in reducing pain, need for analgesia, or secondary post-tonsillectomy hemorrhage (PTH).[23] However, this analysis combined adult and pediatric trials; thus, the applicability to children alone is not clear. Furthermore, this review included only randomized controlled trials (RCTs). The role of perioperative anti-inflammatory medications (e.g., NSAIDs) and systemic steroids have been addressed in prior meta-analyses and reviews, with consistent findings of low risk of PTH and reduced morbidity (pain, time to return to normal diet and activity) associated with perioperative dexamethasone in children,[24-29] and less consistent findings regarding NSAIDs.[30, 31] Two systematic reviews reported no significant risk of PTH with perioperative NSAID use[31, 32] while one reported insufficient data to rule out risk.[30] One review also noted an increased PTH risk with postoperative NSAIDs.[31]

Thus, clinicians and parents need to know three key things: 1) what is the likelihood that the surgery (compared with watchful waiting with supportive care) will improve clinical outcomes around recurrent throat infections and sleep disorders; 2) what is the risk that the child will experience a harm, primarily PTH, with the surgery; and 3) if surgery is indicated, what approach, in terms of both surgical technique and perioperative medical care, has been demonstrated to optimize effectiveness and minimize harms? We address these questions by reviewing the comparative (primarily RCT) data for effectiveness on a specific set of outcomes and also searching a broader set of studies for harms data in order to estimate the frequency of the most common and most severe harms, namely PTH, readmission, and reoperation. The results from this report will be widely applicable; however, lack of consistently reported modifier data (e.g., body mass index [BMI], surgical indications) may limit its generalizability to every child.

Scope and Key Questions

Scope of Review

The current review addresses the comparative effectiveness and harms of tonsillectomy in children with the most common indications for the procedure, namely, OSDB and recurrent throat infections. We targeted the review on these two key indications in order to maximize its utility for a broad population while maintaining a scope of work feasible for the systematic review. The review, nominated by the American Academy of Otolaryngology - Head & Neck Surgery Foundation (AAO-HNSF), addresses key decisional dilemmas identified by stakeholders and through our preliminary scan of the literature in a comprehensive manner. The review also includes Key Questions (KQ) to improve understanding of outcomes in subgroups such as very young children (1-2 years old), children with Down syndrome, and those who are overweight or obese.

Key Questions

We developed KQs in consultation with Key Informants and the Task Order Officer. KQs were posted for review to the Agency for Healthcare Research and
Quality Effective Health Care Web site. We note that OSDB includes breathing difficulties

during sleep as operationalized in each study, including OSA and UARS. As noted, tonsillectomy includes tonsillectomy, partial tonsillectomy, and adenotonsillectomy. We also note that comparative effectiveness includes both the benefits and harms of interventions.

Questions were as follows:

KQ1. In children with obstructive sleep-disordered breathing (OSDB), what is the comparative effectiveness of tonsillectomy compared with continuous positive airway pressure (CPAP) or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1a. In children with OSDB and neuromuscular or craniofacial abnormalities, what is the comparative effectiveness of tonsillectomy compared with CPAP or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1b. In children with OSDB under age 3 years, what is the comparative effectiveness of tonsillectomy compared with watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1c. In children with OSDB and Down syndrome, what is the comparative effectiveness of tonsillectomy compared with CPAP or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ1d. In children with OSDB who are overweight or obese, what is the comparative effectiveness of tonsillectomy compared with CPAP, weight loss, or watchful waiting with supportive care (including pharmacologic treatment) to improve sleep outcomes, cognitive or behavioral outcomes, and health outcomes?

KQ2. Among children with recurrent throat infections, what is the comparative effectiveness, including harms, of tonsillectomy compared with watchful waiting with supportive care (including pharmacologic—antibiotic or nonantibiotic—treatments) on the number and severity of throat infections, quality of life, and health care utilization?

KQ3. Do benefits and harms differ between partial tonsillectomy and total tonsillectomy?

KQ4. Do benefits and harms differ by surgical technique (e.g., cautery, coblation)?

KQ5. What are the benefits and harms of adjunctive perioperative (i.e., preoperative, intraoperative, or in post-anesthesia care) pharmacologic agents intended to improve outcomes?

KQ6. What are the benefits and harms of postoperative (i.e., after discharge from post-anesthesia care and up to 10 days postsurgery) pharmacologic agents intended to reduce pain-related outcomes?

Table 2 outlines population, intervention, comparator, outcomes, timing, and setting (PICOTS) characteristics for each KQ.

Table 2. Population, intervention, comparator, outcome characteristics[*]

KQ	Population	Intervention[†]	Comparators	Outcomes
1	Children (3-18 years of age) with OSDB[**]	Tonsillectomy	-Continuous positive airway pressure (CPAP) -Pharmacologic treatment including anti-inflammatory medications, decongestants, allergy medication, antihistamines, nasal steroids, leukotriene inhibitors	Sleep outcomes -Apnea Hypopnea Index (AHI) -Sleep quality measures (Obstructive Sleep Apnea-18 [OSA-18], Clinical Assessment Score-15 [CAS-15]) -Pediatric Sleep Questionnaire (PSQ) -Modified Epworth Sleepiness Scale -Desaturation nadir -OSDB persistence Cognitive or behavioral outcomes -Validated measures of attention, irritability, and memory Health outcomes -Growth velocity (height, BMI for age) -Cardiopulmonary issues -Self or caregiver-reported enuresis -Health care utilization (number of clinician visits) Harms -Re-admission or ER visit or ICU admission for postoperative pain, dehydration, PTH, or nausea and vomiting -Reoperation for primary or secondary PTH -Velopharyngeal insufficiency -30-day mortality -Harms of comparator agents reported in studies with comparison groups
1a	Children (3-18 years of age) with OSDB and neuromuscular or craniofacial abnormalities	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1)
1b	Children under age 3 with OSDB	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1) Length of stay
1c	Children (3-18 years of age) with OSDB and Down syndrome	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1) Length of stay

Table 2. Population, intervention, comparator, outcome characteristics,[*] continued

KQ	Population	Intervention[†]	Comparators	Outcomes
1d	Children (3-18 years of age) with OSDB who are overweight or obese	Tonsillectomy	-CPAP -Weight loss -Pharmacologic treatment including anti-inflammatory medications, decongestants, allergy medication, antihistamines, nasal steroids, leukotriene inhibitors	See outcomes above (KQ1)
2	Children (3-18 years) with recurrent throat infections	Tonsillectomy	-Antibiotics -Nonantibiotic pharmacologic treatments (e.g., anti-inflammatory agents, decongestants, antihistamines, leukotriene inhibitors, nasal or systemic steroids)	Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Quality of life -Validated quality of life measures -Missed school or work for child or caregiver Other outcomes -Health care utilization (number of clinician visits, number of courses of antibiotics) Harms - ER visit or hospital or ICU admission for postoperative pain, PTH, dehydration, or nausea and vomiting -Reoperation for primary or secondary PTH -Velopharyngeal insufficiency -30-day mortality -Harms of comparator agents reported in studies with comparison groups
3	Children (3-18 years) undergoing tonsillectomy	Total tonsillectomy	-Partial tonsillectomy	See sleep, cognitive or behavioral, and health outcomes (KQ1) and quality of life outcomes (KQ2) Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Other outcomes -Symptomatic tonsillar regrowth -Time to return to usual activity (diet, school) Harms See KQ1 Reoperation for complete tonsillectomy

Table 2. Population, intervention, comparator, outcome characteristics,* continued

KQ	Population	Intervention†	Comparators	Outcomes
4	Children (3-18 years) undergoing tonsillectomy	Tonsillectomy	-Other technique for tonsillectomy	See sleep, cognitive or behavioral, and health outcomes (KQ1) and quality of life outcomes (KQ2) Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Other outcomes -Time to return to usual activity (diet, school) Harms See KQ1
5	Children (3-18 years) undergoing tonsillectomy	Tonsillectomy plus adjunctive perioperative (i.e., preoperative, intraoperative, or immediate postoperative [post-anesthesia care] periods) pharmacologic agents	-Tonsillectomy without adjunctive perioperative pharmacologic agents (i.e., pharmacologic agents given to attempt to reduce postoperative morbidity including pain or nausea and vomiting)	-Pain management (need for rescue medications) -Time to return to usual activities (diet, school) -Health care utilization (number of clinician visits, number of courses of antibiotics) Harms -Harms of agent -Re-admission to hospital or ICU or ER visit for postoperative pain, PTH, dehydration, or nausea and vomiting -Reoperation for primary or secondary PTH -30-day mortality
6	Children (3-18 years) undergoing tonsillectomy and receiving pharmacologic agents for pain postoperatively (i.e., up to 10 days after discharge from post-anesthesia care)	Tonsillectomy plus postoperative pharmacologic agents for pain (e.g., NSAID, ketorolac)	-Tonsillectomy with other postoperative pharmacologic agents for pain	See outcomes and harms for KQ5

*Studies of any length or followup and in any setting, except for KQ6, which includes pharmacologic agents for pain given up to 10 days postsurgery.

**Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome

†Tonsillectomy includes tonsillectomy, adenotonsillectomy, partial tonsillectomy

Abbreviations: AHI = Apnea Hypopnea Index; BMI = Body Mass Index; CAS-15 = Clinical Assessment Score-15; CPAP = Continuous Positive Airway Pressure; ER = Emergency Room; KQ = Key Question; NSAID = Nonsteroidal Anti-Inflammatory Drug; OSA-18 = Obstructive Sleep Apnea-18; OSDB = Obstructive Sleep-Disordered Breathing; PTH = Post-Tonsillectomy Hemorrhage

Analytic Framework

The analytic frameworks illustrate the population, interventions, and outcomes that guided the literature search and synthesis (Appendix A). The frameworks depict the key questions within the context of the population, intervention, comparator, outcomes, timing, and setting (PICOTS) parameters described in Table 2.

Organization of This Report

The Methods section describes the review processes. The Results section presents findings for each key question organized by intervention and outcome area where possible. We discuss harms reported in studies of surgical techniques in a separate section following discussion of effectiveness outcomes in each KQ, including a meta-analysis that provides expected frequency of PTH by surgical approach and by partial versus total tonsillectomy. Summary tables for each key question outline key outcomes.

The Discussion section of the report outlines the current state of the literature and challenges for future research in the field. We also provide a list of abbreviations and acronyms at the end of the report.

Uses of This Evidence Report

We anticipate this report will be of primary value to organizations that develop guidelines for tonsillectomy, to clinicians who provide care for children with indications for tonsillectomy, and for families making treatment decisions. Children who are candidates for tonsillectomy may be treated by clinicians including pediatricians, otolaryngologists, sleep medicine physicians, allergists, family physicians, anesthesiologists, infectious disease physicians, nurse practitioners, physician assistants, and nurses. This report supplies practitioners and researchers up-to-date information about the current state of evidence and assesses the quality of studies that aim to determine the outcomes and safety of tonsillectomy.

Methods

In this chapter, we document the procedures that we used to produce a comparative effectiveness review (CER) on tonsillectomy in children with obstructive sleep-disordered breathing (OSDB) or recurrent throat infections. These procedures follow the methods outlined in the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[33]

Topic Refinement and Review Protocol

The topic for this report was nominated by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNSF) in a public process using the Effective Health Care website. Working from the nomination, we drafted the initial key questions (KQ) and analytic frameworks and refined them with input from key informants representing the fields of pediatrics, otolaryngology, anesthesiology, and sleep medicine. We also spoke with a caregiver representative. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team had any conflicts.

After review from AHRQ, the questions and framework were posted online for public comment. No changes to the questions or frameworks were recommended. We also developed population, interventions, outcomes, timing, and settings (PICOTS) criteria for intervention KQ.

We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of pediatrics, otolaryngology, anesthesiology, infectious disease, and sleep medicine, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included eight members serving as technical or clinical experts. To ensure robust, scientifically relevant work, TEP members participated in conference calls and discussions through e-mail to:

- Help to refine the analytic framework and KQ at the beginning of the project;
- Discuss inclusion/exclusion criteria; and
- Assist with determining key interventions and outcomes of interest.

The final protocol was posted to the AHRQ Effective Health Care web site and registered in the PROSPERO international register of systematic reviews (ID#: CRD42015025600).

Literature Search Strategy

Search Strategy

To ensure comprehensive retrieval of relevant studies of therapies for children undergoing tonsillectomy, we used three key databases: the MEDLINE® medical literature database via the PubMed® interface; EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid® interface; and the Cochrane Library. Search strategies for KQs applied a combination of controlled vocabulary (Medical Subject Headings [MeSH] and Emtree headings) to focus specifically on tonsillectomy and harms of interventions. We restricted literature searches for KQs to studies published from January 1980 to June 2016 to reflect current techniques for tonsillectomy and perioperative or postoperative medications. A second librarian reviewed the search strategies.

We included only studies published in English as a review of non-English citations retrieved by our MEDLINE search identified few studies of relevance. Appendix B lists our search terms and strategies and the yield from each database.

We carried out hand searches of the reference lists of recent systematic reviews or meta-analyses of studies addressing pediatric tonsillectomy. The investigative team also scanned the reference lists of studies included after the full-text review phase for additional studies that potentially could meet our inclusion criteria.

Gray Literature

AHRQ's Scientific Resource Center notified companies that produce surgical instruments used for tonsillectomy or devices such as continuous positive airway pressure (CPAP) machines about the opportunity to provide Scientific Information Packets (SIPs) to inform the review. Because many manufacturers may produce medications used in the peri- or postoperative periods, a notice of the opportunity to submit scientific material to inform the review was posted in the *Federal Register* for 6 weeks.

We also searched ClinicalTrials.gov to assess reporting bias and to identify any study results that may not have been identified in our other database searches. We applied the inclusion criteria in Table 3 to studies identified via our gray literature searches.

Inclusion and Exclusion Criteria

Table 3 lists the inclusion/exclusion criteria we used based on our understanding of the literature, key informant and public comment during the topic refinement phase, input from the TEP, and established principles of systematic review methods. We used a best evidence approach to determine final inclusion of studies. That is, if evidence from randomized studies was insufficient to address a KQ or specific outcomes, we considered evidence from observational literature as well as factors related to the relevance of studies to determine whether including additional studies was warranted).[34] We also included studies considered to have high risk of bias (as described below) in meta-analyses after sensitivity analyses showed no systematic effects on findings.

We limited our searches for comparative effectiveness questions to studies published in English and from January 1980 to June 2016 for studies of the effectiveness of tonsillectomy in children with OSDB or recurrent throat infections (KQs1-2). In consultation with the review nominator, we limited inclusion of studies relevant to KQs3-6 to those published between January 2000 and June 2016 as we identified a large literature base, including many randomized controlled trials (RCTs), addressing these questions.

We also excluded studies including both children and adults if the mean plus standard deviation age of participants was greater than 18 years and data were not reported separately for children (3-18 years of age for most KQs). We included comparative studies (studies including an intervention and a comparison group) evaluating the benefits or harms of tonsillectomy (tonsillectomy, adenotonsillectomy, and partial tonsillectomy conducted using any surgical technique such as cautery or cold dissection) compared with an inactive control or alternate intervention. We also included case series or database studies including at least 1,000 children undergoing tonsillectomy to address harms but not effectiveness. We selected the bound of 1,000 as a conservative value based on a preliminary review in which we identified numerous case series or database studies with 1,000 or more participants.

Table 3. Inclusion criteria for studies of tonsillectomy

Category	Criteria
Population	• Children with OSDB age 3-18 years, inclusive (KQ1) • Children with neuromuscular or craniofacial abnormalities and OSDB age 3-18 years, inclusive (KQ1a) • Children under age 3 years with OSDB (KQ1b) • Children with Down syndrome OSDB age 3-18 years, inclusive (KQ1c) • Children with obesity or overweight and OSDB age 3-18 years, inclusive (KQ1d) • Children with recurrent throat infection age 3-18 years, inclusive (KQ2) • Children with OSDB or recurrent throat infection undergoing tonsillectomy age 3-18 years, inclusive (KQ 4-6)
Intervention	• Tonsillectomy, adenotonsillectomy, or tonsillotomy (partial removal of tonsil) using any surgical approach (e.g., coblation, laser, cold dissection) (KQ 1-6) • Perioperative (preoperative, intraoperative, and immediate postoperative [postanesthesia care] periods) NSAIDs, steroids, or antiemetics (KQ5) • Any postoperative (discharge from post-anesthesia care to up to 10 days postsurgery) agent for pain (KQ6)
Design	• Effectiveness outcomes: Comparative studies (RCTs, prospective or retrospective cohort studies with comparison groups, nonrandomized trials, case-control studies) (KQ1-6) • Harms: Comparative studies (RCTs, prospective or retrospective cohort studies with comparison groups, nonrandomized trials, case-control studies), database or registry studies (harms of tonsillectomy), case series with at least 1000 participants (harms of tonsillectomy)
Other	• Original research (KQ1-6) • Publication language: English (KQ1-6) • Publication year: January 1980-June 2016 (KQ1-2) or January 2000-June 2016 (KQ3-6) • Reports one or more of the outcomes described in Table 2 • Sufficiently detailed methods and results to enable data extraction (KQ1-6) • Reports outcome data by target population or intervention (KQ1-KQ6)

Abbreviations: KQ = Key Question; NSAID = Nonsteroidal Anti-Inflammatory Drug; OSDB = Obstructive Sleep-Disordered Breathing; RCT = Randomized Controlled Trial

Study Selection

Once we identified articles through the electronic database searches and hand-searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts of studies identified in our searches for KQs for inclusion or exclusion, using an Abstract Review Form (Appendix C). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix C) that included questions stemming from our inclusion and exclusion criteria. We adjudicated disagreements through discussion between reviews or final adjudication by a senior reviewer.

We conducted all abstract and full text reviews using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Appendix D includes a list of excluded studies and the reasons for exclusion. Data extracted for each study are available via the Systematic Review Data Repository (srdr.ahrq.gov).

Data Extraction

The staff members and clinical experts who conducted this review (including two otolaryngologists, one pediatrician, one pediatric pulmonology sleep medicine physician, one biostatistician, and three epidemiologists/systematic reviewers) jointly developed the data extraction forms for the KQs. We designed forms to provide sufficient information to enable

readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to the KQs. We used two templates to facilitate the extraction of data based on study type; one form was designed for case series or database studies that reported harms data and one was created to accommodate all types of comparative studies for effectiveness and harms data.

The team was trained to extract data by extracting several articles into the template and then reconvening as a group to discuss the utility of the template. We repeated this process through several iterations until we decided that the templates included the appropriate categories for gathering the information contained in the articles and for potential meta-analyses. Team data extractors shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial entries for accuracy, completeness, and consistency. A senior reviewer reconciled disagreements concerning the information reported.

The full research team met regularly during the data extraction period and discussed issues related to the whole process. In addition to outcomes related to the effectiveness of tonsillectomy (e.g., changes in sleep parameters or quality of life), we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

Data Synthesis

We summarized data for KQs qualitatively using summary tables when meta-analyses were not possible. We used a best evidence approach and focused on lower risk of bias studies when they provided sufficient data to address a KQ.[34]

We identified sufficient data to address studies comparing tonsillectomy with watchful waiting in children with OSDB. Studies used in this fixed effects meta-analysis included children with polysomnography-proven OSDB and reported the Apnea Hypopnea Index (AHI) at baseline and followup. We modeled the difference between followup and baseline scores as a Gaussian random variable.

We also meta-analyzed studies comparing the risk of post-tonsillectomy hemorrhage (PTH) with perioperative steroids compared with placebo. We used a zero-inflated binomial model to account for the relatively high number of studies with no PTH-related outcomes in the available data. We included study random effects to account for correlation among arms in the same study. Finally, we addressed PTH and related readmissions or clinician visits using quantitative meta-analysis methods. We implemented a mixed-effects, arm-based meta-analysis to assess the influence of different surgical procedures and the effect of partial compared with total tonsillectomy on the occurrence of PTH-related outcomes following surgery. We also conducted analyses to estimate the effects of including high risk of bias studies in our analyses. These analyses suggested no systematic effects of these studies; thus, we retained them in all three meta-analyses. Appendix E contains a full description of the meta-analytic methods.

Risk of Bias Assessment of Individual Studies

We used separate tools appropriate for specific study designs to assess the risk of bias of individual studies meeting eligibility criteria for our KQs. We used prespecified questions from *Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions*[35] appropriate to each study design to assess risk of bias of randomized controlled

trials (RCT) and observational studies and a tool adapted from questions outlined in the McMaster McHarms tool to assess reporting of harms.[36]

Questions assessing risk of bias evaluate domains including selection bias, performance bias, attrition bias, detection bias, and reporting bias as well as methods for recruiting cohorts and controlling for confounding. The harms assessment tool addresses questions related to pre-specification and reporting of harms.

Risk of bias assessment of each study was conducted independently by two team members using the forms presented in Appendix C. Any discrepancies were adjudicated by the two team members or a senior investigator. Investigators did not rely on the study design as described by authors of individual papers; rather, the methods section of each paper was reviewed to determine which rating tool to employ. The results of these tools were then translated to "low," "moderate," and "high" risk of bias ratings as described below. Appendix F reports risk of bias scoring for each study.

We required that RCTs receive a positive rating (i.e., low risk of bias) on 12 of 13 of the questions used to assess each study to be considered to have low risk of bias. RCTs had to receive nine to eleven positive ratings to have moderate risk of bias, and studies with ≤ eight positive ratings were considered to have high risk of bias. We considered a rating of "unclear" for a question as a negative rating. We assessed the risk of bias for each major outcome of relevance reported but report an overall assessment unless the risk of bias varied by outcome.

We required that cohort studies receive positive ratings on at least 13 of the 14 questions used to assess each study to have low risk of bias for cohort studies and on nine to 12 questions to be considered to have moderate risk of bias for cohort studies. We considered studies that received positive ratings on ≤ eight questions to have high risk of bias. We required that studies assessed for harms reporting receive positive ratings on all four of the four questions used to assess each study to be considered to have low risk of bias. We considered studies receiving three positive ratings as moderate risk of bias and those with two or fewer positive ratings as high risk of bias.

Strength of the Body of Evidence

We applied explicit criteria for rating the overall strength of the evidence for each key intervention-outcome pair for which the overall risk of bias was not high. We rated the strength of the evidence for the outcomes of interest for our KQs (Table 2) and for clinically important harms. We used established concepts of the quantity of evidence (e.g., numbers of studies, aggregate ending-sample sizes), the quality of evidence (from the risk of bias ratings on individual articles), and the coherence or consistency of findings across similar and dissimilar studies and in relation to known or theoretically sound ideas of clinical knowledge.

The strength of evidence evaluation that we used is described in the Effective Health Care Program's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*[33] and in the updated strength of evidence guide.[37] The latter emphasizes five major domains: study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown or not applicable), directness (direct, indirect), precision (precise, imprecise), and reporting bias (suspected, undetected). Study limitations are derived from the risk of bias assessment of the individual studies that addressed the KQs and specific outcome under consideration (see Appendix C for more information on strength of evidence domains). Each key outcome for each comparison of interest is given an overall evidence grade based on the ratings for the individual domains.

We graded the overall strength of evidence as outlined in Table 4. Two senior staff members independently graded the body of evidence; disagreements were resolved as needed through discussion or third-party adjudication. We recorded strength of evidence assessments in tables, summarizing results for each outcome. We did not consider case series and database studies in the assessment of strength of the evidence for harms.

Table 4. Strength of evidence grades and definitions[*]

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	**We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome**. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

[*] Excerpted from Berkman et al., 2014[37]

Applicability

We assessed the applicability of findings reported in the included literature addressing our KQs to the general population of children undergoing tonsillectomy; our approach involved determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include the indication for tonsillectomy, age at treatment, surgical technique, and population characteristics such as body mass index (BMI), Down syndrome, and craniofacial abnormalities. Applicability tables for each KQ are in Appendix G.

Peer Review and Public Commentary

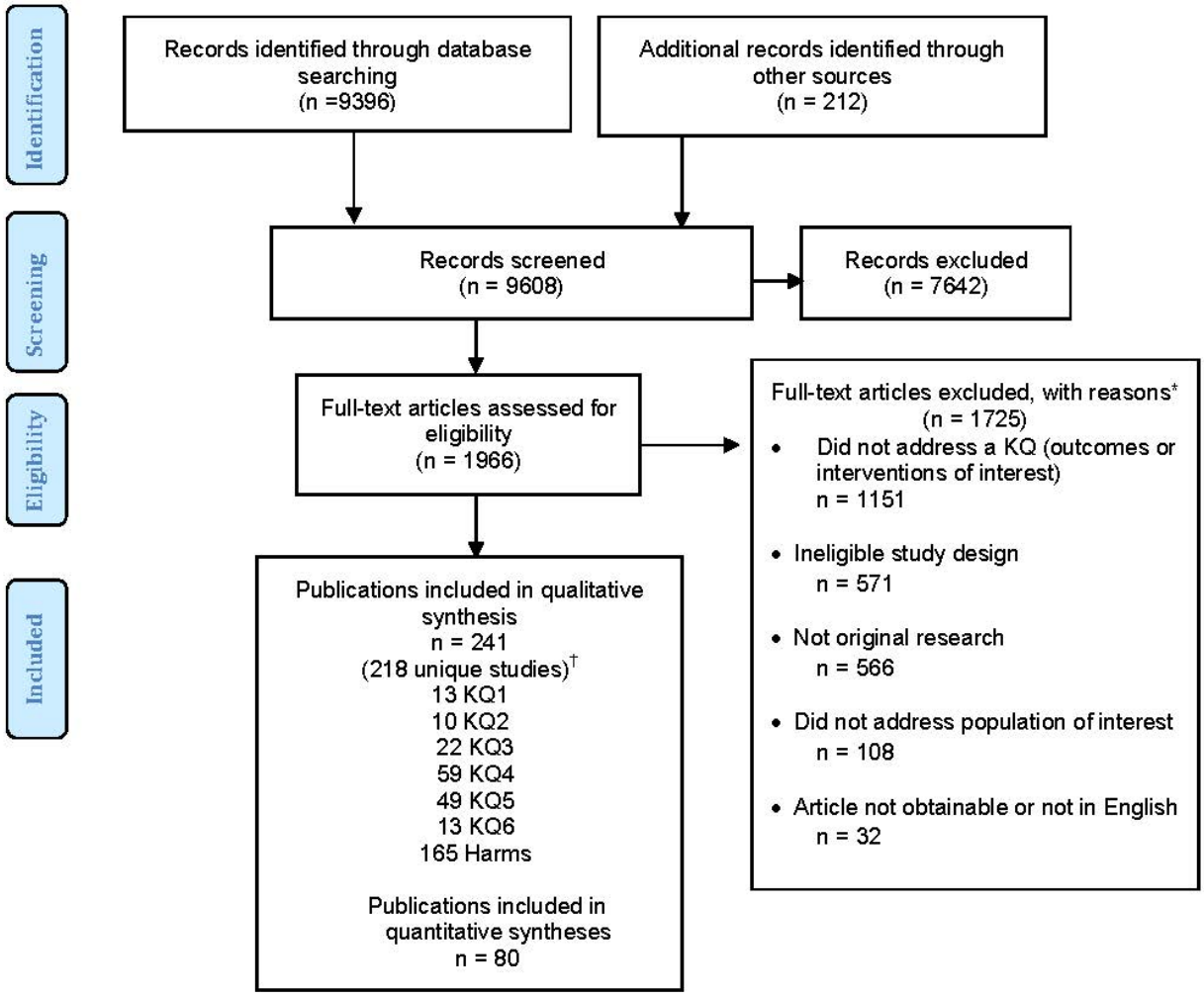
Researchers and clinicians with expertise in tonsillectomy and individuals representing stakeholder and user communities provided external peer review of this report. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment. We addressed all reviewer comments, revised the text as appropriate, and documented changes and revisions to the report in a disposition of comments report that will be made available 3 months after AHRQ posts the final review on the AHRQ Effective Health Care Web site.

Results

Results of Literature Searches for Key Questions

We identified 9608 nonduplicative titles or abstracts with potential relevance, with 1966 proceeding to full text review (Figure 1). We excluded 1725 studies at full text review. We included 218 unique studies (241 publications) in the review. These 218 studies included 165 comparative studies and 53 case series or database or registry studies providing data on harms only.

Figure 1. Disposition of studies identified for this review



†3 papers each reported 2 unique studies in each paper. Numbers next to each Key Question indicate number of unique studies addressing the question. Studies could address more than one Key Question.
*Numbers do not tally as studies could be excluded for multiple reasons.
Abbreviations: KQ = Key Question; n = Number.

Description of Included Studies

The 218 unique included studies (reported in multiple publications) comprised 141 randomized controlled trials (RCTs),[6, 9, 38-192] 12 nonrandomized trials,[6, 179, 193-202] seven prospective[203-209] and five retrospective cohort studies,[210-214] 53 database or registry studies or case series with at least 1000 children (Table 5).[21, 215-276] We used database and registry studies and case series for harms data only. We considered 67 studies to have low risk of bias,[21, 39-41, 43, 49-54, 56, 57, 59, 69, 70, 75, 76, 88-90, 93, 94, 97, 98, 105, 112, 113, 115, 118-120, 123, 125, 128, 131-136, 144, 146, 151, 155, 156, 163, 167-170, 217-222, 225, 226, 228, 229, 231, 233, 235, 236, 241, 247, 248, 250, 251, 258, 266-271] 110 to have moderate risk,[9, 38, 42, 44-48, 58, 60, 62-64, 66, 71, 72, 74, 78-80, 82-87, 91, 92, 95, 96, 103, 106, 107, 109-111, 114, 116, 117, 121, 122, 124, 126, 127, 130, 138, 139, 141, 142, 145, 147-150, 152, 154, 157-161, 164, 166, 171-186, 190-192, 194-197, 200, 201, 203, 206, 207, 210, 211, 213-216, 223, 224, 227, 230, 232, 234, 238, 242, 245, 246, 249, 252, 253, 255-257, 259-263, 272-277] and 41 to have high risk.[6, 55, 61, 65, 67, 68, 73, 77, 81, 99-102, 104, 108, 129, 137, 140, 143, 153, 162, 187-189, 193, 198, 199, 202, 204, 205, 208, 212, 237, 239, 240, 243, 244, 264, 265, 278]

Studies were conducted globally (Table 5), with most conducted in the United States (n=56, including 4 unique studies published in 2 papers),[6, 9, 21, 47, 54, 66, 68, 70, 77, 85, 90, 92, 93, 95, 97-99, 107, 108, 110, 112, 114, 116, 120, 122, 124, 126, 130, 151, 171-178, 191, 201, 211-214, 223, 224, 227, 228, 232-237, 247, 248, 256, 261, 266-268, 270, 272, 273, 279] United Kingdom (n=22, including 2 unique studies reported in one paper),[56, 75, 102, 103, 123, 125, 131, 134, 179, 210, 217-219, 225, 226, 231, 238, 241, 243, 245, 259, 260, 262, 274] Turkey (n=19),[45, 48, 61, 65, 67, 73, 76, 80, 84, 101, 104-106, 113, 121, 139, 143, 194, 195] and Egypt (n=12).[40, 42, 51, 52, 100, 119, 142, 152, 158, 159, 163, 196] Sixty-nine studies were conducted in developing or emerging nations (including, among others, Turkey, Egypt, Iran, Pakistan, Brazil, India, and China) according to United Nations classification.[39, 40, 42, 44-46, 48, 50-52, 55, 61-63, 65, 67, 71-73, 76, 79, 80, 84, 87, 91, 100, 101, 104-106, 109, 113, 117, 119, 121, 139-144, 146-149, 152, 154, 156-163, 188, 189, 194-196, 200, 202, 204-206, 208, 244, 246, 265,280] Ages of children in studies ranged widely from less than 1 to over 18 (mean age ≤18 in all studies), and studies included a total of 1,845,683 children. Most studies did not specify an indication for tonsillectomy (n=89);[38, 39, 42, 46, 47, 49, 50, 64, 72, 73, 75, 76, 79, 87, 88, 92-94, 100, 103, 105, 106, 109, 112, 113, 115, 117-119, 121-123, 126-128, 132, 133, 135-138, 140, 141, 146-150, 153, 154, 156-159, 161, 167, 168, 188, 190, 199, 202, 207, 216, 225-229, 231-234, 241-243, 245-248, 250, 251, 255, 257, 259, 261, 262, 265, 268, 271, 272, 274-276] 65 studies included children with both obstructive sleep-disordered breathing (OSDB) and throat infections;[9, 21, 41, 43, 48, 54, 57, 59-62, 65, 66, 68-70, 74, 78, 81-83, 89, 96, 99, 102, 104, 108, 110, 111, 116, 120, 130, 131, 134, 144, 145, 155, 162, 164-166, 169, 170, 182-184, 192, 194, 195, 209, 215, 217-219, 223, 224, 235-240, 249, 252, 253, 256, 258, 260, 263, 266, 267, 270, 273] 42 specifically noted OSDB as the surgical indication;[44, 53, 58, 63, 67, 71, 77, 84-86, 90, 95, 97, 98, 101, 107, 114, 124, 129, 139, 143, 151, 160, 171-178, 185-187, 189, 191, 193, 198, 201, 203-206, 208, 211, 212, 214, 220-222, 230, 264, 269] and 22 specifically noted recurrent throat infections as the indication.[6, 40, 45, 51, 52, 55, 56, 80, 91, 125, 142, 152, 163, 179-181, 196, 197, 200, 210, 213, 244]

Table 5. Overview of studies addressing tonsillectomy in children

Characteristic	RCTs (n=141)	Nonrandomized Trials (n=12)	Prospective Cohort Studies (n=7)	Retrospective Cohort Studies (n=5)	Case Series, Database, or Registry Studies Reporting Harms (n=53)	Total Literature
Key Question						
KQ1 and 1a-d	3	1	6*	3	0	13
KQ2	5	2	0	2	0	9
KQ3	20	2	0	0	0	22
KQ4	54	4	1	0	0	59
KQ5	48	1	0	0	0	49
KQ6	11	2	0	0	0	13
Harms	99	10	1	2	53	165
Surgical Indication						
OSDB	27	3	5	3	4	42
Throat Infection	14	5	0	2	1	22
OSDB+Throat Infection	42	2	1	0	20	66
Not Specified	58	2	1	0	28	89
Region of Study Conduct						
Africa	11	1	0	0	0	12
Asia	55	5	2	0	5	67
Australia/New Zealand	6	0	1	0	3	10
Europe	35	4	2	1	22	64
North America	33	2	0	4	23	62
South America	1	0	2	0	0	3
Risk of Bias						
Low	48	0	0	0	19	67
Moderate	69	7	3	4	27	110
High	24	5	4	1	7	41
Total N participants	**17506**	**2875**	**518**	**14350**	**1810403**	**1845652**

*One prospective cohort study addressed both KQ1 and KQ2.[209] This table includes the study only under KQ1.
KQ = Key Question; N = Number; OSDB = Obstructive Sleep-Disordered Breathing; RCT = Randomized Controlled Trial

Gray Literature

We did not receive any materials from Federal Register notices. We sought reports of study protocols identified in ClinicalTrials.gov and other registers to assess for reporting bias but identified very few trials (n=8). Our gray literature searches did not contribute additional studies not identified in our database searches.

Key Question 1. Effectiveness of Tonsillectomy Versus No Surgery for OSDB

Key Points

- In five studies of children with polysomnography (PSG) proven OSDB, respiratory parameters measured using the Apnea Hypopnea Index (AHI) improved more in children receiving tonsillectomy than those not undergoing surgery. In a meta-analysis of three studies, children who underwent tonsillectomy had a 4.8-point improvement in AHI scores compared with those who did not have surgery (95% credible interval: -6.5 to -

3.1). The clinical significance of this improvement is likely influenced by baseline disease severity and may be most obvious in children with mild or moderate OSDB (i.e., AHI scores of 1 to 10).

- For tonsillectomy compared with no surgery, we found greater improvement in AHI and negative behaviors with tonsillectomy vs. watchful waiting. Our confidence in these conclusions is low (low strength of evidence). We also found consistently greater improvement in sleep-related quality of life with tonsillectomy vs. watchful waiting and have greater confidence in this conclusion (moderate strength of evidence).
- We could not make conclusions about effects on executive function or intelligence quotient (IQ) (insufficient strength of evidence).
- We could not make conclusions about outcomes following tonsillectomy compared with continuous positive airway pressure (CPAP) and in studies assessing outcomes in sub-populations such as children with Down syndrome (KQ1a-d) (insufficient strength of evidence).

Overview of the Literature

We identified 13 unique studies (20 papers, 1180 participants) addressing tonsillectomy in children with OSDB (Table 6).[44, 114, 171, 172, 174-178, 191, 201, 203-206, 208, 209, 211, 212, 214] One prospective cohort study included both children with OSDB and recurrent throat infection and did not report baseline data or outcomes by indication.[209]

Most studies were conducted in the United States (n=6),[114, 171-176, 178, 191, 201, 211, 212, 214] two in Brazil,[205, 281] two in Israel,[204, 206] and one each in Ireland,[209] Australia[203] and India.[44] Three studies were RCTs, including one multiple-publication study.[44, 114, 171-178] Six were prospective[203-206, 208, 209] and three were retrospective cohort studies.[211, 212, 214] One study was a nonrandomized trial.[201]

Eleven studies compared tonsillectomy to watchful waiting (which could have included supportive treatment with medications such as nasal steroids) or no surgery.[114, 171-178, 191, 201, 203-206, 208, 209, 211, 214] Two studies compared CPAP or oxygen with tonsillectomy.[44, 212] Participant ages ranged from less than 2 years to 16 years across studies. Studies frequently reported change in AHI and cognitive or behavioral outcomes.

We considered eight studies to have moderate risk of bias[44, 114, 171-178, 191, 201, 203, 206, 211, 214] and five to have high risk of bias.[204, 205, 208, 209, 212] Major sources of bias in these studies included the use of unblinded outcome assessors and unclear impact of concurrent interventions or variations in study execution. Given the relatively few studies addressing this question, we retained retrospective studies with low or moderate risk of bias as part of the evidence base. We retained high risk of bias studies in meta-analyses after sensitivity analyses reveal no significant effects on findings.

Table 6. Overview of studies addressing tonsillectomy in children with OSDB

Characteristic	RCTs	Nonrandomized Trial	Prospective Cohort Studies	Retrospective Cohort Studies	Total Literature
Comparisons					
Watchful Waiting or No Surgery	2	1	6	2	11
CPAP	1	0	0	1	2
Effectiveness Outcomes Frequently Reported					
AHI	3	0	2	3	8
Sleep-related Quality of Life (OSA-18, M-ESS, PSQ)	2	1	1*	1	5
Executive Function, Cognitive, or Behavioral Measure	1	0	2	1	4
Risk of Bias					
Low	0	0	0	0	0
Moderate	3	1	2	2	8
High	0	0	4	1	5
Total N participants	**529**	**64**	**386**	**106**	**1085**

AHI = Apnea–Hypopnea Index; CPAP = Continuous Positive Airway Pressure; M-ESS = Modified Epworth Sleepiness Scale; N = Number; OSA-18 = Obstructive Sleep Apnea-18; OSDB = Obstructive Sleep-Disordered Breathing; PSQ = Pediatric Sleep Questionnaire; RCT = Randomized Controlled Trial
*Reports the T14 Pediatric Throat Disorders Outcome Test

Detailed Analysis

Tonsillectomy Versus No Surgery or Watchful Waiting With Supportive Care

OSDB-Related Outcomes

Five studies (reported in multiple publications) of moderate[114, 171-178, 191, 203, 211, 214] risk of bias evaluated the improvement in AHI among children with PSG-proven OSDB. Two studies were RCTs, including the multi-publication Childhood Adenotonsillectomy Trial (CHAT);[114, 171-178] one was a prospective[203] and two were retrospective cohort studies,[211, 214] All reported improvement in children after tonsillectomy compared with observation without intervention or with supportive/medical management (excluding CPAP). The watchful waiting groups also improved from baseline in three studies.[114, 171-178, 191, 211] Differences in AHI between tonsillectomy and watchful waiting groups were statistically significant in three studies[171-178, 191, 211, 214] and not significant in two (Table 7).[114, 203] This benefit was consistent across age ranges (1-18 years), though data were most frequently available on children ages 4 to 12. Benefits seemed durable, with followup ranging from 6 months to 4 years. Where reported, the respiratory disturbance index and oxygen saturation improved significantly after tonsillectomy.[114, 172] Further, in a single, small low risk of bias study, tonsillectomy was associated with clinical benefit in symptoms of children with diagnoses of sleep apnea based on history, but with negative polysomnograms.[114] This study is quite small, however, with fewer than 40 participants.

We combined three studies (the CHAT RCT, reported in multiple publications,[171-178, 191] and

one prospective[211] and retrospective[204] study) reporting AHI outcomes in a fixed effects meta-analysis. We estimated an effect size of -4.81 (95% credible interval: -6.5 to -3.1), indicating a reduction (improvement) in AHI of 4.81 points in children receiving tonsillectomy compared with those not undergoing surgery. The clinical significance of this improvement is likely influenced by baseline disease severity and may be most obvious in children with mild or moderate OSDB (i.e., AHI scores of 1 to 10).Whether this degree of change is clinically important to patients' quality of life is not clear.

Table 7. Key OSDB-related outcomes in studies comparing tonsillectomy with watchful waiting in children with OSDB

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Baseline AHI Scores (Mean±SD)	Followup AHI Scores (Mean±SD)
Trosman 2016[214] Retrospective Cohort Moderate ROB	G1: Tonsillectomy (18) G1a: Tonsillectomy – obese children (8) G1b: Tonsillectomy – Syndromic children (6) G2: Watchful waiting with supportive care (44) G2a: Watchful waiting with supportive care, obese children (11) G2b: Watchful waiting with supportive care, Syndromic children (9)	G1: 3.5 ± 1.1 G1a: 3.83 G1b: 3.08 G2: 3.09 ± 1.1 G2a: 3.2 G2b: 3.31	16-month followup (IQR) G1: 2.69 (1.48 to 3.9) G1a: 3.08 G1b: 2.03 G2: 5.18 (2.46 to 7.9) G2a: 3.4 G2b: 2.84 G1 vs G2: p=0.03 G1a vs G2a: p=0.25 G1b vs G2b: p=0.36
Marcus 2014[171-178, 191] RCT Moderate ROB	G1: Tonsillectomy (193) G2: Watchful Waiting with Supportive Care (208)	Events/hour, median (IQR) G1: 4.8 (2.7 to 8.8) G2: 4.5 (2.5 to 8.9)	Events/hour, change from baseline to 7 months (IQR) G1: -3.5 (-7.1 to -1.8) G2: -1.6 (-3.7 to 0.5) G1 vs. G2: p < 0.001 Effect size: 0.57
Biggs 2014[203] Prospective Cohort Moderate ROB	G1: Tonsillectomy or Nasal Steroids (12) G2: Watchful waiting with supportive care (27)	Events/hour G1: 9.4 ± 9.9 G2: 1.0 ± 1.2	Events/hour (4 year followup) G1: 1.8 ± 5.2 G2: 1.7 ± 6.0 G1 vs. G2: p=NS
Burstein 2013[211] Retrospective Cohort* Moderate ROB	G1: Tonsillectomy (16) G2: Watchful waiting with supportive care (16)	G1: 14.4 (median) G2: 9.3 (median)	G1: 1.1 (median), median change=10.3 G2: 3.7 (median), median change=6.5 G1 vs. G2, median change: p=0.04
Goldstein 2004[114] RCT Moderate ROB	G1: PSG+ plus Tonsillectomy (21) G2: PSG- plus Tonsillectomy (11) G3: PSG- plus Watchful Waiting (9)	G1: 6.2 (median) G2: 0.5 (median) G3: 0.6 (median)	6-month followup G1: 0.9 (median) G2: 0.4 (median) G3: 0 G2 vs. G3: p=NS

*Note: Followup periods differed in this study: mean 1.4 years in the tonsillectomy group and 2.0 years in the no surgery group, p=0.02[211] IQR = Interquartile Range; n = Number; OSDB = Obstructive Sleep-Disordered Breathing; PSG = Polysomnography; NR = Not Reported; NS = Not Significant; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Sleep-Related Quality of Life

Two RCTs,[114, 171, 172, 174-178] one nonrandomized trial,[201] and one retrospective cohort[211](all rated as moderate risk of bias) assessed comparative effectiveness of tonsillectomy versus no surgery in the improvement of sleep quality (Table 8). Studies used several different parent-reported quality measures to assess sleep quality outcomes, limiting the ability to compare effectiveness directly across studies, although outcomes were consistently better in children receiving tonsillectomy.

One RCT and a retrospective cohort used the CAS-15 (Clinical Assessment Score),[114, 211] and both reported significant reduction in scores in the tonsillectomy compared with no tonsillectomy groups, indicating improvement in sleep quality following tonsillectomy. In the one study reporting baseline data, scores in the watchful waiting group improved from baseline to the 6-month followup (p=not reported [NR]).[114]The CHAT RCT used the Modified Epworth Sleepiness Scale (M-ESS) and OSA-18 as a measure of quality of life; while control group scores improved over baseline scores (p=NR), children who had tonsillectomy had significantly greater improvements in sleep quality as measured on both scales (p values ≤ 0.01).[171, 172, 174-178] This RCT also used the Pediatric Sleep Questionnaire Sleep-related Breathing Disorder scale (PSQ-SRBD), which showed significant improvements in sleep quality after tonsillectomy versus watchful waiting ($p \leq 0.01$), and small improvements in the control group from baseline (p=NR). In a nonrandomized trial (moderate risk of bias), children with PSG-proven mild OSA self-allocated to tonsillectomy or observation.[201] At a 4-month followup, quality of life assessed with the OSA-18 was significantly improved in children who had surgery (p=0.001) but not in the control group. Differences between groups, however, were not significant at the 8-month followup.

Finally, overall quality of life as measured by the Pediatric Quality of Life Inventory (PedsQL) improved significantly after tonsillectomy, compared with the untreated group in one RCT.[171, 172, 174-178, 203] Scores improved slightly in the control group from baseline (p=NR). Results for the benefit of tonsillectomy to improve sleep quality in children suffering from OSDB were positive across a number of outcomes and outcome domains. Many parents' chief complaint in bringing their child with OSDB to medical attention related to impaired quality of life. Results were consistently positive for tonsillectomy relative to observation in short time frames, with limited data available in the longer term.

Table 8. Key sleep-related quality of life outcomes in studies comparing tonsillectomy and no surgery in children with OSDB

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean±SD)	Outcome Measure Followup (Mean±SD)
Volksy 2014[201] Nonrandomized trial G1: Tonsillectomy (30) G2: Observation (34) Moderate ROB	G1: Tonsillectomy (30) G2: Watchful waiting with supportive care (34)	**OSA-18 Total Score** G1: 72.3 ± 20 G2: 58.5 ± 21.5	**3 months followup** **OSA-18 Total Score** G1: 33.9 ± 14.6 G2: 58.2 ± 24.5 G1 vs G2: p=0.0001 **8 months followup** **OSA-18 Total Score** G1: 33.6 ± 8.6 G2: 45.1 ± 21.9 G1 vs G2: p=NS
Marcus 2014[171-178, 191] RCT Moderate ROB	G1: Tonsillectomy (193) G2: Watchful waiting with supportive care (208)	**OSA-18 Total Score** G1: 53.1 ± 18.3 G2: 54.1 ± 18.8 **PSQ** G1: 0.5 ± 0.2 G2: 0.5 ± 0.2 **M-ESS** G1: 7.1 ± 4.7 G2: 7.5 ± 5.2 **PedsQL** G1: 77.3 ± 15.3 G2: 76.5 ± 15.7	**OSA-18 Total Score, change from baseline** G1: -21 ±16.5 G2: -4.5 ± 19.3 G1 vs. G2: p≤0.01 Effect size:-0.93 **PSQ, change from baseline** G1: -0.3 ±0.2 G2: -0.0 ± 0.2 G1 vs. G2: p≤0.01 Effect size: -1.35 **M-ESS, change from baseline** G1: -2.01 ± 4.7 G2: 0.28 ± 4.1 G1 vs. G2: p < 0.01 Effect size: -0.42 **PedsQL, change from baseline to 7 months** G1: 5.9 ± 13.6 G2: 0.9 ± 13.3 G1 vs. G2: p≤0.001 Effect size: 0.37

Table 8. Key sleep-related quality of life outcomes in studies comparing tonsillectomy and no surgery in children with OSDB, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean±SD)	Outcome Measure Followup (Mean±SD)
Burstein 2013[211] Retrospective Cohort Moderate ROB	G1: Tonsillectomy (16) G2: Watchful waiting with supportive care (16)	**CAS-15** G1: NR G2: NR	**CAS-15** G1: 8.9 ± 6.1 G2: 29.4 ± 16.2 G1 vs. G2: p<0.001
Goldstein 2004[114] RCT Low ROB	G1: PSG+ plus Tonsillectomy (21) G2: PSG- plus Tonsillectomy (11) G3: PSG- plus Watchful Waiting (9)	**CAS-15 (median)** G1: 77 G2: 64 G3: 50	**CAS-15 (median)** G1: 59 G2: 49 G3: 8 G2 vs. G3: p=0.001

CAS-15 = Clinical Assessment Score-15; M-ESS = Modified Epworth Sleepiness Scale; G = Group; N = Number; NA = Not Applicable; OSA-18 = Obstructive Sleep Apnea-18 ; PedsQL = Pediatric Quality of Life Inventory; PSG = Polysomnography; PSQ = Pediatric Sleep Questionnaire; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Behavioral Outcomes

The CHAT RCT[171-177] and one prospective[203] and one retrospective cohort study[211] addressed behavioral outcomes (Table 9). All studies had a moderate risk of bias and used different scales to assess outcomes, again limiting our ability to compare effectiveness directly across studies. Two studies used the Child Behavior Checklist (CBC) to measure internalizing (emotionally reactive, anxious/depressed, somatic complaints, withdrawn behavior) and externalizing (attention problems and aggressive behavior) behaviors. Total problem scores on the scale reflect the sum of these domains, and lower scores equate to fewer behavioral problems. In all studies reporting baseline data, scores on behavioral measures were not indicative of clinical concern.

Scores on the CBC improved from baseline in both groups in one cohort study, with no significant group differences.[203] In the second study, scores were significantly better in the tonsillectomy compared with no tonsillectomy group at followup, but baseline measures were not reported.[211]

CHAT investigators used the Conners' rating scale to assess behavioral issues including emotional lability and reported improvements (i.e., lowering of scores) in both groups from baseline, with significantly greater improvements in the tonsillectomy arm compared with no tonsillectomy on both teacher and parent-reported scales.[171-177] While children's behaviors improved in these studies, the clinical significance of the improvement is not clear.

Table 9. Key OSDB-related behavioral outcomes in studies comparing tonsillectomy and no surgery in children with OSDB

Author, Year Study Type Groups (N) Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean±SD)	Outcome Measure Followup (Mean±SD)
Marcus 2014[171-177] RCT Moderate ROB	G1: Tonsillectomy (193) G2: Watchful waiting with supportive care (208)	**Conners' (CGI) caregiver** G1: 52.5 ± 11.6 G2: 52.6 ± 11.7 **Conners' (CGI) teacher** G1: 56.4 ± 14.4 G2: 55.1 ± 12.8	**Conners' (CGI) caregiver, change from baseline to 7 months** G1: -2.9 ± 9.9 G2: -0.2 ± 9.4 G1 vs. G2: p=0.01 **Conners' (CGI) teacher, change from baseline to 7 months** G1: -4.9 ± 12.9 G2: -1.5 ± 10.7 G1 vs. G2: p=0.04
Biggs 2014[203] Prospective Cohort Moderate ROB	G1: Tonsillectomy or Nasal Steroids (12) G2: Watchful waiting with supportive care (27)	**CBC Total Problem** G1: 64 ± 9 G2: 59 ± 10	**CBC Total Problem (4 years post-tonsillectomy)** G1: 61 ± 15 G2: 57 ± 12 G1 vs. G2: p=NS
Burstein 2013[211] Retrospective Cohort Moderate ROB	G1: Tonsillectomy (16) G2: Watchful waiting with supportive care (16)	**CBC Total Problem** G1: NR G2: NR	**CBC Total Problem (1.66-1.97 years post-tonsillectomy)** G1: 43.9 G2: 58.9 G1 vs. G2: p < 0.001

CBC = Child Behavior Checklist; CGI = Connors Global Index; G = Group; N = Number; NA = Not Applicable; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Executive Function

One RCT and one prospective cohort study used the Developmental NEuroPSYchological Assessment (NEPSY) to evaluate attention and the Behavior Rating Inventory of Executive Function (BRIEF) to assess behavioral regulation and meta-cognition (Table 10).[171-177, 203] In the RCT, scores on the NEPSY improved from baseline in both groups, but group differences were not significant. Global scores on the BRIEF improved significantly among treated children compared with untreated children when evaluated by caregivers.[171-177, 203]When BRIEF was completed by teachers in a single study, both groups improved, and differences between groups were not significant.[171-177]

Table 10. Key OSDB-related executive function outcomes in studies comparing tonsillectomy and no surgery in children with OSDB

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Marcus 2014[171, 172, 174-177] RCT Moderate ROB	G1: Tonsillectomy (193) G2: Watchful waiting with supportive care (208)	**NEPSY*** G1: 101.5 ± 15.9 G2: 101.1 ± 15 **BRIEF (GEC) caregiver** G1: 50.1 ± 11.2 G2: 50.1 ± 11.5 **BRIEF (GEC) teacher** G1: 57.2 ± 14.1 G2: 56.4 ± 11.7	**Change from baseline to 7 months** **NEPSY*** G1: 7.1 ± 13.9 G2: 5.1 ± 13.4 G1 vs. G2: p=NS Effect size: 0.15 **BRIEF (GEC) caregiver** G1: -3.3 ± 8.5 G2: 0.4 ± 8.8 G1 vs. G2: p < 0.001 Effect size: 0.28 **BRIEF (GEC) teacher** G1: -3.1 ± 12.6 G2: -1.0 ± 11.2 G1 vs. G2: p=NS Effect size: 0.18
Biggs 2014[203] Prospective Cohort Moderate ROB	G1: Tonsillectomy or Nasal Steroids (12) G2: Watchful waiting with supportive care (27)	**BRIEF (GEC) caregiver** G1: 62 ± 11 G2: 58 ± 11	**BRIEF (GEC) caregiver (4 years post-tonsillectomy)** G1: 58 ± 16 G2: 57 ± 12 G1 vs. G2: p < 0.05

BRIEF (GEC) = Behavior Rating Inventory of Executive Function (Global Executive Composite); G = Group; N = Number; NA = Not Applicable; NEPSY = Neuropsychological Assessment; NS = Not Significant; OSDB = Obstructive Sleep-Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation
*NEPSY attention and executive function

Cardiopulmonary and Physiologic Outcomes

One RCT reported in multiple publications[171-178] (moderate risk of bias) addressed outcomes including cardiometabolic measures. Evidence was insufficient to comment on physiologic parameters, with a single RCT reporting no change in cardiometabolic measures, including insulin, lipids, and C-reactive protein levels.[171, 172, 174-178] Underweight children also showed a significant increase in weight and BMI in this RCT.[171-178]

Utilization and Other Outcomes

Two cohort studies with moderate risk of bias assessed health care utilization, measured by number of clinician contacts or antibiotic prescriptions, or cognitive outcomes (Table 11). A single moderate risk of bias cohort study reported a 33 percent reduction in gross health care utilization, including a 60 percent reduction in hospital admissions over one year following tonsillectomy in children with PSG-proven OSDB, while admissions in the untreated group increased (p=NR).[206]

One cohort study using the Weschler Abbreviated Scale of Intelligence reported a significant

improvement in performance IQ at 4-years post-tonsillectomy in children undergoing tonsillectomy, but both the tonsillectomy and no surgery groups had declines or no change in full scale IQ and verbal IQ over the same period.[203]

Table 11. Other outcomes in studies comparing tonsillectomy with watchful waiting in children with OSDB

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Tarasiuk 2004[206] Prospective cohort Moderate ROB	G1: Tonsillectomy (130) G2: Watchful waiting with supportive care (90)	G1+G2: NR	**Number of new admissions, mean±standard error/patient/year** Year 1 G1: 0.15±0.04 G2: 0.08±0.03 Year 2 G1: 0.06±0.02 G2: 0.25±0.07 **Number of emergency department visits, mean±standard error/patient/year** Year 1 G1: 0.57±0.09 G2: 0.52±0.09 Year 2 G1: 0.35±0.05 G2: 0.37±0.10 **Number of consultations, mean±standard error/patient/year** Year 1 G1: 3.6±0.37 G2: 4.4±0.40 G1 vs. G2: p= NR Year 2 G1: 1.9±0.26 G2: 3.5±0.46 G1 vs. G2: p= NR
Biggs 2014[203] Prospective Cohort Moderate ROB	G1: Tonsillectomy (12) G2: Watchful waiting with supportive care (27)	**WASI Full Scale IQ** G1:102 ± 13 G2: 106 ±14	**WASI Full Scale IQ** 4 Years Post-tonsillectomy G1: 101 ± 12 G2: 104 ± 15 G1 vs. G2: p=NS

G = Group; IQ = Intelligence Quotient; N = Number; NA = Not Applicable; NS = Not significant; ROB = Risk of Bias; SD = Standard Deviation; WASI = Wechsler Abbreviated Scale of Intelligence

Tonsillectomy Versus CPAP

OSDB-Related and Sleep Outcomes

One RCTwith moderate risk of bias addressed OSDB- and sleep-related outcomes in children with OSDB who received tonsillectomy compared with CPAP[44] (Table 12). Children in the RCT

had concomitant Down syndrome or mucopolysaccharidoses (n=32). AHI scores improved from baseline in both groups, but group differences were not significant in this small study.[44] More children in the tonsillectomy arm had resolution of OSDB (defined as AHI < 1, 91.8% vs. 86.1%, p=NR). The RCT also evaluated sleep outcomes using the ESS and OSA-18. Both groups improved on these measures from baseline with no significant group differences.[44] Immediate improvement occurred on initiation with CPAP versus a gradual progression with tonsillectomy.

Table 12. OSDB resolution and sleep outcomes in studies comparing tonsillectomy with CPAP

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline	Outcome Measure Followup
Sudarsan 2014[44] RCT Moderate ROB	G1: Tonsillectomy (37) G2: CPAP (36)	**AHI, mean±SD** G1: 3.83 ± 1.36 G2: 3.46 ± 0.87 **Sleep Outcomes** **OSA-18 Total Score, mean±SD** G1:116.97 ± 2.25 G2: 116.87 ± 1.3 **ESS-C** G1: 13.76 ± 1.32 G2: 14.44 ± 2.18	**AHI, mean±SD** G1: 1.06 ± 0.74 G2: 1.07 ± 0.57 G1 vs. G2: p=NS **Resolution rate** (resolution=AHI < 1), (%) G1: 91.8 G2: 86.1 G1 vs. G2: p= NR AHI < 1, % G1+G2: 89 **Sleep Outcomes** **OSA-18 Total Score, mean±SD** G1: 73.59 ± 4.14 G2: 75.02 ± 2.5 G1 vs. G2: p=NS **ESS-C** G1: 5.46 ± 1.35 G2: 7.86 ± 1.69 G1 vs. G2: p=NS

AHI = Apnea-Hypopnea Index; CI = Confidence Interval; CPAP = Continuous Positive Airway Pressure; ESS-C = Epworth Sleepiness Scale - Child ; G = Group; M-ESS = Modified Epworth Sleepiness Scale; N = Number; NR = Not Reported; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Key Question 1a. Effectiveness of Tonsillectomy for Children With OSDB and Neuromuscular or Craniofacial Abnormalities

A single RCT (moderate risk of bias) compared the efficacy of tonsillectomy to immediate initiation of CPAP in children with Down syndrome and mucopolysaccharidoses who were diagnosed with obstructive sleep apnea by polysomnogram.[44] Both groups showed improvement in AHI at 6-month followup, with maintenance at 12-month followup (no significant group differences). Within this study, three patients (8.1%) who underwent tonsillectomy had persistent symptoms of OSDB and five patients (13.8%) who initiated CPAP had persistent OSDB symptoms. Baseline mean AHI scores for children in this study were far higher than normative scores reported in studies of healthy patients. One retrospective cohort study that included 15 children with syndromic comorbidities (7 with Down syndrome, 1 with Pierre Robin Sequence and 1 with Digeorge syndrome) reported no significant group differences in improvements in

AHI in children with syndromic conditions.[214]

Key Question 1b. Effectiveness of Tonsillectomy for Children With OSDB Under 3 Years of Age

We did not identify studies addressing the question. While several studies included children under 3, these data were not extractable from the aggregate data of the entire study population.

Key Question 1c. Effectiveness of Tonsillectomy for Children With OSDB and Down Syndrome

One RCT and one retrospective cohort study (both with moderate risk of bias) specifically studied children with Down syndrome.[44, 214] Data were reported along with children with mucopolysaccharidoses in the RCT and along with patients with various syndromic comorbidities in the cohort. These studies are discussed in detail above.

Key Question 1d. Effectiveness of Tonsillectomy for Children With OSDB and Obesity

One retrospective cohort study (moderate risk of bias) examining a mostly overweight/obese population with PSG-proven OSDB reported a significant improvement in AHI in children who received tonsillectomy compared with those who did not; however, data were insufficient to suggest effect modification by obesity/overweight status in this single, small study.[211] In another retrospective cohort including children with mild OSA, analysis of subgroups of obese children and those with syndromic comorbidities showed no significant benefit between groups in these populations.[214]

Key Question 2. Effectiveness of Tonsillectomy Versus No Surgery for Recurrent Throat Infection

Key Points

- Overall, children undergoing tonsillectomy to improve number of throat infections, associated health care utilization, and days of work/school missed had improvements in these outcomes in the first postsurgical year vs. children not receiving surgery. These benefits did not persist over time. Data on long-term outcomes of children with recurrent sore throat who do not undergo tonsillectomy are limited.
- We have moderate confidence in the conclusion that, compared with no surgery, tonsillectomy reduces throat infections or streptococcal infections in the short term (≤12 months) (moderate strength of evidence).
- Compared with no surgery, tonsillectomy reduced utilization (clinician contacts), and missed school/work in the short term. We have low confidence in this conclusion (low strength of evidence).
- In the longer term (>12 months) we found no difference between groups in reduction in streptococcal infections. We have low confidence in this conclusion (low strength of evidence).We found no differences between groups in missed school/work or quality of

life in the long term (>12 months) and have low confidence in this conclusion (low strength of evidence).

- We could not make a conclusion about effects of tonsillectomy on throat infections in the long term (>12 months) (insufficient strength of evidence)

Overview of the Literature

We identified ten unique studies addressing tonsillectomy specifically for recurrent throat infections (Table 13).[6, 9, 164-166, 179-181, 209, 210, 213] As noted above, one study included both children with recurrent throat infection and OSDB.[209] Four unique studies (3 RCTs and 1 nonrandomized trial) were reported in two papers,[6, 9] and one set of investigators reported RCT and nonrandomized trial results together in multiple papers.[179-181] Another RCT was reported in multiple papers.[164-166] Five studies were conducted in the United States,[6, 9, 213] three in the United Kingdom,[179-181, 210] one in Ireland,[209] and one in the Netherlands.[164-166]Studies included five RCTs,[6, 9, 164-166, 179-181] two nonrandomized trials,[6, 179-181] and one prospective[209] and two retrospective cohorts.[210, 213] Studies compared tonsillectomy to watchful waiting, which could have included medical treatment including antibiotics or other conventional medical management[6, 9, 164-166, 179-181, 209, 210, 213] Studies included a total of 15,754 participants (at time of randomization or the start of the study) ranging in age from 2 to 16 years. Outcomes reported in most studies included number of throat infections or streptococcal infections.

Four RCTs and one nonrandomized trial and two retrospective cohort studies had moderate risk of bias,[9, 164-166, 179-181, 210, 213] and one RCT, one prospective cohort study, and one nonrandomized trial had high risk of bias.[6, 209] Major sources of bias in these studies included unclear concealment of study group allocation and unclear fidelity to the intervention protocol. Given the relatively few studies addressing this question, we retained retrospective studies as part of the evidence base.

Table 13. Overview of studies addressing tonsillectomy in children with recurrent throat infections

Characteristic	RCTs	Nonrandomized Trials	Prospective Cohort Studies	Retrospective Cohort Studies	Total Literature
Surgical Indication					
Throat Infection	2	2	0	2	6
OSDB+Throat Infection	3	0	1	0	3
Effectiveness Outcomes Frequently Reported					
Number Throat Infections	5	2	0	1	8
Number Streptococcal Infections	3	1	0	1	5
Utilization (# clinician consultations or antibiotic prescriptions)	1	1	0	1	3
Missed School or Work	4	1	0	0	5
Quality of life	1	1	1	0	3
Risk of Bias					
Low	0	0	0	0	0
Moderate	4	1	0	2	7
High	1	1	1	0	2
Total N participants	**944**	**557**	**71**	**14182**	**15754**

N = number; OSDB = obstructive sleep-disordered breathing; RCT = randomized controlled trial

Detailed Analysis

Tonsillectomy Versus No Surgery/Watchful Waiting

Four RCTs[9, 164-166, 179-181] (including 2 reported in one publication[9] and 2 reported in multiple publications[164-166, 179-181]), one nonrandomized trial[179-181] and one retrospective cohort study[213] included children with at least 3 throat infections in the 3 months to one year prior to surgery and reported on recurrent throat infections and clinician visits following surgery or no surgery (Tables 14-15). We considered four RCTs (including 2 published in one paper[9]) to have moderate risk of bias.[9, 164, 166, 179-181, 277] Another nonrandomized trial had moderate risk of bias.[179-181] We considered one retrospective cohort study addressing these outcomes to have moderate risk of bias.[213]

In all studies reporting baseline data, number of infections decreased from baseline in both groups, with significantly greater decreases in sore throat days and diagnosed Group A streptococcal throat infections in children who received tonsillectomy vs. no surgery/watchful waiting with supportive care in the short term (< 12 months). As noted, in two papers in this section, investigators report multiple RCTs and/or nonrandomized trials conducted by the same team (but with unique populations) in single papers. In one such paper, both the RCT and nonrandomized trial[179-181] reported that children in both studies who received tonsillectomy had fewer recorded days of sore throat in a symptom diary than children who had medical management. Using an intention-to-treat analysis for the RCT patients, the study found a decrease of 3.5 (95% CI: 1.8 to 5.2) sore throat episodes over the full 2-year study period for children who underwent tonsillectomy. The benefit was greatest in those quick to receive tonsillectomy after the onset of infections, with the relative benefit decreasing with longer times to intervention. Children who underwent tonsillectomy within 4 weeks of enrollment had an estimated 8.5 episodes of sore throat avoided, whereas children who waited longer times (up to 52 weeks) had 3.5 episodes of sore throats saved. Limitations of this study family include strong parental preference for surgery when the child had more severe symptoms, thus affecting the generalizability of the patients who were randomized. The study points out that the children who were ultimately randomized fell into the middle of the pack in terms of how much they were impacted by their symptoms. The study also had significant attrition in return of the symptom diaries over time and difficulty obtaining provider records for review.

In another paper reporting two unique RCTs, benefits of tonsillectomy or adenotonsillectomy were reported for children who experienced at least one sore throat.[282] These studies had surgical and watchful waiting groups, and while the surgical groups had fewer visits for sore throat after surgery, the number of visits for sore throat in the watchful waiting groups was also low. The first year postsurgery, the tonsillectomy group had 1.74 (95% CI: 1.54 to 2.00) episodes of throat infection while the control group had 2.93 (95% CI: 2.69 to 3.22) episodes. Although statistically significant, it is unclear whether this difference is clinically meaningful. ,

In another RCT (moderate risk of bias) including children with mild symptoms of throat infection or hypertrophy (< 7 or more throat infections in prior year or 5 or more in prior 2 years or 3 or more in prior 3 years and Brouillette's OSA score of less than 3.5—i.e., in no apnea or possible apnea range), children who received tonsillectomy had fewer throat infections (throat pain+fever) compared with those who had no surgery (0.56/person year vs. 0.77, p= NR).[164-166] Of note, many children originally allocated to no surgery/watchful waiting (n=50 of 149) crossed over to the surgery arm.

One retrospective cohort found that children who did not undergo tonsillectomy were 3.1 times (95% CI: 2.1 to 4.6, $p < 0.001$) more likely to test positive for Group A streptococcal (GAS) throat infection that their counterparts who underwent surgery.[213]Children who did not have tonsillectomy also experienced GAS infection at a shorter time interval than the children without tonsils.

Two RCTs and one nonrandomized trial reported quality of life data, which were not markedly different between any of the study arms at any time point.[164, 179-181] Overall, comparative effectiveness assessment of tonsillectomy vs. no surgery to improve number of throat infections, associated health care utilization, and work/school absences shows a benefit in the first postsurgical year. These benefits did not persist over time. Quality of life improved in both groups (p=NR).

One retrospective cohort study included children who may have had fewer than three throat infections in the prior year.[210] The study reported a net reduction in the 3-year mean sore throat visits for children who underwent tonsillectomy compared with those who did not. , This reduction decreased over time with 2.46 fewer visits (95% CI: 2.29 to 2.63, $p < 0.001$) in years 1-3 and 1.21 fewer visits (95% CI: 1.04 to 1.38, $p < 0.001$) in years 4-6, or 0.61 sore throat visits per child per year (over the 6 year study period). This study focused on provider visits rather than sore throat episodes that did not generate a provider visit, or visits with multiple concerns, coded under another primary complaint.

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Lock 2010[179-181] RCT G1: Tonsillectomy (119) G2: Medical management, (112) Moderate ROB	G1: Tonsillectomy (119) G2: Watchful waiting with supportive care (112)	**<u>Throat Infections</u>** **N sore throats, 3 months prior to study entry, mean±SD** G1: 3.09±2.08 G2: 3.34±2.63 **<u>Utilization</u>** **# general practitioner consultations in 2 years prior to study entry, mean±SD** G1+G2: 10.3±6.3 **# consultations for sore throat in 2 years prior to study entry, mean±SD** G1+G2: 6.0±3.7 **<u>Quality of Life</u>** **N respondents** G1: 111 G2: 108 **PedsQL 4.0 Physical Health** G1: 76.26±19.50 G2: 78.75±18.01 **N respondents** G1: 111 G2: 110 **PedsQL 4.0 Psychosocial Health** G1: 70.95±14.18 G2: 72.33±14.86	**<u>Throat Infections</u>** **Sore throats/month, mean±SD** Year 1 G1: 0.50±0.43 (n respondents=119) G2: 0.64±0.49 (n respondents=112) RR=0.70 (95% CI: 0.61 to 0.80), p < 0.001 Year 2 G1: 0.13±0.21(n respondents=83) G2: 0.33±0.43 (n respondents=74) RR=0.54 (95%CI: 042 to 0.70), p < 0.001 **<u>Utilization</u>** **Year 1** **# clinician consultations, mean±SD** G1: 3.99±3.74 G2: 4.38±3.48 RR: 0.91 (95% CI: 0.71 to 1.17) **# sore throat consultations, mean±SD** G1: 1.90±2.84 G2: 2.35±2.35 RR: 0.81 (95% CI: 0.59 to 1.10)

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Lock 2010[179-181] RCT, continued			**Year 2** **# clinician consultations, mean±SD** G1: 2.84±2.90 G2: 3.40±3.20 RR: 0.83 (95% CI: 0.63 to 1.10) **# sore throat consultations, mean±SD** G1: 0.89±1.44 G2: 1.33±1.56 RR: 0.67 (95% CI: 0.46 to 0.97) **Quality of Life** **12 months, N respondents** G1: 71 G2: 52 **PedsQL 4.0 Physical Health** G1: 89.95±16.37 (adjusted effect size: 3.08 [95% CI: 3.11 to 9.27]) G2: 85.34±17.86 **PedsQL 4.0 Psychosocial Health** G1: 83.81±15.31 (adjusted effect size: 2.43 [95% CI: -3.08 to 7.03]) G2: 79.97±17.49 **24 months, N respondents** G1: 63 G2: 53 **PedsQL 4.0 Physical Health** G1: 88.79±17.66 (adjusted effect size: 0.31 [95% CI: -5.74 to 6.37]) G2: 88.05±12.76 **PedsQL 4.0 Psychosocial Health** G1: 84.30±15.02 (adjusted effect size: 0.39 [95% CI: -4.52 to 5.29]) G2: 83.897±12.95

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Lock 2010[179-181] Nonrandomized trial G1: Tonsillectomy (349) G2: Medical management, (67) Moderate ROB	G1: Tonsillectomy (349) G2: Watchful waiting with supportive care (67)	**Throat Infections** **N sore throat lasting < 2 weeks in 3 months prior to study entry, mean±SD** G1: 3.6±2.5 G2: 2.7±1.6 **Utilization** **# general practitioner consultations in 2 years prior to study entry, mean±SD** G1: 8.6±5.8 G2: 10.3±6.9 **# consultations for sore throat in 2 years prior to study entry, mean±SD** G1: 5.4±3.4 G2: 6.2±4.2 **Quality of Life** **N respondents** G1: 338 G2: 65 **PedsQL 4.0 Physical Health** G1: 76.26±19.50 G2: 78.75±18.01 **N respondents** G1: 334 G2: 66 **PedsQL 4.0 Psychosocial Health** G1: 70.95±14.18 G2: 72.33±14.86	**Throat Infections** **Sore throats/month, mean±SD** Year 1 G1: 0.71±0.50 G2: 0.59±0.44 Year 2 G1: 0.19±0.36 G2: 0.38±0.34 **Utilization** **Year 1** **# clinician consultations, mean±SD** G1: 3.69±3.33 G2: 3.16±3.14 **# sore throat consultations, mean±SD** G1: 1.86±2.23 G2: 1.63±1.98 **Year 2** **# clinician consultations, mean±SD** G1: 2.71±3.51 G2: 3.12±3.10 **# sore throat consultations, mean±SD** G1: 0.78±1.31 G2: 1.45±2.07 **Quality of Life—12 months** **N respondents** G1: 117 G2: 27 **PedsQL 4.0 Physical Health** G1: 87.15±15.00 G2: 84.66±16.00 **N respondents** G1: 118 G2: 27 **PedsQL 4.0 Psychosocial Health** G1: 82.27±15.83 G2: 82.78±16.12 **24 months** **N respondents** G1: 96 G2: 25 **PedsQL 4.0 Physical Health** G1: 91.35±14.48 G2: 91.88±9.59 **N respondents** G1: 95 G2: 25 **PedsQL 4.0 Psychosocial Health** G1: 85.85±13.78 G2: 87.46±10.38

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Orvidas 2006[213] Retrospective Cohort Moderate ROB	G1: Tonsillectomy (145) G2: Watchful waiting with supportive care (145)	**Throat Infections** **N with infection within one year prior to tonsillectomy/study entry, (%)** G1: 141 (97.2) G2: 130 (89.7)	**Throat Infections** **Cumulative Incidence of Developing Group A Beta-hemolytic Streptococcal Throat Infection, % (95%CI)** At 6 months G1: 13.2 (7.5 to 18.6) Number still at risk: 124 G2: 39.3 (30.8 to 46.8) Number still at risk: 87 At 1 year G1: 23.1 (15.9 to 29.7) Number still at risk: 107 G2: 58.5 (49.6 to 65.9) Number still at risk: 57 At 2 years G1: 38.5 (29.8 to 46) Number still at risk: 83 G2: 74.8 (66.4 to 81.1) Number still at risk: 34 At 3 years G1: 46.1 (37.1 to 53.9) Number still at risk: 65 G2: 82.2 (74.5 to 87.6) Number still at risk: 21 At 4 years G1: 51.9 (42.4 to 59.8) Number still at risk: 39 G2: 84.6 (76.7 to 89.8) Number still at risk: 12
Van Staaij 2004[164-166] RCT Moderate ROB	G1: Tonsillectomy (133) G2: Watchful waiting with supportive care (124)	**Throat Infections** **Throat infections in year prior to study, median (range)** G1: 3 (0-6) G2: 3 (0-6)	**Throat Infections** **Episodes of throat infection/person year, n** G1: 0.56 G2: 0.83 Difference: -0.21 (95% CI: -0.36 to -0.06) **Incidence rate** G1+G2: 0.73 (95% CI: 0.58 to 0.92) **Quality of Life** Data in figures only; study notes no clinically significant differences

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Paradise 2002[9] RCT A Moderate ROB	G1: Tonsillectomy (58 randomized, 52 received intervention) G2: Adenotonsillectomy (59 randomized, 50 received intervention) G3: Watchful waiting with supportive care (60 randomized, 60 received intervention)	**Throat Infections** G1+G2: NR	**Throat Infections** **Episodes of Any Throat Infection, Mean (95% CI)** Years 1-3 G1: 1.55 (95% CI: 1.33 to 1.82) G2: 1.63 (95% CI: 1.37 to 1.93) G3: 2.77 (95% CI: 2.52 to 3.13) G1 vs. G3: p < 0.001 G2 vs. G3: p < 0.001 **Episodes of Group A Beta-hemolytic Streptococcal Throat Infection, Mean (95% CI)** Years 1-3 G1: 0.29 (95% CI: 0.20 to 0.41) G2: 0.20 (95% CI: 0.12 to 0.32) G3: 0.82 (95% CI: 0.67 to 1.01) G1 vs. G3: p < 0.001 G2 vs. G3: p < 0.001 **Episodes of Moderate or Severe Throat Infection, Mean (95% CI)** Years 1-3 G1: 0.09 (95% CI: 0.04 to 0.17) G2: 0.08 (95% CI: 0.03 to 0.17) G3: 0.33 (95% CI: 0.24 to 0.45) G1 vs. G3: p=0.002 G2 vs. G3: p=0.003
Paradise 2002[9] RCT B Moderate ROB	G1: Adenotonsillectomy (73 randomized, 63 received intervention) G2: Watchful waiting with supportive care (78 randomized, 78 received intervention)	**Throat Infections** G1+G2: NR	**Throat Infections** **Episodes of Any Throat Infection, Mean (95% CI)** Years 1-3 G1: 1.74 (95% CI: 1.54 to 2.00) G2: 2.93 (95% CI: 2.69 to 3.22) G1 vs. G2: p < 0.001 **Episodes of Group A Beta-hemolytic Streptococcal Throat Infection, Mean (95% CI)** Years 1-3 G1: 0.29 (95% CI: 0.21 to 0.40) G2: 0.77 (95% CI: 0.65 to 0.92) G1 vs. G2: p < 0.001 **Episodes of Moderate or Severe Throat Infection, Mean (95% CI)** Years 1-3 G1: 0.07 (95% CI: 0.03 to 0.13) G2: 0.28 (95% CI: 0.21 to 0.37) G1 vs. G2: p=0.003

Table 14. Key infection outcomes in studies comparing tonsillectomy and no surgery in children with recurrent throat infections, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Outcome Measure Baseline (Mean)	Outcome Measure Followup (Mean)
Koshy 2015[210] Retrospective Cohort G1: Tonsillectomy and ≤3 acute throat infection consultations (450) G2: No tonsillectomy and ≤3 acute throat infection (13442) Moderate ROB	G1: Tonsillectomy and ≤3 acute throat infection consultations (450) G2: No tonsillectomy and ≤3 acute throat infection (13442)	**Utilization** **# throat infection consultations in 3 years prior to study index date, mean±SD** G1: 1.3±1.1 G2: 0.4±0.8 G1 vs. G2: p < 0.001	**Utilization** **# throat infection consultations 4-6 years post-index date, mean** G1: 0.6 G2: 0.93 **Mean difference in consultations, baseline to followup** G1: −0.72 (95% CI: −0.88 to −0.56), p < 0.001 G2: +0.49 (95% CI: 0.46 to 0.52), p < 0.001

CI = Confidence Interval; G = Group; n = Number; NR = Not Reported; NS = Not Significant; PedsQL = Pediatric Quality of Life Questionnaire; ROB = Risk of Bias

Fewer days of missed school or work were associated with tonsillectomy in the short term, with differences diminishing over time in two RCTs[9] while another RCT noted comparable school absences between groups[164-166] (Table 15).

Table 15. Missed school or work outcomes reported in studies comparing tonsillectomy and no surgery in children with recurrent throat infections

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Sore Throat-Associated School Absences, Mean±SD Days/Year (Number Days/Year)
Van Staaij 2004[164-166] RCT Moderate ROB	G1: Tonsillectomy (133) G2: Watchful waiting with supportive care 124)	Difference in school absences G1 vs. G2: 0.09 (95% CI: -0.27 to 0.44)
Paradise 2002[9] RCT A G1: Tonsillectomy (58 randomized, 52 received intervention) G2: Adenotonsillectomy (59 randomized, 50 received intervention) G3: No surgery (60 randomized, 60 received intervention) Moderate ROB	G1: Tonsillectomy (58 randomized, 52 received intervention) G2: Adenotonsillectomy (59 randomized, 50 received intervention) G3: No sur Watchful waiting with supportive care (60 randomized, 60 received intervention)	Year 1 G1: 3.3±4.0 (42) G2: 3.9±3.7 (44) G3: 5.3±4.7 (50) G1 vs. G3: p < 0.05 Year 2 G1: 3.2±3.9 (39) G2: 2.4±3.2 (38) G3: 5.0±5.2 (44) G2 vs. G3: p < 0.05 Year 3 G1: 2.5±3.2 (37) G2: 2.9±2.9 (29) G3: 3.7±3.2 (42) G2 vs. G3: p=NS
Paradise 2002[9] RCT B Moderate ROB	G1: Tonsillectomy (73 randomized, 63 received intervention) G2: Watchful waiting with supportive care (78 randomized, 78 received intervention)	Year 1 G1: 3.5±4.2 (52) G2: 6.6±6.2 (58) G1 vs. G2: p < 0.01 Year 2 G1: 3.2±4.1 (47) G2: 5.4±6.7 (56) G1 vs. G2: p=NS Year 3 G1: 2.6±3.4 (45) G2: 4.2±5.2 (55) G1 vs. G2: p=NS

G = Group; n = Number; NS = Not Significant; RCT = Randomized Controlled Trial; ROB = Risk of Bias

Key Question 3. Effectiveness of Partial Versus Total Tonsillectomy

Key Points

- Few studies compared the same surgical technique for partial or total tonsillectomy. In studies comparing partial and total cold dissection tonsillectomy, return to normal diet and activity was faster in children undergoing partial tonsillectomy. Our confidence in this conclusion is low (low strength of evidence).
- In studies comparing partial and total cold dissection tonsillectomy, we could not make conclusions about effects on throat infections or OSDB persistence (insufficient strength of evidence).
- In studies comparing either partial and total coblation tonsillectomy or partial and total electrocautery tonsillectomy, we could not make conclusions about effects on return to normal diet or activity (insufficient strength of evidence).
- In studies comparing mixed techniques for partial or total tonsillectomy, return to normal diet and activity was more favorable in children undergoing partial versus total tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). These effects may be due to confounding by indication as indication varied across studies.
- In studies comparing mixed techniques for partial or total tonsillectomy, we found no difference in effects on long-term (>12 months) persistence of OSDB symptoms, quality of life, behavioral outcomes, or throat infections between partial and total tonsillectomy. Our confidence in these conclusions is low (low strength of evidence).

Overview of the Literature

We identified 22 unique studies (20 RCTs,[53, 71, 84-86, 90, 95, 97, 98, 101, 107, 110, 129, 139, 151, 158, 182-187, 189] and 2 nonrandomized trials[193, 198]) addressing partial tonsillectomy compared with total tonsillectomy (Table 16). Most studies were conducted in Europe[53, 84, 86, 101, 129, 185, 186, 193, 198] or North America.[85, 90, 95, 97, 98, 107, 110, 151] Four studies were conducted in Asia,[71, 139, 187, 189] and one in Africa.[158] Participants (n=2925) ranged in age from 1 to 18 years. In addition to comparing partial with total tonsil removal, most studies (n=16) also compared surgical techniques including microdebrider, laser, coblation, and electrocautery partial tonsillectomy and cold dissection, coblation, and electrocautery total tonsillectomy. In studies comparing both extent of surgical removal (i.e., partial vs. total removal) and different surgical techniques (e.g., partial coblation vs. total electrocautery), it is not possible to determine whether effects are due to the technique or due to the extent of surgery. Thus, except for in those studies that compared partial or total removal of the tonsils using the same technique (e.g., partial cold dissection vs. total cold dissection), we considered the comparison of interest broadly as partial vs. total tonsil removal. We present results by partial vs. total cold dissection, partial vs. total coblation or electrocautery; and partial vs. total regardless of technique below.

Across studies, definitions of "partial" tonsillectomy varied or were not explicit. Five studies explicitly noted leaving anywhere from 10 to 70 percent of the tonsil intact,[53, 84, 86, 110, 129] while others noted leaving a thin rim of tissue or removing the bulk of the tonsil,[71, 85, 90, 107, 189, 198] and yet others reported removing the obstructive or protruding portion of the tonsil only.[182-187, 193] Six studies did not describe the portion of tissue removed.[95, 97, 98, 139, 151, 158]

We considered five RCTs to have low risk of bias.[53, 90, 97, 98, 151, 158] Eleven RCTs[71, 84-86, 95, 107, 110, 139, 182-186] had moderate risk of bias, and four RCTs[187, 189, 283, 284] and two nonrandomized trials[193, 198] had high risk of bias. Major sources of bias in these studies include unclear methods for randomization and unclear methods for concealment of treatment group allocation. We do not discuss high risk of bias studies in the detailed analyses below.

Table 16. Overview of studies comparing partial versus total tonsillectomy

Characteristic	RCTs	Nonrandomized Trials	Total Literature
Comparisons			
Total cold dissection vs. partial cold dissection	3	1	4
Total coblation vs. partial coblation	1	0	1
Total electrocautery vs. partial electrocautery	1	0	1
Partial vs. total	15	1	16
Surgical Indication			
OSDB	17	2	19
OSDB+Throat Infection	2	0	2
Not specified	1	0	1
Effectiveness Outcomes Frequently Reported			
Return to normal diet or activity	10	0	10
Number of throat infections	6	0	6
Tonsillar regrowth	5	1	6
Risk of Bias			
Low	5	0	5
Moderate	11	0	11
High	4	2	6
Total N participants	**1709**	**1216**	**2925**

n = Number; OSDB = Obstructive Sleep-Disordered Breathing; RCT = Randomized Controlled Trial

Detailed Analysis

Partial Cold Dissection Versus Total Cold Dissection Tonsillectomy

Three RCTs and one nonrandomized trial compared total and partial cold dissection and included 348 children in the partial tonsillectomy arms and 378 in the total tonsillectomy arms.[53, 84, 86, 198] Few of these studies reported the same outcomes (Table 17).

OSDB Persistence

In one RCT (low risk of bias) reporting on the persistence of OSDB, children in both arms had recurrence of snoring.[53] Differences were not statistically significant.

Tonsillar Regrowth and Reoperation

Two RCTs (low[53] and moderate[84] risk of bias) addressed regrowth and/or revision surgery. In one RCT including 40 children with OSDB undergoing partial tonsillectomy and 41 undergoing total, no children had tonsillar regrowth (0 of 68 followed up) in the 2-year followup period.[84] In a second study, 6 out of 43 children undergoing partial tonsillectomy and followed for 6 years had regrowth, in two cases requiring total tonsillectomy.[53]

Growth

No studies provided baseline comparative data that could be used to assess the comparative effectiveness of surgery on growth outcomes.

Return to Normal Diet or Activity

Children in the partial tonsillectomy arm had significantly faster return to normal diet in the two RCTs (low and moderate risk of bias) addressing this outcome (p values< 0.001).[53, 86]

Throat Infection

In one low risk of bias RCT with 6-year followup, no children (0/91) in either group had throat infections, although the study reports that five children in the partial tonsillectomy arm had at least one episode of tonsillitis/year in the followup period.[53] The study did not define throat infection or tonsillitis.

Table 17. Comparative effectiveness outcomes in studies addressing partial versus total cold dissection tonsillectomy

Author, Year Study Design Risk of Bias	Comparison Groups (N)	OSDB Persistence	Tonsillar Regrowth	Return to Normal Diet or Activity	Throat Infections
Chaidas 2013[53] RCT Low ROB	G1: Partial cold tonsillectomy (50) G2: Total cold tonsillectomy (51)	Snoring (6-years post-tonsillectomy) G1: 13/43 (30.2) G2: 12/48 (25) G1 vs. G2: p=NS Episodes of apnea (6-years post-tonsillectomy) G1: 2/43 (4.7) G2: 0 (0) G1 vs. G2: p=NS	Tonsillar regrowth, 6 years postsurgery, n (%) G1: 6/13 (46.2) G2: NA Tonsillar regrowth requiring revision surgery, n (%) G1: 2/13 (5) G2: 0	Time to return to normal diet, mean days ± SD G1: 3.8 ± 0.2 G2: 7.1 ± 0.3 G1 vs.G2: P < 0.001	At least 1 episode of tonsillitis/year, 1-6 years post-tonsillectomy, n (%) G1: 5 (11.6) G2: 0 G1 vs. G2: p= NR Number throat infections/year, 1-6 years post-tonsillectomy, median (IQR) G1: 0 (0-1) G2: 0 (0-1) G1 vs. G2: p=NS
Korkmaz 2008[84] RCT Moderate ROB	G1: Partial cold tonsillectomy (40) G2: Total cold tonsillectomy (41)	NR	Tonsillar regrowth within 2-years post-tonsillectomy, n G1+G2: 0/68	NR	NR
Skoulakis 2007[86] RCT Moderate ROB	G1: Partial cold tonsillectomy (15) G2: Total cold tonsillectomy (15)	NR	NR	Time to return to normal diet G1: 4 days earlier than G2 G1 < G2: p < 0.001	NR

G = Group; N = Number; NA = Not Applicable; NR = Not Reported; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Partial Coblation or Electrocautery Versus Total Coblation or Electrocautery

Two small RCTs with low[90] and moderate[85] risk of bias addressed outcomes following partial vs. total coblation or electrocautery and reported only on return to usual diet or activity (Table 18). In the coblation study, children in the partial tonsillectomy arm consumed a significantly greater percentage of their normal diet and were engaged in a greater portion of their normal activity than were children in the total tonsillectomy arm at all time points assessed.[85] In the one study comparing partial vs. total electrocautery tonsillectomy, differences in return to normal activity were not statistically significantly different between groups.[90]

Table 18. Return to usual diet or activity in studies addressing partial versus total tonsillectomy with coblation or electrocautery

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Time to Return to Normal Diet or Activity, N (%)
Chang 2008[85] RCT Moderate ROB	G1: Partial coblation tonsillectomy (34) G2: Total coblation tonsillectomy (35)	**Mean % of normal diet resumed (POD1-2)** G1: 56 G2: 42 G1 vs.G2: p = 0.05 **Mean % of normal diet resumed (POD5-6)** G1: 73 G2: 48 G1 vs.G2: p < 0.05 **Mean % of normal activity resumed (POD1-2)** G1: 65 G2: 49 G1 vs.G2: p = 0.031 **Mean % of normal activity resumed (POD5-6)** G1: 84 G2: 64 G1 vs.G2: p = 0.002
Park 2007[90] RCT Low ROB	G1: Partial electrocautery tonsillectomy (19) G2: Total electrocautery tonsillectomy (21)	**Time to return to normal activity** G1 vs.G2: p = NS

G = Group; N = Number; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; POD = Postoperative Day; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Partial Tonsillectomy Versus Total Tonsillectomy With Mixed Surgical Approaches

Among the studies with low or moderate risk of bias addressing partial vs. total tonsillectomy without using the same surgical technique, eight (reported in multiple publications) addressed effectiveness outcomes[95, 97, 98, 107, 110, 139, 182-186] and three reported only harms (addressed in Harms section).[71, 151, 158] As with the studies outlined above, few studies addressed the same outcomes and because these studies differ in both extent of surgery and surgical technique, it is difficult to isolate the effect of partial tonsillectomy.

OSDB Persistence

Three RCTs (in multiple publications) addressed outcomes related to the persistence of OSDB (Table 19).[110, 182-186] In two studies with low[90] and moderate[185, 186] risk of bias, obstructive symptoms including snoring worsened in the short term in the partial tonsillectomy arm compared with total tonsillectomy, but differences between groups were not significant at longer-term followup (12-24 months post-tonsillectomy. In the third RCT, no children in either group had snoring or apnea at 1 and 3 years postoperatively.[182-184]

Table 19. OSDB persistence reported in studies comparing partial and total tonsillectomy

Study, Year Study Design Risk of Bias	Comparison Groups (N)	OSDB Persistence
Chan 2004[110] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (27) G2: Total tonsillectomy-electrocautery (28)	**Worsening of obstructive symptoms (3-months post-tonsillectomy), n (%)** G1: 10/21 (48) G2: 6/19 (25) p=NR Improvement in obstructive symptoms (12 months post-tonsillectomy) G1 vs. G2: p=NS
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (35) G2: Total tonsillectomy-cold dissection (32)	**Persistence of snoring** 6-months post-tonsillectomy Greater number of children in G1 vs. G2 had snoring, p < 0.05 24-months post-tonsillectomy G1 vs. G2; p=NS
Hultcrantz 2004[182-184] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (49) G2: Total tonsillectomy-cold dissection (43)	**Persistence of snoring** 12-months and 3-years post-tonsillectomy No difference in frequency or loudness of snoring between groups Presence of apnea,1-3 years post-tonsillectomy G1: 0 G2: 0

G = Group; N = Number; NR = Not Reported; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Tonsillar Regrowth

Two RCTs (moderate risk of bias) reported low rates of tonsillar regrowth after partial tonsillectomy (Table 20).[182-186] Out of an estimated 126 children providing followup data, three (2.4%) reported regrowth and had total tonsillectomy.

Table 20. Tonsillar regrowth or reoperation after partial tonsillectomy

Study, Year Study Design Risk of Bias	Comparison Groups (N)	Tonsillar Regrowth
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (35) G2: Total tonsillectomy-cold dissection (32)	**Total tonsillectomy for OSDB-symptom persistence, n (%)** G1: 2/35 (5.7) G2: NA
Hultcrantz 2004[182-184] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (49) G2: Total tonsillectomy- Cold dissection (43)	**Total tonsillectomy for OSDB-symptom persistence, n** G1: 1 (denominator not clear, 91 children in both groups assessed at 1 year) G2: NA

G = Group; N = Number; NA = Not Applicable; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Return to Normal Diet or Activity

Six RCTs (four with moderate and two with low risk of bias) addressed time to return to normal diet or activity (Table 21).[95, 97, 98, 107, 110, 185, 186] Studies were typically small (< 100 children) with short term followup and used a variety of methods for assessing these outcomes (e.g., mean days, mean percentage, number of children). In all six studies addressing return to normal diet, children in the partial tonsillectomy arms had more favorable outcomes compared with those receiving total tonsillectomy. Two studies reported that children undergoing partial surgeries either consumed a significantly greater proportion of their normal diet[107] or returned to normal diet in fewer days[97] than did children in total tonsillectomy arms. Four RCTs reported faster return in the partial tonsillectomy groups or greater numbers of children consuming a normal diet after partial compared with total tonsillectomy, but differences were not statistically significant[98, 185, 186] or significance was not assessed.[95, 110]

Five RCTs (2 low and 3 moderate risk of bias) addressed return to normal activity.[97, 98, 107, 110, 185, 186] As with diet, in all studies children undergoing partial tonsillectomy had a faster return to normal activity or engaged in a greater percentage of normal activity than did children who had total tonsillectomy. Differences were statistically significant in two RCTs[98, 107]

Table 21. Return to normal diet or activity in studies comparing partial and total tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Time to Return to Normal Diet or Activity, N (%)
Chang 2005 [107] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (52) G2: Total tonsillectomy- electrocautery (49)	**Mean % of normal diet resumed (POD1-2)** G1: 49 G2: 30 G1 vs.G2: p < 0.005 **Mean % of normal diet resumed (POD5-6)** G1: 74 G2: 42 G1 vs.G2: p < 0.005 **Mean % of normal activity resumed (POD1-2)** G1: 53 G2: 42 G1 vs.G2: p = NS **Mean % of normal activity resumed (POD5-6)** G1: 82 G2: 56 G1 vs.G2: p < 0.005
Chan 2004 [110] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (25) G2: Total tonsillectomy- electrosurgery (25)	**Time to return to normal diet, median days** G1: 4.4 G2: 7.5 G1 vs.G2: p = NR **Time to return to normal activity, median days** G1: 4.1 G2: 8 G1 vs.G2: p = NR

Table 21. Return to normal diet or activity in studies comparing partial and total tonsillectomy, continued

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Time to Return to Normal Diet or Activity, N (%)
Coticchia 2006[95] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (13) G2: Total tonsillectomy-cold (10)	**N children resuming normal diet by POD7, (%)** G1: 11 (85) G2: 0 (0) G1 vs.G2: p = NR
Sobol 2006[97] RCT Low ROB	G1: Partial tonsillectomy-microdebrider (36) G2: Total tonsillectomy-electrocautery (38)	**Time to return to normal diet, mean days ± SD** G1: 2.7 ± 2.3 G2: 4.4 ± 3.4 G1 vs.G2: p = 0.04 **Time to return to normal activity, mean days ± SD** G1: 2.4 ± 1.8 G2: 3.8 ± 3 G1 vs.G2: p = NS
Derkay 2006[98] RCT Low ROB	G1: Partial tonsillectomy-microdebrider (150) G2: Total tonsillectomy-electrocautery (150)	**Time to return to normal diet, median days (Q1 – Q3)** G1: 3 (1.5-6) G2: 3.5 (1.5-6.5) G1 vs.G2: p = NS **Time to return to normal activity, median days(Q1 – Q3)** G1: 2.5 (1-5) G2: 4 (2.5-6.5) G1 vs.G2: p < 0.01
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (35) G2: Total tonsillectomy-cold dissection (32)	**Time to return to normal diet** G1: 4 days earlier than G2 G1 vs. G2: p=NS **Time to return to normal activity** G1: 3 days earlier than G2 G1 vs. G2: p=NS

G = Group; N = Number; NR = Not Reported; NS = Not Significant; POD = Postoperative Day; OSDB = Obstructive Sleep Disordered Breathing; Q=quartile; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Throat Infections

Four RCTs (multiple publications, all moderate risk of bias) addressed recurrent throat infections (Table 22).[110, 139, 182-186] One study included children with OSDB (hypertrophy causing obstruction) as the primary indication for surgery,[285] while the others included children with both OSDB and recurrent throat infections. Two studies explicitly reported on baseline or previous throat infections (number of episodes/year),[110, 182-184] and one explicitly excluded children with >3 streptococcal throat infections in the 2 years prior to surgery.[139] One study reported that 21 percent of all children had had ≤ one episode of tonsillitis before the 3 months prior to surgery.[185, 186] In three of the four studies, children in the partial tonsillectomy arm had more throat infections than did those in the total tonsillectomy arms, though differences were not statistically significant in three studies.[110, 182-186] In two studies, children experienced fewer infections compared with baseline rates,[182-186] but other studies did not comment on changes from baseline.

Table 22. Throat infections following partial or total tonsillectomy

Study, Year Study Design Risk of Bias	Comparison Groups (N)	Throat Infections
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy- coblation (35) G2: Total tonsillectomy- cold dissection (32)	**Sore throats requiring antibiotics, 6-months post-tonsillectomy, n** G1: 4 G2: 2 G1 vs. G2: p=NS Sore throats requiring antibiotics, 24-months post-tonsillectomy, n G1: 8 G2: 1 G1 vs. G2: p= NR
Hultcrantz 2004[182-184] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (49) G2: Total tonsillectomy-cold dissection (43)	**Sore throats requiring antibiotics, 12-months post-tonsillectomy, n** G1: 6 G2: 4 G1 vs. G2: p=NS **Sore throats requiring antibiotics, 1-3 years post-tonsillectomy, n** G1: 6 G2: 5 G1 vs. G2: p=NS
Beriat 2013[139] RCT Moderate ROB	G1: Partial tonsillectomy-microdebrider (37) G2: Total tonsillectomy- cold dissection (45)	**Recurrent throat infection (within 12-months post-tonsillectomy), n** G1: 2 G2: 0 G1 vs. G2: p= NR
Chan 2004[110] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (27) G2: Total tonsillectomy-electrocautery (28)	**Incidence of sore throat or antibiotic use (3 and 12 months post-tonsillectomy)** G1 vs. G2: p=NS

G = Group; N = Number; NR = Not Reported; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Quality of Life

Three RCTs (1 low and 2 moderate risk of bias) assessed quality of life using different scales and at different time points (Table 23).[98, 182-186] In one study with assessment at 1-month postsurgery, changes in physical suffering, sleep disturbances, speech issues, or caregiver concerns did not differ significantly between groups, but decreases in emotional distress and in activity limitations were greater in the partial tonsillectomy arm than in the total tonsillectomy arm.[98] In two additional studies (one using the OSA-18, which uses a 7-point scale to assess frequency of symptoms from 1 [none of the time] to 7 [all of the time] and also assesses disease-specific quality of life) and one using the Glasgow Children's Benefit Inventory [GCBI]), changes in quality of life were not significantly different between groups, and both groups improved from baseline. In one study more than 30 percent of children in both arms had large improvements in disease-specific quality of life at 6 months and 2 years postsurgery, but group differences were not significant.[185, 186]

Table 23. Quality of life following partial or total tonsillectomy

Study, Year Study Design Risk of Bias	Comparison Groups (N)	Baseline Outcome Measure, Mean±SD	Followup Outcome Measure, Mean±SD
Derkay 2006[98] RCT Low ROB	G1: Partial tonsillectomy-microdebrider (150) G2: Total tonsillectomy-electrocautery (150)	NR	**Baseline to postoperative changes in physical suffering, sleep disturbance, speech or swallowing problems, and caregiver concerns, 1 month post-tonsillectomy** G1 vs. G2: p=NS Decrease in emotional distress G1>G2: p < 0.01 Decrease in activity limitation G1>G2: p < 0.01
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (35) G2: Total tonsillectomy- cold dissection (32)	**OSA-18 (Total), Mean±SD** G1: 3.5±1.0 G2: 3.4±1.0	**OSA-18 (Total)** Change score 6-months post-tonsillectomy G1: 1.8±1.2 G2: 1.8±1.0 G1 vs. G2: p=NS Change score 24-months post-tonsillectomy G1: 1.8±1.2 G2: 1.9±1.4 G1 vs. G2: p=NS Disease-specific quality of life data in figures only
Hultcrantz 2004[182-184] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (49) G2: Total tonsillectomy- cold dissection (43)	**Glasgow Children's Benefit Inventory** G1+G2: NR	**Glasgow Children's Benefit Inventory, %** 33 months post-tonsillectomy Overall QoL-Much better G1: 61 G2: 79 Overall QoL-A little better G1: 35 G2: 18 Overall QoL-No change G1: 5 G2: 3 G1 vs. G2: all p=NS

G = Group; IQR = Interquartile Range; N = Number; NR = Not Reported; NS = Not Significant; OSA-18 = Obstructive Sleep Apnea - 18; OSDB = Obstructive Sleep Disordered Breathing; QoL = Quality of Life; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Behavioral Outcomes

Two RCTs with moderate risk of bias reported changes in behavior using the Child Behavior Checklist (CBC) (Table 24).[182-186] Both groups improved from baseline overall and in each domain assessed (internalization, externalization), with no significant differences between groups in the short or longer (≥12 months) term. One study also assessed behavior changes with the GCBI and reported no significant differences between groups.[182-184]

Table 24. Behavioral outcomes following partial or total tonsillectomy

Study, Year Study Design Risk of Bias	Comparison Groups (N)	Baseline Outcome Measure, Mean±SD	Followup Outcome Measure, Mean±SD
Ericsson 2009[185, 186] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (35) G2: Total tonsillectomy-cold dissection (32)	**Child Behavior Checklist, Total Score** G1: 25.6±19.1 G2: 20.9±12.4 G1 vs. G2: p=NS	**Child Behavior Checklist, Total Score** 6-months post-tonsillectomy G1: 19.5 ±18.4 G2: 13.5 ±9.8 G1 vs. G2: p=NS 24-months post-tonsillectomy G1: 13.9±12.9 G2: 13.6±21.7 G1 vs. G2: p=NS
Hultcrantz 2004[182-184] RCT Moderate ROB	G1: Partial tonsillectomy-coblation (49) G2: Total tonsillectomy-cold dissection (43)	**Child Behavior Checklist, Total Score, Mean±SD** G1: 21.3±17.4 G2: 17.3±12.8 G1 vs. G2: p < 0.001	**Child Behavior Checklist, Total Score** 12-months post-tonsillectomy No differences in degree of improvement between groups Glasgow Children's Benefit Inventory, % 33 months post-tonsillectomy Behavior-Much better G1: 19 G2: 10 Behavior-A little better G1: 19 G2: 15 Behavior-No change G1: 62 G2: 74 G1 vs. G2: all p=NS

G = Group; N = Number; NS = Not Significant; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Other Outcomes

Two RCTs with moderate risk of bias also addressed enuresis.[182-186] One study reported a second partial tonsillectomy in a child with pre-existing enuresis and encopresis temporarily improved by the index partial tonsillectomy; encopresis did not improve after the second surgery.[185, 186] Another reported that 7 children undergoing total tonsillectomy and 3 undergoing partial had baseline enuresis, which improved in nine children (treatment group not specified) postoperatively.[182-184]

Key Question 4. Effectiveness of Surgical Techniques

Key Points

- Few studies reported effectiveness outcomes. In those that did, commonly used "hot" techniques such as coblation and electrocautery were generally associated with faster return to normal diet or activity compared with cold dissection (roughly 1 to 3 days). We found a

faster return to diet with coblation or electrocautery tonsillectomy compared with cold dissection and have low confidence in these conclusions (low strength of evidence).
- Few studies, typically addressing different measures and using different comparison techniques, addressed newer techniques such as thermal welding, laser, or harmonic scalpel, thus limiting our ability to draw conclusions about these approaches.
- We could not make conclusions about effects associated with other techniques (insufficient strength of evidence).

Overview of the Literature

We identified 59 unique studies (reported in 61 publications) comparing surgical techniques for tonsillectomy (Table 25).[43, 48, 56, 58, 61, 63-70, 74, 75, 77, 79-83, 87, 89, 91, 93, 96, 99, 100, 102-104, 108, 111, 116, 120, 123-125, 127, 130, 131, 134, 141, 143-145, 152-154, 160, 163, 167-170, 192, 195-197, 200, 207] Most (n=54) studies were RCTs;[43, 48, 56, 58, 61, 63-70, 74, 75, 77, 79-83, 87, 89, 91, 93, 96, 99, 100, 102-104, 108, 111, 116, 120, 123-125, 127, 130, 131, 134, 141, 143-145, 152-154, 160, 163, 167-170, 192] four were nonrandomized trials,[195-197, 200] and one was a prospective cohort study.[207] Twenty-two studies were conducted in Europe.[43, 56, 58, 69, 74, 75, 82, 83, 89, 102, 103, 111, 123, 125, 131, 134, 145, 167-170, 192, 197, 207] Nineteen studies were conducted in Asia (including Turkey),[48, 61, 63-65, 67, 79-81, 87, 91, 104, 141, 143, 144, 153, 154, 195, 200] and 12 in North America (11 in the United States).[66, 68, 70, 77, 93, 99, 108, 116, 120, 124, 127, 130] Four studies were conducted in Egypt,[100, 152, 163, 196] and one each in New Zealand[96] and Brazil.[160] Study participants (n=6984) ranged in age from 6 months to 41 years (mean age in study under 18 years). Studies compared multiple techniques including coblation, cold dissection, electrocautery, laser, harmonic scalpel, and thermal welding, and the majority of studies reported only harms data. Twenty-one studies reported effectiveness data, chiefly time to return to normal diet or activity.[66, 75, 80, 83, 89, 91, 93, 103, 111, 116, 124, 127, 130, 131, 134, 144, 152, 163, 169, 170, 195, 197]

We considered 16 studies to have low risk of bias[43, 56, 69, 70, 75, 89, 93, 120, 123, 125, 131, 134, 144, 163, 167-170] 30 to have moderate risk,[48, 58, 63, 64, 66, 74, 79, 80, 82, 83, 87, 91, 96, 103, 111, 116, 124, 127, 130, 141, 145, 152, 154, 160, 192, 195-197, 200, 207] and 13 to have high risk.[61, 65, 67, 68, 77, 81, 99, 100, 102, 104, 108, 143, 153] Major sources of bias in these studies included unclear methods for randomization, for accounting for potential confounding or modifying variables, and for handling imbalances between study groups. We do not discuss high risk of bias studies in the detailed analyses below.

Table 25. Overview of studies comparing surgical techniques for tonsillectomy

Characteristic	RCTs	Nonrandomized Trials	Prospective Cohort Studies	Total Literature
Comparisons				
Coblation vs. Cold Techniques	6	1	0	7
Coblation vs. Electrocautery	7	0	0	7
Coblation vs. Laser	2	0	0	2
Cold Techniques vs. Electrocautery	11	2	1	14
Cold Techniques vs. Harmonic Scalpel	4	0	0	4
Cold Techniques vs. Laser	2	0	0	2
Cold Techniques vs. Thermal Welding	3	0	0	3
Electrocautery vs. Electrocautery	1	1	0	2

Electrocautery vs. Harmonic Scalpel	5	0	0	5
Other*	13	0	0	13
Study Characteristics				
Allocates Intervention by Tonsil	8	2	0	10
Assesses Total Tonsillectomy	51	4	1	56
Assesses Partial Tonsillectomy	3	0	0	3
Surgical Indication				
Throat Infection	6	3	0	9
OSDB	7	0	0	7
OSDB+Throat Infection	28	1	0	29
Not specified	13	0	1	14
Effectiveness Outcomes Frequently Reported				
Time to Return to Normal Diet	14	1	0	15
Time to Return to Normal Activity	6	1	0	7
Risk of Bias				
Low	16	1	1	18
Moderate	25	3	0	28
High	13	0	0	13
Total N participants	**6446**	**478**	**60**	**6984**

*Includes comparisons of 3 techniques;[43, 77, 82, 99, 163] cold techniques vs. other cold techniques[56] or molecular resonance;[83, 192] electrocautery vs. laser[111] or molecular resonance,[64] or unspecified tonsillectomy;[141] coblation vs. molecular resonance;[74] and laser vs. other lasers.[58]

N = number; OSDB = obstructive sleep-disordered breathing; RCT = randomized controlled trial

Detailed Analysis

As noted, most studies reported harms data (see Harms of Tonsillectomy section below). Nineteen studies (17 RCTs and 2 nonrandomized trials)—eight with low[75, 89, 93, 131, 134, 144, 163, 169, 170]and 11 with moderate risk of bias[66, 80, 91, 103, 111, 116, 124, 127, 130, 152, 197]—reported on return to normal diet or activity—the only usable effectiveness outcomes reported.

Findings By Surgical Comparison

Coblation Versus Cold Dissection Tonsillectomy

Five RCTs (4 low[89, 93, 144, 169, 170] and 1 moderate[75] risk of bias) and one nonrandomized trial with moderate risk of bias[197] compared coblation and cold dissection tonsillectomy (Table 26). Across these small, short-term studies, coblation tonsillectomy was generally associated with faster return to normal diet or activity. Four studies reported on return to normal diet, with mixed results. In two low risk of bias studies, children receiving coblation tonsillectomy returned to normal diet sooner (roughly 2-3 days) than those undergoing cold dissection;[89, 144] in two other studies (one low, one moderate risk of bias), differences were not significant between groups.[75, 93] Return to normal activity occurred significantly earlier after coblation in three low risk of bias studies.[89, 144, 169, 170] In one moderate risk of bias nonrandomized study, children undergoing coblation tonsillectomy had fewer post-procedure school absences than those receiving cold dissection (mean 5.3 vs. 8.9 days, $p<0.001$).[197]

Table 26. Return to normal diet and activity in studies comparing coblation and cold dissection tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity

Omrani 2012[144] RCT Low ROB	G1: Coblation tonsillectomy(47) G2: Cold dissection Tonsillectomy (47)	**Time to return to normal diet, mean days ± SD** G1: 6.27 ± 1.07 G2: 9.25 ± 1.3 G1 vs. G2: p < 0.0001 **Time to return to normal activity, mean days ± SD** G1: 7.63 ± 1.16 G2: 11.7 ± 1.68 G1 vs. G2: p < 0.0001
Roje 2009[169, 170] RCT Low ROB	G1: Coblation tonsillectomy (50) G2: Cold dissection tonsillectomy (50)	**Time to return to normal activity, mean days (range)** G1: 2 (1-7) G2: 4 (1-9) G1 vs. G2: p < 0.001
Parker 2009[75] RCT Moderate ROB	G1: Coblation tonsillectomy (35) G2: Cold steel tonsillectomy (35)	**Return to normal diet, days** Data reported only in figures G1 vs.G2: p=NS
Di Rienzo Businco 2008[197] Nonrandomized trial Moderate ROB	G1: Coblation tonsillectomy (21) G2: Cold dissection tonsillectomy (21)	**Days absent from school post-procedure, mean±SD** G1: 5.3 ± 1.7 G2: 8.9 ± 1.5 G1 vs. G2: p<0.001
Shapiro 2007[93] RCT Low ROB	G1: Coblation tonsillectomy (23) G2: Cold dissection tonsillectomy (23)	**Time to return to normal diet, mean days** G1: 4 G2: 3 G1 vs. G2: p = NS
Mitic 2007[89] RCT Low ROB	G1: Coblation tonsillectomy (20) G2: Cold dissection tonsillectomy (20)	**Expected postoperative day to achieve normal diet** G1: 6.80 G2: 8.93 G1 vs. G2: p<0.001 **Expected postoperative day to achieve normal activity** G1: 6.62 G2: 8.45 G1 vs. G2: p<0.001

G=group; N=number; NS=not significant; ROB=risk of bias

Electrocautery Versus Cold Dissection Tonsillectomy

Electrocautery was generally associated with more favorable results in three small RCTs addressing this comparison (one with low[134] and two with moderate risk of bias[79, 127]) (Table 27). Electrocautery was superior to cold dissection in a faster return to normal diet in two studies[79, 134] and did not differ in the third.[127] Return to activity was significantly faster in the electrocautery arm in one study,[134] but no different in two others.[79, 127]

Table 27. Return to normal diet and activity in studies comparing electrocautery and cold dissection tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity
Nunez 2000[134] RCT Low ROB	G1: Electrocautery tonsillectomy (24) G2: Cold dissection tonsillectomy (26)	**Time to return to normal diet, median days (95% CI)** G1: 7.5 (5-8) G2: 5 (3-7) G1 vs. G2: p < 0.05 **Time to return to normal activity, median days (95% CI)** G1: 7 (5-8)

		G2: 5 (3-8) G1 vs. G2: p < 0.05
Hesham 2009[79] RCT Moderate ROB	G1: Electrocautery tonsillectomy (71) G2: Cold dissection tonsillectomy (69)	**Mean % of normal diet resumed (POD1), mean ± SD** G1: 54.67 ± 13.69 G2: 48.53 ± 21.54 G1 vs.G2: p <0.05 **Mean % of normal diet resumed (POD7), mean ± SD** G1: 84 ± 19 G2: 91.3 ± 14.17 G1 vs.G2: p <0.05 **Mean % of normal activity resumed (POD1), mean ± SD** G1: 73.33 ± 19.68 G2: 78.13 ± 16.9 G1 vs. G2: p=NS **Mean % of normal activity resumed (POD7), mean ± SD** G1: 92.67 ± 14.92 G2: 96 ± 7.17 G1 vs. G2: p=NS
Young 2001[127] RCT Moderate ROB	G1: Electrocautery tonsillectomy (26) G2: Cold dissection tonsillectomy (31)	**Time to return to normal diet and activity** G1 vs.G2: p=NS

G=group; N=number; NS=not significant; POD=postoperative day; ROB=risk of bias

Coblation Versus Electrocautery Tonsillectomy

Four RCTs with moderate risk of bias compared coblation and electrocautery tonsillectomy with mixed results (Table 28).[66, 116, 124, 131] Children who underwent coblation returned to normal diet more quickly than those who underwent electrocautery tonsillectomy in two studies,[66, 131] but return did not differ significantly between groups in two others.[116, 124] Children who underwent coblation also returned to normal activity roughly two days more quickly than those who underwent electrocautery in two studies.[116, 124]

Table 28. Return to normal diet and activity in studies comparing coblation and electrocautery tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity
Temple 2001[131] RCT Low ROB	G1: Coblation tonsillectomy (18) G2: Electrocautery tonsillectomy (20)	**Time to return to normal diet, mean days** G1: 2.4 G2: 7.6 G1 vs. G2: p < 0.0001
Parker 2011[66] RCT Moderate ROB	G1: Coblation tonsillectomy (40) G2: Electrocautery tonsillectomy (40)	**Time to return to normal diet, mean days** G1: 5.2 G2: 6.2 G1 vs.G2: p=0.04
Stoker 2004[116] RCT Moderate ROB	G1: Coblation tonsillectomy (44) G2: Electrocautery tonsillectomy (45)	**Time to return to normal diet, mean days ± SD** G1: 4.6 ± 2.1 G2: 5.2 ± 2 G1 vs. G2: p = NS **Time to return to normal activity, mean days ± SD** G1: 7.4 ± 1.9 G2: 6.7 ± 1.8 G1 vs. G2: p = NS
Shah 2002[124] RCT Moderate ROB	G1: Coblation tonsillectomy (17) G2: Electrocautery tonsillectomy (17)	**Time to return to normal diet for >50% of participants** G1: within 7 days postoperatively G2: >10 days postoperatively G1 vs.G2: p=NS **Time to return to normal activity for >50% of participants** G1: 8 days postoperatively G2: 10 days postoperatively G1 vs.G2: p=NR **Parental return to work** G1 vs. G2: p=NS

G=group; N=number; NR=not reported; NS=not significant; POD=postoperative day; ROB=risk of bias

Harmonic Scalpel Versus Other Tonsillectomy Techniques

Three RCTs with moderate risk of bias evaluated tonsillectomy with a harmonic scalpel (which uses ultrasonic frequency to cut and cauterize tissue) compared with electrocautery,[130] coblation,[152] or cold dissection[103] (Table 29). Studies compared different measures of return to normal diet or activity, thus limiting our ability to draw conclusions about differences in effectiveness. In the most recent RCT, children who had harmonic scalpel tonsillectomy returned to school after surgery in a median of 6 days compared with 8 who had coblation (p=NR). Another RCT comparing harmonic scalpel and cold dissection reported "dietary intake scores" ranging from zero to 3, with a score of zero indicating fluids only and a score of 3 indicating fluids plus normal diet.[103] Children in the harmonic scalpel group had better dietary scores at each postoperative measurement (days 1, 3, 5, 7, 9), but scores in both groups declined over time. A final RCT reported the number of children who returned to normal diet and activity.[130] Significantly more children in the harmonic scalpel group resumed their normal diet or activity compared with children undergoing electrocautery at postoperative day 1 and day 3.

Table 29. Return to normal diet and activity in studies comparing harmonic scalpel and other techniques for tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity
Salama 2012[152] RCT Moderate ROB	G1: Harmonic scalpel tonsillectomy (75) G2: Coblation tonsillectomy (75)	**Days to return to school post-tonsillectomy, median** G1: 6 G2: 8
Oko 2005[103] RCT Moderate ROB	G1: Harmonic scalpel tonsillectomy (45) G2: Cold dissection (48)	**Dietary intake scores, median (range)** POD1 G1: 1 (0-1) G2: 0 (0-1) G1 vs. G2: p<0.0001 POD9 G1: 0 (0-1) G2: 0 (0-1) G1 vs. G2: p=0.006
Walker 2001[130] RCT Moderate ROB	G1: Harmonic scalpel tonsillectomy (97) G2: Electrocautery tonsillectomy (75)	**N returned to normal diet by POD1** G1: 43 (44.3) G2: 17 (22.7) G1 vs. G2: p = 0.004 **N returned to normal diet by POD3** G1: 72 (74.2) G2: 35 (46.7) G1 vs. G2: p = 0.001 **N returned to normal activity by POD1** G1: 27 (27.8) G2: 9 (12) G1 vs. G2: p = 0.011 **N returned to normal activity by POD3** G1: 48 (49.5) G2: 17 (22.7) G1 vs. G2: p = 0.001

G=group; N=number; NR=not reported; POD=postoperative day; ROB=risk of bias

Laser Versus Coblation and/or Cold Dissection Tonsillectomy

Only two small RCTs addressed laser and did not provide sufficient data to draw conclusions about effectiveness compared with more standard techniques (Table 30). Two RCTs with low[163] and moderate[91] risk of bias comparing either potassium titanyl phosphate (KTP) laser or diode laser tonsillectomy to coblation and/or cold dissection reported no significant group differences in time to return to normal diet.

Table 30. Return to normal diet and activity in studies comparing laser and coblation and/or cold dissection for tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity
Elabdawey 2015[163] RCT G1: Coblation tonsillectomy (40) G2: Cold dissection tonsillectomy (40) G3: Diode laser tonsillectomy (40) Low ROB	G1: Laser tonsillectomy (40) G3: Coblation tonsillectomy (40) G2: Cold dissection tonsillectomy (40)	**Time to return to normal diet, mean day** G1: 5 G2: 4 G3: 4 G1 vs.G2 vs.G3: p = NS
Hegazy 2008[91] RCT Moderate ROB	G1: Laser tonsillectomy (40) G2: Coblation tonsillectomy (40)	**Time to return to normal diet or activity** G1 vs.G2: p = NS

G=group; N=number; NS=not significant; ROB=risk of bias

Thermal Welding Versus Cold Dissection and/or Electrocautery Tonsillectomy

Two studies compared thermal welding tonsillectomy (a newer tonsillectomy technique which uses heated forceps to cut and cauterize tissue) and either cold dissection[80] or cold dissection and electrocautery (Table 31).[195] Studies reported different measures, which limits our ability to draw conclusions. The RCT comparing thermal welding and cold dissection (moderate risk of bias) reported no differences in return to normal activity (mean of 5 days post-tonsillectomy).[80] Time to return to normal diet was lowest in the cold dissection group followed by thermal welding ($p<0.001$) followed by the electrocautery arm in the nonrandomized trial.[195]

Table 31. Return to normal diet and activity in studies comparing thermal welding and other techniques for tonsillectomy

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Return to Normal Diet or Activity
Ozkiris 2012[195] Nonrandomized trial Moderate ROB	G1: Thermal welding tonsillectomy (104) G2: Cold dissection tonsillectomy (99) G3: Electrocautery tonsillectomy (102)	**Time to return to normal diet, mean days ± SD (range)** G1: 7.3 ± 0.7 (7-9) G2: 7 ± 1.5 (6-9) G3: 9.3 ± 1.7 (9-11) G1 vs.G2: p < 0.001 Other p values=NR
Sezen 2008[80] RCT Moderate ROB	G1: Thermal welding tonsillectomy (25) G2: Cold dissection tonsillectomy (25)	**Time to return to normal activity, mean days** G1+G2: 5 G1 vs.G2: p = NS

G = group; N = number, NR = not reported; NS = not significant; ROB = risk of bias

Harms of Tonsillectomy

Key Points

- We found a low frequency of post-tonsillectomy hemorrhage (PTH) and utilization harms across surgical techniques and have confidence in these findings (high strength of evidence).
- In meta-analyses, the frequency of primary and secondary PTH associated with total and partial tonsillectomy was below 4 percent for any technique and with overlapping confidence bounds. Overall, estimates of PTH and utilization harms associated with tonsillectomy were below 8 percent.
- The pooled frequency (without adjustment) of PTH was below 5 percent overall (4.2% for total tonsillectomy; 1.5% for partial tonsillectomy) in comparative studies.
- We found a low frequency of revisits or readmission for dehydration associated with partial tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). We have greater confidence in a low frequency of nonbleeding readmissions/revisits associated with total tonsillectomy (moderate strength of evidence).
- We could not draw conclusions about effects on admissions or revisits for pain or postoperative nausea and vomiting (PONV) associated with partial tonsillectomy given the few comparative studies addressing the outcome (insufficient strength of evidence).
- Overall unadjusted frequencies of revisits for pain, dehydration, or PONV were below 5 percent.
- Other harms were disparate and generally not clinically significant. No comparative studies reported deaths.
- The frequency of harms in case series and database or registry studies was consistent with that in comparative studies. At least four deaths were reported in case series including 1,778,342 children.

Overview of the Literature

In order to account fully for potential harms of tonsillectomy, primarily PTH, readmission and reoperation, we compiled all comparative studies and examined rates of harms by arm, then reviewed case series and database studies, which were not included in the effectiveness analysis. We considered PTH to comprise any report of post-tonsillectomy bleeding, including the entire of range of bleeding as reported in each study, from bloody sputum to frank bleeding requiring readmission or reoperation. We did not assess harms separately by indication because there is no reason to expect that they would differ; therefore, we do not separate them into the KQ1 through KQ4 results sections but combine surgical harms here.

We present the data obtained from comparative studies that had low or moderate risk of bias followed by that of the case series and database studies (low or moderate risk of bias) and comment on their consistency. Finally, we conducted a Bayesian meta-analysis to estimate predicted primary PTH, secondary PTH, reoperation and readmission by partial and total tonsillectomy, and by surgical approach.

Comparative Study Arms Reporting PTH or Other Harms Data

One-hundred and one comparative studies of low or moderate risk of bias reported harms data.[6, 9, 38-41, 43-45, 47-49, 52-54, 56-60, 63, 64, 66, 69, 71, 74, 75, 78-80, 82, 84-87, 89-91, 93, 95, 96, 98, 103, 105-108, 110-112, 114-117, 119-125, 127, 128, 130-132, 134, 136, 138, 139, 141, 144, 145, 148, 150-155, 158, 160, 161, 163-172, 174-178, 182-186, 190, 192, 194-

[197, 199, 200, 207, 212, 213, 286] Most studies (n=85) reported PTH-related outcomes including number of PTH, which may have been reported as primary (generally defined as occurring within 24 hours of surgery), secondary (generally defined as occurring more than 24 hours postoperatively), or at an undefined or unspecified time.[9, 38, 40, 41, 43-45, 47, 48, 53, 54, 56-60, 63, 64, 66, 69, 71, 74, 75, 78-80, 82, 84-87, 89-91, 93, 95, 96, 98, 103, 105, 106, 108, 110-112, 115-117, 119, 120, 123-125, 127, 130, 131, 134, 138, 139, 141, 144, 145, 148, 150-153, 158, 160, 161, 163-178, 182-186, 192, 194-197, 199, 200, 207] Other frequently reported harms in comparative studies (n=32) included revisits or readmissions for postoperative pain, dehydration, or PONV.[39, 43, 52, 66, 69, 74, 85, 93, 98, 103, 107, 111, 112, 114, 116, 119, 121-125, 130, 134, 139, 148, 154, 164-166, 171-178, 185, 186, 207, 212, 213] Twenty-four studies also reported other non-PTH harms of surgical procedures.[6, 9, 43, 44, 54, 58, 69, 70, 85, 107, 111, 112, 114, 120, 124, 125, 130, 145, 158, 196, 207, 213, 287]

We present detailed harms tables in Appendix H. The tables in this appendix report pooled frequency of harms without adjustment, typically presented by technique (e.g., coblation, cold dissection), extent of surgery (partial or total tonsillectomy), and indication (OSDB, throat infection, mixed [OSDB and throat infection], or unspecified) where possible. We included studies with low or moderate risk of bias in our unadjusted estimates.

Studies Reporting Harms Combined in Meta-Analysis

Seventy-three studies contributed data to the meta-analysis (66 RCTs,[43, 44, 48, 53, 56, 58, 61, 63-66, 69, 71, 74, 75, 77, 79-86, 89-91, 93, 95-100, 102-104, 108, 110, 111, 116, 120, 123-125, 127, 129-131, 134, 139, 141, 143-145, 151-153, 158, 160, 163, 169, 170, 182-184, 187, 189, 192] 6 nonrandomized trials,[193, 195-198, 200] and 1 prospective cohort study[207]). We included study arms in the meta-analysis if they evaluated total (71 arms[43, 44, 48, 53, 56, 61, 63-66, 69, 71, 74, 75, 77, 79-86, 89-91, 93, 95, 96, 98-100, 102, 103, 108, 110, 111, 116, 120, 123-125, 127, 129-131, 134, 139, 141, 143-145, 151-153, 158, 160, 163, 169, 170, 182-184, 187, 189, 192, 193, 195-198, 200, 207, 286]) or partial tonsillectomy (20 arms[53, 58, 71, 84-86, 90, 95, 98, 110, 129, 139, 143, 151, 158, 182-184, 187, 189, 193, 198]). The resulting subset of studies included the following tonsillectomy techniques: cold dissection, electrocautery, coblation, harmonic scalpel, laser, molecular resonance, thermal welding, and microdebrider. We further partitioned data based on PTH outcomes, and included primary (occurring within 24 hours of surgery) PTH (21 studies, 44 arms), secondary (occurring >24 hours postsurgery) PTH (30 studies, 63 arms), non-operative readmission associated with PTH (19 studies, 39 arms), and reoperation associated with PTH (30 studies, 64 arms).

Twenty studies included in the meta-analysis had low risk of bias;[43, 53, 56, 66, 69, 75, 89, 90, 93, 97, 98, 120, 123, 125, 131, 134, 144, 151, 163, 169, 170] 37 had moderate risk,[44, 48, 58, 63, 64, 71, 74, 79, 80, 82-86, 91, 95, 96, 103, 110, 111, 116, 124, 127, 130, 139, 141, 145, 152, 158, 160, 182-184, 192, 195-197, 200, 207] and 16 had high risk.[61, 65, 77, 81, 99, 100, 102, 104, 108, 129, 143, 153, 187, 189, 193, 198] As noted, in sensitivity analyses, high risk of bias studies did not affect findings, so we included them in final analyses.

Case Series and Database Studies Reporting Harms

In addition, we captured PTH reported in case series and database analyses to determine whether the frequency supported findings in the comparative literature and to assess harms in larger study populations. We identified 53 unique database or registry studies or case series with ≥ 1000 children (reported in 63 papers) addressing PTH or other harms including readmissions or revisits for dehydration or nausea.[21, 215-276] Twenty-three studies were conducted in North America.[21, 215, 223, 224, 227, 228, 232-237, 239, 247, 248, 256, 257, 261, 266-268, 270-273] Twenty-two were conducted in Europe;[216-222, 225, 226, 229, 231, 238, 241, 243, 245, 250-255, 258-260, 262-264, 269, 274, 276] five in Asia;[230, 244, 246, 249, 265] and three in Australia or New Zealand.[240, 242, 275] We rated 19 studies as low risk of bias[21, 217-221, 225, 226, 228, 229, 231, 233, 235-237, 239-241, 243, 244, 247, 248, 250, 251, 258, 266-271] and 27 as moderate.[215, 216,

[223, 224, 227, 230, 232, 234, 238, 242, 245, 246, 249, 252-257, 259-263, 272-276] We considered seven studies[237, 239, 240, 243, 244, 264, 265] to have a high risk of bias and do not present them in the detailed analysis.

Studies included a total of 1,808,568 children, with numbers of participants ranging from 1,109 to over 500,000 across studies. Most studies (n=36) reported generally on PTH or other sequelae of tonsillectomy without specifying surgical technique.[21, 215, 216, 223, 225-229, 231-233, 237-244, 247, 248, 255, 257-259, 262, 265-268, 270-272, 274-276] Twelve studies reported PTH or other harms by surgical technique or instrument,[217-221, 224, 245, 246, 249-254, 256, 261, 263, 264] three reported specifically on PTH related to dexamethasone or nonsteroidal anti-inflammatory drug (NSAID) use,[230, 234, 236, 271] and four reported PTH by surgical indication and technique,[220, 221, 230, 256, 260] one reported readmission data by comorbidity,[238] and one reported specifically on reoperation following partial or total tonsillectomy.[269]

PTH was reported in nearly all studies. Eleven studies reported on readmission for non-PTH indications.[21, 220-222, 224, 232, 233, 235, 236, 242, 248, 255, 260, 275, 288] Twelve studies reported mortality or other harms.[224, 228, 232, 238, 245, 247, 250-255, 262, 270, 275] Appendix H provides more details on harms reported in each study and tables of unadjusted pooled frequency of PTH and other harms reported in studies with low or moderate risk of bias.

Detailed Analysis

Unadjusted PTH-Related Outcomes in Comparative Studies Addressing Tonsillectomy

Total Tonsillectomy

One-hundred and four study arms reported postoperative PTH after total tonsillectomy.[9, 43, 44, 48, 53, 56, 63, 64, 66, 69, 71, 74, 75, 79, 80, 82, 84, 86, 87, 89-91, 93, 95, 96, 98, 103, 108, 110, 111, 116, 120, 123-125, 127, 130, 131, 134, 139, 141, 144, 145, 151-153, 158, 160, 163-166, 169-178, 185, 186, 192, 195-197, 200, 207, 213] We first present unadjusted PTH frequency. The 6299 children across studies who were treated with total tonsillectomy experienced 265 episodes (4.2%) of PTH (Table 32). Among these episodes, 33 were primary (typically occurring within 24 hours of tonsillectomy), 166 were secondary (occurring more than 24 hours post-tonsillectomy), and for 66, timing was not specified. Sixty-eight children required reoperation to control PTH (2.2%), and 80 had nonoperative revisits or readmissions for PTH (3.0%). Children who underwent tonsillectomy with harmonic scalpel had the highest frequency of PTH (11.3%), although few children underwent this procedure (n=397). Few children also had laser tonsillectomy (n=189), with 5.3 percent experiencing PTH. Frequencies were similar among techniques that are more commonly used: cold dissection=3.8 percent; electrocautery =4.9 percent; and coblation=3.2 percent. The frequency of revisits and reoperations overall was typically less than 6 percent. Tables in Appendix H outline rates associated with each technique in each study arm.

Table 32. Unadjusted PTH-related outcomes in study arms evaluating total tonsillectomy

Technique (N arms)	Total N	Total PTH (%)	Total Primary PTH (%)	Total Secondary PTH (%)	Total Unspecified PTH (%)	Total Nonoperative Revisits/ Readmissions for PTH (%)	Total Reoperations for PTH (%)
All arms (105)	6299	265 (4.2)	33 (1.3)	166 (4.8)	66 (2.7)	80 (3)	68 (2.2)
Electrocautery (29)	1668	82 (4.9)	5 (0.37)	62 (6.3)	15 (2.3)	36 (5)	21 (2.6)
Cold dissection (34)	1904	72 (3.8)	6 (0.54)	49 (4)	17 (2.7)	9 (1.6)	19 (2.3)
Coblation (19)	728	23 (3.2)	3 (2.1)	7 (2.4)	12 (2.7)	2 (1.1)	4 (2.5)
Unspecified/ other technique (5)	748	25 (3.3)	9 (3.1)	NR	16 (3.5)	8 (2)	10 (2.3)
Molecular resonance (5)	466	4 (0.86)	0 (0)	4 (1.22)	0 (0)	1 (0.23)	1 (0.31)
Harmonic scalpel (5)	397	45 (11.3)	1 (0.63)	38 (11.3)	6 (9.8)	15 (5.5)	9 (2.8)
Thermal welding (4)	199	5 (2.5)	0 (0)	5 (2.96)	0 (0)	NR	1 (0.96)
Laser (4)	189	10 (5.3)	9 (11.4)	1 (0.91)	NR	9 (11.4)	3 (2.8)

Note: Percentages for primary and secondary PTH, readmissions/revisits, and reoperations reflect the number of each instance of bleeding or reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.
N = Number; PTH = Post-Tonsillectomy Hemorrhage

Partial Tonsillectomy

Total PTH did not exceed 5 percent among the 18 study arms contributing data to assess bleeding after partial tonsillectomy (Table 33).[53, 58, 71, 84-86, 90, 95, 98, 110, 139, 151, 158, 167, 168, 183-186, 289] PTH was highest after coblation tonsillectomy (4.2%). No PTH was associated with laser approaches, but few studies assessed this modality.[58, 167, 168]

Table 33. Unadjusted PTH-related outcomes in study arms evaluating partial tonsillectomy

Technique (n arms)	Total N	Total PTH (%)	Total Primary PTH (%)	Total Secondary PTH (%)	Total Undefined PTH (%)	Total Nonoperative Revisits/ Readmissions for PTH (%)	Total Reoperations for PTH (%)
All arms (18)	599	8 (1.5)	0 (0)	2 (1.6)	6 (1.4)	5 (1.8)	1 (0.64)
Microdebrider (5)	252	3 (1.2)	NR	NR	3 (1.2)	3 (1.5)	NR
Coblation (6)	169	4 (4.2)	0 (0)	2 (6.3)	2 (2.2)	2 (2.8)	0 (0)
Cold dissection (4)	124	1 (0.81)	0 (0)	0 (0)	1 (1.4)	NR	1 (1.1)
Laser (3)	54	0 (0)	0 (0)	0 (0)	0 (0)	NR	NR

Note: Percentages for primary and secondary PTH, readmissions/revisits, and reoperations reflect the number of each instance of bleeding or reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.
N = Number; PTH = Post-Tonsillectomy Hemorrhage

PTH by Indication

Across all techniques and types of tonsillectomy (partial or total), the overall occurrence of PTH after surgery was lowest in children with OSDB (Table 34).

Table 34. Unadjusted PTH-related outcomes by indication in study arms evaluating total or partial tonsillectomy

Indication (N arms)	Total N	Total PTH (%)	Total Primary PTH (%)	Total Secondary PTH (%)	Total Undefined PTH (%)	Total Nonoperative Revisits/ Readmissions for PTH (%)	Total Reoperations for PTH (%)
OSDB (28)	1219	22 (1.9)	2 (0.4)	11 (2.1)	9 (1.4)	8 (1.4)	3 (0.85)
Throat infection (28)	1764	88 (5.0)	12 (1.8)	64 (6.2)	12 (2.3)	29 (3.4)	10 (1.6)

Note: Percentages for primary and secondary PTH, readmissions/revisits, and reoperations reflect the number of each instance of bleeding or reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.
N = Number; PTH = Post-Tonsillectomy Hemorrhage

Revisits for Pain, Dehydration, or PONV Following Tonsillectomy Reported in Comparative Studies

Revisits for pain, dehydration, or PONV typically occurred in less than 10 percent of children (Table 35). Eight studies reported zero revisits for non-PTH indications associated with interventions studied.[52, 93, 114, 119, 121, 125, 134, 148] Two studies reported that more than 10 percent of children had revisits or readmissions (see Appendix H for full details).[116, 123] One RCT comparing KTP laser and cold dissection total tonsillectomy as day-stay procedures reported 25 total admissions for pain (13 for cold dissection and 12 in laser) and 29 for vomiting (16 in cold dissection arm and 13 in laser) on the day of surgery.[123] In another RCT comparing electrocautery and coblation tonsillectomy, revisits comprised both return visits and phone calls to the provider; thus, numbers are higher than those reported in other studies.[116]

Table 35. Unadjusted revisits for pain, dehydration, or PONV reported after tonsillectomy in arms of comparative studies

Technique (N arms)	Total Arm N	Pain Revisits/ Readmissions, n (%)	Dehydration Revisits/ Readmissions, n (%)	PONV Revisits/ Readmissions, n (%)	Other Revisits/ Readmissions, n (%)
All arms (37)	2969	45 (1.5)	39 (1.6)	45 (1.5)	3 (0.09)
Electrocautery-total (12)	883	12 (7.3)	20 (2.3)	7 (5.1)	NR
Cold dissection-total (9)	622	14 (5.4)	1 (0.21)	16 (10.5)	NR
Unspecified tonsillectomy (4)	529	NR	9 (2.4)	5 (0.85)	NR
Molecular resonance-total (2)	362	NR	0	NR	NR
Harmonic scalpel-total (2)	216	NR	2 (1.3)	NR	3 (4.9)
Coblation-total (5)	198	6 (8.8)	7 (3.5)	4 (9.8)	NR
Laser-total (3)	159	13 (10.1)	0	13 (16.5)	NR
Microdebrider-partial (2)	187	0	5 (2.5)	NR	NR
Coblation-partial (1)	34	NR	0	NR	NR

Note: Percents for readmissions/revisits reflect the number of each reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.
N = Number, NR = Not Reported; PONV = Postoperative Nausea and Vomiting

Other Harms Following Tonsillectomy Reported in Comparative Studies

Twenty-three studies also reported other non-PTH harms of surgical procedures.[6, 9, 43, 44, 54, 58, 69, 70, 85, 107, 111, 112, 114, 120, 124, 125, 130, 145, 158, 196, 207, 213, 287] Harms were largely minor and included burns or unspecified breathing complications (Table 36), and two studies including children with OSDB reported velopharyngeal insufficiency (VPI).[85, 124] One study noted that VPI resolved within two months,[85] and the other did not comment on resolution or severity.[124] Eight studies explicitly reported that no non-PTH harms occurred (not shown in table);[58, 70, 107, 120, 125, 145, 158, 207] Seven studies (15 arms) explicitly reported that no deaths occurred,[43, 54, 69, 74, 111, 130, 213] and two studies reported that no cases of VPI occurred.[107, 125]

Table 36. Other harms reported in studies of surgical techniques compared with medical treatment or other surgical techniques

Nonbleeding Harms of Surgical Techniques	Number of Studies (# Participants With Harm/Total Participants)	Reported Occurrence Across Studies
Electrocautery total tonsillectomy		
Thermal burns in oral mucosa and tongue or other burns[196]	1 (14/91)	15%
Burn to thigh from improper grounding of electrocautery unit –hospitalized 3 days[114]	1 (1/21)	4.7%
Coblation total tonsillectomy		
VPI[85, 124]	2 (2/52)	2.8%-5.8%
Airway obstruction[124]	1 (2/34)	5.9%
Cold dissection partial tonsillectomy		
Breathing complications[198]	1 (1/243)	0.4%
Other complications[198]	1 (0/243)	0%
Cold dissection total tonsillectomy		
Lip burn from cautery[112]	1 (1/57)	1.7%
Breathing complications[198]	1 (2/780)	0.2%
Other (unspecified) complications[198]	1 (1/780)	0.1%
CPAP		
Rash from mask[44]	1 (1/36)	2.7%
Total tonsillectomy (not specified)		
Complications from GABHS infection or medical treatment of infection (drug reaction, peritonsillar abscess, scarlet fever)[213]	1 (16/145)	5.7%
Erythematous rash from penicillin for throat infection[6]	1 (1/96)*	1%
Erythematous rash while receiving antimicrobial drug[9]	2 (4/190)*	2.1%

Note: 4 children in a no tonsillectomy arm also experienced erythematous rash while receiving penicillin in studies described in one publication,[6] and three children in nonsurgical arms in another publication reporting 2 studies developed an antibiotic-associated erythematous rash.[9] The table notes one study reporting these outcomes as the publications combined data from each of the 2 studies reported in each paper and did not present harms data by study.
CPAP = Continuous Positive Airway Pressure

Meta-Analysis Results

Harms Associated With Total Tonsillectomy

Frequency of primary PTH associated with total tonsillectomy in the meta-analysis was below 4 percent and with overlapping confidence bounds (Table 37). Electrocautery and harmonic scalpel were associated with the highest frequency of secondary PTH (occurring >24 hours postprocedure), with estimates of 4.2 to 4.3 percent and wide 95% Bayesian credible intervals (BCI). Readmission ranged from 0.2 percent to 6 percent. Although laser tonsillectomy was associated with the highest estimated readmissions, the confidence bounds were very wide.

Table 37. PTH and PTH-associated readmissions or revisits after total tonsillectomy: percent (95% BCI)

Technique	Primary PTH	Secondary PTH	Nonoperative Revisit or Readmission	Reoperation
Cold	0.7 (0.1 to 1.5)	3.3 (1.9 to 5.3)	2.7 (0.7 to 4.9)	1.3 (0.5 to 2.1)
Electrocautery	0.6 (0 to 1.5)	4.2 (2.4 to 6.5)	2.9 (0.7 to 5.3)	1.2 (0.5 to 1.9)
Coblation	1.1 (0 to 3.0)	2.3 (0.7 to 4.4)	1.4 (0.1 to 3.3)	1.2 (0.3 to 2.4)
Harmonic Scalpel	1.0 (0 to 3.3)	4.3 (1.8 to 7)	1.5 (0.2 to 3.1)	3.9 (1.6 to 6.9)
Laser	2.2 (1.0 to 5.8)	1.2 (0 to 3.4)	5.7 (0.7 to 12.6)	5.2 (0.2 to 13.7)
Molecular Resonance	0.6 (0 to 2.5)	1.1 (0.2 to 2.4)	0.2 (0 to 0.6)	0.2 (0 to 0.5)
Thermal Welding	0.5 (0 to 2.1)	3.6 (0.5 to 7.5)	2.7 (0 to 12.7)	0.8 (0 to 2.4)

BCI = Bayesian credible interval; PTH = post-tonsillectomy hemorrhage

Harms Associated With Partial Tonsillectomy

Primary PTH associated with partial tonsillectomy was predicted to be below 4 percent regardless of technique, and secondary bleeding at or below 3 percent. Data on readmissions and reoperations were sparse; thus confidence bounds are very wide, and it is difficult to predict PTH and PTH-related outcomes with any certainty (Table 38).

Table 38. PTH and PTH-associated readmissions or revisits after partial tonsillectomy: percent (95% BCI)

Technique	Primary PTH	Secondary PTH	Nonoperative Revisit or Readmission	Reoperation
Cold	1.5 (0 to 4.7)	2.3 (1 to 5.9)	3.7 (0.1 to 10.3)	0.5 (0 to 1.3)
Electrocautery	1.5 (0 to 5.3)	3 (0.2 to 8)	4 (0.2 to 12.3)	0.4 (0 to 1.2)
Coblation	1.5 (0.1 to 4.2)	1.4 (1 to 3.5)	1.4 (0.1 to 3.1)	0.4 (0 to 1.1)
Harmonic Scalpel	2.2 (0 to 8.3)	3 (1 to 7.9)	2.1 (0 to 6.3)	1.4 (0 to 3.9)
Laser	3.9 (0 to 12.9)	0.7 (0 to 2.4)	7.3 (0.2 to 20.7)	1.8 (0 to 5.4)
Molecular Resonance	1.4 (0 to 6)	0.8 (0 to 2.3)	0.3 (0 to 1)	0.1 (0 to 2)
Thermal Welding	1 (0 to 4.5)	2.6 (0 to 7.7)	3.4 (0 to 17)	0.3 (0 to 1)

BCI = Bayesian credible interval; PTH = post-tonsillectomy hemorrhage

Case Series and Database Analyses

Overall, 2.1 percent of children in case series experienced a PTH episode (Appendix H). Few children in these studies required readmission or reoperation for PTH (0.41% to 0.72%).

Few cases of revisits for pain, dehydration, or PONV (ranging from 1% to 11%) were reported in the 11 studies providing data. At least four deaths were reported across four case series or database studies reporting mortality.[247, 252, 253, 270, 275, 290] In one study, a 10-year old child with muscular dystrophy and other comorbidities died from suspected ventricular fibrillation one month after tonsillectomy;[275] investigators did not consider the death related to

surgery. In another, a 42-month old child with recurrent PTH died from bleeding-related shock after he was discharged 6 days post-tonsillectomy.[252, 253, 290] Another database study reported two deaths (out of 36,221 tonsillectomies, 0.006%) but did not report cause of death.[247] Finally, a fourth database study did not report exact numbers or cause of death but compared tonsillectomy complications occurring in different hospital types (teaching or nonteaching children's hospitals, nonteaching hospitals).[270] In each hospital type ≤10 deaths occurred, but the study does not report specific numbers.

Other harms reported in these studies were disparate and typically not clinically significant (Appendix H). One registry specifically examined the rate of reoperation following partial vs. total tonsillectomy and reported a greater risk of reoperation after partial tonsillectomy (hazard ratio=7.16, 95% CI: 5.52 to 9.13).[269] Seventy-five of 11,741(0.6%) children who underwent total tonsillectomy required reoperation compared with 609 of 15,794 who underwent partial (3.9%, p<0.0001). The most common indication for reoperation after either type of tonsillectomy was upper airway obstruction (80% of cases). Three studies reported respiratory-related harms (Appendix H). In one database study, 383 out of 40,591 children had respiratory failure requiring mechanical ventilation (0.94%).[270] In another database study evaluating outcomes in 21,434 obese or non-obese children undergoing tonsillectomy, 5 percent of obese children had major respiratory complications (pulmonary insufficiency, respiratory failure) compared with 3 percent of non-obese children.[228] One case series including 1735 children reported postoperative desaturation, pulmonary edema, or lung collapse in 13 children (0.75%).[238]

Key Question 5. Effectiveness of Perioperative Medications To Improve Outcomes

Key Points

- We found a reduced need for analgesia with NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence).
- We found no difference in effects on return to normal diet or activity with perioperative NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence).
- We found a low frequency of PTH and associated utilization with perioperative NSAIDs. Our confidence in this conclusion is low (low strength of evidence).
- We could not make conclusions about non-PTH related readmissions or revisits following NSAID use as few studies addressed these outcomes (insufficient strength of evidence).
- We found a reduced need for analgesics or antiemetics associated with steroids (IV or infiltrated dexamethasone) compared with placebo. Our confidence in this conclusion is low (low strength of evidence).
- Studies of steroids reported few cases of PTH and PTH-related utilization. We have moderate confidence that steroids are associated with a low frequency of PTH (moderate strength of evidence).
- Meta-analysis of nine studies comparing steroids and placebo did not indicate a significantly increased risk of PTH with steroids vs. placebo; confidence bounds were wide for all estimates, and we have low confidence in this conclusion (low strength of evidence).
- We could not make conclusions about the effects of steroids on time to return to normal diet or activity or non-PTH-related readmissions or revisits (insufficient strength of evidence).

- We found a reduced need for postoperative antiemetics in studies of perioperative antiemetics; our confidence in this conclusion is low (low strength of evidence).
- We found no effect of 5-hydroxytryptamine (5-HT) perioperative antiemetics on postoperative analgesia requirements. We have moderate confidence in this conclusion (moderate strength of evidence).

Overview of the Literature

Forty-nine studies (48 RCTs [39, 40, 42, 45-47, 50-52, 54, 57, 59, 62, 72, 73, 76, 78, 88, 92, 94, 105, 106, 109, 112, 113, 117-119, 121, 122, 126, 128, 132, 133, 135, 136, 140, 142, 146-150, 156, 157, 161, 162, 188] and one nonrandomized trial[199]) involving 5817 children ranging in age from less than 1 to 18 years addressed perioperative medications (NSAIDs, steroids, antiemetics, alone or in combination) for improving post-tonsillectomy outcomes (Table 39). Studies were primarily conducted in Asia (including China, India, Turkey, and Japan).[39, 45, 46, 50, 59, 62, 72, 73, 76, 105, 106, 109, 113, 117, 118, 121, 132, 133, 140, 146-150, 156, 157, 161, 162, 188, 199] Six studies were conducted in Europe,[57, 78, 94, 128, 135, 136] and six in North America (United States).[47, 54, 92, 112, 122, 126] Six studies were conducted in Africa,[40, 42, 51, 52, 119, 142] and one in Australia.[88]

Twenty-three studies had low risk of bias;[39, 40, 50-52, 54, 57, 59, 76, 88, 94, 105, 112, 113, 118, 119, 128, 132, 133, 135, 136, 146, 156] 21 had moderate; [42, 45-47, 62, 72, 78, 92, 106, 109, 117, 121, 122, 126, 142, 147-150, 157, 161]and five had high.[73, 140, 162, 188, 199] Major sources of bias in these studies included unclear methods for randomization and for concealment of study group allocation. We do not discuss high risk of bias studies in the detailed analyses below.

Outcomes reported varied among studies: PTH, use of rescue medications, and use of rescue antiemetics were most frequently reported.

Table 39. Overview of studies addressing perioperative pharmacologic agents to improve outcomes

Characteristic	NSAIDs	Steroids	Antiemetics	Multi-agent Therapy*	Total Literature
Study design					
RCT	14	18	6	10	48
Nonrandomized trial	0	1	0	0	1
Surgical Indication					
Throat Infection	2	0	0	2	4
OSDB +Throat Infection	0	6	0	1	7
Unspecified	11	12	5	10	38
Key Effectiveness Outcomes Reported					
Rescue analgesics	7	12	1	11	31
Rescue antiemetics	1	12	2	7	22
Time to return to normal diet/activity	2	2	0	3	7
Risk of Bias					
Low	3	8	5	7	23
Moderate	9	6	0	6	21
High	1	4	0	0	5
Total N participants	**1103**	**2368**	**1040**	**1306**	**5817**

*Combination of drug classes. NSAIDs = nonsteroidal anti-inflammatory drugs; OSDB = obstructive sleep-disordered breathing; RCT = randomized controlled trial

Detailed Analysis

Most studies addressed the outcomes of time to return to normal diet or activity or need for rescue medications, which we defined as the need for additional or higher doses of pain medications or antiemetics beyond those given as part of the standard surgical protocol. We discuss findings by agent and key outcome below. Appendix H includes a detailed table of findings for each study.

NSAIDs

Return to Normal Diet and Activity

In two RCTs with moderate risk of bias comparing diclofenac suppository with or without other analgesics (acetaminophen plus tramadol) to lidocaine[72] or placebo,[126] time to resume normal activity or diet did not differ significantly between groups.

Need for Rescue Analgesics

Diclofenac

Analgesics. Two low [52, 156] and three moderate [72, 121, 149] risk of bias RCTs evaluated perioperative diclofenac. Two RCTs compared diclofenac suppository to placebo.[121, 156] In both, consumption of opioids was significantly lower in diclofenac groups. Another study comparing oral gabapentin, diclofenac suppository, and placebo found the mean 24h opioid consumption was equivalent in gabapentin and diclofenac groups but significantly less than placebo.[156]

Other trials were not placebo-controlled and used a variety of comparative treatments. One that compared 2 percent viscous lidocaine post-tonsillectomy vs. diclofenac suppository reported no difference in analgesic need during the immediate 2 postoperative hours.[72] Another study comparing diclofenac suppository vs. intravenous [IV] pethidine found fewer children in the diclofenac arm required analgesia medication and used a significantly lower mean paracetamol dose in the first 24 postoperative hours.[149] A third trial compared triple analgesic regimen (diclofenac suppository, IV paracetamol, and IV tramadol) vs. placebo and reported that, in the immediate 4-6 postoperative period, no child in study group used rescue analgesia compared with 70 percent and 45 percent of controls who required rescue analgesia in the PACU and on the day surgery ward, respectively.[52]

Antiemetics. A single moderate risk of bias study that evaluated effectiveness of peritonsillar bupivacaine infiltration vs. diclofenac suppository reported no difference in antiemetic rescue use between arms.[161]

Ibuprofen

Analgesics. Three moderate risk of bias RCTs compared the effect of perioperative ibuprofen treatment vs. multiple different comparators and assessed postoperative analgesic requirements.[47, 106, 157] Two evaluated IV ibuprofen,[47, 157] while one used ibuprofen syrup.[106] One trial comparing IV paracetamol alone, IV paracetamol + mefenamic acid, and IV paracetamol + ibuprofen reported that over the 24 hour followup period, the ibuprofen group used significantly less postoperative analgesia than paracetamol alone.[157] A second trial compared single dose IV ibuprofen vs. placebo and assessed opioid use in the PACU.[47] In intent to treat analysis, percentage of opioid use did not differ between groups, mean number of rescue opioid doses, or mean dose. Another trial compared ibuprofen syrup (administered 1 hour pre-operatively) + peri-tonsillar infiltrated epinephrine vs. infiltrated lidocaine with epinephrine and reported no differences in mean paracetamol dose between arms.[106]

Ketoprofen

Analgesics. Two low risk of bias RCTs evaluated the post-tonsillectomy analgesic use among patients treated with ketoprofen vs. placebo.[94, 128] Study results differed. In one trial, no difference was observed in mean dose or proportion of patients receiving analgesia between those treated with IV ketoprofen at induction, IV ketoprofen after surgery, or placebo[128] Another RCT compared ketoprofen, tramadol, and placebo and reported that patient-controlled analgesia requests were significantly lower in the ketoprofen group. No difference was observed in 24 hour total opioid use.[94]

Lornoxicam

Analgesics. A single moderate risk of bias RCT comparing IV lornoxicam, infiltrated lornoxicam, and placebo, reported rescue diclofenac consumption during first 24 hours was significantly lower in the IV group compared with either infiltration or placebo group ($p<0.000$).[142] No difference was observed between infiltration and placebo groups.

Ketorolac

Analgesics. A single moderate risk of bias trial compared IV ketorolac vs. fentanyl and reported that fewer children in the ketorolac arm required rescue analgesia than in fentanyl arm (8% [n=2] vs. 28% [n=9]) in the immediate postoperative period in PACU.[117] No overall difference in use of rescue medications was observed the first 24-hours postoperatively.

Steroids

Return to Normal Diet and Activity

Two low risk of bias RCTs assessed whether steroids affected time to return to normal diet post-tonsillectomy.[112, 135] One comparing IV dexamethasone vs. placebo found that those treated with steroids were ingesting a significantly higher percentage of their normal diet than those in the placebo group on postoperative day (POD) one.[112] A second trial comparing tropisetron and tropisetron + dexamethasone found no difference in the percentage of children returning to normal diet on POD one or five.[135]

A single low risk of bias RCT compared time to normal activity between children treated with IV dexamethasone vs. no steroid (both groups had peritonsillar infiltration of ropivacaine + clonidine) and found a nonsignificant longer time to resume normal activity in the steroid group.[52]

Need for Rescue Medications

Dose Escalation Trials

Analgesics. Four low- and moderate-risk of bias RCTs evaluated the efficacy of escalating doses of dexamethasone on post-tonsillectomy analgesia requirements.[57, 78, 92, 113] Doses studied varied by trial, ranging from 0.05 to 1 mg/kg. Three of four trials of dexamethasone at escalating doses,[92]or escalating doses and placebo,[57] or doses of dexamethasone compared with ondansetron or placebo,[113] showed no differences in postoperative analgesic requirements by dose.[57, 92, 113]

In contrast, one placebo controlled dose-escalation trial showed that children who received dexamethasone required significantly less ibuprofen during 24 hour followup.[78] Higher doses of dexamethasone did not significantly alter ibuprofen requirements.

Antiemetics. Two dexamethasone dose escalation trials assessed the postoperative need for antiemetic rescue.[57, 78] Both studies showed significantly reduced use in groups treated with dexamethasone vs. placebo. One compared dexamethasone 0.05, 0.15, or 0.5 mg/kg vs. placebo after induction of anesthesia and found the need for rescue antiemetic to be significantly less in all steroid arms at 24 hour followup.[78] A second study comparing IV dexamethasone at 0.15 mg/kg, 0.5 mg/kg vs. placebo reported that the use of alizapride was significantly lower in the steroid groups than placebo. In contrast, the use of tropisetron did not differ between arms.[57]

IV Dexamethasone Versus Placebo

Analgesics. Eight trials compared outcomes among children treated with IV dexamethasone vs. placebo.[50, 105, 109, 119, 126, 146-148] This included four low [50, 105, 119, 146] and four moderate[109, 126, 147, 148] risk of bias studies. Time of followup varied from assessment of PACU or surgical ward analgesic use,[50, 105, 119, 126, 146] to 24 hours postoperatively,[109, 147, 148] to 3 postoperative days.[126]The majority of studies found steroid treatment significantly reduced postoperative analgesic requirements vs. placebo or other agents such as ropivacaine.[50, 119, 146-148] However, in three studies, no differences between those treated with dexamethasone or placebo were observed.[105, 109, 126]

Antiemetics. Two of five placebo-controlled studies showed reduced antiemetic use in children treated with dexamethasone.[105, 109, 119, 126, 146] One trial comparing IV dexamethasone vs. placebo reported significantly lower 24 hour antiemetic requirement in the dexamethasone arm.[146] Another trial that compared IV dexamethasone and placebo found no difference in antiemetic use in the PACU, but did show significantly reduced 24 hour and overall antiemetic rescue use in steroid arm.[119]

In contrast, three trials demonstrated no difference in need for antiemetic rescue between dexamethasone and placebo. For example, one trial found no difference in PACU or day surgical ward use of rescue metoclopramide or ondansetron between groups.[105] A second trial comparing IV dexamethasone vs. placebo (both groups receiving peritonsillar infiltration of ropivacaine + clonidine) found no group differences in antiemetic rescue us in the first 4 hours postoperatively.[126] A third trial found no statistical difference in PACU need for rescue antiemetic.[109]

Dexamethasone Versus Other Comparators

Analgesics. Four RCTs including one low[59] and three moderate [42, 46, 62] risk of bias studies compared postoperative analgesic requirements between IV dexamethasone and other comparators. One found no difference in PACU or 24 hour followup doses of morphine or paracetamol between those treated with a single dose of IV dexamethasone vs. IV methylprednisolone.[59] Another trial that compared IV dexamethasone vs. oral gabapentin, vs. the combination for 18 hours post-tonsillectomy found that the combined treatment group had fewer rescue medication (pethidine) requirements.[42] Intravenous dexamethasone was compared with IV acetaminophen in another trial that observed no difference in meperidine usage during 24 hour followup. A fourth trial compared IV dexamethasone vs. IV ketamine vs. the combination vs. placebo and found the combined therapy group had no 24-hour postoperative analgesia requirements. Both the steroid and ketamine alone groups had lower analgesia needs than placebo.[62]

Antiemetics. One trial comparing IV dexamethasone vs. IV methylprednisolone observed no difference in percentage of patients receiving antiemetic medications in the PACU.[59] Another study assessed effectiveness of IV dexamethasone + infiltrated ropivacaine vs. ropivacaine alone showed a significantly reduced rate of antiemetic use in the dexamethasone arm.[50] Another RCT compared IV dexamethasone vs. ketamine vs. the combination, vs. placebo showed that all treatment groups had significantly lower antiemetic use (ondansetron) than placebo.[62]

IV Versus Infiltrated Dexamethasone

Analgesics. Two low-risk of bias RCTs evaluated the efficacy of IV versus peritonsillar infiltrated dexamethasone with or without concomitant levobupivacaine among children undergoing tonsillectomy.[39, 51] Both RCTs found infiltrated dexamethasone reduced postoperative analgesic requirements significantly.

Antiemetics. A single RCT compared IV vs. infiltrated dexamethasone vs. placebo and found use of postoperative rescue anti-emetic medications was significantly lower in both steroid groups compared with placebo.[39] Investigators observed no differences between dexamethasone groups.

Infiltrated Dexamethasone Versus Placebo

Analgesics. One moderate risk of bias trial compared dexamethasone infiltration, 0.25-percent levobupivacaine with epinephrine infiltration, and saline placebo.[45] The total doses of rescue analgesia were significantly fewer for dexamethasone than other groups at all time points during the first postoperative week.

Antiemetics

Need for Rescue Medications

Analgesics. Five RCTs (four low risk of bias[88, 118, 132, 133] and one moderate[122]) evaluated the effect of perioperative antiemetic use on post-tonsillectomy analgesic requirements. All studies evaluated 5-HT receptor antagonists including ramosetron,[118, 133] granisetron,[132, 133] ondansetron,[88, 122] and dolasetron.[122] Antiemetic medications did not have any effect on pain control in any trial.

Two compared different 5-HT antagonists. In one trial, children were randomized to IV granisetron vs. ramosetron at the end of surgery and demonstrated no difference in analgesics administered 24 hour postoperatively.[133]Another compared IV ondansetron vs. dolasetron, vs. placebo and found opioid use in the PACU did not differ between arms.

Two compared 5-HT antagonists to antiemetic from other classes including droperidol,[132] metoclopramide.[88, 132] In one trial that assessed the effectiveness of IV granisetron vs. droperidol vs. metoclopramide found no difference in analgesic use during 24 hour postoperatively.[132] Another RCT compared ondansetron vs. metoclopramide and also reported no difference in opioid use in the first 24 hours.[88]

One dose-escalating trial of ramosetron evaluated IV placebo vs. IV ramosetron at 3, 6, or 12 microgram/kg immediately after end of surgery.[118] It found no difference in 24 hour post-tonsillectomy analgesia use between groups.

Postoperative antiemetics. Three studies including two low [118, 136] and one moderate [122] risk of bias RCTs assessed the effect of pre-emptive antiemetic use in reducing need for postoperative antiemetic rescue. Pre-emptive use of 5-HT receptor antagonists reduced the need for immediate postoperative anti-emetic use compared with placebo.

One study that compared IV tropisetron vs. placebo found significantly reduced 24 hour need for postoperative rescue-antiemetic use in the tropisetron arm (tropisetron 1/35, placebo 12/36, $p<0.01$). A second trial assessed preoperative IV ondansetron vs. dolasetron vs. placebo with each group pretreated with dexamethasone.[122] Both 5-HT receptor antagonists had significantly

less antiemetic rescue needs in PACU than placebo (ondansetron 4%, dolasetron 6%, placebo 22%, p<0.05). No child in any arm required antiemetic rescue in the 48 hours post-PACU. However, the overall antiemetic rescue requirement was significantly less overall for 5-HT receptor antagonists (ondansetron 4%, dolasetron 8%, placebo 24%, p<0.05). A third trial compared placebo vs. escalating ramosetron doses (3, 6, or 12 μg/kg).[118] Requirement for antiemetic rescue in first 24 hours were 30 percent for placebo, 25 percent for 3 μg/kg (p=NS), while none required rescue in higher dose ramosetron arms. Similarly, during 24-48 hour followup, 25 percent of placebo and 25 percent of the 3 μg/kg-ramosetron arm required rescue antiemetic, while none in higher dose arms needed it.

Harms Associated With Perioperative Medications

PTH

Seventeen studies provided data on PTH associated with perioperative medications for pain.[40, 45, 47, 54, 57, 59, 78, 105, 106, 112, 117, 119, 148, 150, 161, 291] PTH frequency overall ranged from 0 percent to 8.9 percent, with higher PTH frequency reported in patients who received anesthetics and steroids than those in other perioperative medications.

NSAIDs. Few studies of NSAIDs (6 studies,[40, 47, 106, 117, 150, 161] 7 treatment arms) reported PTH (6 PTH in 277 treated children, 2.6%). Three cases of PTH were associated with diclofenac,[161] two with ibuprofen,[47] and one with ketorolac.[150] Two studies (one of ketorolac and one of lornoxicam) reported no cases of PTH.[40, 117]

Steroids. Dexamethasone was the most commonly used steroid (9/10 studies).[45, 54, 57, 59, 78, 105, 112, 119, 148, 199] The tenth study used methylprednisolone.[59] Three steroid studies explicitly noted no PTH,[45, 59, 119]and three did not explicitly note number of bleeds but reported that no children receiving steroids had revisits or reoperation for PTH.[57, 105, 148]Another study did not explicitly note number of bleeds but reported that one child in the placebo and one in the steroid arm required reoperation.[112]

In one study comparing dexamethasone with placebo, 17 children in the steroid arm and 13 in the placebo arm had PTH (p=NR).[54] Revisits and reoperations differed significantly between groups, with more revisits occurring in the placebo arm (3.2% vs. 1.9%, p<0.001) but more reoperations for hemostasis in the steroid arm (1.9% vs. 0.6%, p=0.002). In another RCT comparing 3 doses of dexamethasone (0.05, 0.15, or 0.5 mg/kg) with placebo, dexamethasone decreased the incidence of PONV but increased the risk of PTH.[78] In total 22 children experienced 26 PTH episodes, which included any PTH, with or without evidence at clinical examination (placebo, n=2, dexamethasone 0.05 mg, n=6, dexamethasone 0.15 mg, n=2, and dexamethasone 0.5 mg, n=12, p=.003). The highest dose of dexamethasone was associated with the greatest PTH risk (adjusted RR compared with placebo=6.80; 95% CI: 1.77 to16.5. p=0.05). Eight children, all receiving steroids, required reoperation for hemostasis. In a third study comparing dexamethasone with placebo, two children in each arm had PTH requiring readmission but not reoperation for hemostasis.[199]

We combined nine studies comparing dexamethasone with placebo in a random effects meta-analysis to assess effects on risk of PTH. These studies comprised eight RCTs with low,[54, 57, 105, 112, 119] moderate,[78, 148] and high[188] risk of bias and one nonrandomized trial with high risk of bias.[199] We retained high risk of bias studies as an analysis indicated no systematic effects on the

model. To account for the relatively high number of zero cases of PTH in the data, we used a zero-inflated binomial model. Sixteen percent of studies had no PTH; among the 84 percent that did, the odds of primary, secondary, and undefined (either primary or secondary) PTH and PTH-associated reoperation or readmission were each nominally ≥ 1, with wide 95% credible intervals (Table 40). Pooling the outcomes did not systematically affect the estimates. These wide intervals prohibit firm conclusions about the effects of dexamethasone on PTH. Table 41 lists the unadjusted frequency of PTH in these studies.

Table 40. Odds estimates in meta-analysis of PTH risk associated with perioperative dexamethasone compared with placebo

Outcome	Odds Ratio	95% Credible Interval
Primary PTH	1.9	0.03 to 6
Secondary PTH	1.3	0.04 to 3.3
Undefined PTH	2.1	0.9 to 3.7
PTH-associated revisit or readmission	1.0	0.1 to 2.2
PTH-associated reoperation	3.1	0.3 to 7.8

Other medications. Among arms addressing anesthetics (reported in two studies[45, 161]), four cases of PTH occurred with bupivacaine in one study,[161] and none with levobupivacaine.[45] No PTH was reported with non-NSAID analgesics (propacetamol, fentanyl) in the two studies addressing these agents.[117, 150]

Table 41. Unadjusted PTH-related outcomes in study arms evaluating perioperative medications for pain

Drug Class (n arms)	Total N	Total PTH (%)	Total Primary PTH (%)	Total Secondary PTH (%)	Total Other/ Undefined PTH (%)	Total Non-operative Readmission or Revisit for PTH (%)	Total Re-operation for PTH (%)
All arms	1839	69 (3.8)	4 (0.7)	3 (0.66)	61 (4.3)	13 (1.4)	14 (1.2)
Steroids (14)	811	38 (4.7)	2 (0.61)	0 (0)	36 (5.3)	4 (0.84)	11 (1.8)
Placebo (12)	672	21 (3.3)	2 (0.89)	3 (1.8)	16 (3.6)	9 (2.1)	2 (0.43)
NSAIDs (7)	227	6 (2.6)	NR	NR	5 (2.96)	0 (0)	1 (0.93)
Anesthetics (2)	45	4 (8.9)	0 (0)	0 (0)	4 (8.9)	0 (0)	0 (0)
Non-NSAID Analgesics (3)	84	0 (0)	NR	0 (0)	0 (0)	NR	NR

Note: Percentages for primary and secondary PTH, readmissions/revisits, and reoperations reflect the number of each instance of bleeding or reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.

Concordance With Case Series and Database Studies

Four case series or database studies reported PTH associated with perioperative medications.[230, 234-236, 271] One study evaluated differences in PTH requiring reoperation among children (≤ age 15) who had (n=1680) and had not (n=30254) received perioperative steroids (intravenous dexamethasone or hydrocortisone).[230] Most children had obstructive symptoms (over 65% in each arm), and 20 children in the steroid arm (1.2%) and 140 control children (0.5) had PTH requiring reoperation (p<0.001). Steroid use was associated with an increased rate of reoperation in children but not in adults in this study (OR for children=2.50, 95% CI: 1.47 to 4.23, p=0.001). Age was also noted as a risk factor in children (OR=1.10, 95% CI: 1.04 to 1.17,

p<0.001) but the direction of effect was not clearly reported. Female children were also less likely to require reoperation than male (OR=0.73, 95%CI: 0.54 to 1.00, p=0.05).[230]

Another study evaluating adherence to 2011 AAO-HNSF guideline recommendations related to perioperative dexamethasone and antibiotic use also reported PTH associated with these medications.[234] Out of all 15950 children (1-18 years of age) included in analyses, 432 experienced PTH (2.7%). PTH occurred in 92 of 7432 children in the pre-guideline era (1.2%) and in 229 of 8518 children after guidelines were issued (2.7%). Differences between physicians or hospitals that did or did not use these medications perioperatively, either before or after the publication of guidelines, were not significant.

Another study assessed how well hospitals adhered to evidence-based process measures including use of perioperative dexamethasone and antibiotics using data from the Pediatric Health Information System database and reported a significantly greater risk of PTH-associated revisits in children who received dexamethasone (3.11%, 95% CI: 2.99% to 3.23%) compared with those who did not (2.71% , 95% CI: 2.50% to 2.91%; standardized difference=0.40%, 95% CI: 0.13% to 0.67%, p=0.003). A final case series evaluated PTH after tonsillectomy with perioperative ibuprofen and reported 98 readmissions for PTH among 2697 children (3.6%).[271] Fifty-eight children (2.2%) required reoperation for hemostasis.

Non-PTH Revisits

Few studies evaluating perioperative agents reported any revisits for non-PTH indications[39, 52, 112, 119, 121, 148] (Table 42); in 8 of 11 study arms, no revisits or readmissions occurred. Higher, though still low, frequency of revisits typically occurred with combination agents such as dexamethasone plus antiemetics[122] or in placebo arms.[112, 122, 148] In one study that compared perioperative IV dexamethasone with placebo, four children in the placebo arm (11%) were readmitted for dysphagia and throat pain compared with none in the dexamethasone arm (p=NR).[148]

Table 42. Unadjusted revisits or readmissions for pain, dehydration, and PONV reported in comparative study arms addressing perioperative agents

Drug Class (N arms)	Total Arm N	N Pain Revisits/ Readmissions (%)	N Dehydration Revisits/ Readmissions (%)	N PONV Revisits/ Readmissions (%)
All arms (11)	542	4 (1.1)	1 (0.33)	1 (0.26)
Steroids (5)	279	0	1 (1.6)	0
NSAIDs (1)	20	0	0	0
Anesthetic (1)	80	0	0	0
Placebo (4)	163	4 (6.9)	0	1 (1.4)

Note: Percentages for readmissions/revisits reflect the number of each instance of reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.
N = number; NSAID=nonsteroidal anti-inflammatory drug; PONV = postoperative nausea and vomiting

Key Question 6. Effectiveness of Postoperative Medications To Reduce Pain-Related Outcomes After Tonsillectomy

Key Points

- Few studies of postoperative medications addressed the same intervention and outcomes, limiting our ability to make conclusions about this body of literature.

- In studies of postoperative NSAIDs, we found a low frequency of PTH. Our confidence in this estimate is low (low strength of evidence).
- We could not make conclusions about the effects of postoperative analgesics on need for rescue medications; return to normal diet or activity; or PTH (insufficient strength of evidence).
- In studies of postoperative steroids, we found no difference in effects on return to normal diet or activity between steroids and placebo. Our confidence in this conclusion is low (low strength of evidence).
- In studies of postoperative steroids, we found no difference in effects on bleeding between steroids and placebo or no treatment. Our confidence in this conclusion is low (low strength of evidence).

Overview of the Literature

Of 13 studies addressing postoperative medications for pain-related outcomes identified, 11 were RCTs,[38, 41, 49, 55, 60, 115, 137, 138, 155, 159, 190] and two were nonrandomized trials[194, 202] (Table 43). Study country of origin included New Zealand,[49, 60] Canada,[38, 155] Denmark,[137, 138, 190] Serbia,[115] Egypt,[159] Pakistan,[202] Jordan,[55] and South Korea.[41] Studies included a total of 2660 children ranging in age from 1 to 18 years.

Studies assessed three categories of postoperative medications: analgesics (n=9),[38, 49, 115, 137, 138, 155, 159, 190, 194] steroids (n=2),[41, 60] and antibiotics (n=2).[55, 202] Specific analgesics considered included nonsteroidal anti-inflammatory drugs (NSAID),[38, 49, 138, 155, 159, 190, 194] acetaminophen,[49, 138, 159, 190, 194] morphine,[155] benzydamine oral rinse plus ibuprofen,[115] and metamizole.[194] Two studies evaluated oral prednisolone[41, 60] and two evaluated the effect of amoxicillin + clavulanic acid[55, 202](one comparing it to cefaclor[202]) on postoperative outcomes.

Indication for tonsillectomy varied among studies. Most included a combination of patients with recurrent infection and OSDB (n=4).[41, 60, 155, 194] One study enrolled children with recurrent tonsillitis,[55] and several studies did not specify tonsillectomy indication(s) (n=8).[38, 49, 115, 137, 138, 159, 190, 202] All but three trials[55, 137, 202] had low[41, 49, 115, 155] or moderate risk of bias,[38, 60, 138, 159, 190, 194] and were included in further analyses. Major sources of bias in these studies included use of unblinded outcome assessors and unclear methods for concealment of study group allocation.

Table 43. Overview of studies addressing postoperative medications for pain-related outcomes

Characteristic	RCTs	Nonrandomized Trials	Total Literature
Comparisons			
Acetaminophen vs. Non-NSAID Analgesic or Acetaminophen	4	0	4
Acetaminophen vs. NSAID	2	1	3
Steroid vs. Placebo or No Steroid	2	0	2
NSAID vs. Placebo	1	0	1
Other*	2	1	3
Surgical Indication			
Throat Infection	1	0	1
OSDB + Throat Infection	3	1	4
Unspecified	7	1	8
Effectiveness Outcomes Frequently Reported			
Rescue analgesic use	5	1	6
Time to return to normal diet/activity	5	1	6
Quality of life	1	0	1
Risk of Bias			
Low	4	0	4
Moderate	5	1	6
High	2	1	3
Total N participants	**2200**	**440**	**2660**

*Antibiotic vs. no antibiotic[55] or antibiotic vs. antibiotic vs. placebo[202] or benzydamine oral rise vs. other oral rinse[115]
N = Number; NSAID = Nonsteroidal Anti-Inflammatory Drug; OSDB = Obstructive Sleep-Disordered Breathing; RCT = Randomized Controlled Trial

Detailed Analysis

Only four studies evaluating postoperative analgesic medications provided effectiveness outcomes, which included need for rescue medication[38, 49, 159] and return to normal diet.[155, 159] Four studies reported postoperative PTH or harms outcomes, but no effectiveness data.[115, 138, 190, 194]

Analgesics

Pain-Related Outcomes

Studies investigating the need for postoperative rescue medication after tonsillectomy considered different treatment comparisons. One RCT (moderate risk of bias) randomized 282 children to celecoxib given preoperatively (6mg/kg) and twice daily (3mg/kg) postoperatively for 5 doses or placebo.[38] Children who received celecoxib had lower mean consumption of acetaminophen on postoperative days (POD) 0-2 (celecoxib 78 vs. placebo 97 mg/kg, p=0.03), but no difference in mean morphine consumption (celecoxib 0.56 vs. placebo 0.70 mg/kg, p=NS).

Another low risk of bias trial randomized 152 children who underwent tonsillectomy to acetaminophen + ibuprofen, acetaminophen alone, or ibuprofen alone (60mg per 5 mL suspension) for postoperative pain control.[49] Groups did not differ in the use of rescue analgesia in the recovery room, but after discharge from the recovery room during postoperative days 0-2, fewer patients required rescue analgesia (i.e., acetaminophen + ibuprofen) in the combination group than in the other arms (0% combined, 16% acetaminophen, 15% ibuprofen). A third study (moderate risk of bias) compared postoperative treatment with acetaminophen or diclofenac

(dose NR) to be administered every 8 hours or as needed for pain.[159] Mean analgesic use did not differ between groups in the first 24 hours.

All trials assessing analgesia outcomes had short-term followup ranging from 24 to 48 hours postoperatively and assessed a heterogeneous group of medications. Available data are conflicting as to whether postoperative use of NSAIDs (celecoxib, ibuprofen, diclofenac) decreases rescue pain medication requirement in the first 24-48 hours among children post-tonsillectomy. Longer-term effectiveness of these medications cannot be gleaned from currently available data (Table 44).

Table 44. Need for rescue medications reported in studies of postoperative medications

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Need for Rescue Medications
Merry 2013[49] RCT Low ROB	G1: Acetaminophen 120 mg+ ibuprofen 60 mg/5mL suspension (52) G2: Acetaminophen 120 mg/5 mL suspension (49) G3: Ibuprofen 60 mg/5 mL suspension (51)	**N requiring rescue analgesia, (%)** In PACU G1: 1 (2) G2: 1 (2) G3: 1 (2) Post-PACU discharge G1: 0 G2: 8 (16) G3: 8 (15)
Monem 2005[159] RCT Moderate ROB	G1: Acetaminophen (32) G2: Diclofenac (34)	**N requiring additional analgesia, (%)** G1: 3 (9) G2: 2 (6) No significant group differences in total analgesic use in first postoperative day or in at-home antiemetic use
Murto 2015[38] RCT Moderate ROB	G1: Celecoxib (141) G2: Placebo (141)	**Analgesic consumption** • No group differences in opioid consumption in PACU • No group differences in cumulative co-analgesic consumption in postoperative days 0-7 • No group differences in N morphine-free patients **Postoperative day 0-2 acetaminophen consumption, mean** G1: 78 mg/kg^{-1} (95% CI: 68 to 89) G2: 97 mg/kg^{-1} (95% CI: 85 to 109) G1 vs. G2: p=0.03 **Postoperative day 0-2 morphine consumption** G1: 0.56 mg/kg^{-1} (95% CI: 0.47 to 0.65) G2: 0.70 mg/kg^{-1} (95% CI: 0.59 to 0.81) G1 vs. G2: p=NS

CI=Confidence Interval; G=Group; kg = Kilogram; mg = Milligram; N=Number; NR=Not Reported; NS=Not Significant; PACU=Post-Anesthesia Care Unit; RCT=Randomized Controlled Trial; ROB=Risk of Bias

Return to Normal Diet

Return to normal diet was evaluated and defined differently in two studies (Table 45). In one RCT with low risk of bias, 91 children (1-10 years of age) with OSDB with or without recurrent tonsillitis undergoing tonsillectomy were randomized to postoperative acetaminophen + ibuprofen or acetaminophen + morphine.[155] Both groups used pain medications for a mean of 4 postoperative days (ibuprofen 4.64 vs. morphine 4.04 days). No difference was observed in days to return to preoperative diet between arms (morphine 7.31 vs. ibuprofen 7.17 days, p=0.89).

Another moderate risk of bias trial randomized children undergoing tonsillectomy to postoperative acetaminophen or diclofenac.[159] Children in the acetaminophen group had faster return to normal oral intake compared with those getting diclofenac, and this reached significance on the first 5 postoperative days. Altogether, current data do not consistently indicate a differential return to preoperative/normal diet among children treated with NSAIDs (i.e., ibuprofen, diclofenac), morphine, or acetaminophen.

Table 45. Return to normal diet or activity in studies of postoperative medications

Author, Year Study Type Groups (N) Risk of Bias	Comparison Groups (N)	Time to Return to Normal Diet/Activity
Kelly 2015[155] RCT Low ROB	G1: Acetaminophen + morphine (46) G2: Acetaminophen + ibuprofen (38)	N days to return to preoperative diet, mean±SD G1: 7.31±3.82 G2: 7.17±5.23 G1 vs. G2: p=NS
Monem 2005[159] RCT Moderate ROB	G1: Acetaminophen (32) G2: Diclofenac (34)	Significantly greater percent of normal diet consumed in G1 vs. G2, $p < 0.05$

G = Group; NR = Not Reported; NS = Not Significant; RCT = Randomized Controlled Trial; ROB = Risk of Bias; SD = Standard Deviation

Steroids

Return to Normal Diet

Two RCTs evaluated the effectiveness of postoperative prednisolone in children undergoing tonsillectomy (Table 46).[41, 60] In one trial (low risk of bias) 138 children (≥4 years of age) undergoing elective tonsillectomy for tonsillitis or hypertrophy were randomized to oral prednisolone (0.25 mg/kg/day) for seven postoperative days or no prednisolone.[41] No difference in type of diet (i.e., none, fluid, soft, normal) was seen between arms on POD 1 (p=0.30); however, significantly more children had normal diet (46% vs. 25%, $p < 0.001$) and a higher activity level in the prednisolone arm on postoperative day 7 (p=0.004). No difference between groups in either diet or activity was present on postoperative day 14. Although not reported specifically for children, outcomes did differ based on tonsillectomy indication. In a stratified *post hoc* analysis, those undergoing tonsillectomy for OSDB were significantly more likely to have normal diet and improved activity by postoperative day 7 if treated postoperatively with prednisolone compared with controls. These associations were not observed in patients whose indication was recurrent tonsillitis.

A second trial (low risk of bias) randomized 215 children to a 5-day postoperative course of prednisolone (0.5 mg/kg up to 20 mg/day) or placebo.[60] Time to return to preoperative diet or activity did not differ between groups (p values > 0.2). Overall, data from these studies provide inconsistent evidence that postoperative treatment with oral prednisolone decreases time to return to preoperative/normal diet or activity level.

Table 46. Time to return to normal diet or activity in studies addressing postoperative steroids

Author, Year Study Type Risk of Bias	Comparison Groups (N)	Time to Return to Normal Diet/Activity
Park 2015[41] RCT Low ROB	G1: Prednisolone 0.25 mg/kg/day (69) G2: No prednisolone (69)	**Normal diet at day 14 postoperative, N (%)** G1: 64 (93) G2: 65 (94) G1 vs. G2: p=NS **Normal activity at day 14, N (%)** G1: 69 (100) G2: 66 (96) G1 vs. G2: p=NS
Macassey 2012[60] RCT Moderate ROB	G1: Prednisolone (106) G2: Placebo (107)	**Time to normal diet** G1 vs. G2: p=NS **Time to normal activity** G1 vs. G2: p=NS

G=group; NR=not reported; NS=not significant; RCT=randomized controlled trial; ROB=risk of bias

Harms Associated With Postoperative Medications

PTH

Six studies of low or moderate risk of bias addressed postoperative medications for pain and reported PTH-related outcomes.[38, 41, 60, 115, 138, 194] PTH occurred in less than 10 percent of children overall (Table 47). In steroid studies 8.1 percent of children had PTH overall, but numbers of PTH in steroid and placebo arms in the two studies addressing that comparison were similar ($n^{\text{PTH in steroid arms}}$=13, $n^{\text{placebo/no treatment arms}}$=15).[41, 60] Frequency of PTH in studies comparing NSAIDs (celecoxib, ibuprofen) to placebo or other medications were also similar ($n^{\text{PTH in NSAID arms}}$=14, $n^{\text{comparison arms}}$=16).[38, 194] Frequency of PTH were similar among studies of non-NSAID analgesics (2%-4%).[115, 138, 194] One NSAID study did not specify adverse effects assessed but noted that no events occurred in children receiving either diclofenac or placebo.[190]

Table 47. Unadjusted PTH-related outcomes in study arms evaluating postoperative medications for pain

Drug Class (n arms)	Total N	Total PTH (%)	Total Primary PTH (%)	Total Secondary PTH (%)	Total Other/ Undefined PTH (%)	Total Nonoperative Readmission or Revisit for PTH (%)	Total Reoperation for PTH (%)
All arms (13)	2063	97 (4.7)	12 (1.4)	15 (1.8)	70 (5.7)	18 (3.8)	17 (1.2)
Non-NSAID analgesics (4)	772	23 (3.0)	7 (1.7)	2 (0.49)	14 (3.9)	NR	3 (0.47)
NSAIDs (3)	679	32 (4.7)	5 (1.2)	13 (3.1)	14 (5.5)	8 (5.7)	12 (1.8)
No treatment/ Placebo (3)	312	23 (7.4)	NR	NR	23 (7.4)	9 (3.7)	2 (1.4)
Steroids (2)	160	13 (8.1)	NR	NR	13 (8.1)	1 (1.1)	NR
Other (1)	140	6 (4.3)	NR	NR	6 (4.3)	NR	NR

Note: Percentages for primary and secondary PTH, readmissions/revisits, and reoperations reflect the number of each instance of bleeding or reencounter divided by the total number of patients in the studies reporting such data, and not in the total number of participants across all studies in a given row.

N = Number; NR = Not Reported; NSAID = Nonsteroidal Anti-Inflammatory Drug; PTH = Post-Tonsillectomy Hemorrhage

Discussion

State of the Literature

We identified 218 unique studies addressing the benefits and harms of tonsillectomy (which we consider to encompass tonsillectomy, adenotonsillectomy, partial tonsillectomy or tonsillotomy). These unique studies (reported in multiple publications) comprised 141 randomized controlled trials (RCTs), 12 nonrandomized trials, seven prospective and five retrospective cohort studies, and 53 database or registry studies or case series including at 1000 children. Key Questions (KQs) addressed in this review assessed the likelihood that tonsillectomy will improve clinical outcomes around throat infections and sleep disorders; the risk of harm associated with tonsillectomy, primarily post-tonsillectomy hemorrhage (PTH); and whether different approaches to tonsillectomy (e.g., partial vs. total tonsil removal, surgical technique such as coblation or laser) optimize effectiveness and minimize harms. We addressed these questions by reviewing the comparative (primarily RCT) data for effectiveness on a specific set of outcomes, then by searching a broader set of studies (case series and database or registry studies including at least 1000 children) for harms data in order to estimate the frequency of the most common and most severe harms (PTH, readmission, and reoperation). While we attempted to stratify on key covariates, including body mass index (BMI), documentation of throat infections, and surgical indication, such data were rarely available.

The literature on tonsillectomy in children for obstructive sleep-disordered breathing (OSDB) or recurrent throat infection is heterogeneous in terms of populations, interventions, comparators, and outcomes. Most studies included children with widely varying ages (e.g., 2 to 14 years), unspecified or mixed (both OSDB and throat infections) indications for surgery, and varying degrees of severity. Few studies stratified on potential confounding factors such as degree of tonsillar hypertrophy.

Anesthetic, analgesic, and anti-emetic regimens varied across studies, as did surgical techniques and perioperative and postoperative agents or combinations of agents assessed. Comparison groups included placebo, observation, historical control groups, and other active interventions. While studies typically addressed similar effectiveness outcomes including changes in respiratory or sleep parameters (e.g., Apnea Hypopnea Index [AHI], sleep-related quality of life), number and severity of throat infections, return to normal diet and activity, need for rescue analgesia or antiemetics postoperatively, and behavioral outcomes, measures used to evaluate the outcomes varied. Although a large number of studies reported PTH, definitions of "bleeding" varied and ranged from episodes of blood-tinged sputum to profuse bleeding requiring reoperation for hemostasis. Outcome measures were also frequently caregiver- or child-reported pain or bleeding diaries.

Summary of Key Findings and Strength of the Evidence

KQ1. Effectiveness of Tonsillectomy for OSDB

Key Findings

Relative to no intervention, most studies reported better sleep-related outcomes in children who had a tonsillectomy, but improvements were modest overall. In five studies that included children whose OSDB was confirmed with polysomnography (PSG), AHI scores improved more

in children receiving tonsillectomy than in those with no surgery (significant group differences in 3 studies).[114, 172, 203, 204, 211]). Meta-analysis of three studies showed a 4.8-point decline (improvement) in AHI in children who underwent tonsillectomy compared with no surgery.[172, 204, 211] Sleep-related quality of life and negative behaviors (e.g., anxiety, emotional lability) also improved more among children who had tonsillectomy, but the clinical significance of these changes is not clear.[114, 172, 211] Children in the studies typically did not have behavioral scores indicative of clinical concern at baseline. Changes in executive function were not significantly different between groups.[172, 203]

We did not find tonsillectomy to be superior to continuous positive airway pressure (CPAP) in the one RCT addressing this comparison, which included children with significant comorbidities.

Strength of the Evidence

For tonsillectomy compared with no surgery, we found greater improvement in AHI and negative behaviors with tonsillectomy vs. watchful waiting. Our confidence in these conclusions is low (low strength of evidence). We also found consistently greater improvement in sleep-related quality of life with tonsillectomy vs. watchful waiting and have more confidence in this conclusion (moderate strength of evidence). We could not make conclusions about effects on executive function and other outcomes including cognitive changes (insufficient strength of evidence). Table 48 outlines strength of evidence findings for this KQ. We could not make conclusions about outcomes following tonsillectomy compared with CPAP and in studies assessing outcomes in sub-populations such as children with Down syndrome (KQ1a-d) given the few studies addressing CPAP or these populations (insufficient strength of evidence).

Table 48. Strength of evidence for effectiveness of tonsillectomy versus watchful waiting/no treatment for OSDB

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Finding
Tonsillectomy vs. No Tonsillectomy						
AHI Meta-analysis RCT: 2 moderate[114, 172] (N=456) Prospective Cohort: 1 moderate[203] (N=38) Retrospective Cohort: 2 moderate[211,214] (N=94)	Medium	Inconsistent	Indirect	Precise	Undetected	**Low SOE for greater improvement of AHI with tonsillectomy compared with no surgery** Significant improvement in tonsillectomy vs. no surgery groups in 1 RCT and 2 retrospective cohort studies; no significant group differences in 1 RCT and 1 prospective cohort. In 3 studies, children in control arms improved from baseline. 4.8-point improvement in AHI in tonsillectomy arms in meta-analysis.
Sleep-related Quality of Life RCT: 2 moderate[114, 172] (N=456) Retrospective Cohort: 1 moderate[211] (N=32)	Medium	Consistent	Direct	Precise	Undetected	**Moderate SOE for improvement in sleep-related quality of life after tonsillectomy vs. no surgery** Significant improvements in tonsillectomy vs. no tonsillectomy groups on measures of sleep-related quality of life in 2 RCTs and 1 cohort study in the short term
Behavioral Outcomes RCT: 1 moderate[172] (N=397) Prospective Cohort: 1 moderate[203] (N=38) Retrospective Cohort: 1 moderate[211] (N=32)	Medium	Inconsistent	Direct	Im-precise	Not suspected	**Low SOE for improvements in negative behaviors after tonsillectomy vs. no surgery** Significant improvements in tonsillectomy vs. no surgery in 1 RCT and 1 retrospective cohort; no significant differences in 1 prospective cohort; differences in measurement time frames across studies (7 months-4 years) and unclear clinical significance of changes

AHI = apnea-hypopnea index; OSDB = obstructive-sleep disordered breathing; RCT = randomized controlled trial; SOE = strength of the evidence

KQ1a-d. Effectiveness of Tonsillectomy for Subpopulations of Children With OSDB

Key Findings

While studies may have included some children with craniofacial abnormalities, only a single, small RCT compared the efficacy of tonsillectomy to immediate initiation of CPAP in children with OSDB and concurrent Down syndrome or mucopolysaccharidoses.[44] Both groups showed improvement in AHI at 6-month followup, with no significant group differences in AHI at 12 months. Another study reported no significant group differences in outcomes in analyses of children with syndromic comorbidities receiving tonsillectomy or watchful waiting.[214]

Several studies included children who were overweight or obese; however, only two retrospective cohorts specifically evaluated overweight/obese populations with OSDB. One reported a significant decrease in AHI in children who received tonsillectomy compared with those who did not.[211] In another including children with mild OSA, analysis of subgroups of obese children showed no significant differences in outcomes between groups in these populations.[214]

While several studies included children less than 3 years of age, these data were not extractable from the aggregate study population data. We did not identify studies explicitly addressing this question.

Strength of the Evidence

Strength of the evidence is insufficient to assess effects on outcomes in subpopulations of children with OSDB (children with neuromuscular or craniofacial abnormalities, those under 3 years of age, those with Down syndrome, or those with obesity).

KQ2. Effectiveness of Tonsillectomy for Recurrent Throat Infection

Key Findings

Although studies assessed frequency of infections and a number of utilization measures, such as missed school in the short term, longer-term results were rarely reported, and studies that did report longer-term results suffered from high attrition and incomplete data. In addition, "throat infection" was not defined consistently across studies and very rarely was bacterial infection confirmed.

Overall, children undergoing tonsillectomy to improve number of throat infections, associated health care utilization (clinician visits), and days of work/school missed had improvements in these outcomes in the first postsurgical year compared with children not receiving surgery.[9, 164, 179, 210, 213] These benefits diminished over time, however, and data on the longer-term outcomes are limited.

Strength of the Evidence

Compared with no surgery, tonsillectomy reduced utilization (clinician contacts) and missed school/work in the short term. We have low confidence in this conclusion (low strength of evidence). We have moderate confidence that compared with no surgery, tonsillectomy reduced throat infections or streptococcal infections in the short term (<12 months) (moderate strength of evidence). In the longer term (>12 months) we found no difference between groups in reduction

in streptococcal infections (low strength of evidence). We found no significant differences between groups in missed school/work or quality of life in the long term (>12 months) and have low confidence in these conclusions (low strength of evidence). Table 49 outlines strength of evidence ratings.

We could not make a conclusion about long term (>12 months) effects on throat infections (insufficient strength of evidence) as few studies reported longer-term data, and those that did had high attrition rates. Only one study included children with less than 3 episodes of throat infection in the year prior to surgery;[210] we could not make conclusions about outcomes (utilization) reported in this single study (insufficient strength of evidence).

Table 49. Strength of evidence for effectiveness of tonsillectomy versus watchful waiting/no treatment for recurrent throat infections

Intervention/ Outcome **Study Design** **Risk of Bias and Number of Studies (N Total)**	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Reporting Bias**	**Strength of Evidence Grade** **Findings**
Tonsillectomy vs. No tonsillectomy in children with at least 3 episodes of sore throat in year prior to study						
Throat Infection RCT: 4 moderate[9, 164, 179] (N=761) Non-RCT: 1 moderate[179] (N=303) Retrospective Cohort: 1 moderate[213] (N=290)	Medium	Consistent	Direct	Precise	Undetected	**Moderate SOE for reduction in throat infection after tonsillectomy vs. no treatment in short-term (12 months)** Fewer throat infections in tonsillectomy arms in short-term

Table 49. Strength of evidence for effectiveness of tonsillectomy vs. watchful waiting/no treatment for recurrent throat infections, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Tonsillectomy vs. No tonsillectomy in children with at least 3 episodes of sore throat in year prior to study						
Streptococcal Infection (≤ 12 months post-tonsillectomy) RCT: 2 moderate[9] (N=273) Retrospective Cohort: 1 moderate[213] (N=290)	Medium	Consistent	Direct	Precise	Undetected	**Moderate SOE for reduction in streptococcal infection after tonsillectomy vs. no tonsillectomy in short term (12 months)** Fewer streptococcal infections in tonsillectomy arms in short-term
Streptococcal Infection (2-3 years post tonsillectomy) RCT: 2 moderate[9](N=203) Retrospective Cohort: 1 moderate[213] (N=290)	Medium	Inconsistent	Direct	Imprecise	Undetected	**Low SOE for no difference in reduction in streptococcal infection after tonsillectomy vs.no surgery over longer term (2-3 years)** Similar proportion of infections in retrospective cohort and significantly more infections in nonsurgical groups in 2 RCTs
Utilization (clinician contacts) RCT: 1 moderate[179] (N=231) Non-RCT: 1 moderate[179] (N=303)	Medium	Consistent	Direct	Precise	Undetected	**Low SOE for reduction in clinician contacts after tonsillectomy vs. no surgery in short term (<12 months)** Fewer consultations in tonsillectomy arms vs. no surgery, but high loss to followup and differences in outcome assessment

Table 49. Strength of evidence for effectiveness of tonsillectomy vs. watchful waiting/no treatment for recurrent throat infections, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Tonsillectomy vs. No tonsillectomy in children with at least 3 episodes of sore throat in year prior to study						
Missed school/work (≤ 12 months post tonsillectomy) RCT: 3 moderate[9, 164] (N=503)	Medium	Inconsistent	Direct	Im-precise	Undetected	**Low SOE for improvements in missed school after tonsillectomy vs. no surgery in short term (< 12 months)** Significantly fewer missed days in tonsillectomy arms vs. no surgery in 2 RCTs with medium study limitations at 12 month followup; no differences in third RCT
Missed school/work (> 12 months post tonsillectomy) RCT: 3 moderate[9, 164] (N=245)	Medium	Consistent	Direct	Im-precise	Undetected	**Low SOE for no difference in effects between in longer term (>12 months)** No significant differences between groups in all studies at longer-term followup; SOE is low given medium study limitations and relatively low number of participants
Quality of Life (>12 months) RCT: 2 moderate[164, 179] (N=373) Non-RCT: 1 moderate[179] (N=123)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no difference in longer term (>12 months) quality of life** Modest improvements in quality of life in both groups in all studies; SOE is low given high attrition in studies

Non-RCT = nonrandomized trial; RCT = randomized controlled trial; SOE = strength of the evidence

KQ3. Effectiveness of Partial Versus Total Tonsillectomy

Key Findings

Few studies compared partial and total tonsillectomy using the same surgical technique.[53, 84-86, 90] In studies comparing cold dissection or coblation for partial or total tonsillectomy, return to

normal diet or activity were faster in children undergoing partial removal. [53, 84-86] Differences in time to return to normal activity were not significant in a study comparing partial and total electrocautery.[90]

In studies evaluating partial vs. total tonsillectomy using differing surgical techniques, differences between partial and total tonsillectomy were generally not significant for outcomes related to OSDB persistence, quality of life, or behavior (although it is not possible to be certain that effects are due to the surgical technique rather than the extent of surgery).[71, 95, 97, 98, 107, 110, 139, 151, 158, 182-186]

In six studies, children in the partial tonsillectomy arms had faster return to diet and normal activity compared with those in total tonsillectomy groups; however, these effects may be due to confounding by indication as surgical indication varied across studies. Across all studies, 10 out of an estimated 166 children (6%) had tonsillar regrowth after partial tonsillectomy, 5 of whom ultimately underwent revision surgery. Data from these studies do not allow firm conclusions about the benefits or harms of one technique over another or about the comparative benefit of partial vs. total removal; however, neither surgical technique or extent of surgery appear to have a marked effect on outcomes.

Strength of the Evidence

In studies comparing partial and total cold dissection tonsillectomy, return to normal diet was faster in children undergoing partial tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). We could not assess effects on throat infections, OSDB persistence, or return to normal activity in these studies (insufficient SOE).

In studies comparing either partial and total coblation tonsillectomy or partial and total electrocautery tonsillectomy, we could not make conclusions about effects on return to normal diet or activity (insufficient strength of evidence).

In studies comparing mixed techniques for partial or total tonsillectomy, return to normal diet and activity was more favorable in children undergoing partial versus total tonsillectomy. Our confidence in this conclusion is low (low strength of evidence). These effects may be due to confounding by indication as indication varied across studies. In studies comparing mixed techniques for partial or total tonsillectomy, we found no difference in effects on long-term (>12 months) persistence of OSDB symptoms, quality of life, behavioral outcomes, or throat infections between partial and total tonsillectomy. Our confidence in these conclusions is low (low strength of evidence). Table 50 outlines strength of evidence findings.

Table 50. Strength of evidence for effectiveness of total tonsillectomy versus partial tonsillectomy

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Total vs.partial cold dissection tonsillectomy						
Return to Normal Diet RCT: 1 low,[53] 1 moderate[86] (N=131)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for faster return to normal diet after partial vs. total tonsillectomy** Children undergoing partial tonsillectomy returned to normal diet approximately 4 days sooner than children undergoing total tonsillectomy according to parent report
Total vs. Partial tonsillectomy (mixed techniques)						
Return to Normal Diet or Activity RCT: 2 low,[97, 98] 4 moderate,[95, 107, 110, 185, 186] (N=620)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for more favorable return to normal diet and activity in children undergoing partial vs. total tonsillectomy** Children undergoing partial vs. total tonsillectomy had consistently favorable outcomes but unit of measure varied across studies (e.g., mean days, N children)

Table 50. Strength of evidence for effectiveness of total tonsillectomy vs. partial tonsillectomy, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Total vs. Partial Tonsillectomy (mixed techniques)						
OSDB Persistence (≥12 months post-tonsillectomy) RCT: 3 moderate[110, 182-186] (N=214)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no difference in effects on long-term persistence of OSDB symptoms between partial and total tonsillectomy** More children undergoing partial vs. total tonsillectomy had short-term snoring or obstructive symptoms in 2 studies but no group differences in longer term in any study
Quality of Life (≥12 months post-tonsillectomy) RCT: 2 moderate[182-186] (N=159)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no long-term differences in quality of life after partial vs. total tonsillectomy** Improvements from baseline in both groups in 2 small studies, but no significant group differences in quality of life in either study
Behavioral Outcomes (≥12 months post-tonsillectomy) RCT: 2 moderate[182-186] (N=159)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no long-term differences in behavioral outcomes after partial vs. total tonsillectomy** Improvements from baseline in both groups on the Child Behavior Checklist in 2 small studies, but no significant group differences in either study
Throat Infections (≥12 months post-tonsillectomy) RCT: 1 low,[185, 186] 3 moderate[110, 139, 182-184] (N=296)	Medium	Inconsistent	Direct	Imprecise	Undetected	**Low SOE for no effect on throat infections following partial vs. total tonsillectomy** More throat infections or sore throats following partial vs. total tonsillectomy in 3 of 4 RCTs but no significant group differences

N = number; OSDB = obstructive sleep-disordered breathing; RCT = randomized controlled trial; SOE = strength of the evidence

KQ4. Effectiveness of Surgical Techniques for Tonsillectomy

Key Findings

Few studies addressing this question reported effectiveness data. Nineteen studies reported resumption of normal activity and/or diet. Commonly used "hot" techniques were generally associated with faster return to normal diet or activity than was cold dissection (roughly 1 to 4 days). Few studies, typically addressing different measures and using different comparison techniques, addressed newer techniques such as thermal welding, laser, or harmonic scalpel, thus limiting our ability to draw conclusions about these approaches.

Strength of the Evidence

We found a faster return to diet with coblation or electrocautery tonsillectomy compared with cold dissection and have low confidence in these conclusions (low strength of evidence) (Table 51). We could not make conclusions about effects associated with other techniques including laser, thermal welding, and harmonic scalpel (insufficient strength of evidence) on these outcomes given that studies were typically small and evaluated different measures (e.g., dietary intake score, number of children consuming normal diet, parental return to work).

Table 51. Strength of evidence for return to normal diet or activity in studies of surgical techniques for tonsillectomy

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Coblation vs. Cold dissection tonsillectomy						
Return to normal activity RCT: 3 low[89, 144, 169, 170] 1 moderate[197] (N=276)	Low	Consistent	Direct	Imprecise	Undetected	**Low SOE for faster return with coblation** Coblation, compared with cold dissection, associated with moderately faster return to normal activity in 4 small studies
Electrocautery vs. cold dissection tonsillectomy						
Return to normal diet RCT: 1 low[134] 2 moderate[79, 127] (N=254)	Medium	Inconsistent	Direct	Imprecise	Undetected	**Low SOE for faster return with electrocautery** Electrocautery associated with faster return to normal diet in 2 studies and not significantly faster in a third

N = number; RCT = randomized controlled trial; SOE = strength of the evidence

Harms of Surgical Techniques

Key Findings

We included harms data reported in comparative studies and case series and database and registry studies to address this KQ; however, we considered only data from meta-analyses and comparative studies in our assessment of the strength of the evidence. Overall, estimates of PTH and utilization harms associated with tonsillectomy are less than 5 percent. In meta-analyses, the frequency of primary and secondary PTH associated with total and partial tonsillectomy was below 4 percent for any technique and with overlapping confidence bounds. Pooled frequencies (without adjustment) of PTH were also less than 5 percent overall (4.2% for total tonsillectomy; 1.5% for partial tonsillectomy) in comparative studies. Unadjusted frequencies of revisits for pain, dehydration, or postoperative nausea and vomiting (PONV) were less than 2 percent. Other harms were disparate and generally not clinically significant (e.g., thermal burn from a cautery apparatus). No comparative studies reported deaths. Frequency of PTH in case series and database or registry studies generally aligned with that in comparative studies. At least four deaths were reported across case series or database studies (low or moderate risk of bias) including 1,778,342 children.

Strength of the Evidence

We found a low frequency of PTH and PTH-related utilization across surgical techniques and have confidence in these findings (high strength of evidence). We found a low frequency of revisits or readmission for dehydration associated with partial tonsillectomy. Our confidence in this conclusion is low given the few studies reporting these outcomes (low strength of evidence). We have greater confidence in a low frequency of nonbleeding readmissions/revisits associated with total tonsillectomy (moderate strength of evidence). We could not draw conclusions about effects on admissions or revisits for pain or PONV associated with partial tonsillectomy given the few comparative studies addressing the outcome (insufficient strength of evidence). Table 52 outlines strength of evidence.

Table 52. Strength of evidence for harms associated with surgical techniques for tonsillectomy

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Partial tonsillectomy						
PTH and PTH-associated utilization Meta-analysis RCT: 5 low,[53, 90, 98, 151, 167, 168] 11 moderate[58, 71, 84-86, 95, 110, 139, 158, 182-186] (N=1234)	**Medium**	**Consistent**	**Direct**	**Precise**	**Undetected**	**High SOE for low frequency of PTH associated with partial tonsillectomy** Frequency did not exceed 4% for total PTH; fewer data available to assess associated utilization, but frequency is likely low given the low frequency of PTH
Readmissions /revisits for dehydration RCT: 1 low,[98] 2 moderate[85, 139] (N=221)	**Medium**	**Consistent**	**Direct**	**Imprecise**	**Undetected**	**Low SOE for low frequency of dehydration revisits/readmissions associated with partial tonsillectomy** 5 readmissions reported across 3 study arms
Total tonsillectomy						
PTH and PTH-associated utilization Meta-analysis RCT: 18 low,[43, 53, 56, 69, 75, 89, 90, 93, 98, 120, 123, 125, 131, 134, 144, 151, 163, 169, 170] 34 moderate[9, 44, 48, 63, 64, 66, 71, 74, 79, 80, 82, 84, 86, 87, 91, 95, 96, 103, 110, 111, 116, 124, 127, 130, 139, 141, 145, 152, 158, 160, 164, 178, 185, 186] (N=6293) Non-RCT: 4 moderate[195-197, 200] (N=478) Cohort studies: 2 moderate[213, 292] (N=350)	**Medium**	**Consistent**	**Direct**	**Precise**	**Undetected**	**High SOE for low frequency of PTH associated with total tonsillectomy** Frequency of <5% of PTH and PTH-associated utilization in both meta-analysis and unadjusted analyses associated with commonly used techniques

Table 52. Strength of evidence for harms associated with surgical techniques for tonsillectomy, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Total tonsillectomy						
Readmissions for pain, PONV, dehydration RCT: 9 low,[43, 66, 69, 93, 103, 114, 123, 125, 134] 8 moderate[74, 110, 111, 116, 124, 130, 154, 164] (N=2269) Prospective cohort: 1 moderate[207] (N=29) Retrospective cohort: 1 moderate[213] (N=145)	**Medium**	**Consistent**	**Direct**	**Precise**	**Undetected**	**Moderate SOE for low frequency of non-PTH readmissions/revisits associated with total tonsillectomy** In 37 study arms, overall frequency of nonbleeding revisits/readmissions was below 2%; SOE is moderate given smaller sample size

N = number; PTH = post-tonsillectomy hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence

KQ5. Effectiveness of Adjunctive Perioperative Medications To Improve Outcomes After Tonsillectomy

Key Findings

A variety of medications have been the focus of research including different steroids (dexamethasone, prednisolone); nonsteroidal anti-inflammatory drugs (NSAIDs) including diclofenac, ibuprofen, ketoprofen, lornoxicam, and ketorolac; and antiemetics (ramosetron, granisetron, dolasetron, ondansetron Studies were heterogeneous, addressing multiple agents, combinations of agents, routes of administration and dosage, timing of agents, and rescue medications provided. This heterogeneity limits our ability to draw conclusions about perioperative medications.

NSAIDs. Studies comparing NSAIDs with placebo reported reduced need for analgesia (significant group differences in 4 of 5 studies).[47, 121, 142, 156] Results in trials comparing NSAIDs vs. other agents were not consistent in terms of effects on need for additional analgesia. A single study found no effect of NSAIDS on reducing anti-emetic use.[161] NSAIDs were not associated with a faster return to normal diet or activity.[72, 126] Few studies reported PTH.

Steroids. Most placebo-controlled steroid trials (5/8) found that perioperative intravenous dexamethasone administration reduced the need for analgesics immediately after surgery (postanesthesia care unit [PACU] and up to 24 hours postoperatively), but no longer-term results were reported.[50, 119, 146-148] Two studies reported that peritonsillar infiltration of dexamethasone also reduced immediate postoperative analgesic requirements (PACU, surgical day ward) compared with placebo.[39, 51] Five RCTs found perioperative steroid administration decreased postoperative anti-emetic use in the immediate postoperative period (PACU and up to 24 hours postoperatively).[57, 62, 78, 119, 146] While most studies reported reductions in analgesic or anti-emetic use associated with perioperative steroids, roughly half of studies addressing each outcome reported no group differences. Steroids had little effect on return to normal diet in two RCTs.[112, 135]

Antiemetics. Data were consistent in terms of antiemetic medications. All five trials of 5-hydroxytryptamine (5-HT) receptor antagonists found their administration to have no effect on postoperative analgesic requirements.[88, 118, 122, 132, 133] Three trials consistently reported reduced postoperative antiemetic requirements in patients treated with intraoperative 5-HT receptor antagonists.[118, 122, 136]

Strength of the Evidence

We considered the strength of the evidence for studies with placebo comparison in most cases given the heterogeneity of agents and comparators ( ). We considered the drug class (instead of individual agent such as diclofenac) in assessing strength of evidence for NSAIDs and antiemetics. All steroid studies addressed dexamethasone.

NSAIDs. We found a reduced need for analgesia with NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence). We found no difference in effects on return to normal diet or activity with perioperative NSAIDs compared with placebo. Our confidence in this conclusion is low (low strength of evidence). We found a low frequency of PTH (< 6%) and associated utilization with perioperative NSAIDs. Our confidence in this conclusion is low (low strength of evidence). We could not make conclusions about non-PTH related readmissions or revisits following NSAID use as few studies addressed these outcomes (insufficient strength of evidence).

Steroids. We found a reduced need for analgesics or antiemetics associated with steroids (IV or infiltrated dexamethasone) compared with placebo. Our confidence in this conclusion is low (low strength of evidence). Studies of steroids reported few cases of PTH and PTH-related utilization. We have moderate confidence that steroids are associated with a low frequency of PTH (moderate strength of evidence).

Meta-analysis of nine studies comparing steroids and placebo did not indicate a significantly increased risk of PTH with steroids vs. placebo; confidence bounds were wide for all estimates, and we have low confidence in this conclusion (low strength of evidence). We could not make conclusions about the effects of steroids on return to normal diet or activity, as the two small studies addressing the outcome reported inconsistent results, or on non-PTH-related readmissions or revisits as few studies reported these outcomes (insufficient strength of evidence).

Antiemetics. We found a reduced need for postoperative antiemetics in studies of perioperative antiemetics; our confidence in this conclusion is low (low strength of evidence). We found no effect of 5-HT perioperative antiemetics on postoperative analgesia requirements. We have moderate confidence in this conclusion (moderate strength of evidence).
need for postoperative antiemetics given the small number of children evaluated in these studies.

Table 53. Strength of the evidence for studies addressing perioperative medications

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
NSAID vs. Placebo						
Need for rescue analgesic RCT: 3 low,[94, 128, 156] 2 moderate[121, 142] (N=345)	Medium	Inconsistent	Direct	Imprecise	Undetected	**Low SOE for reduced need for rescue analgesia with NSAIDs vs. placebo** Significantly less need in 4 small studies, no group differences in a 5th study
Return to Normal diet and activity RCT: 2 moderate[72, 126] (N=180)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no difference in return to normal diet or activity with NSAIDs vs. placebo** No significant group differences in 2 small studies with medium study limitations
PTH and PTH-related revists/ readmissions RCT: 1 low,[40] 5 moderate[47, 106, 117, 150, 161] (N=277)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for low frequency of PTH or PTH-related revisits/readmissions associated with perioperative dexamethasone** Frequency of PTH or associated utilization <3% (unadjusted analyses) in 277 children receiving NSAIDs

Table 53. Strength of the evidence for studies addressing perioperative medications, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Dexamethasone vs. Placebo						
Need for rescue analgesic RCT: 4 low, [50, 105, 119, 146] 6 moderate[45, 78, 109, 126, 147, 148] (N=979)	Medium	Inconsistent	Direct	Precise	Undetected	**Low SOE for reduction in analgesic need with dexamethasone vs. placebo** Significantly less need for analgesics after dexamethasone (IV or infiltration) vs. placebo in 7 small studies; no significant differences in 3 studies; inconsistency precludes higher SOE
Need for rescue anti-emetic RCT: 4 low,[57, 105, 119, 146] 4 moderate[62, 78, 109, 126] (N=812)	Medium	In-consistent	Direct	Precise	Undetected	**Low SOE for reduction in anti-emetic need with dexamethasone vs. placebo** Significantly less need for antiemetics after dexamethasone vs. placebo in 5 small studies; no significant differences in 3 studies; inconsistency precludes higher SOE
PTH Meta analysis	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no increased risk of PTH with dexamethasone compared with placebo** Odds ratios ≥1 with wide credible intervals. SOE is low given imprecision of estimates

Table 53. Strength of the evidence for studies addressing perioperative medications, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Dexamethasone						
PTH and PTH-related revists/ readmissions RCT: 6 low,[54, 57, 59, 105, 112, 119] 3 moderate[45, 78, 148] (N=811)	Medium	Consistent	Direct	Precise	Undetected	**Moderate SOE for low frequency of PTH or PTH-related revisits/readmissions associated with perioperative dexamethasone** Frequency of PTH or associated utilization <6% (unadjusted analyses) in 811 children receiving steroids
5-HT Anti-emetics vs. Placebo or Other Comparators						
Need for rescue analgesic RCT: 4 low[88, 118, 132, 133] 1 moderate[122] (N=964)	Low	Consistent	Direct	Precise	Undetected	**Moderate SOE for no effect of antiemetics (5-hydroxytryptamine [5-HT] receptor antagonists)** No significant group differences in 5 RCTs comparing 5-HT antagonists with other antiemetics, other 5-HTantagonists, or placebo
Need for postoperative rescue anti-emetic RCT: 2 low[118, 136] 1 moderate[122] (N=303)	Low	Consistent	Direct	Imprecise	Undetected	**Low SOE for reduced need for postoperative antiemetics with perioperative 5-HT antiemetics vs. placebo** Significantly less need for postoperative antiemetics in 3 small RCTs comparing 5-HT antagonists and placebo; imprecision precludes higher SOE

5-HT = 5-hydroxytryptamine; N = number; PTH = post-tonsillectomy hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence

KQ6. Effectiveness of Postoperative Medications for Pain After Tonsillectomy

Key Findings

Drugs assessed in studies addressing this question included steroids (prednisolone), NSAIDs (diclofenac, ibuprofen, celecoxib, aspirin), non-NSAID analgesics (acetaminophen) and

antibiotics (amoxicillin). Few studies addressed the same interventions and comparisons, and studies typically reported on need for rescue pain medication, PTH, and return to normal diet or activity as outcomes. Data on the effect of NSAIDS on rescue pain medication in the first 24 to 48 hours after surgery are conflicting, and no long-term data are available. Two studies compared prednisolone and placebo and found no effect on return to normal diet or activity.[41, 60]

PTH frequency overall was less than 10 percent. The frequency of PTH in steroid and placebo arms in the two studies addressing that comparison were similar.[41, 60] In studies comparing NSAIDs (celecoxib, ibuprofen) and non-NSAID analgesics to placebo or other medications, occurrences of PTH were also similar.[38, 49, 137, 138, 155, 159, 194]

Strength of the Evidence

In studies of postoperative NSAIDs, we found a low frequency of PTH. Our confidence in this estimate is low (low strength of evidence). We could not make conclusions about the effects of postoperative analgesics on need for rescue medications; return to normal diet or activity; or PTH (insufficient strength of evidence).

In studies of postoperative steroids, we found no difference in effects on return to normal diet or activity between steroids and placebo. Our confidence in this conclusion is low (low strength of evidence). We also found no difference in effects on bleeding between postoperative steroids and placebo or no treatment. Our confidence in this conclusion is low (low strength of evidence). Table 54 outlines these findings.

Table 54. Strength of evidence for effectiveness of postoperative medications for pain-related outcomes

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
Prednisolone vs. Placebo						
Return to Normal Diet or activity in longer term (≥5 days) RCT: 1 low,[41] 1 moderate[60] (N=331)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no difference in effects of prednisolone vs. placebo on return to normal diet or activity** Number of children consuming normal diet or engaging in normal activity did not differ at 14 days post-tonsillectomy in one study; time to return to normal diet or activity did not differ in second small RCT
PTH RCT: 1 low,[41] 1 moderate[60] (N=331)	Medium	Consistent	Direct	Imprecise	Undetected	**Low SOE for no difference in PTH associated with steroids vs. placebo/no treatment** Numbers of PTH in steroid and placebo arms were similar in 2 studies (13 PTH in steroid arms vs. 15 in placebo/no treatment)

Table 54. Strength of evidence for effectiveness of postoperative medications for pain-related outcomes, continued

Intervention/ Outcome Study Design Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade Findings
NSAIDs						
PTH RCT: 2 moderate[38, 138] (N=564) Non-RCT: 1 moderate[194] (N=115)	Medium	Consistent	Direct	Precise	Undetected	**Low SOE for a low frequency of PTH** Unadjusted frequency ranged from 0-6% across agents; higher frequency associated with celecoxib; SOE is low given small sample size

RCT = randomized controlled trial; SOE = strength of the evidence

Findings in Relation to What Is Already Known

We identified 23 recent (2011-present) systematic reviews or meta-analyses assessing tonsillectomy.[23-27, 29-32, 293-306] Most reviews or meta-analyses (n=9) addressed perioperative medications and PTH risk or other morbidity: three addressed NSAIDs[30-32] five addressed dexamethasone;[24-27, 29] and one addressed antibiotics.[23] Two reviews addressed tonsillectomy for recurrent tonsillitis;[302, 303] seven addressed tonsillectomy for OSDB (including one comparing partial and total tonsillectomy in children with OSDB and two comparing outcomes among children with or without OSA or with obesity)[296-301, 306] and five addressed partial vs. total tonsillectomy or specific surgical techniques.[293-295, 304, 305]

Across reviews, investigators commented on methodologic limitations such as lack of blinding and limited allocation concealment; heterogeneity of techniques and indications for tonsillectomy; use of subjective outcome measures; short-term followup; small sample sizes; and generally low to moderate quality studies. Appendix I includes an overview of findings of all reviews. Findings in prior reviews and meta-analyses generally aligned with our findings in the current report. Reviews of tonsillectomy specifically in children with OSDB or tonsillitis reported modest benefits in obstructive symptoms or sore throat reduction, typically in the short-term, for tonsillectomy compared with no surgery. Reviews comparing partial and total tonsillectomy reported few differences between techniques: partial tonsillectomy was generally associated with faster return to normal diet and activity and less PTH, but changes in resolution of OSDB symptoms or recurrent throat infections were not significantly different between approaches. Reviews comparing surgical techniques (e.g., coblation, electrocautery) similarly reported few significant differences among techniques. Reviews of perioperative steroids consistently reported no significant association with PTH in children, though one review reported greater need for reintervention when PTH occurred. Reviews of perioperative NSAIDs and PTH risk were less consistent, with two reporting no increased risk in children and one

noting insufficient data to rule out risk. One review of antibiotics reported no evidence for a consistent effect of antibiotics on pain, PTH, or need for pain medications. Finally, in one review assessing weight gain in a general population of normal and overweight children undergoing tonsillectomy, participants gained more weight than expected postoperatively.

Applicability

Studies included in this review typically did not describe severity of indications of tonsillectomy and comorbidities for populations adequately, which makes applicability difficult to assess. As would be expected, studies addressing KQ1 (tonsillectomy in children with OSDB) and KQ2 (tonsillectomy in children with recurrent throat infection) specified surgical indication and generally provided greater characterization of study participants. Baseline severity of OSDB or throat infection varied across these studies as did definitions of "cure" or resolution of symptoms. Of note, the largest U.S.-based RCT addressing tonsillectomy vs. no surgery for children with OSDB included a majority African-American and majority overweight or obese population[171-178, 191] as did two additional studies addressing this comparison.[114, 211] Two other studies addressing this comparison included a majority of children with Down syndrome or mucopolysaccharidoses[44] or children under 2 years of age.[212] RCTs addressing tonsillectomy vs. no surgery for recurrent throat infection explicitly included children with mild to moderate baseline symptoms, and definitions of "throat infection" varied across studies.[164-166, 307] Two larger studies addressing this comparison (2 studies reported in one paper) included majority white populations.[9]

Studies addressing surgical approaches and peri- or post-operative medications typically did not specify surgical indications or included both children with OSDB or recurrent throat infections without stratifying analyses. Roughly one-third of studies were conducted in less developed countries in which surgical techniques and procedures may differ from those used in the United States. Regardless of the country in which studies were performed, anesthetic approaches, analgesic agents and dosing, surgical expertise, and surgical and hemostatic techniques (including definitions of "partial tonsillectomy") varied widely across studies. Studies reporting weight or BMI typically did not address whether children were under- or over- weight for age at baseline, and few studies reported baseline comorbidities such as asthma or Down syndrome; thus assessing applicability to these sub-populations is challenging. Most studies used subjective outcome measures or relied on caregiver- or child-completed diaries to assess longer-term outcomes. Objective measures such as the AHI or other PSG parameters may not accurately reflect effects on the totality of symptoms associated with OSDB (e.g., behavioral issues, sleepiness, overall quality of life).[173, 175, 308, 309] We also included only studies addressing tonsillectomy for the two most common indications for the surgery: OSDB and recurrent throat infection; thus, individuals seeking information about tonsillectomy for Periodic Fever, Aphthous Stomatitis, Pharyngitis, Cervical Adenitis (PFAPA) or other indications will not find applicable studies in the current review.

Despite these limitations to generalizability, findings reported here are likely widely applicable given the heterogeneous population of children without comorbidities who undergo tonsillectomy for OSDB or recurrent throat infection. Applicability of findings to children with Down syndrome, craniofacial abnormalities, obesity, or under age 2 is limited. Although studies included some children with these comorbidities or in the younger age range, few provided explicit analyses of these subgroups. Appendix G includes applicability tables for each KQ.

Implications for Clinical and Policy Decisionmaking

This review provides evidence for decisionmaking in the care of children who are potential candidates for tonsillectomy. Despite the large body of literature, most evidence addresses effects in the short term. The literature reports short-term improvements in obstructive symptoms and throat infections following tonsillectomy compared with no surgery. Evidence about long-term benefits of tonsillectomy for either OSDB or throat infection is limited. Thus, individual decisionmaking needs to balance needs for relief of illness-related outcomes (including missing school and work) with the risks associated with surgery. Caregivers and providers may wish to consider the potential benefits and drawbacks of attempting to manage children's illnesses for a period of time to see if they outgrow the propensity for infection and may be able to avoid surgery. That said, shared decisionmaking rests in the hands of families and their clinicians, and decisions should be made on an individual basis. Harms are rare and generally minor, and clinicians have information from this review with which to counsel their patients and families.

In cases where families are considering surgery or CPAP for OSDB, comparative evidence is currently inconclusive to inform decisionmaking. Families with children in special subgroups, including those with Down syndrome, similarly cannot rely solely on currently available scientific evidence for their decision as few studies address these populations explicitly. Data on specific approaches to tonsillectomy (either partial versus total or by surgical technique) offer little clear guidance for clinicians. Some evidence suggests that partial removal may speed time to return to normal diet or activity relative to total removal; however, we found a roughly 6 percent rate of regrowth with partial tonsillectomy. PTH typically occurred in less than 5 percent of children across all surgical techniques, and no clear evidence exists for a superior approach. Familiarity with a technique and surgical skill may both have a role in driving outcomes, as has been demonstrated in other fields.[310-312]

Decisional dilemmas still exist regarding the perioperative use of medications and whether they speed postoperative return to normal diet and activity and reduce the need for post-tonsillectomy analgesia and rescue anti-emetic use. Clinical care would be improved by optimizing perioperative use of medication to improve outcomes. The literature base on this subject was insufficient to inform guidance on whether any perioperative medications affect time to normal diet or activity. Low strength of evidence suggested that a single dose of IV dexamethasone intraoperatively reduces analgesic requirement in the PACU and up to 24 hours postoperatively. Evidence is mixed as to whether dexamethasone reduces the need for postoperative rescue antiemetics. In contrast, clinicians can have some confidence that pre-emptive 5-HT receptor antagonists given intra-operatively do reduce the need for rescue antiemetics post-tonsillectomy.

Limitations of the Comparative Effectiveness Review Process

We included studies published in English only. We scanned a random sample of 100 non-English abstracts retrieved by our MEDLINE search (25 selected from each decade 1980 to 2015). Most studies appeared to be case series, narrative reviews, imaging or basic science studies, or studies dealing with malignant lesions. Only two studies appeared to meet inclusion criteria; thus, given the high percentage of ineligible items in this scan (98%), we concluded that excluding non-English studies would not introduce significant bias into the review.

We also included only studies of perioperative NSAID, steroids, and antiemetics to address KQ5. Although this focus means that some medications are not included in this review, the drug classes addressed in the review comprise key agents frequently used in the perioperative period. We also did not include studies addressing adenoidectomy alone or studies comparing tonsillectomy with adenoidectomy as the choice of procedure is likely driven by the indication for surgery; thus, comparing these approaches would not be appropriate.

Given heterogeneity in anesthetic regimens, surgical techniques, postoperative analgesia and medications, and patient populations themselves, we were limited in our ability to stratify findings or identify potential subgroups that may respond more favorably to tonsillectomy or to supportive care.

Limitations of the Evidence Base

A relatively large number of studies have been published on tonsillectomy, including for OSDB and throat infections, but risk of bias is mixed, with fewer studies (31%) having low risk of bias than moderate or high risk. Furthermore, most available studies provided little to no clinical outcome data, focusing instead on intermediate outcomes and harms. In addition, few studies addressed questions about the need for tonsillectomy compared with a nonsurgical treatment. Patient populations were generally poorly characterized, and little information was available on first-line treatment attempts before surgery. Very few studies focused on high risk or special populations at particular risk.

Particularly in studies intended to assess effects of tonsillectomy on throat infections, parents of severely affected children were noted to refuse randomization and cross over to surgery at high rates. Long-term effects are limited in the literature base, particularly regarding outcomes that include growth and development, sleep quality outcomes, and behavioral outcomes for children with OSDB. Exploration of demographics of patient populations more likely to be refractory to initial management strategies is also limited. It appears clear that throat infections decline in children over time regardless of treatment group, but with high loss to followup, the relative contribution of this decline on apparent effectiveness is unknown.

A particular problem in the literature is a lack of full characterization of the patient population, particularly about clinically documented severity of both sleep-disordered breathing and throat infections. Understanding of "obstructive sleep disordered breathing" varied from study to study as did degree of hypertrophy and number and severity of throat infections or sore throats. In the context of general lay expectations of the benefit of tonsillectomy, and common opinions that tonsillectomy is a "minor" surgery, patients undergoing tonsillectomy may vary widely in the severity of their clinical states. Among those studies focused on throat infection that did characterize patients, most had low numbers of reported infections, and few reported culture-confirmed bacterial infections.

Of particular importance for this surgical topic is a complete assessment of potential harms, particularly frequency of PTH, including PTH that leads to further intervention. However, the severity or degree, number of repeat episodes, and timing of PTH were rarely defined or measured; thus outcomes can be broadly defined only in terms of primary versus secondary PTH, readmissions, and reoperations, where reported. Our estimates include PTH as reported in eligible studies, which could have ranged from parent-reported bleeding that did not require a clinician visit to PTH requiring surgical hemostasis. Few studies of postoperative medications for pain met our inclusion criteria as we did not identify many comparative studies with low or

moderate risk of bias; thus, evidence in the current review is inadequate to draw firm conclusions about PTH associated with postoperative NSAIDs.

In attempting to assess partial versus total tonsillectomy we note that partial tonsillectomy was rarely precisely specified. These studies also most often used different techniques for the partial and total tonsillectomy, thus introducing confounding that cannot be disentangled.

Research Gaps and Areas for Future Research

Tonsillectomy is heavily researched, with far more data available to assess safety than efficacy. Despite substantial research, the literature is largely silent on the natural history of OSDB or throat infections that would provide a basis for the need for tonsillectomy in the long term. Many young patients may outgrow the need for intervention, but more data are needed to describe the potential to outgrow these indications to parents and to describe population factors that may predict resolution.[175, 313, 314] Indeed, in many studies, outcomes for children in nonsurgical groups also improved, though improvements were generally greater in children receiving tonsillectomy. Long-term data are needed in order to enable caregivers to weigh the benefits of surgery versus the reality of managing their child's condition as they wait for it to resolve; obtaining longer-term data, however, is difficult, as evidenced by the high rate of attrition in most studies with more than 6 months followup included in this review.

Future studies should take more care to characterize patient populations completely—including severity of OSDB or throat infections—such that applicability can be much more specifically described and potential candidates for surgery or watchful waiting identified. Indeed the literature lacks a consistent, consensus definition of infection; defining infection consistently is critical for promoting synthesis of research in the area. Tonsillitis or "sore throat" may also include cases of entities such as PFAPA; clear characterization of children in studies is key for understanding effects on subpopulations.

Similarly, studies also typically did not clearly characterize severity of PTH, and many did not clearly specify timing or number of repeat episodes. Severity of bleeding or repeat episodes may be more predictive of serious morbidity than simple frequency; [251, 315-317] however, our ability to assess this association was limited. Improved characterization could allow analyses to inform our understanding of factors that may contribute to revisits or readmissions and outcomes such as mortality.

As new technologies for tonsillectomy emerge, as they continuously have over the past few decades, high quality research will continue to be needed to evaluate these technologies, in terms of both efficacy and safety. As we learn more about the deleterious effects of sleep apnea and detection rates increase, more refined and specific treatment algorithms will be in demand. Related to this issue, more data are needed on the use of CPAP in children as an initial modality; such data should address compliance and duration of use.

Future research should also address the current gaps in data surrounding treatment of special populations including very young children and children with comorbidities such as obesity and neuromuscular disease. Further, concerns about perioperative and postoperative management persist, including over-narcotization and potential respiratory suppression. Better data regarding optimal medication regimens are essential, both in terms of symptomatic relief and minimizing iatrogenic harm.

Measures commonly used to assess objective improvements in obstructed breathing, such as the AHI, are not patient-centered and may not reflect subjective reports of improvements or worsening of outcomes experienced by patients. Future research exploring the alignment of the

AHI with patient-reported outcomes such as quality of life would help to gauge effects of tonsillectomy more precisely. Additionally, standardized measures of sleep outcomes are lacking.

Finally, relatively little data exist regarding predictable factors contributing to recurrence of symptoms of OSDB and throat infections following tonsillectomy for primary management. A better understanding of these factors would allow for more specific patient selection.

Conclusions

Tonsillectomy can produce short-term improvement in sleep outcomes and reduction in throat infections compared with no surgery in children with OSDB or recurrent throat infections. Relative to no surgery, most studies reported better sleep-related outcomes in children with OSDB who had a tonsillectomy, but longer term data on durability of outcomes are limited. Children undergoing tonsillectomy to improve number of throat infections, associated health care utilization (clinician visits), and work/school absences had improvements in these outcomes in the first postsurgical year compared with children not receiving surgery. These benefits did not persist over time, and data on longer-term results are lacking. This short-term improvement must be weighed against a roughly 4 percent frequency of PTH. Surgical technique had little bearing on either return to normal diet or activity or PTH frequency. Perioperative dexamethasone improved pain and pre-emptive 5-HT receptor antagonist antiemetics reduced antiemetic use in the immediate postoperative period. Dexamethasone did not increase risk of PTH compared with placebo, but estimates had wide confidence bounds. Little evidence addressed the use of postoperative medications for pain-related outcomes.

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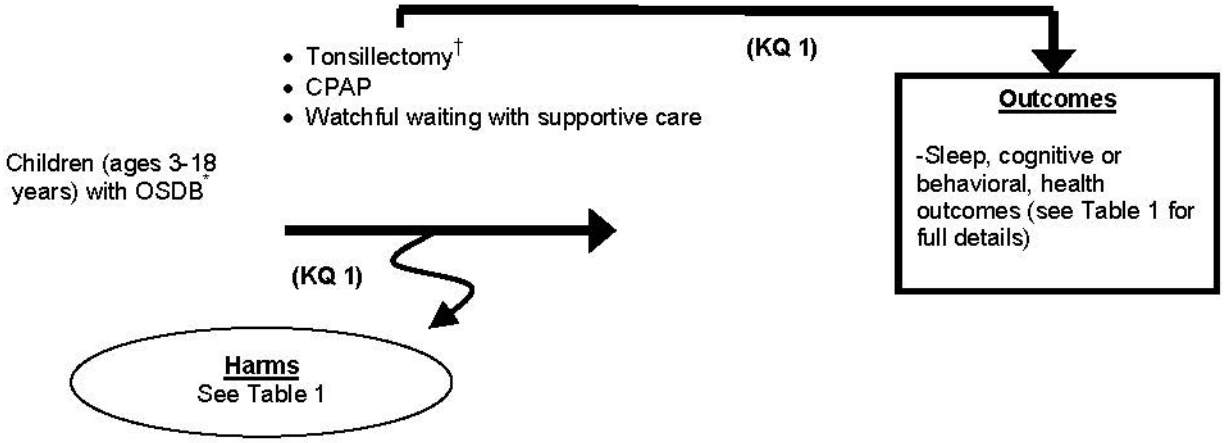
Acronyms and Abbreviations

AAO-HNSF	American Academy Of Otolaryngology - Head & Neck Surgery Foundation
AHI	Apnea Hypopnea Index
AHRQ	Agency For Healthcare Research And Quality
BCI	Bayesian Credible Intervals
BMI	Body Mass Index
BRIEF	Behavior Rating Inventory Of Executive Function
CAS-15	Clinical Assessment Score-15
CBC	Child Behavior Checklist
CGI	Connors Global Index
CHAT	Childhood Adenotonsillectomy Trial
CI	Confidence Interval
CPAP	Continuous Positive Airway Pressure
ER	Emergency Room
ESS-C	Epworth Sleepiness Scale - Child
G	Group
GAS	Group A Strep
CGBI	Glasgow Children's Benefit Inventory
GEC	Global Executive Composite
ICU	Intensive Care Unit
IQ	Intelligence Quotient
IQR	Interquartile Range
IV	Intravenous
kg	Kilograms
KQ	Key Question
M-ESS	Modified Epworth Sleepiness Scale
mg	Milligrams
N	Number
NA	Not Applicable
NEPSY	Developmental Neuropsychological Assessment
NR	Not Reported
NS	Not Significant
NSAID	Nonsteroidal Anti-Inflammatory Drug
OSDB	Obstructive-Sleep Disordered Breathing
OSA	Obstructive Sleep Apnea
OSA-18	Obstructive Sleep Apnea-18
PACU	Post-Anesthesia Care Unit
PFAPA	Periodic Fever, Aphthous Stomatitis, Pharyngitis, Cervical Adenitis
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, And Setting
PedsQL	Pediatric Quality Of Life Inventory
POD	Post-op Day
PONV	Postoperative Nausea and Vomiting
PSG	Polysomnography
PSQ	Pediatric Sleep Questionnaire
PSQ-SRBD	Pediatric Sleep Questionnaire Sleep-Related Breathing Disorder
PTH	Post-Tonsillectomy Hemorrhage
QoL	Quality of Life
RCT	Randomized Controlled Trial
ROB	Risk of Bias
RR	Risk Ratio
SD	Standard Deviation
SOE	Strength Of Evidence
TEP	Technical Expert Panel
UARS	Upper Airway Resistance Syndrome
WASI	Wechsler Abbreviated Scale Of Intelligence

Appendix A. Analytic Frameworks

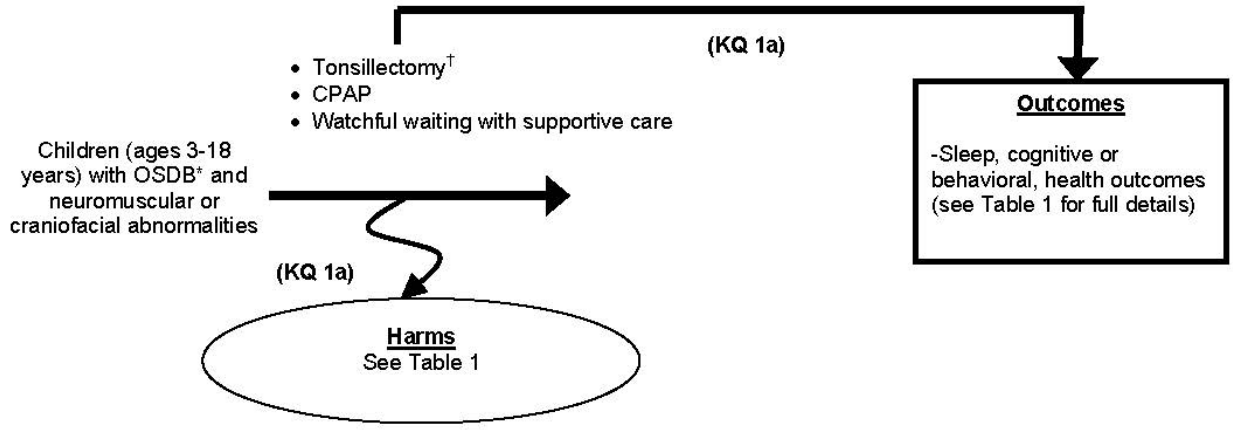
Figure A-1. Analytic framework for Key Question 1



Abbreviations: CPAP = Continuous Positive Airway Pressure; KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, or partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

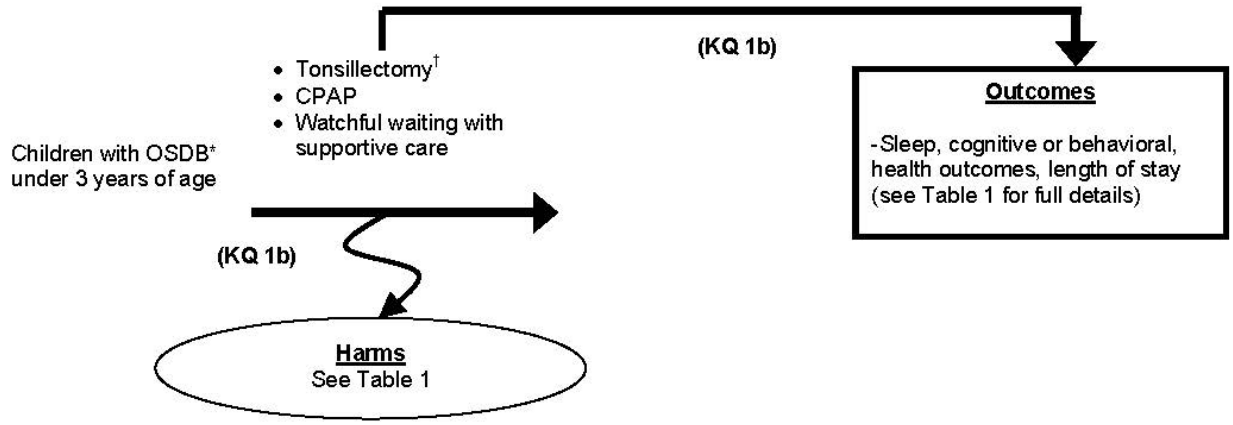
Figure A-2. Analytic framework for Key Question 1a



Abbreviations: CPAP = Continuous Positive Airway Pressure; KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

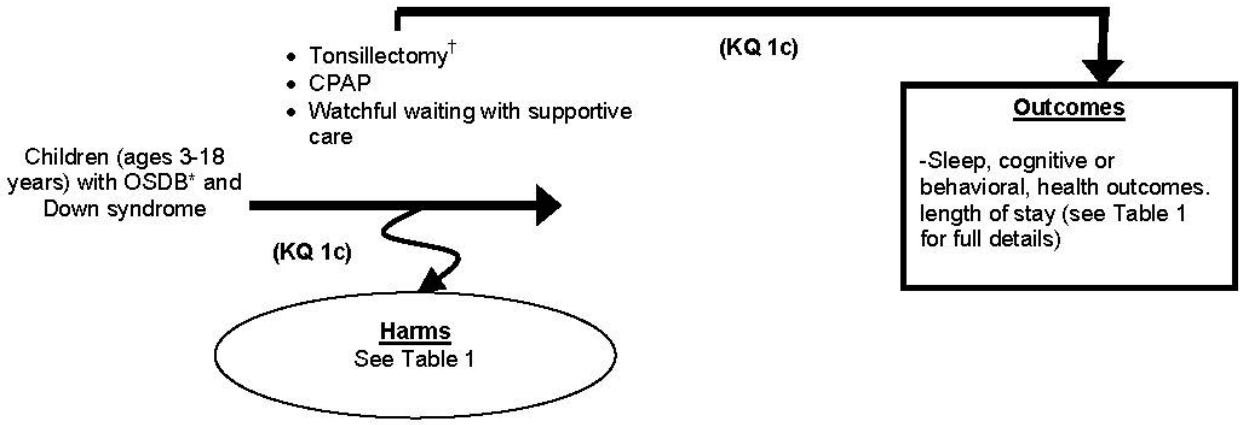
Figure A-3. Analytic framework for Key Question 1b



Abbreviations: CPAP = Continuous Positive Airway Pressure; KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

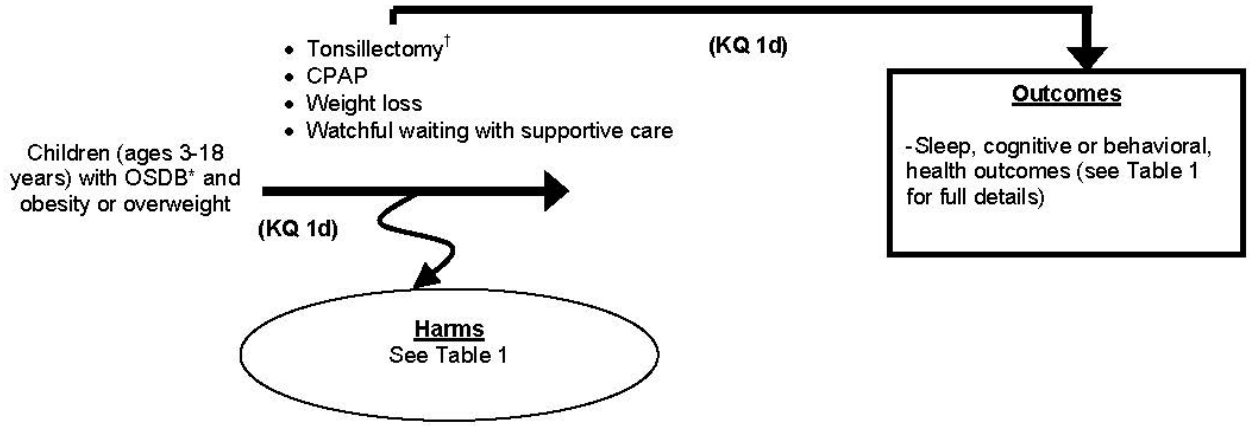
Figure A-4. Analytic framework for Key Question 1c



Abbreviations: CPAP = Continuous Positive Airway Pressure; KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

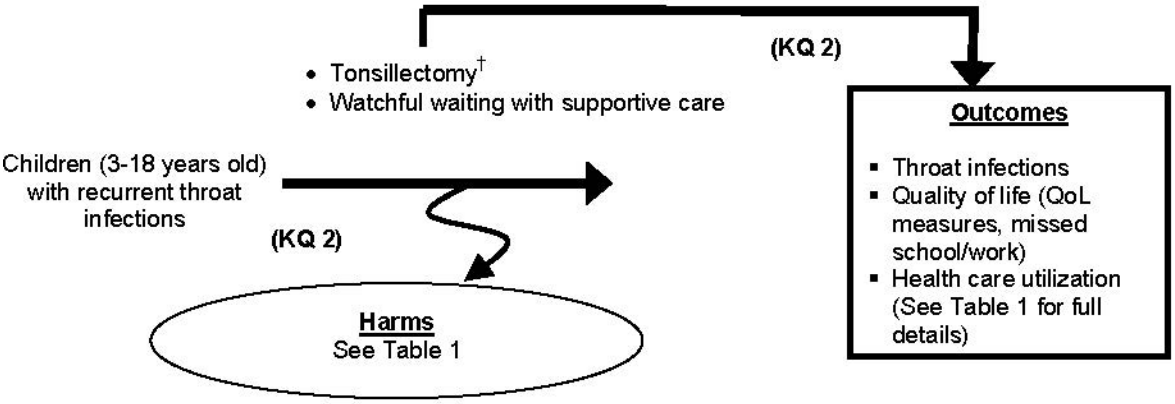
Figure A-5. Analytic framework for Key Question 1d



Abbreviations: CPAP = Continuous Positive Airway Pressure; KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

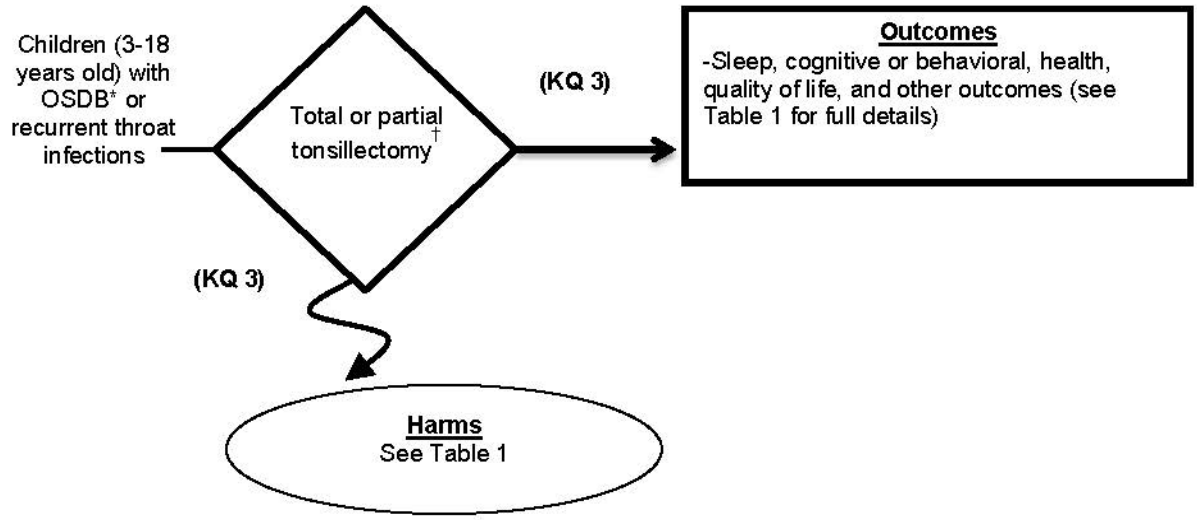
Figure A-6. Analytic framework for Key Question 2



Abbreviations: KQ = Key Question; QoL = Quality of Life

†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser)

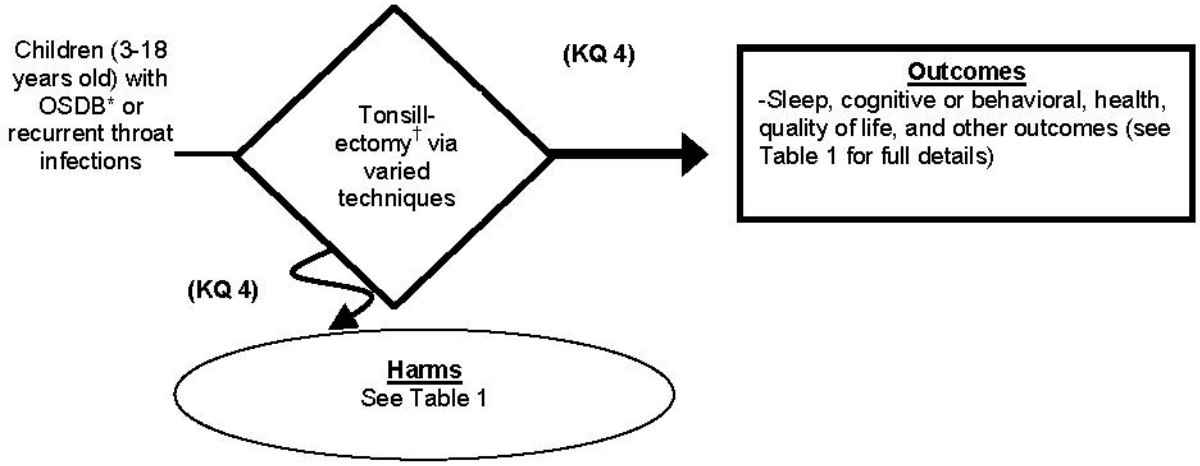
Figure A-7. Analytic framework for Key Question 3



Abbreviations: KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy or adenotonsillectomy.

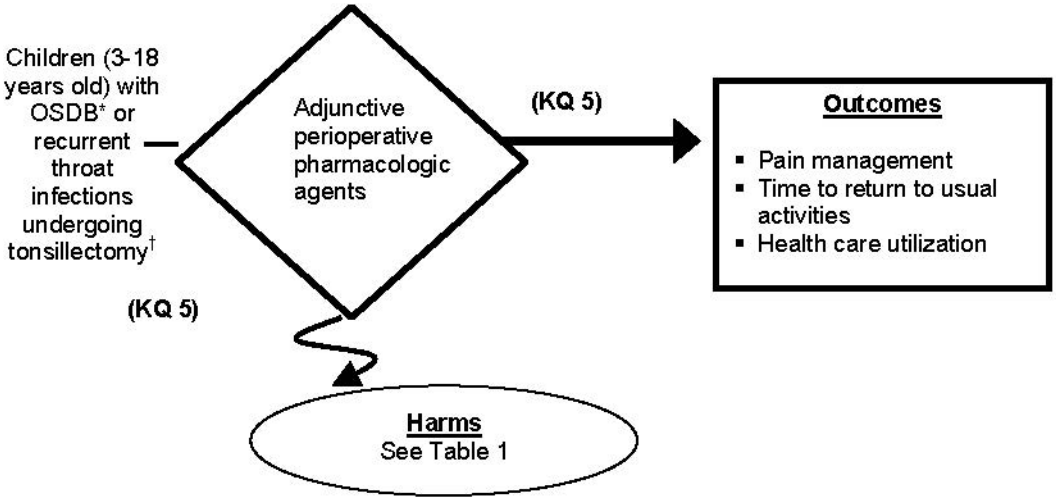
Figure A-8. Analytic framework for Key Question 4



Abbreviations: KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy or adenotonsillectomy.

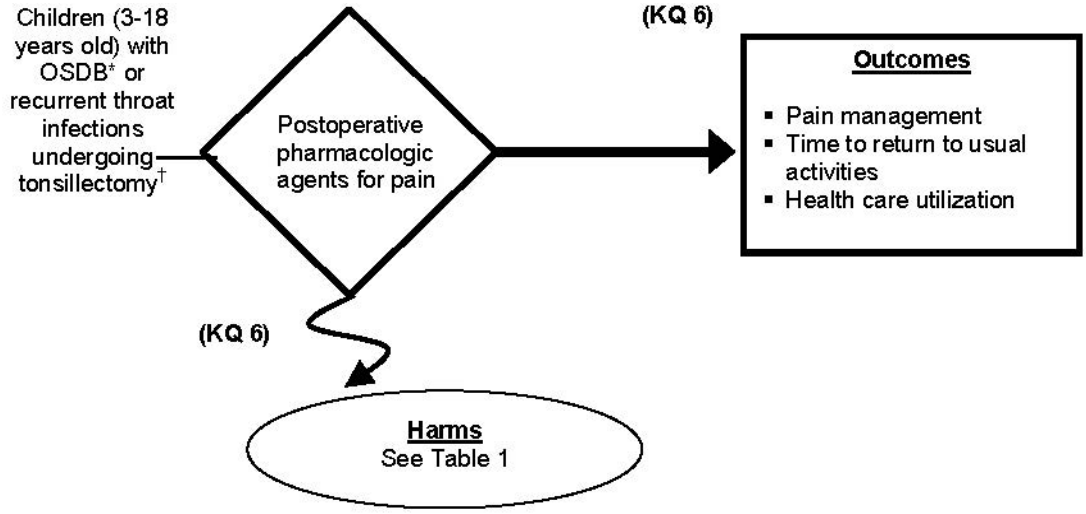
Figure A-9. Analytic framework for Key Question 5



Abbreviations: KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser).

Figure A-10. Analytic framework for Key Question 6



Abbreviations: KQ = Key Question; OSDB = Obstructive Sleep-Disordered Breathing

*Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome
†*Includes tonsillectomy, adenotonsillectomy, partial tonsillectomy performed using any method or approach (e.g., coblation, cold dissection, laser).

Table A-1. Population, intervention, comparator, outcome characteristics[*]

KQ	Population	Intervention[†]	Comparators	Outcomes
1	Children (3-18 years of age) with OSDB[**]	Tonsillectomy	-Continuous positive airway pressure (CPAP) -Pharmacologic treatment including anti-inflammatory medications, decongestants, allergy medication, antihistamines, nasal steroids, leukotriene inhibitors	Sleep outcomes -Apnea Hypopnea Index (AHI) -Sleep quality measures (Obstructive Sleep Apnea-18 [OSA-18], Clinical Assessment Score-15 [CAS-15]) -Pediatric Sleep Questionnaire (PSQ) -Modified Epworth Sleepiness Scale -Desaturation nadir -OSDB persistence Cognitive or behavioral outcomes -Validated measures of attention, irritability, and memory Health outcomes -Growth velocity (height, BMI for age) -Cardiopulmonary issues -Self or caregiver-reported enuresis -Health care utilization (number of clinician visits) Harms -Re-admission or ER visit or ICU admission for postoperative pain, dehydration, bleeding, or nausea and vomiting -Reoperation for primary or secondary bleeding -Velopharyngeal insufficiency -30-day mortality -Harms of comparator agents reported in studies with comparison groups
1a	Children (3-18 years of age) with OSDB and neuromuscular or craniofacial abnormalities	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1)
1b	Children under age 3 with OSDB	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1) Length of stay
1c	Children (3-18 years of age) with OSDB and Down syndrome	Tonsillectomy	See comparators above (KQ1)	See outcomes above (KQ1) Length of stay
1d	Children (3-18 years of age) with OSDB who are overweight or obese	Tonsillectomy	-CPAP -Weight loss -Pharmacologic treatment including anti-inflammatory medications, decongestants, allergy medication,	See outcomes above (KQ1)

KQ	Population	Intervention[T]	Comparators	Outcomes
			antihistamines, nasal steroids, leukotriene inhibitors	
2	Children (3-18 years) with recurrent throat infections	Tonsillectomy	-Antibiotics -Nonantibiotic pharmacologic treatments (e.g., anti-inflammatory agents, decongestants, antihistamines, leukotriene inhibitors, nasal or systemic steroids)	Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Quality of life -Validated quality of life measures -Missed school or work for child or caregiver Other outcomes -Health care utilization (number of clinician visits, number of courses of antibiotics) Harms - ER visit or hospital or ICU admission for postoperative pain, bleeding, dehydration, or nausea and vomiting -Reoperation for primary or secondary bleeding -Velopharyngeal insufficiency -30-day mortality -Harms of comparator agents reported in studies with comparison groups
3	Children (3-18 years) undergoing tonsillectomy	Total tonsillectomy	-Partial tonsillectomy	See sleep, cognitive or behavioral, and health outcomes (KQ1) and quality of life outcomes (KQ2) Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Other outcomes -Symptomatic tonsillar regrowth -Time to return to usual activity (diet, school) Harms See KQ1 Reoperation for complete tonsillectomy
4	Children (3-18 years) undergoing tonsillectomy	Tonsillectomy	-Other technique for tonsillectomy	See sleep, cognitive or behavioral, and health outcomes (KQ1) and quality of life outcomes (KQ2) Throat infections -Number of throat infections/year -Severity of throat infections -Number of streptococcal infections/year Other outcomes

KQ	Population	Intervention[†]	Comparators	Outcomes
				-Time to return to usual activity (diet, school) Harms See KQ1
5	Children (3-18 years) undergoing tonsillectomy	Tonsillectomy plus adjunctive perioperative (i.e., preoperative, intraoperative, or immediate postoperative [post-anesthesia care] periods) pharmacologic agents	-Tonsillectomy without adjunctive perioperative pharmacologic agents (i.e., pharmacologic agents given to attempt to reduce postoperative morbidity including pain or nausea and vomiting)	-Pain management (need for or # of rescue medications) -Time to return to usual activities (diet, school) -Health care utilization (number of clinician visits, number of courses of antibiotics) Harms -Harms of agent -Re-admission to hospital or ICU or ER visit for postoperative pain, bleeding, dehydration, or nausea and vomiting -Reoperation for primary or secondary bleeding -30-day mortality
6	Children (3-18 years) undergoing tonsillectomy and receiving pharmacologic agents for pain postoperatively (i.e., up to 10 days after discharge from post-anesthesia care)	Tonsillectomy plus postoperative pharmacologic agents for pain (e.g., NSAID, ketorolac)	-Tonsillectomy with other postoperative pharmacologic agents for pain	See outcomes and harms for KQ5

[*]Studies of any length or follow-up and in any setting, except for KQ6, which includes pharmacologic agents for pain given up to 10 days post-surgery.

[**]Includes breathing difficulties during sleep as operationalized in each study, including obstructive sleep apnea and upper airway resistance syndrome

[†]Tonsillectomy includes tonsillectomy, adenotonsillectomy, partial tonsillectomy

Abbreviations: AHI = Apnea Hypopnea Index; BMI = Body Mass Index; CAS-15 = Clinical Assessment Score-15; CPAP = Continuous Positive Airway Pressure; ER = Emergency Room; KQ = Key Question; NSAID = Non-steroidal Anti-Inflammatory Drug; OSA-18 = Obstructive Sleep Apnea-18; OSDB = Obstructive Sleep-Disordered Breathing

Appendix B. Search Strategies

Table B-1. Preliminary PubMed search strategy (July 2015)

Search terms		Search results
1	tonsillectomy [mh] OR adenotonsillectomy OR tonsillotomy OR adenoidectomy	10158
2	therapeutics[mh] OR therapy[sh] OR "treatment outcome"[mh] OR therapy[tiab] OR therapies[tiab] OR therapeutic[tiab] OR therapeutics[tiab] OR outcome[tiab] OR outcomes[tiab] OR treatment[tiab] OR treatments[tiab] OR treatment* OR treat* OR intervention OR interven* OR surgical procedures, operative[mh] OR surgery[tiab] OR surgeries[tiab] OR surgical[tiab] OR manage[tiab] OR management[tiab] OR evaluate[tiab] OR evaluation[tiab] OR sleep[tiab] OR Anti-Inflammatory Agents [mh] OR Multi-Ingredient Cold, Flu, and Allergy Medications [mh] OR Respiratory System Agents [mh] OR Anti-Bacterial Agents [mh] OR antibiotic [tiab] OR Anti-Allergic Agents [mh]	11304977
3	palatine tonsil[mh] OR tonsil*[tiab] OR adenoids [mh] OR adenoid [tiab]	32464
4	Sleep Apnea Syndromes [mh] OR Pharyngitis [mh] OR Craniofacial Abnormalities [mh] OR tonsillitis [tiab] OR “sleep apnea” [tiab] OR “throat infection” [tiab] OR “sleep disordered breathing” [tiab] OR “down syndrome” [tiab]	103125
5	#3 AND (#1 OR #2)	20464
6	((#4 AND #3) AND (#1 OR #2))	6026
7	#5 OR #6 OR #1	23407
8	#7 AND (child* OR adoles* OR pediatr* OR young OR youth OR infant)	12142
9	#8 AND eng [la]	8854
10	#9 NOT newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR legal cases[pt] OR congresses[pt] OR review [pt]	6676
11	#10 AND 1980:2016[dp]	5897

Key: [la] language; [mh] medical subject heading; [pt] publication type.

Table B-2. EMBASE search (August 2015)

Search terms		Search results
1	tonsillectomy/ or palatine tonsillectomy/ or tonsillectomy.mp.	11409
2	adenotonsillectomy.mp. or adenotonsillectomy/	2843
3	1 or 2	13036
4	Limit 3 to English, 1980-current, non-medline journals	613

Table B-3. Cochrane Trials Register

Search terms		Search results
1	Tonsillectomy or adenotonsillectomy	1860
2	1980-2015	1789

Appendix C. Information for Screening, Risk of Bias Assessment, and Strength of the Evidence

Tonsillectomy Abstract Review Form

1. Paper addresses one or more of the following in children (check all that apply):
□ Benefits or harms of tonsillectomy (total or partial tonsillectomy or adenotonsillectomy) for obstructive sleep disordered breathing or throat infection (KQ1-2)
□ Benefits/harms of undergoing tonsillectomy or not undergoing tonsillectomy after a given number of throat infections (KQ2a)
□ Benefits or harms of different tonsillectomy techniques (coblation, cautery, etc.) or surgical types (partial, total) (KQ3-4)
□ Benefits or harms of adjunctive perioperative pharmacologic treatments (steroids, analgesics, etc.) used with tonsillectomy (KQ5)
□ Benefits or harms of postoperative pharmacologic agents for pain following tonsillectomy (KQ6)
□ Cannot determine
□ None of the above

2. Paper is original research?
□ Yes □ No □ Cannot Determine

3. Study includes children ≤ 18 years of age?
□ Yes □ No □ Cannot Determine

4. Record the total N children/total population (e.g., 70/100):
_____

5. Study is a:
□ Comparative study (i.e., has a treatment and comparison group. Includes case-control studies)
□ Controlled pre-post study
□ Case series or database/registry study with at least 1000 participants addressing harms
□ Narrative review or SER/MA
□ Other (please indicate design)
□ Cannot determine

6. If excluded, retain for review of references/background?
□ Yes □ No

7. If excluded, retain for potential data source for former KQ2a (threshold # throat infections/untreated throat infection)
□ Yes □ No

Comments:

Tonsillectomy Full Text Review Form

1. Is the study original research (does not include systematic reviews or meta-analyses) ADRESSING TONSILLECTOMY?
□ Yes □ No

2. Does the study address tonsillectomy in children with OSDB or recurrent throat infection?
□ OSDB
□ Throat infection
□ Not specified
□ None of the above

3. Is the overall mean or median age of participants ≤ 18 years OR are at least 80% of participants ≤ 18 years of age OR are data for children (0-18 years) presented separately?
□ Yes □ No

3a. List total N:
_____

4. Is this a comparative study (includes a treatment and a comparison group) OR database/registry study or case series with at least 1000 eligible participants reporting harms data?
□ Yes □ No

5. Does the study provide data related to at least one of the following of interest for the current review?
□ Benefits or harms of tonsillectomy (total or partial tonsillectomy or adenotonsillectomy) for obstructive sleep-disordered breathing or throat infection (KQ1-2)
□ Benefits or harms of different tonsillectomy techniques (coblation, cautery, etc.) or surgical types (partial, total) (KQ3-4)
□ Benefits or harms of adjunctive perioperative pharmacologic treatments (steroids, analgesics, etc.) used with tonsillectomy (KQ5)
□ Benefits or harms of postoperative pharmacologic agents for pain following tonsillectomy (KQ6)
□ None of the above

6. Does the study provide outcome data on subpopulation of interest (children under age 3; Down syndrome; obesity or overweight; craniofacial or neuromuscular abnormalities)?
□ Yes □ No

7. Does the study provide data to address threshold number of throat infections (Among children with recurrent throat infections, what are the harms of not intervening at different clinical thresholds based on numbers of infections and severity)?
□ Yes □ No

8. Does the study provide data to address criteria for admission (i.e., which children should be admitted postoperatively and where (ICU, observation, etc.))?
□ Yes □ No

9. If excluded, retain this paper for review of references or background?
□ Yes □ No

10. Comments:
_____

Harms Risk of Bias Assessment Form

RefID: _____ Reviewer:_____

Question	Yes	No	Unclear	Comments
1. List harms reported:				
2. Were the harms pre-defined using standardized or precise definitions? *Pre-defined indicates that the harms that were expected are explicitly defined prior to the collection of these expected events. For example, if bleeding is listed as a harmful event, the criteria by which they determine the bleeding (i.e. body location, type, or amount of blood loss that counts as an event, etc) should be specified. Standardized classification of harms can be derived from any of the following:* *1) reference to standard terminology or classifications of harms from a recognized external organization(s)(such as government regulatory or health agencies. Examples of standardized terminology for harms includes, WHO-ART, MEDra, HTA report on the Measurement and Monitoring of Surgical Adverse Events)* *2) previously explicitly defined classifications of harms in the literature, or* *3) based on pre-specified clinical criteria, or* 4) *pre-specified laboratory test (may not need to have a specific cut-off level specified in all cases)* *In some instances only some of the harms identified in a study will be precisely defined. In this case, there must be some judgement if the nature of the harms not pre-defined.*				
3. Are all pre-specified harms reported?				
4. Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection? ***Standard*** *scales or checklists are those that have at least one of the following:* *-Established reliability and validity (specified in the text);* *-Are very widely used within the discipline (may have to check the reference list for the scale)* *In the instance where the methods indicate that a **NEW** scale or checklist was developed for the study specifically, the author(s) must*				

	explicitly specify the CONTENT of the new scale or checklist in sufficient detail (for example, the body systems evaluated, or the specific tests or questions included.)				
5.	Are the statistical methods used to assess the main harm or adverse event outcomes adequate?				

Good= 4-5 “yes”; Fair=3 “yes” out of 5; Poor=2 “yes” or less

Risk of Bias Assessment for Observational Studies

RefID: _____ Reviewer:_____

QUESTION						**COMMENTS**
1. Please list observational study design	Prospective cohort	Non-randomized trial	Other prospective comparative	Case-control	Retrospective cohort or other retrospective comparative study	
2. Were the inclusion/exclusion criteria the same across the comparison groups of the study?	Yes	Partially: some, but not all	No, criteria vary	Cannot determine		
3. Is the strategy for recruiting participants into the study the same across groups?	Yes	No, differs	Cannot determine	Not applicable		
4. Is the selection of the comparison group appropriate, after taking into account feasibility and ethical considerations?	Yes, appropriate	No, inappropriate	Cannot determine or no description of the derivation of the comparison group	Not applicable		
5. Does the study account for important variations in the execution of the study from the proposed protocol?	Yes, accounts for variations	Partially, fails to account	No, does not account	Cannot determine	Not applicable; no variations	
6. Was the outcome assessor blinded to the intervention or exposure status of participants?	Yes, blinded	No, not blinded	Not applicable: assessor cannot be blinded			

7. Were valid and reliable measures, implemented consistently across all study participants, used to assess inclusion/exclusion criteria?	Yes, valid and reliable measure used	No, valid and reliable measure not used	Cannot determine or measurement approach not reported			
8. Were valid and reliable measures, implemented consistently across all study participants, used to assess intervention/exposure outcomes and participant health benefits?	Yes, valid and reliable measure used for all outcomes of interest	Partially, valid and reliable measures used for some outcomes of interest	No, valid and reliable measure not used	Cannot determine or measurement approach not reported		
9. Were valid and reliable measures, implemented consistently across all study participants used to assess confounding?	Yes, valid and reliable measure used	No, valid and reliable measure not used	Cannot determine or measurement approach not reported			
10. Any attempt to balance the allocation between the groups or match groups (e.g., through stratification, matching, propensity scores)?	Yes, or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	No or cannot determine	Not applicable: study does not include a comparison group (case series or one study group)			
11. Were important confounding variables taken into account in the design or analysis (e.g., through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment such as instrumental variables)?	Yes, accounted for or none identified	Partially; some variables taken into account or adjustment achieved to some extent	No, not taken into account	Cannot determine		
12. Are all important primary outcomes reported in the results?	Yes, all important outcome(s) reported	No, important outcome(s) are missing	Cannot determine			

13. Was the length of follow-up the same across study groups?	Yes, same length of follow-up or remedied through analysis	No, different length of follow-up	Not applicable: cross-sectional or only one group followed over time			
14. In cases of high loss to follow-up (or differential loss to follow-up), was the impact assessed (e.g., through sensitivity analysis or other adjustment method)?	Yes, impact assessed	No, impact not assessed	Cannot determine	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high		

Risk of Bias for RCTs Form

Reviewer Initials: _____ Ref ID: _____

Risk of Bias	Criterion	Yes	No	Unclear	COMMENTS
Selection bias	Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?				
	Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?				
	Were participants analyzed within the groups they were originally assigned to?				
	Does the design or analysis control account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?				
Performance bias	Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results? *(Look for differences in anesthesia regimen, additional analgesics or medications at the time of anesthesia.)*				
	Did the study maintain fidelity to the intervention protocol? *(Consider differences in effects from crossover of pts—how much power was diminished; this is especially important to consider if there are no differences in effects.)*				
Attrition bias	If attrition (overall or differential nonresponse, dropout, loss to follow-up, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?				
Detection bias	Was the length of follow-up different between the groups?				
	Were the outcome assessors blinded to the intervention or exposure status of participants? *(For bleeding, if only a subjective assessment was reported, we would expect to see something about method of follow-up in a lower RoB study.)*				
	Were interventions/exposures assessed/defined using clearly defined measures, implemented consistently across all study participants?				
	Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?				
Reporting bias	Were the potential outcomes prespecified by the researchers?				
	Are all prespecified outcomes reported?				

Other	List outcomes of interest assessed in this study: _____ Would answers to any of these questions vary by the specific outcome assessed? If yes, please explain.				
		High risk of bias	**Moderate risk of bias**	**Low risk of bias**	**COMMENTS**
	What is your overall assessment of the risk of bias of this study?				

Strength of the Evidence Domains

Table C-1. Domains used to assess strength of evidence*

Domain	Explanation
Study Limitations	Degree to which included studies for a given outcome have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through study design and study conduct.
Consistency	Degree to which included studies find either the same direction or similar magnitude of effect. Assessed through two main elements: • Direction of effect: Effect sizes have the same sign (that is, are on the same side of no effect or a minimally important difference). • Magnitude of effect: The range of effect sizes is similar.
Directness	Extent to which evidence links interventions directly to a health outcome of specific importance for the review, and for comparative studies, whether the comparisons are based on head-to-head studies. Evidence may be indirect in several situations such as: • Outcome being graded is considered intermediate in a review that is focused on clinical health outcomes (such as morbidity, mortality). • Data do not come from head-to-head comparisons but rather from two or more bodies of evidence to compare. • Data are available only for proxy respondents instead of directly from patients for situations in which patients are capable of self-reporting and self-report is more reliable.
Precision	Degree of certainty surrounding an effect estimate with respect to a given outcome, based on the sufficiency of sample size and number of events. A body of evidence will generally be imprecise if the optimal information size (OIS) is not met. OIS refers to the minimum number of patients (and events when assessing dichotomous outcomes) needed for an evidence base to be considered adequately powered.
Reporting bias	Degree of selective publishing or reporting of research findings based on the favorability of direction or magnitude of effect.

* Excerpted from Berkman et al. Grading the strength of a body of evidence when assessing health care interventions: an EPC update. J Clin Epidemiol. 2014 Dec 20. pii: S0895-4356(14)00536-8. doi: 10.1016/j.jclinepi.2014.11.023.

Appendix D. Excluded Studies

Reasons for Exclusion

X-1 Does not address interventions or outcomes of interest in study conducted in relevant timeframe
X-2 Not original research
X-3 Does not address population of interest
X-5 Not an eligible study design
X-6 Not in English or not obtainable

1. Al-Sheikhli AR. Secretory otitis media in children. (A retrospective study of 249 cases). J Laryngol Otol. 1980 Oct;94(10):1117-24. PMID: 7430773.X-1

2. Bernstein JM, Myers D, Kosinski D, et al. Antibody coated bacteria in otitis media with effusions. Ann Otol Rhinol Laryngol Suppl. 1980 May-Jun;89(3 Pt 2):104-9. PMID: 6778287.X-1

3. Boliston TA, Upton JJ. Infiltration with lignocaine and adrenaline in adult tonsillectomy. J Laryngol Otol. 1980 Nov;94(11):1257-9. PMID: 7003039.X-1

4. Bosch A, Brandenburg JH, Gilchrist KW. Lymph node metastases in adenoid cystic carcinoma of the submaxillary gland. Cancer. 1980 Jun 1;45(11):2872-7. PMID: 6247058.X-1

5. Brook I, Calhoun L, Yocum P. Beta-lactamase-producing isolates of Bacteroides species from children. Antimicrob Agents Chemother. 1980 Jul;18(1):164-6. PMID: 6968177.X-1

6. Brook I, Yocum P, Shah K. Surface vs core-tonsillar aerobic and anaerobic flora in recurrent tonsillitis. JAMA. 1980 Oct 10;244(15):1696-8. PMID: 7411827.X-1

7. Brooks DN, Dogra TS. Long term results of treatment of middle ear effusion. J Laryngol Otol. 1980 Oct;94(10):1107-15. PMID: 7430772.X-1

8. Buchwach KA, Birck HG. Serous otitis media and type 1 tympanoplasties in children. A retrospective study. Ann Otol Rhinol Laryngol Suppl. 1980 May-Jun;89(3 Pt 2):324-5. PMID: 6778339.X-1

9. Colling A, Kerr I, Maxted WR, et al. Streptococcal infection in a Junior Detention Centre: a five-year study. J Hyg (Lond). 1980 Dec;85(3):331-41. PMID: 7007484.X-1

10. Davidson TM, Calloway CA. Tonsillectomy and adenoidectomy-- its indications and its problems. West J Med. 1980 Nov;133(5):451-4. PMID: 7467304. X-2

11. Diamond O. Tonsils and adenoids: why the dilemma? Am J Orthod. 1980 Nov;78(5):495-503. PMID: 6933856.X-1

12. Eggenberger K, Christen JP, Delarue C, et al. Streptococcal pharyngitis-tonsillitis in Swiss children. Diagnosis and management. Paediatrician. 1980;9(5-6):295-308. PMID: 7017549.X-1

13. Eliaschar I, Lavie P, Halperin E, et al. Sleep apneic episodes as indications for adenotonsillectomy. Arch Otolaryngol. 1980 Aug;106(8):492-6. PMID: 7396797.X-5

14. Enomoto T, Enomoto T, Matsui K, et al. Papillary hypertrophy of the palatine tonsils. Ann Otol Rhinol Laryngol. 1980 Mar-Apr;89(2 Pt 1):132-4. PMID: 7369647.X-1, X-5

15. Erviti VF, Templeton B, Bunce JV, et al. The relationship of pediatric resident recording behavior across medical conditions. Med Care. 1980 Oct;18(10):1020-31. PMID: 7453264.X-1

16. Fiellau-Nikolajsen M, Falbe-Hansen J, Knudstrup P. Adenoidectomy for middle ear disorders: a randomized controlled trial. Clin Otolaryngol Allied Sci. 1980 Oct;5(5):323-7. PMID: 7002375.X-1

17. Flint EF. The use of the bipolar microcoagulator for haemostasis in tonsillectomy. Clin Otolaryngol Allied Sci. 1980 Aug;5(4):273-5. PMID: 7408227. X-2

18. Flint EF. The use of the bipolar microcoagulator for hemostasis in tonsillectomy. Clinical otolaryngology and allied sciences. 1980;5(4):273-5. PMID: CN-00398382. X-1, X-2

19. Frenkiel S, Black MJ, Small P. Persistent adenoid presenting as a nasopharyngeal mass. J Otolaryngol. 1980 Aug;9(4):357-60. PMID: 7191445.X-1

20. Freyss GE, Narcy PP, Manac'h Y, et al. Acoustic reflex as a predictor of middle ear effusion. Ann Otol Rhinol Laryngol Suppl. 1980 May-Jun;89(3 Pt 2):196-9. PMID: 6778305.X-1

21. Ginsburg CM, McCracken GH, Jr., Crow SD, et al. A controlled comparative study of penicillin V and cefadroxil therapy of group A streptococcal tonsillopharyngitis. J Int Med Res. 1980;8(Suppl 1):82-6. PMID: 6777212. X-2

22. Grote JJ, Kuijpers W. Middle ear effusion and sinusitis. J Laryngol Otol. 1980 Feb;94(2):177-83. PMID: 7373122.X-1

23. Hibbert J, Stell PM, Wright A. Value of physical signs in the diagnosis of enlarged adenoids. Clin Otolaryngol Allied Sci. 1980 Jun;5(3):191-4. PMID: 7408220.X-1

24. Hsu SM, Ree HJ. Self-sandwich method. An improved immunoperoxidase technic for the detection of small amounts of antigens. Am J Clin Pathol. 1980 Jul;74(1):32-40. PMID: 6156599.X-1

25. Jackson IT, McGlynn MJ, Huskie CF, et al. Velopharyngeal incompetence in the absence of cleft palate: results of treatment in 20 cases. Plast Reconstr Surg. 1980 Aug;66(2):211-3. PMID: 7403311.X-1

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Appendix E. Methods for Meta-Analyses

Key Question 1

To assess whether treatment of children suffering from obstructive sleep-disordered breathing (OSDB) with tonsillectomy results in improved outcomes compared with continuous positive airway pressure (CPAP), or watchful waiting with supportive care (including pharmacologic treatment), we constructed a simple meta-analysis using the change in apnea hypopnea index (AHI) as a measure of treatment efficacy. Because there were only three studies included in the final dataset, we fit a fixed effects model for the treatment effect. The expected arm response was modeled as:

$$\theta_i = \mu + \delta I(t_i)$$

where I is the indicator function, t_i is a dummy variable that equals one for a treatment arm and zero for a control arm.

The response variable d_i is the difference between the outcome and baseline for arm i, and is hypothesized to have the sampling distribution:

$$d_i \sim N(\theta_i, s_i)$$

where s_i is assumed to be the empirical standard error of the difference between the sample means of the outcome and baseline response variables:

$$s_i = \sqrt{\frac{s_i(o)^2}{n_i(o)} + \frac{s_i(b)^2}{n_i(b)}}$$

The effectiveness of the treatment was assessed by examining the estimate of δ and its associated 95% credible interval.

Key Questions 3 and 4 (Harms)

We implemented a mixed-effects, arm-based meta-analysis to assess the influence of different surgical procedures as well as the effect of partial vs. total removal procedures on the occurrence of bleeding outcomes following tonsillectomy. The occurrence of bleeding events in most studies are reported as counts, and can therefore be modeled as a binomial response, with inference derived from estimates of the probability of a bleeding event.

$$x_{\mathrm{ki}} \sim \mathrm{Binomial}(n_i, \pi_{\mathrm{ki}})$$

where π_{ki} is the probability of a bleeding event for intervention k for study i. This probability is modeled hierarchically as a logit-linear model with treatment effects and a study-specific random effect as follows:

$$\mathrm{logit}(p_{\mathrm{ki}}) = \theta_k + \beta I(\mathrm{partial}_k) + \alpha I(\text{high RoB}_i) + \epsilon_i$$

here, θ_k is a surgery-specific mean and β the effect of a partial removal when partial_k is true, while ϵ_i and α_i are a study random effect and a high risk of bias effect, respectively, that correspond to study i.

Logit-linear model parameters were given zero-mean normal priors with $\sigma = 5$, which correspond to diffuse information when transformed to the inverse-logit scale. The study random effect was assumed normally distributed with an unknown standard deviation that was estimated from data, with a broad half-Cauchy prior distribution.

This model was fit to each of four bleeding outcome data: re-operation bleeding, re-admission bleeding, primary bleeding, and secondary bleeding.

Key Question 5

To assess the effectiveness of perioperative steroids on post-operative bleeding rates associated with tonsillectomy, we employed a Bayesian mixed-effects binomial meta-analytic model. We assumed bleeding type-specific baseline rates of bleeding, as well as bleeding type-specific intervention effects, and a fixed effect for dose. Additionally, we included study random effects to account for correlation among arms in the same study.

$$\text{logit}(p_{\text{ijk}}) = \theta_k + \alpha x_i^{(dose)} + \delta_k x_i^{(treat)} + \epsilon_i$$

However, the model above showed substantial lack of fit due to the prevalence of zeros in the bleeding counts. There appeared to be a mixture of outcomes, one of which never results in bleeding, and the other which may (according to the binomial model). Thus, we expanded the model to account for the zero-inflated data. Hence the distribution of the observed bleeding cases becomes:

$$y_i \sim \begin{cases} 0, \text{with probability } (1-\psi) \\ \text{Binomial}(n_i, p_{\text{ijk}}), \text{with probability } \psi \end{cases}$$

In other words, some study arms had no chance of post-operative bleeding, with probability $1-\psi$, while the remainder experienced bleeding with probability p_{ijk}.

Logit-linear model parameters were given zero-mean normal priors with $\sigma = 5$, which correspond to diffuse information when transformed to the inverse-logit scale. Random effects were assumed normally distributed with an unknown standard deviation that was estimated from data, with a broad half-Cauchy prior distribution.

Model Fitting

All models were fit using the No U-turn Sampler (Hoffman and Gelman 2014), a self-tuning, gradient-based Markov chain Monte Carlo (MCMC) algorithm. Models were checked for convergence using the Gelman-Rubin statistic (Gelman and Rubin 1992) and for goodness of fit using posterior predictive checks (Gelman et al. 2013). None of the final models showed evidence for lack of convergence or fit using these criteria.

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Appendix F. Risk of Bias Ratings

Table F-1. Risk of bias assessment for randomized controlled trials

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Kordeluk 2016[1]	Unclear	Unclear	Yes	Yes	Unclear	No	Yes or NA	Yes	Yes	Yes	No	Yes	Yes	High
Murto 2015[2]	Yes	Yes	Yes	No	Yes	Yes or no indication of lack of fidelity	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Gao 2015[3]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Abdel-Ghaffar 2015[4]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Park 2015[5]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Kelly 2015[6]	Yes	Yes	Yes	Yes	Yes	Yes or no indication	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						of fidelity								
Elbadawey 2015[7]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Larusso 2015[8]	Unclear	Unclear	Yes	No	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Amin 2014[9]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
D'Eredita 2014[10]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Sudarsan 2014[11]	No	No	Yes	Yes	No	Yes or no indication of lack of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Aysenur 2014[12]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of lack of	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						fidelity								
Moss 2014[13]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Aydin 2014[14]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of lack of fidelity	NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Gabr 2014[15]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Quante 2014[16-21]	Yes	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Ericsson 2014[22, 23]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Faiz 2013[24]	Yes	Yes	Yes	Yes	No	Yes or no indication of lack of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Merry 2013[25]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ju 2013[26]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Basuni 2013[27]	Yes	Yes	Yes	Yes	Ye	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
El-Fattah 2013[28]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Chaidas 2013[29]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Al-Layla 2013[30]	No	No	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Beriat 2013[31]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Matin 2013[32]	Unclear	Unclear	Yes	No	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Unclear	Yes	Yes	High
Muhammad 2013[33]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Gallagher 2012[34]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Frampton 2012[35]	No	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Hermans 2012[36]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Low
Havel 2012[37]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Aouad 2012[38]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Macassey 2012[39]	Yes	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Yilmaz 2012[40]	Unclear	Unclear	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Safavi 2012[41]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Paramasivan 2012[42]	Unclear	Unclear	Yes	Unclear	NA	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Chang 2012[43]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Kemal 2012[44]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Hamza 2012[45]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High
Al-Shehri 2012[46]	Unclear	Unclear	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Abdel-Ghaffar 2012[47]	Yes	Unclear	Yes	Yes	No	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Beriat 2012[48]	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Omrani 2012[49]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Salama 2012[50]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Matin 2012[51]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Moghaddam 2012[52]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Solanki 2012[53]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Stelter 2012[54, 55]	No	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Parker 2011[56]	No	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Roje 2011[5770]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Babademez 2011[58]	Unclear	No	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Jones 2011[59]	Unclear	No	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Ferri 2011[60]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	No	Yes	Yes	Yes	Yes	Moderate
Haraldsson 2011[61]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
D'Eredita 2010[62]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ferreira 2010[63]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Pruegsanusak 2010[64]	Unclear	Unclear	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Rhendra Hardy 2010[65]	No	No	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Lock 2010[66-68]	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Karaman 2009[69]	No	No	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Unclear	No	Unclear	High
D'Eredita 2009[70]	Yes	Yes	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Unclear	Unclear	Moderate
Parker 2009[71]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stephens 2009[72]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Erdem 2009[73]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Wilson 2009[74]	Unclear	Unclear	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	No	Unclear	High
Hesham 2009[75]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Khani 2009[76]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Bhattacharya 2009[77]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	Yes	Yes	Moderate
Lee 2009[78]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Czarnetzki 2008[79]	Unclear	Unclear	Yes	NA	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Sezen 2008[80]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Erdem 2008[81]	Unclear	Yes	Yes	Yes	Yes	Yes or no	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						indication of fidelity								
Lee 2008[82]	Yes	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	No	Yes	No	Yes	Yes	Yes	No	High
Chimona 2008[83]	Unclear	Unclear	Yes	NA	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
D'Agostino 2008[84]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Korkmaz 2008[85]	Unclear	No	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Davis 2008[86]	Yes	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Chang 2008[87]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Bitar 2008[88]	No	No	No	Unclear	Unclear	Unclear	Yes or NA	Yes	No	Unclear	Yes	Yes	Yes	High

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Hegazy 2008[89]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Alajmi 2008[90]	No	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Skoulakis 2007[91]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Bukhari 2007[92]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Bolton 2007[93]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Mitic 2007[94]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Park 2007[95]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Kim 2007[96]	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Shapiro 2007[97]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Salomone 2007[98]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Antila 2006[99]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Coticchia 2006[100]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Leaper 2006[101]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Sobol 2006[102]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Derkay 2006[103]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Parsons 2006[104]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						indication of fidelity								
Kamal 2006[105]	Unclear	Unclear	Yes	Unclear	No	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Kaan 2006[106]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ericsson 2006[107]	Yes	No	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	No	Yes	Yes	Yes	Moderate
Lister 2006[108]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Hussain 2006[109]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Ericsson 2006[107, 110, 111]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Mohammad 2006[112]	Unclear	Unclear	Yes	Yes	Unclear	No	Yes or NA	Yes	Yes	Yes	No	Yes	Yes	High

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Ragab 2005[113]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High
Kutluhan 2005[114]	Unclear	No	Unclear	No	Unclear	Yes or no indication of fidelity	Unclear	Yes	No	Unclear	Unclear	Unclear	Unclear	High
Oko 2005[115]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Kirazli 2005[116]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Kedek 2005[117]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Chang 2005[118]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	Yes	Yes	Moderate
Bhattacharya 2005[119]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Lister 2005[108]	Yes	Yes	Yes	Yes	Yes	Yes or no	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						indication of fidelity								
Abdul Monem 2005[120]	Unclear	Unclear	Yes	Yes	Unclear	Yes or no indication	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Collison 2004[121]	No	No	Yes	No	Unclear	Unclear	Yes or NA	NA	Yes	Yes	Yes	Yes	Yes	High
Samarkandi 2004[122]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	Yes	Yes	Moderate
Chan 2004[123]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	No	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
D'Eredita 2004[124]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Unclear	Moderate
Hanasono 2004[125]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Low
Celiker 2004[126]	Yes	Yes	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Goldstein 2004[127]	Yes	Unclear	Yes	Yes	Yes	Yes or no	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
						indication of fidelity								
Lalicevic 2004[128]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stoker 2004[129]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Keidan 2004[130]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
van Staaij 2004[131-133]	Yes	Unclear	Yes	Yes	Yes	Unclear	Unclear	Yes	No	Yes	Yes	Yes	Yes	Moderate
Fujii 2003[134]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Perkins 2003[135]	Unclear	No	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Elhakim 2003[136]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Low

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Willging 2003[137]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stoker 2003[138]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Oztekin 2002[139]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Sukhani 2002[140]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Kothari 2002[141]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Shah 2002[142]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Raut 2002[143]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Giannoni 2002[144]	Yes	Yes	Yes	Yes	No	No	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Kokki 2002[145]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Paradise 2002[146_a]	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Paradise 2002[146_b]	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Young 2001[147]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Densert 2001[148]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Walker 2001[149]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Temple 2001[150]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Bergler 2001[151]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Romsing 2001[152]	Yes	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Fujii 2001[153]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Fujii 2001[154]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Nunez 2000[155]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Pizzuto 2000[156]	Yes	Yes	Yes	Unclear	No	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Holt 2000[157]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Jensen 2000[158]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Romsing 1998[159]	Unclear	Unclear	Yes	Yes	No	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High

Author Year	Allocation Sequence Generated Adequately	Allocation Treatment Adequately Concealed	Participants Analyzed In Groups Originally Assigned	Design Account for Confounding	Rule Out Impact from Concurrent Intervention or Unintended Exposure	Fidelity Maintained to Intervention Protocol	If Attrition, Were Missing Data Handled Appropriately	Difference in Length of Follow-up Between Groups	Outcome Assessors Blinded	Interventions/ Exposures Assessed Clearly	Outcomes Assessed Clearly	Potential Outcomes Prespecified	All Prespecified Outcomes Reported	Risk of Bias Rating
Stage 1988[160]	No	Unclear	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Paradise 1984[161_a]	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	No	Yes	No	Yes	Yes	Yes	Yes	High

Table F-2. Risk of bias assessment for observational studies

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
Mukhatiyar, 2016[162]	Yes	Yes	Cannot determine or no description of the derivation of the comparison group	Not applicable; no variations	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	Yes or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Thong, 2016 [163]	Partially: some, but not all criteria, applied to all groups or not clearly stated if some criteria are applied to all groups	No, differs	yes, appropriate	Not applicable; no variations	No, not blinded	Cannot determine or measurement approach not reported	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	Yes or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	No, impact not assessed	High

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
Trosman, 2016[164]	Yes	Yes	Yes, appropriate	Not applicable; no variations	No, not blinded	cannot determine or measurement approach not reported	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	Yes or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Koshy, 2015[165]	Yes	Yes	Yes, appropriate	Not applicable, no variations	No, not blinded	Cannot Determine	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	No or cannot determine	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	NA	Moderate
Volsky, 2014[166]	Yes	Cannot Determine	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	Yes or study accounts for imbalance between groups through a post hoc approach such as	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	No, impact not assessed	Moderate

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
									multivariate analysis					
Chettri, 2014[167]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	Yes, blinded	Yes, valid and reliable measure used	Partially, valid and reliable measures used for some outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	No, not taken into account	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Biggs, 2014[168]	Yes	Yes	No, inappropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	No or cannot determine	Yes, accounted for or none identified	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Burstein, 2013[169]	Yes	Yes	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	Yes or study accounts for imbalance between groups through a post hoc approach such as	Partially: some variables taken into account or adjustment achieved to some extent	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
									multivariate analysis					
Moriniere, 2013[170]	Partially: some, but not all criteria, applied to all groups or not clearly stated if some criteria are applied to all groups	Yes	Yes, appropriate	Yes, accounts for variations	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	No, valid and reliable measure not used	No or cannot determine	No, not taken into account	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Cannot determine	High
Ozkiris, 2012[171]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	Yes, blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Yes, valid and reliable measure used	No or cannot determine	Cannot determine	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Ozkiris, 2012[172]	Yes	Yes	Yes, appropriate	Yes, accounts for	No, not blinded	Yes, valid and reliable	Yes, valid and reliable	Cannot determine or measurement	No or cannot determine	Cannot determine	Yes, all important	Yes, same length of	Not applicable: no loss to	Moderate

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
				variations		measure used	measure used for all outcomes of interest	approach not reported			outcome (s) reported	follow-up or remedied through analysis	follow-up or loss to follow-up was not considered to be high	
Ragab, 2011[173]	Yes	Yes	Not applicable	Yes, accounts for variations	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	Not applicable: study does not include a comparison group (case series or one study group)	Cannot determine	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Ben-Israel, 2011[174]	Yes	No, differs	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	Cannot determine	Yes, all important outcome (s) reported	No, different length of follow-up	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Lock, 2010[66-68]	Yes	Yes	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all	Cannot determine or measurement approach not reported	Yes or study accounts for imbalance between	Cannot determine	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied	Yes	Moderate

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
							outcomes of interest		groups through a post hoc approach such as multivariate analysis			through analysis		
Brigance, 2009[175]	Yes	Yes	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	No, valid and reliable measure not used	No or cannot determine	Partially: some variables taken into account or adjustment achieved to some extent	Yes, all important outcome (s) reported	No, different length of follow-up	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Di Rienzo, 2008[176]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	Unclear	Cannot determine or measurement approach not reported	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	Cannot determine	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Vlastos, 2008[177]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	No, not blinded	Yes, valid and reliable measure used	Partially, valid and reliable measures used for	No, valid and reliable measure not used	No or cannot determine	No, not taken into account	Yes, all important outcome (s)	Yes, same length of follow-up or	Cannot determine	High

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
							some outcomes of interest				reported	remedied through analysis		
Fernandes, 2008[178]	Yes	Cannot Determine	Cannot determine or no description of the derivation of the comparison group	Cannot determine	Unclear	No, valid and reliable measure not used	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	No, not taken into account	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Orvidas, 2006[179]	Yes	Yes	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	Partially: some variables taken into account or adjustment achieved to some extent	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate
Tarasiuk, 2004[180]	Yes	Yes	Yes, appropriate	Not applicable; no variations	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	No, valid and reliable measure not used	No or cannot determine	Yes, accounted for or none identified	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	Moderate

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
Silveira, 2003[181]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	Yes, blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	Yes or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	Yes, accounted for or none identified	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable	Moderate
Udaipurwala, 2002[182]	Partially: some, but not all criteria, applied to all groups or not clearly stated if some criteria are applied to all groups	Cannot Determine	Cannot determine or no description of the derivation of the comparison group	Yes, accounts for variations	No, not blinded	Cannot determine or measurement approach not reported	Yes, valid and reliable measure used for all outcomes of interest	Cannot determine or measurement approach not reported	No or cannot determine	Partially: some variables taken into account or adjustment achieved to some extent	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Dualibi, 2002[183]	Yes	Cannot	Cannot determine	Cannot determine	No, not blinded	Cannot determin	Yes, valid and	Cannot determine or	No or cannot	Cannot determine	Yes, all importan	Yes, same	Cannot determine	High

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
		Deter mine	or no description of the derivation of the comparison group			e or measure ment approac h not reported	reliable measure used for all outcomes of interest	measurement approach not reported	determine		t outcome (s) reported	length of follow-up or remedied through analysis		
Nawasreh , 2000[184]	Yes	Canno t Deter mine	Cannot determine or no description of the derivation of the comparison group	Cannot determine	No, not blinded	Cannot determin e or measure ment approac h not reported	Cannot determine	No, valid and reliable measure not used	No or cannot determine	No, not taken into account	Yes, all importan t outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Paradise, 1984[161_b]	Partially: some, but not all criteria, applied to all groups or not clearly stated if some criteria are applied to all	Yes	Yes, appropriate	Yes, accounts for variations	No, not blinded	Yes, valid and reliable measure used	Cannot determine	Cannot determine or measurement approach not reported	No or cannot determine	No, not taken into account	Yes, all importan t outcome (s) reported	No, different length of follow-up	No	High

Author, Year	Inclusion/Exclusion Criteria Same	Participant Recruiting Strategy Same	Comparison Group Selection Appropriate	Important Variations in Execution of Study	Outcome Assessor Blinded	Valid and Reliable Measures Used to Assess Inclusion Criteria	Valid and Reliable Measures Used to Assess Outcomes	Valid and Reliable Measures Used to Assess Confounding	Balance Allocation Between Groups	Confounding Variables In Design or Analysis	Primary Outcomes Reported	Length of Follow-up Same	High Loss to Follow-up Assessed	Risk of Bias Rating
	groups													

Table F-3. Risk of bias assessment for studies reporting harms

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm or adverse event outcomes adequate?	Rating
Mahadevan, 2016[185]	Yes	Yes	No	Yes	Moderate
Spektor, 2016[186]	Yes	Yes	Yes	Yes	Low
Kshirsagar, 2016[187]	Yes	Yes	Yes	Yes	Low
Harounian, 2016[188]	Yes	Yes	Yes	Yes	Low
Elinder, 2016[189]	Yes	Yes	Yes	Yes	Low
Odhagen, 2016[190]	Yes	Yes	Yes	Yes	Low
Raol, 2016[191]	Yes	Yes	Yes	Yes	Low
Pfaff, 2016[192]	Yes	Yes	Yes	Yes	Low
Padia, 2015[193]	No	Yes	Yes	Yes	Moderate
Achar, 2015[194]	Yes	Yes	Unclear	Yes	Moderate
Edmonson, 2015[195]	Yes	Yes	Yes	Yes	Low
Bangiyev, 2015[196]	Unclear	Unclear	Unclear	Yes	High
Lavin, 2015[197]	Yes	Yes	Yes	Yes	Low

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm or adverse event outcomes adequate?	Rating
Duval, 2015[198]	Yes	Yes	Yes	Yes	Low
Abdullah, 2015[199]	No	Yes	Unclear	Yes	High
Suzuki, 2014[200]	Yes	Yes	Unclear	Yes	Moderate
Mahant, 2014[201, 202]	Yes	Yes	Yes	Yes	Low
Bhattacharyya, 2014[203, 204]	Yes	Yes	Yes	Yes	Low
Sarny, 2013[205, 206]	Yes	Yes	Yes	Yes	Low
Hultcrantz, 2013[207, 208]	Yes	Yes	Yes	Yes	Low
Walner, 2012[209]	Yes	Yes	Unclear	Yes	Moderate
Perkins, 2012[210]	Yes	Yes	Unclear	Yes	Moderate
Tweedie, 2012[211]	Yes	Yes	Unclear	Yes	Moderate
Tomkinson, 2012[212, 213]	Yes	Yes	Yes	Yes	Low
Hessen, 2011[214]	Yes	Yes	Yes	Yes	Low
Vlastos, 2010[215]	No	Unclear	No	Unclear	High
Bhattacharyya, 2010[216]	Yes	Yes	Unclear	Yes	Moderate

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm or adverse event outcomes adequate?	Rating
Kim, 2010[217]	Yes	Yes	Unclear	Yes	Moderate
Gooda, 2010[218]	Yes	Yes	Unclear	Yes	Moderate
D'Agostino, 2009[219]	Yes	Yes	Unclear	Yes	Moderate
Kvaerner, 2009[220]	Yes	Yes	Yes	Yes	Low
Arnoldner, 2008[221]	Yes	Yes	Unclear	Yes	Moderate
Jones, 2007[222]Yes	Yes	Unclear	Yes	Yes	Moderate
Lowe, 2007[223]	Yes	Yes	Yes	Yes	Low
Abou-Jaoude, 2006[224]	Unclear	Unclear	Unclear	Yes	High
Zhao, 2006[225]	Unclear	Unclear	Unclear	Yes	High
Tomkinson, 2005[226]	Yes	Yes	Yes	Yes	Low
Clark, 2004[227]	Yes	Yes	Yes	Yes	Low
Mills, 2004[228]	Yes	Yes	Unclear	Yes	Moderate
Granell, 2004[229]	Yes	Unclear	Yes	Yes	High
Windfuhr, 2002[230, 231]	Yes	Yes	Unclear	Yes	Moderate

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm or adverse event outcomes adequate?	Rating
Liu, 2001[232]	Yes	Yes	Unclear	Yes	Moderate
Peeters, 1999[233]	Yes	Yes	Unclear	Yes	Moderate
Kang, 1994[234]	Yes	Yes	Unclear	Yes	Moderate
Yardley, 1992 [235]	Yes	Yes	Unclear	Yes	Moderate
Lannigan, 1993[236]	Yes	Yes	Unclear	Yes	Moderate
Colclasure, 1990[237]	Yes	Yes	Unclear	Yes	Moderate
Chowdhury, 1988[238]	Yes	Yes	Unclear	Yes	Moderate
Carithers, 1987[239]	Yes	Yes	Unclear	Yes	Moderate
Crysdale, 1986[240]	Yes	Yes	Unclear	Yes	Moderate
Herdman, 1986[241]	Yes	Yes	Unclear	Yes	Moderate
Capper, 1984[242]	Unclear	Yes	Unclear	Yes	High
Yuan, 1984[243]	No	Yes	No	Yes	High
Carmody, 1982[244]	Yes	Yes	Unclear	Yes	Moderate

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Appendix G. Applicability of Findings

Table G-1. Tonsillectomy vs. no surgery/watchful waiting for children with OSDB

Domain	Description of applicability of evidence
Population	Studies included children ages less than 2 to 16 years. In most studies children had PSG-proven OSDB. Three studies—including the largest RCT—had majority African-American populations.[1-3], and two studies also reported that more than 50% of participants were overweight or obese.[1, 2] One study included children with Down Syndrome or mucopolysaccharidosis[4] and another included children under 24 months.[5]
Intervention	Tonsillectomy or tonsillectomy with adenoidectomy
Comparators	Comparators included watchful waiting or medical management.
Outcomes	Studies outcomes included changes in AHI, sleep-related quality of life, and behavioral and cognitive outcomes. Data were collected from PSG, direct interviews/assessments, provider records, and quality of life surveys. Outcomes were collected at various time points with followup times ranging from 5 months to 4 years. Most studies reported outcomes at 5-7 months.
Setting	Studies were conducted in the United States (6), Brazil (2), Israel (2), Australia (1), Ireland (1), and India (1). Patients were typically selected from otolaryngology clinics or their information was collected from a database.

PSG = Polysomnography; OSDB = Obstructive Sleep Disordered Breathing; RCT = Randomized Controlled Trial

Table G-2. Tonsillectomy vs. no surgery/watchful waiting for children with recurrent throat infections

Domain	Description of applicability of evidence
Population	Studies included children ages 3-16 with differing requirements for inclusion based on number of sore throat episodes from mildly impacted children with a minimum of one sore throat episode in the previous year to more severely impacted children with more than 7 sore throat episodes in the previous year. One study based inclusion on three or more documented episodes of Group A Strep throat infections. Studies typically did not report race/ethnicity or BMI. Four RCTs or non-randomized trials included majority Caucasian populations.
Intervention	Tonsillectomy or tonsillectomy with adenoidectomy
Comparators	Comparators included watchful waiting or medical management.
Outcomes	Study outcomes included number of sore throat days, healthcare visits, missed school or work, quality of life. Data were collected from patient diaries, direct interviews, provider records and quality of life surveys. Outcomes were collected at various time points with most studies offering a time point of one year post procedure and at least one additional study year. One study reported data 6-years post-procedure and had the longest duration.
Setting	Studies were conducted in the United States, Netherlands, Ireland, and the United Kingdom and patients were selected from otolaryngology or primary care clinics or their information was collected from a database.

BMI = Body Mass Index; RCT = Randomized Controlled Trial

Table G-3. Partial vs. total tonsillectomy

Domain	Description of applicability of evidence
Population	Studies included children ages less than 2 to 17 years. Most studies (19) included children with OSDB (typically based on clinical diagnosis vs. PSG). Neither race/ethnicity nor BMI were typically reported.
Intervention	Partial or total tonsillectomy/adenotonsillectomy. "Partial" tonsillectomy was variously defined (ranging from 10-70% removal or removal of protruding tissue only or removal of all but a thin rim of tissue) or not described across studies.
Comparators	Comparators included surgical technique (e.g., coblation, electrocautery) and partial or total removal of tonsils.
Outcomes	Outcomes included persistence of OSDB, return to normal diet or activity, recurrent throat infection, tonsillar regrowth, quality of life, postoperative bleeding, and behavioral outcomes. Outcomes were reported in multiple ways (means, %, days, N, etc.). Studies collected data from patient diaries, direct interviews/assessments, provider records, and quality of life or other outcome surveys. Outcomes were collected at various time points with followup times ranging from 5-7 days post-procedure to 6 years.
Setting	Studies were conducted in the United States (8), Greece (3), Sweden (2), Turkey (2), Brazil (2), Lebanon (1), Israel (1), Egypt (1), France (1), and Thailand (1). Patients were typically selected from otolaryngology clinics.

BMI = Body Mass Index; N = Number; PSG = Polysomnography; OSDB = Obstructive Sleep Disordered Breathing

Table G-4. Techniques for tonsillectomy

Domain	Description of applicability of evidence
Population	Studies included individuals ages less than 2 to 41 years (mean age in all studies <18 years). Most studies (28) included children with OSDB (typically based on clinical diagnosis vs. PSG) and recurrent throat infection (typically not defined). Studies typically did not report race/ethnicity or BMI.
Intervention	Partial or total tonsillectomy/adenotonsillectomy using various surgical techniques.
Comparators	Comparators included other surgical techniques (e.g., coblation, electrocautery).
Outcomes	Outcomes included return to normal diet or activity and postoperative bleeding and were reported in multiple ways (days, %, n children, etc.). Studies collected data from patient diaries and direct interviews/assessments. Outcomes were collected at various time points with followup times ranging from 9 days post-procedure to 12 months. Most studies had short-term (< 6 months) followup.
Setting	Studies were conducted in the United States (8), Greece (3), Sweden (2), Turkey (2), Brazil (2), Egypt (1), France (1), and Thailand (1). Patients were typically selected from otolaryngology clinics.

BMI = Body Mass Index; N = Number; PSG = Polysomnography; OSDB = Obstructive Sleep Disordered Breathing

Table G-5. Perioperative medications

Domain	Description of applicability of evidence
Population	Studies included individuals from 1-18 years of age. Most studies (38) did not specify indications for tonsillectomy. Six studies included children with mixed indications, and five studies included children with recurrent throat infection (typically not defined). Studies typically did not report race/ethnicity and BMI.
Intervention	NSAIDs, anti-emetics, or steroids (different doses and/or routes or combinations of these agents or these agents plus a non-NSAID analgesic or anesthetic) given perioperatively during tonsillectomy. Doses and routes of administration of intervention and comparator agents and of rescue medications varied widely.
Comparators	Comparators included other agents or no agent/placebo.
Outcomes	Outcomes included return to normal diet or activity, need for rescue medications, and postoperative bleeding. Studies reported outcomes in multiple ways (days, %, n children, mean dose, etc.). Data were collected from patient diaries and direct interviews/assessments. Most studies had short-term followup (24 hours post-op to ≤ 5 months).
Setting	Most studies (32) were conducted in less developed countries; 17 were conducted in the US, European countries, Japan, South Korea, or Australia. Studies typically recruited patients from otolaryngology or pediatric clinics.

BMI = Body Mass Index; N = Number; NSAID = Nonsteroidal Anti-Inflammatory Drug

Table G-6. Postoperative medications

Domain	Description of applicability of evidence
Population	Studies included children between 1 and 18 years of age. Most studies did not specify the indication for tonsillectomy (8). Four studies included children who had either OSDB or recurrent throat infection as surgical indications, and one included only children with throat infection. Neither race/ethnicity nor BMI were typically reported. One study included primarily Asian children.[6]
Intervention	Postoperative medications for pain following tonsillectomy (typically via unspecified techniques). Agents included steroids, NSAIDs, non-NSAID analgesics, and antibiotics, individually or in combination.
Comparators	Other agents or no agent/placebo.
Outcomes	Studies reported primarily on need for rescue medications, bleeding, and time to return to normal diet or activity. Outcomes were primarily reported using diaries or questionnaires, and studies typically had short-term followup (3-16 days post-procedure. One study had 5-month followup.
Setting	Studies were conducted in Denmark (3), New Zealand (2), Canada (2) Jordan (1), Serbia (1), Korea (1), Egypt (1), Pakistan (1), and Turkey (1). Patients were recruited primarily from otolaryngology clinics or pediatric surgery units.

NSAID = Nonsteroidal Anti-Inflammatory Drug; OSDB = Obstructive Sleep Disordered Breathing

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Appendix H. Detailed Tables of Findings

Bleeding-Related Harms in Comparative Studies Addressing Tonsillectomy

Table H-1. Postoperative hemorrhage reported in comparative study arms addressing total tonsillectomy

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
Coblation	**OSDB**							
	Sudarsan 2014[1]	37	2	NR	2 (5.4)	NR	NR	NR
	Paramasivan 2012[2]	50	1	1 (2)	0	NR	NR	NR
	Chang 2008[3]	35	1	NR	NR	1 (2.9)	NR	1 (2.9)
	D'Eredita 2009[4]	74	1	NR	NR	1 (1)	1 (1)	NR
	Throat Infection							
	Salama 2012[5]	75	3	NR	3 (10)	NR	0	NR
	Elbadawey 2015[6]	40	1	NR	1 (2.5)	NR	NR	NR
	Hegazy 2008[7]	40	0	NR	0	NR	NR	NR
	Temple 2001[8]	18	0	NR	NR	0	NR	NR
	Di Renzo 2008[9]	21	0	NR	NR	0	NR	NR
	Mixed							
	Stoker 2004[10]	44	4	1 (2)	NR	3 (7)	NR	1 (2)
	Omrani 2012[11]	47	2	1 (2.12)	1 (2.12)	NR	NR	NR
	Chimona 2008[12]	30	1	NR	NR	1 (3)	NR	NR
	Roje 2011[13, 14]	50	1	NR	NR	1 (2)	NR	NR
	D'Eredita 2010[15]	32	1	NR	NR	1 (3)	1 (3)	NR
	Mitic 2007[16]	20	0	NR	NR	0	NR	NR
	Unspecified							
	Parker 2009[17]	35	2	NR	NR	2 (6)	NR	NR
	Shapiro 2007[18]	23	1	NR	NR	1 (4.3)	NR	1 (4.3)
	Parker 2011[19]	40	1	NR	NR	1 (3)	NR	1 (3)
	Shah 2002[20]	17	0	NR	NR	0	NR	0
Cold Dissection	**OSDB**							
	Salomone 2007[21]	50	7	0	7 (14)	NR	NR	NR
	Ericsson 2009[22, 23]	32	0	0	0	NR	0	0

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
	Paramasivan 2012[2]	50	1	1 (2)	0	NR	NR	NR
	Korkmaz 2008[24]	41	1	NR	NR	1 (2)	NR	1 (2)
	Aydin 2014[25]	40	0	0	0	NR	0	0
	Skoulakis 2007[26]	15	0	NR	NR	0	NR	NR
	Chaidas 2013,[27]	51	0	0	0	NR	NR	0
	Beriat 2013[28]	45	0	NR	NR	0	0	NR
	Throat Infection							
	Paradise et al.(2002)[29]	203	7	NR	NR	7 (2)	5 (1.6)	NR
	Raut 2002[30]	32	5	1 (3)	4 (12.5)	NR	NR	NR
	Frampton 2012[31]	100	3	0	3 (3)	NR	NR	NR
	Elbadawey 2015[6]	40	1	NR	1 (2.5)	NR	NR	NR
	Sezen 2008[32]	25	0	0	0	NR	NR	NR
	Frampton 2012[31]	100	0	0	0	NR	0	0
	Di Renzo 2008[9]	21	0	NR	NR	0	NR	NR
	Chettri 2014[33]	40	0	NR	NR	0	NR	NR
	Mixed							
	D'Eredita 2014[34]	285	15	0	15 (5.3)	NR	NR	15 (5.3)
	Omrani 2012[11]	47	7	2 (4.26)	5 (10.64)	NR	NR	NR
	Haraldsson 2007[35]	49	2	0	2 (4.1)	NR	NR	NR
	Roje 2009[13, 14]	50	2	NR	NR	2 (4)	NR	NR
	Ozkiris 2012[36]	99	2	0	2 (2)	NR	NR	NR
	Chimona 2008[12]	30	1	NR	NR	1 (3)	NR	NR
	Nunez 2000[37]	25	1	NR	1 (3.8)	NR	NR	NR
	Hultcrantz 2004[38-40]	43	1	1 (2)	NR	NR	NR	NR
	Gabr 2014[41]	20	0	NR	NR	0	NR	NR
	Lorusso 2015[42]	40	1	0	1 (2.5)	NR	0	1 (2.5)
	Unspecified							
	Oko 2005[43]	61	7	1 (2)	6 (10)	NR	NR	1 (2)
	Kothari 2002[44]	72	4	NR	NR	4 (5.5)	4 (5.5)	0
	Parker 2009[17]	35	2	NR	NR	2 (6)	NR	NR
	Hesham 2009[45]	69	1	NR	1 (1.33)	NR	NR	0
	Silveira 2008[46]	28	1	NR	1 (3.6)	NR	NR	1 (3.6)

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
	Shapiro 2007[18]	23	0	NR	NR	0	NR	0
	Young 2001[47]	23	0	NR	NR	0	NR	NR
	Pruegsanusak 2010[48]	20	0	NR	NR	0	0	NR
Electrocautery	**OSDB**							
	Coticchia 2006[49]	10	0	NR	NR	0	0	NR
	Lister 2006[50]	25	0	NR	NR	0	NR	NR
	Salomone 2007[21]	50	0	0	0	NR	NR	NR
	Throat Infection							
	Leaper 2006[51]	101	21	NR	21 (21)	NR	11(11)	2 (2)
	Raut 2002[30]	18	4	1 (5.5)	3 (16.6)	NR	NR	NR
	Ragab 2011[52]	91	3	2 (2.2)	1 (1.1)	NR	NR	NR
	Ragab 2011[52]	91	2	1 (1.1)	1 (1.1)	NR	NR	NR
	Temple 2001[8]	20	0	NR	NR	0	NR	NR
	Chettri 2014[33]	40	0	NR	NR	0	NR	NR
	Mixed							
	D'Eredita 2014[34]	285	12	NR	12 (4.2)	NR	12 (4.2)	12 (4.2)
	Ozkiris 2012[36]	102	6	0	6 (5.9)	NR	NR	0
	Haraldsson 2007[35]	49	3	0	3 (6.1)	NR	NR	NR
	D'Eredita 2010[15]	32	2	NR	NR	2 (6)	2 (6)	NR
	Stoker 2004[10]	45	2	NR	NR	2 (4.4)	1	0
	Nunez 2000[37]	22	2	NR	2 (8.3)	NR	NR	NR
	D'Eredita 2004[53]	28	0	NR	0	NR	NR	NR
	Mitic 2007[16]	20	0	NR	NR	0	NR	NR
	Unspecified							
	Walker 2001[54]	75	9	0	9 (12)	NR	6 (8)	3 (4)
	Hesham 2009[45]	71	4	NR	4 (5.33)	NR	NR	1 (1.33)
	Willging 2003[55]	59	3	NR	NR	3 (5)	NR	1 (2)
	Derkay 2006[56]	150	3	NR	NR	3 (2)	3 (2)	NR
	Al-Shehri 2012[57]	93	2	NR	NR	2 (2.2)	NR	NR
	Shah 2002[20]	17	1	NR	NR	1 (6)	NR	1 (6)
	Parker 2011[19]	40	1	NR	NR	1 (3)	NR	1 (3)
	Silveira 2008[46]	29	1	1 (3.4)	NR	NR	NR	NR

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
	Chan 2004,[58]	28	1	NR	NR	1 (4)	1 (4)	NR
	Young 2001[47]	23	0	NR	NR	0	NR	NR
	Chang 2012[59]	33	0	NR	NR	0	NR	NR
	Park 2007[60]	21	0	NR	NR	0	NR	NR
Harmonic Scalpel	**Throat Infection**							
	Leaper 2006[51]	103	24	NR	24 (23)	NR	9 (9)	4 (4)
	Salama 2012[5]	75	1	NR	1 (3.3)	NR	1 (3.3)	NR
	Unspecified							
	Oko 2005[43]	61	9	1 (2)	8 (13)	NR	NR	1 (2)
	Willging 2003[55]	61	6	NR	NR	6 (10)	NR	3 (5)
	Walker 2001[54]	97	5	0	5 (5.2)	NR	5 (5.2)	1 (1)
Laser	**Throat Infection**							
	Hegazy 2008[7]	40	1	NR	1 (2.5)	NR	NR	NR
	Elbadawey 2015[6]	40	0	NR	0	NR	NR	NR
	Mixed							
	D'Eredita 2004[53]	30	0	NR	0	NR	NR	0
	Unspecified							
	Kothari 2002[44]	79	9	9 (11.3)	NR	NR	9 (11.3)	3 (3.7)
Molecular Resonance	**OSDB**							
	D'Eredita 2009[4]	74	0	NR	NR	0	0	NR
	Mixed							
	D'Eredita 2014[34]	287	2	NR	2 (1)	NR	0	0
	D'Eredita 2010[15]	32	0	NR	NR	0	0	NR
	Lorusso 2015[42]	40	2	0	2 (5)	NR	1 (2.5)	1 (2.5)
	Unspecified							
	Chang 2012[59]	33	0	NR	NR	0	NR	NR
Thermal Welding	**OSDB**							
	Aydin 2014[25]	40	0	0	0	NR	NR	NR
	Throat Infection							
	Sezen 2008[32]	25	0	0	0	NR	NR	NR
	Mixed							
	Ozkiris 2012[36]	104	5	0	5 (4.8)	NR	NR	1 (1)
	Chimona 2008[12]	30	0	NR	NR	0	NR	NR

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
Unspecified/ Other Techniques	**OSDB**							
	Marcus 2013[61-67] Unspecified tonsillectomy	212	5	NR	NR	5 (2.4)	5 (2.4)	NR
	Throat Infection							
	Orvidas et al.2006[68] Unspecified tonsillectomy	145	5	NR	NR	5 (3.4)	NR	2 (1.4)
	Van Staaij 2004[69-71] Unspecified tonsillectomy	194	7	7 (4)	NR	NR	3 (2)	2 (1)
	Unspecified							
	Al-Shehri 2012[57] Unspecified tonsillectomy	97	6	NR	NR	6 (6.2)	NR	6 (6.2)
	Bukhari 2007[72] Electrocautery and cold dissection (left or right tonsil)	100	2	2 (2)	NR	NR	NR	NR
Totals	**(N arms)**							
	All arms (105)	6299	265 (4.2)	33 (1.3)	166 (4.8)	66 (2.7)	80 (3.0)	66 (2.2)
	Electrocautery (29)	1668	82 (4.9)	5 (0.99)	62 (6.3)	15 (2.3)	36 (5)	21 (2.6)
	Cold dissection (34)	1904	72 (3.8)	6 (0.54)	49 (4)	17 (2.7)	9 (1.6)	19 (2.3)
	Harmonic scalpel (5)	397	45 (11.3)	1 (0.63)	38 (11.3)	6 (9.8)	15 (5.5)	9 (2.8)
	Unspecified/ other technique (5)	748	25 (3.3)	9 (3.1)	NR	16 (3.5)	8 (2.0)	10 (2.3)
	Coblation (19)	748	25 (3.3)	3 (2.1)	7 (2.4)	12 (2.7)	2 (1.1)	4 (2.5)
	Laser (4)	189	10 (5.3)	9 (11.4)	1 (0.91)	NR	9 (11.4)	3 (2.8)
	Thermal welding (4)	199	5 (2.5)	0 (0)	5 (2.96)	0 (0)	NR	1 (0.96)
	Molecular resonance (5)	466	4 (0.86)	0 (0)	4 (1.22)	0 (0)	1 (0.23)	1 (0.31)

N=Number; NR=Not Reported; OSDB=Obstructive Sleep Disordered Breathing; PTH=Post-Tonsillectomy Hemorrhage

Table H-2. Postoperative hemorrhage reported in comparative study arms addressing partial tonsillectomy

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
Coblation	**OSDB**							
	Ericsson 2009[22, 23]	32	2	0	2 (6)	NR	2 (6)	0 (0)
	Chang 2008[3]	34	NR	NR	NR	NR	NR	0
	Coticchia 2006 [49]	13	NR	NR	NR	NR	0	NR
	Throat infection							
	Stelter 2012 [73_1437]	14	0	NR	NR	0	NR	NR
	Mixed							
	Hultcrantz 2004[38-40]	49	2	NR	NR	2 (4)	NR	NR
	Chan 2004[58]	27	NR	NR	NR	0	0	NR
Cold dissection	**OSDB**							
	Skoulakis 2007[26]	15	0	NR	NR	0	NR	NR
	Chaidas 2013 [27]	50	0	0	0	NR	NR	0
	Korkmaz 2008[24]	40	1	NR	NR	1 (3)	NR	1 (3)
	Unspecified							
	Park 2007[60]	19	0	NR	NR	0	NR	NR
Laser	**OSDB**							
	Havel 2012[74] (diode laser)	21	0	0	0	NR	NR	NR
	Havel 2012[74] (CO_2 laser)	21	0	0	0	NR	NR	NR
	Throat infection							
	Stelter 2010[73, 75]	12	0	NR	NR	0	NR	NR
Microdebrider	**OSDB**							
	Lister 2006[50]	25	0	NR	NR	0	NR	NR
	Beriat 2013 [28]	37	0	NR	NR	0	0	NR
	Mixed							
	Gabr	20	0	NR	NR	0	NR	NR

Technique	Indication Author, Year	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Revisit or Readmission for PTH n (%)	Reoperation for PTH n (%)
	2014[41]							
	Unspecified							
	Pruegsanusak 2010 [48]	20	1	NR	NR	1 (5)	1 (5)	NR
	Derkay 2006 [56]	150	2	NR	NR	2 (1.3)	2 (1.3)	NR
Totals	**(N arms)**							
	All arms (18)	599	8 (1.5)	0 (0)	2 (1.6)	6 (1.4)	5 (1.8)	1 (0.64)
	Coblation (6)	169	4 (4.2)	0 (0)	2 (6.3)	2 (2.2)	2 (2.8)	0 (0)
	Microdebrider (5)	252	3 (1.2)	NR	NR	3 (1.2)	3 (1.45)	NR
	Cold dissection (4)	124	1 (0.81)	0 (0)	0 (0)	1 (1.4)	NR	1 (1.1)
	Laser (3)	54	0 (0)	0 (0)	0 (0)	0 (0)	NR	NR

N=Number; NR=Not Reported; OSDB=Obstructive Sleep Disordered Breathing; PTH=Post-Tonsillectomy Hemorrhage

Non-Bleeding Harms

Table H-3. Revisits for pain or dehydration reported after partial tonsillectomy in arms of comparative studies

Technique for Partial Tonsillectomy	Author, Year Indication	Total Arm N	Pain Revisits/Readmissions, n (%)	Dehydration Revisits/Readmissions, n (%)	PONV Revisits/Readmissions, n (%)
Microdebrider	**OSDB**				
	Derkay 2006[56]	150	NR	5 (3.3)	NR
	Beriat 2013[28]	37	0	0 (0)	NR
Coblation	Chang 2008[3]	34	NR	0 (0)	NR
Totals	**(N arms)**				
	Microdebrider (2)	187	0	5 (3.3)	NR
	Coblation (1)	34	NR	0	NR

N=Number; NR=Not Reported; PONV=Post-Operative Nausea Vomiting

Table H-4. Revisits for pain, dehydration, PONV reported after total tonsillectomy in arms of comparative studies

Technique for Total Tonsillectomy	Author, Year Indication	Total Arm N	Pain Revisits/Readmissions, n (%)	Dehydration Revisits/Readmissions, n (%)	PONV Revisits/Readmissions, n (%)	Other Revisits/Readmissions, n (%)
Laser	**Not specified**					
	Kothari 2002[44]	79	12 (15.1)	NR	13 (16.4)	NR
	Matin 2012[76]	50	1 (2)	NR	NR	NR
	D'Eredita 2004[53]	30	NR	0	NR	NR
Electrocautery	**OSDB**					
	Derkay 2006[56]	150	NR	4 (2.6)	NR	NR
	Chang 2005[77]	49	0 (0)	1 (2)	0	NR
	Throat Infection					
	Walker 2001[54]	161	NR	4 (2.5)	NR	NR
	Raut 2002[30]	18	0 (0)	0	0	NR
	Mixed					
	D'Eredita 2014[34]	279	NR	0	NR	NR
	Stoker 2004[10]	45	Post-op calls/visits to doctor 11 (24.4)	Post-op calls/visits to doctor 7 (15.5)	Post-op calls/visits to doctor 7 (15.5)	NR
	Parker 2011[19]	40	NR	1 (2.5)	NR	NR
	D'Eredita 2010[15]	32	NR	2 (6.2)	NR	NR

Technique for Total Tonsillectomy	Author, Year Indication	Total Arm N	Pain Revisits/Readmissions, n (%)	Dehydration Revisits/Readmissions, n (%)	PONV Revisits/Readmissions, n (%)	Other Revisits/Readmissions, n (%)
	Chan 2014[22]	28	NR	1 (3.7)	NR	NR
	D'Eredita 2004[53]	28	NR	0	NR	NR
	Nunez 2000[37]	24	0 (0)	0	0	NR
	Not Specified					
	Silveira 2003[46]	29	Stayed extra day after surgery 1 (3.4)	NR	NR	NR
Cold dissection	**OSDB**					
	Beriat 2013[28]	45	0 (0)	0	NR	NR
	Throat infection					
	Raut 2002[30]	32	0 (0)	0	0	NR
	Mixed					
	D'Eredita 2014[34]	279	NR	0	NR	NR
	Kothari 2002[44]	72	13 (18)	NR	16 (22.2)	NR
	Oko 2005[43]	61	1 (1.6)	NR	NR	NR
	Nunez 2000[37]	26	0 (0)	0	0	NR
	Shapiro 2007[18]	23	0 (0)	NR	0	NR
	Not Specified					
	Oko 2005[43]	61	NR	1 (1.6)	NR	NR
	Shapiro 2007[18]	23	NR	0	NR	NR
Coblation	**OSDB**					
	Chang 2008[3]	35	NR	0	NR	NR
	Shah 2002[20]	17	NR	1 (5.8)	Post-op calls/visits to doctor 4 (9)	NR
	Mixed					
	D'Eredita 2009 [4]	78	NR	0	NR	NR
	Stoker 2004[10]	44	Post-op calls/visits to doctor 6 (13.6)	Post-op calls/visits to doctor 6 (13.6)	NR	NR
	Not Specified					
	Shapiro 2007[18]	24	0	0	0	NR
Harmonic Scalpel	**Mixed**					
	Walker 2001[54]	155	NR	2 (1.3)	NR	NR

Technique for Total Tonsillectomy	Author, Year Indication	Total Arm N	Pain Revisits/Readmissions, n (%)	Dehydration Revisits/Readmissions, n (%)	PONV Revisits/Readmissions, n (%)	Other Revisits/Readmissions, n (%)
	Oko 2005[43]	61	NR	NR	NR	Readmit for dehydration and pain 3 (4.9)
Molecular resonance	**Mixed**					
	D'Eredita 2014[34]	283	NR	0	NR	NR
	D'Eredita 2009[4]	79	NR	0	NR	NR
Unspecified tonsillectomy	**OSDB**					
	Marcus 2013[61-67]	212	NR	7 (3.3)	NR	NR
	Van Staaij et al. 2004[69-71]	151	NR	NR	5 (3)	NR
	Orvidas 2006[68]	145	NR	2 (1.4)	NR	NR
	Goldstein 2004[78]	21	NR	0 (0)	0	NR
Totals	**(N arms)**					
	All arms (37)	2969	45 (1.5)	39 (1.6)	45 (1.5)	3 (0.09)
	Electrocautery-total (12)	883	12 (7.3)	20 (2.3)	7 (5.1)	NR
	Cold dissection-total (9)	622	14 (5.4)	1 (0.21)	16 (10.5)	NR
	Unspecified tonsillectomy (4)	529	NR	9 (2.4)	5 (0.85)	NR
	Molecular resonance-total (2)	362	NR	0	NR	NR
	Harmonic scalpel-total (2)	216	NR	2 (1.3)	NR	3 (4.9)
	Coblation-total (5)	198	6 (8.8)	7 (3.5)	4 (9.8)	NR
	Laser-total (3)	159	13 (10.1)	0	13 (16.5)	NR
	Microdebrider-partial (2)	187	0	5 (2.5)	NR	NR
	Coblation-partial (1)	34	NR	0	NR	NR

N=Number; NR=Not Reported; PONV=Post-Operative Nausea Vomiting

Bleeding-Related Harms in Case Series, Database, and Registry Studies

Table H-5. Post-tonsillectomy hemorrhage rates reported across all studies

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
Database Studies								
Edmonson 2015[79] Low	0-24 Mixed CA hospital discharge database-return visits within 30 days postop	30092	1331	NR	NR	1331 (3.8)	1331 (3.8)	NR
Bhattacharyya 2015[80, 81] Low	<18 years (mean=7.5 years) Unspecified CA, IA, FL, NY ER and ambulatory surgery and ER databases-return visits within 14 days postop	79520	1652	NR	NR	1652 (2.1)	1652 (2.1)	NR
Duval 2015[82] Low	1-18 Unspecified Hospital system database-return visits within 21 days postop	39906	935	NR	NR	935 (2.3)	NR	463 (1.2)
Padia 2015[83] Moderate	1-18 Unspecified Hospital system database-return visits within 21 days post-same-day tonsillectomy	15953	1187	NR	NR	1187 (7.4)	NR	413 (2.6)
Mahant 2014[84, 85] Low	1-18 Mixed	139715	4182	NR	NR	4182 (3)	4182 (3)	NR

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
	Pediatric Health Information System-return visits within 30 days post-same day tonsillectomy							
Suzuki 2014[86] Moderate	≤15 years OSDB Japanese national inpatient database-7 years	31934	160	NR	NR	160 (0.50)	NR	160 (0.50)
Tomkinson 2012[87, 88] Low	<12 years Mixed Wales Surgical Instrument Surveillance Programme Database-5 years	4225	63	24 (0.6)	39 (0.9)	NR	NR	38 (0.9)
*Tomkinson 2005[89] Low	<12 years Unspecified Patient Episode Database for Wales-return visits within 28 days post-tonsillectomy	6730	225	53 (0.79)	172 (3)	NR	153 (2.3)	41 (0.61)
Clark 2004[90] Low	0-14 Unspecified Hospital Episode Statistics for England-4 years	131577	500	NR	NR	500 (0.38)	NR	500 (0.38)
Kshirsagar 2016[91] Low	1-17 years Mixed California Ambulatory Surgery Data records-6 years	138998	156	NR	NR	156 (0.1)	NR	NR
Harounian 2016[92]	1-17 years	305860	8518	NR	NR	8518 (2.8)	500 (0.16)	2480 (0.81)

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
Low	Unspecified MarketScan database records-5 years							
Raol 2016[93] Low	0-18 Mixed Kids' Inpatient Database records -3 years	38631	446	NR	NR	446 (1.2)	NR	NR
Case Series								
Achar 2015[94] Moderate	0-17 Mixed Single institution ER chart review of 5 years	3527	222	NR	222 (6.3)	NR	NR	NR
Walner 2012[95] Moderate	1-18 Mixed Single institution chart review of 7 years	1918	87	5 (0.5)	82 (4)	NR	NR	31 (1.6)
Perkins 2012[96] Moderate	6.90±4.02 (mean yrs±SD) Mixed Single institution chart review of 7 years	9023	212	48 (0.5)	164 (2)	NR	109 (1.2)	103 (1.1)
Kim 2010[97] Moderate	≤15 years Mixed Single institution chart review of 3 years	1109	33	0	33 (3)	NR	3 (0.27)	2 (0.18)
Gooda 2010[98] Moderate	5-15 Throat infection	1500	9	NR	NR	9 (0.6)	NR	2 (0.13)

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
	Chart review of 8 years							
D'Agostino 2009[99] Moderate	2-13 Mixed Single institution chart review of 5 years	3306	59	44 (1.3)	15 (0.45)	NR	NR	15 (0.45)
Arnolder 2008[100] Moderate	1-15 Mixed Single institution chart review for 13 years	3657	54	NR	NR	54 (1.5)	NR	54 (1.5)
Jones 2007[101] Moderate	0.5-34.8 Mixed Children's Hospital, Boston, MA patient records- 4 years	2319	295	NR	NR	295 (12.7)	NR	63 (2.7)
Mills 2004[102] Moderate	9 months-17 years Mixed Single institution chart review of admitted or re-admitted patients over 9 years	4850	209	46 (0.9; 95% CI: 0.68% to 1.22%)	163 (3; 95% CI: 2.8% to 3.9%)	0	38 (0.78)	18 (0.37)
Granell 2004[103] Moderate	0-14 Mixed Single institution chart review of 6 years	1243	84	78 (6)	6 (0.48)	NR	NR	36 (2.9)
Windfuhr 2001[104-106] Moderate	6 months-14 years Mixed Single institution chart	2567	41	27 (1)	14 (0.54)	NR	NR	41 (1.6)

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
	review of 12 years							
Liu 2001[107] Moderate	2.5 months-20 years Unspecified Single institution chart review of 1 year	1438	134 (evaluations for PTH in 112 children)	9 (0.63)	125 (9)	NR	60 (4.2)	20 (1.4)
Kang 1994[108] Moderate	1-19 Unspecified In-patient and out-patient clinic records from the Children's Hospital of Buffalo- 4 years	1061	64	64 (6)	0 (0)	NR	44 (4.1)	14 (1.3)
Lannigan 1993[109] Moderate	3-13 Unspecified Single institution chart review of 4 years	4386	25	25 (0.6)	NR	NR	NR	18 (0.41)
Yardley 1992[110] Moderate	NR Unspecified Two South Yorkshire hospitals- 3 years	2091	11	NR	NR	11 (0.52)	NR	11 (0.52)
Colclasure 1990[111] Moderate	6 years (mean) Unspecified Single institution chart review of 8 years	2011	36	7 (0.35)	29 (1.4)	0 (0)	12 (0.60)	7 (0.35)
Chowdhury 1988[112] Moderate	“Pediatric” (under 4 -over 12) Mixed	6842	171	90 (1.3)	81 (1.2)	NR	46 (0.67)	29 (0.42)

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
	Single institution chart review of 13 years							
Carithers 1987[113] Moderate	1-23 (mean=6.3) Mixed Single institution chart review of 1 year	2563	78	30 (1.2)	48 (1.9)	NR	NR	NR
Crysdale 1986[114] Moderate	≤2 -17 Unspecified Single institution chart review of 4 years	7974	199	199 (2.5)	NR	NR	0	NR
Herdman 1986[115] Moderate	≤14 years Unspecified Single institution chart review of 7 years	2400	13	13 (0.54)	0	NR	NR	0
Carmody 1982[116] Moderate	0-19 Not specified Single institution chart review of 5 years	3380	54	30 (0.8)	24 (0.7)	NR	NR	NR
Mahadevan 2016[117] Moderate	1-15 Unspecified Starship Children's Hospital database records- 10 years	5400	234	25 (0.5)	209 (3.9)	NR	9 (0.17)	57 (1.1)
Spektor 2016[118] Low	1-19 Mixed Electronic medical records of the Center for Pediatric ENT – 5 years	2237	91	NR	NR	91 (4.1)	NR	21 (1)

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
Peeters 1999[119] Moderate	1-16 Unspecified ENT dept at children's hospital- 10 years	1508	44	39 (2.6)	5 (0.3)	NR	NR	NR
Pfaff 2016[120] Low	0-18 Unspecified Tertiary care children's hospital- 4 years	2697	97	NR	NR	97 (3.6)	NR	59 (2.2)
Registries								
Hultcrantz 2014[121-123] Low	2-18 OSDB Swedish National Registry for Tonsil Surgery-data at 30 days and 6 months postop	10826	304	149 (1.4)	155 (1.4)	NR	NR	54 (0.49)
Soderman 2011[124] Low	0-19 years Mixed Swedish National Tonsil Register-11 years	40322	431	NR	NR	431 (1.1)	NR	NR
Sarny 2011[125, 126] Low	1-18 Mixed Nationwide data collection for 12 months	3372	283	NR	NR	283 (8.4)	NR	47 (1.4)
Kvarner 2009[127] Low	≤16 years Unspecified Norwegian Patient Registry-7 years	34955	157	NR	NR	157 (0.45)	157 (0.45)	NR
Lowe	<5 to 15 years	21063	575	NR	NR	575 (3)	NR	NR

Author, Year RoB	Age Range, Years Surgical Indication Data Source Description	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Nonoperative revisit or readmission for PTH, n (%)	Reoperation for PTH, n (%)
2007[128-130] Low	Mixed UK National Tonsillectomy Audit-1 year							
Totals								
All studies	NA	1154686	23661 (2.1)	1005 (1.2)	1586 (2.1)	21070 (1.97)	8451 (1.3)	4797 (0.78)
Database studies	NA	963141	19355 (2.0)	77 (0.70)	211 (1.9)	19067 (2.0)	7818 (1.4)	4095 (0.76)
Case series	NA	81007	2556 (3.2)	779 (1.2)	1220 (2.3)	557 (3.4)	321 (0.81)	601 (0.97)
Registry studies	NA	110538	1750 (1.6)	149 (1.4)	155 (1.4)	1446 (1.5)	312 (0.68)	101 (0.71)

Note: primary typically defined as within 24 hours postoperatively and secondary as greater than 24 hours.
*Defined primary as during the initial admission and secondary as PTH requiring admission up to 28 days postoperatively
CI=Confidence Interval; N=Number; NR=Not Reported; OSDB=Obstructive Sleep Disordered Breathing; PTH=Post-Tonsillectomy Hemorrhage

Table H-6. PTH rates reported by technique in case series, database, or registry studies

Surgical Technique	Author, Year RoB	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
Electro-cautery (total tonsillectomy)	Gooda 2010[98] Moderate	1500	9	NR	NR	9 (0.6)	NR	2 (0.13)
	Kim 2010[97] Moderate	1109	33	0	33 (3)	NR	3 (0.27)	2 (0.18)
	Lowe 2007[128-130] Low	6161	204	NR	NR	204 (3.3)	NR	NR
	Liu 2001[107] Moderate	1438	134 (evaluations for PTH in 112 children)	9 (0.63)	125 (9)	NR	60 (4.2)	20 (1.4)
	Tomkinson 2005[89]	6730	225	53 (0.79)	172 (3)	NR	153 (2.3)	41 (0.61)
Cold dissection (total tonsillectomy)	Hultcrantz* 2014[121-123] Low	3945	192	74 (1.9)	118 (3)	NR	NR	46 (1.5)
	Arnolder 2008[100] Moderate	3657	54	NR	NR	54 (1.5)	NR	54 (1.5)
	Lowe 2007[128-130] Low	5176	106	NR	NR	106 (2.04)	NR	NR
	Windfuhr 2001[104-106] Moderate	2567	41	27 (1)	14 (0.54)	NR	NR	41 (1.6)
	Carmody 1982[116] Moderate	3380	54	30 (0.8)	24 (0.7)	NR	NR	NR
	Peeters 1999[119] Moderate	1508	44	39 (2.6)	5 (0.3)	NR	NR	NR
	Chowdhury 1988[112]	6842	171	90 (1.3)	81 (1.2)	NR	46 (0.67)	29 (0.42)
	Crysdale 1986[114]	7974	199	199 (2.5)	NR	NR	0	NR
	D'Agostino 2009[99]	3306	59	44 (1.3)	15 (0.45)	NR	NR	15 (0.45)
	Kang 1994[108] Moderate	1061	64	64 (6)	0 (0)	NR	44 (4.1)	14 (1.3)
Coblation (total tonsillectomy)	Walner 2012[95] Moderate	1918	87	5 (0.5)	82 (4)	NR	NR	31 (1.6)
	Pfaff 2016[120] Low	2697	97	NR	NR	97 (3.6)	NR	59 (2.2)
	Spektor 2016[118]	2237	91	NR	NR	91 (4.1)	NR	21 (1)

Surgical Technique	Author, Year RoB	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
	Low							
Other techniques	Hultcrantz* 2014[121-123] Coblation-partial Low	6881	112	75 (1.1)	37 (0.54)	NR	NR	8 (0.07)
	Sarny 2011[125, 126] Total tonsillectomy-unspecified Low	2080	255	NR	NR	255 (12.3)	NR	36 (1.7)
	Sarny 2011[125, 126] Partial tonsillectomy-unspecified Low	1292	28	NR	NR	28 (2.2)	NR	11 (0.85)
	Perkins 2012[96] Total tonsillectomy-unspecified Moderate	9023	212	48 (0.5)	164 (1.8)	NR	109 (1.2)	103 (1.1)
	Yardley 1992[110] Tonsillectomy - unspecified Moderate	2091	11	NR	NR	11 (0.52)	NR	11 (0.52)
	Jones 2007[101] Tonsillectomy - unspecified Moderate	2319	295	NR	NR	295 (12.7)	NR	63 (2.7)
	Raol 2016[93] Tonsillectomy - unspecified Low	38631	446	NR	NR	446 (1.2)	NR	NR
	Harounian 2016[92]	305860	8518	NR	NR	8518 (2.8)	500 (0.16)	2480 (0.81)

Surgical Technique	Author, Year RoB	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
	Tonsillectomy - unspecified Low							
	Kshirsagar 2016[91] Tonsillectomy - unspecified Low	138998	156	NR	NR	156 (0.1)	NR	NR
	Mahadevan 2016[117] Adenotonsillectomy–multiple techniques Moderate	5400	234	25 (0.5)	209 (3.9)	NR	9 (0.17)	57 (1.1)
	Bhattacharyya 2015[80, 81] Tonsillectomy - unspecified Low	79520	1652	NR	NR	1652 (2.1)	1652 (2.1)	NR
	Clark 2004[90] Tonsillectomy - unspecified Low	131577	500	NR	NR	500 (0.38)	NR	500 (0.38)
	Duval 2015[82] Tonsillectomy - unspecified Low	39906	935	NR	NR	935 (2.3)	NR	463 (1.2)
	Edmonson 2015[79] Tonsillectomy - unspecified Low	30092	1331	NR	NR	1331 (3.8)	1331 (3.8)	NR
	Kvarner 2009[127] Tonsillectomy - unspecified Low	34955	157	NR	NR	157 (0.45)	157 (0.45)	NR

Surgical Technique	Author, Year RoB	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
	Mahant 2014[84, 85] Tonsillectomy – unspecified Low	139715	4182	NR	NR	4182 (3)	4182 (3)	NR
	Soderman 2011[124] Tonsillectomy - unspecified Low	40322	431	NR	NR	431 (1.1)	NR	NR
	Tomkinson 2012[87, 88] Tonsillectomy - unspecified Low	4225	63	24 (0.6)	39 (0.9)	NR	NR	38 (0.9)
	Achar 2015[94] Tonsillectomy- multiple techinques Moderate	3527	222	NR	NR	222 (6.3)	NR	NR
	Carithers 1987[113] Tonsillectomy - unspecified Moderate	2563	78	30 (1.2)	48 (1.9)	NR	NR	NR
	Colclasure 1990[111] Tonsillectomy - unspecified Moderate	2011	36	7 (0.35)	29 (1.4)	0 (0)	12 (0.60)	7 (0.35)
	Herdman 1986[115] Tonsillectomy - unspecified Moderate	2400	13	13 (0.54)	0	NR	NR	0
	Lannigan 1993[109] Adenotonsillectom	4386	25	25 (0.6)	NR	NR	NR	18 (0.41)

Surgical Technique	Author, Year RoB	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
	y - unspecified Moderate							
	Padia 2015[83] Tonsillectomy-unspecified Moderate	15953	1187	NR	NR	1187 (7.4)	NR	413 (2.6)
	Suzuki 2014[86] Tonsillectomy-unspecified Moderate	31934	160	NR	NR	160 (0.50)	NR	160 (0.50)
	Mills 2004[102] Tonsillectomy-unspecified Moderate	4850	209	46 (0.95)	163 (3.4)	NR	38 (0.78)	18 (0.37)
	Granell 2004[103] Tonsillectomy-unspecified Moderate	1243	84	78 (6)	6 (0.48)	NR	NR	36 (2.9)
Totals								
All arms	NA	23284 (2.03)	23284 (2.04)	1005 (0.87)	1586 (0.14)	20805 (1.8)	8451 (0.74)	4797 (0.42)
Electrocautery	NA	16938	605 (3.6)	62 (0.7)	330 (3.6)	213 (2.8)	216 (2.3)	65 (0.6)
Cold dissection	NA	39416	984 (2.5)	567 (2.5)	257 (1.9)	160 (1.8)	208 (1.1)	199 (0.9)
Coblation	NA	6852	275 (4.01)	5 (0.3)	82 (4.3)	188 (3.8)	NR	111 (1.62)
Other Techniques	NA	21532 (2.04)	21420 (1.98)	371 (0.9)	917 (2.2)	20244 (1.95)	8027 (0.74)	4422 (0.41)

*Study notes that most total tonsillectomies were performed using cold dissection. Non-operative revisits may have included reoperations.
N=Number; NR=Not Reported; PTH=Post-Tonsillectomy Hemorrhage

Table H-7. PTH by indication in case series, database, or registry studies

Indication	Author, Year	Total N	Total PTH	Primary PTH, n (%)	Secondary PTH, n (%)	Unspecified PTH, n (%)	Non-operative revisit or readmission, n (%)	Reoperation, n (%)
OSDB	Achar 2015[94]	417	65	NR	NR	65 (15.6)	NR	NR
	Suzuki 2014[86]	31934	160	NR	NR	160 (0.50)	NR	160 (0.50)
	*Hultcrantz 2014[121, 122]	10820	304	149 (1.4)	155 (1.4)	NR	155 (1.4)	54 (0.50)
	Perkins 2012[96]	1141	105	NR	NR	105 (9.2)	NR	NR
Recurrent throat infection	Achar 2015[94]	2398	150	NR	150 (6.3)	NR	NR	NR
	Gooda 2010[98]	1500	9	NR	NR	9 (0.6)	NR	2 (0.13)
	Perkins 2012[96]	158	28	NR	NR	28 (17.7)	NR	NR
Mixed	Achar 2015[94]	564	37	NR	37 (6.6)	NR	NR	NR
	Perkins 2012[96]	330	65	NR	NR	65 (19.7)	NR	NR
	Kshirsagar 2016[91]	138998	156	NR	NR	156 (0.1)	NR	NR
	Raol 2016[93]	38631	446	NR	NR	446 (1.2)	NR	NR
	Spektor 2016[118]	2237	91	NR	NR	91 (4.1)	NR	21 (1)
	Edmonson 2015[79]	30092	1331	NR	NR	1331 (3.8)	1331 (3.8)	NR
	Mahant 2014[84, 85]	139715	4182	NR	NR	4182 (3)	4182 (3)	NR
	Soderman 2011[124]	40322	431	NR	NR	431 (1.1)	NR	NR
	Tomkinson 2012[87, 88]	4225	63	24 (0.6)	39 (0.9)	NR	NR	38 (0.9)
	Arnolder 2008[100]	3657	54	NR	NR	54 (1.5)	NR	54 (1.5)
	Carithers 1987[113]	2563	78	30 (1.2)	48 (1.9)	NR	NR	NR
	Chowdhury 1988[112]	6842	171	90 (1.3)	81 (1.2)	NR	46 (0.67)	29 (0.42)
	D'Agostino 2009[99]	3306	59	44 (1.3)	15 (0.45)	NR	NR	15 (0.45)
	Kim 2010[97]	1109	33	0	33 (3)	NR	3 (0.27)	2 (0.18)
	Walner 2012[95]	1918	87	5 (0.5)	82 (4)	NR	NR	31 (1.6)
	Windfuhr	2567	41	27 (1)	14 (0.54)	NR	NR	41 (1.6)

	2001[104-106]							
	Granell 2004[103]	1243	84	78 (6)	6 (0.48)	NR	NR	36 (2.9)
	Mills 2004[102]	4850	209	46 (0.9; 95% CI: 0.68% to 1.22%)	163 (3; 95% CI: 2.8% to 3.9%)	0	38 (0.78)	18 (0.37)
	Lowe 2007[128-130]	21063	575	NR	NR	575 (3)	NR	NR
	Sarny 20136[205, 206]	3372	283	NR	NR	283 (8.4)	NR	47 (1.4)
	Jones 2007[101]	2319	295	NR	NR	295 (12.7)	NR	63 (2.7)
Other (not specified)	Achar 2015[94]	106	7	NR	7 (0.20)	NR	NR	NR
	Perkins 2012[96]	71	14	NR	NR	14 (19.7)	NR	NR
	Harounian 2016[92]	305860	8518	NR	NR	8518 (2.8)	500 (0.16)	2480 (0.81)
	Kang 1994[108]	1061	64	64 (6)	0 (0)	NR	44 (4.1)	14 (1.3)
	Yardley 1992[110]	2091	11	NR	NR	11 (0.52)	NR	11 (0.52)
	Mahadevan 2016[117]	5400	234	25 (0.5)	209 (3.9)	NR	9 (0.17)	57 (1.1)
	Carmody 1982[244]	3380	54	30 (0.8)	24 (0.7)	NR	NR	NR
	Tomkinson 2005[89]	6730	225	53 (0.79)	172 (3)	NR	153 (2.3)	41 (0.61)
	Peeters 1999[119]	1508	44	39 (2.6)	5 (0.3)	NR	NR	NR
	Pfaff 2016[120]	2697	97	97 (3.6)	NR	NR	NR	59 (2.2)
	Bhattacharyya 2015[80, 81]	79520	1652	NR	NR	1652 (2.1)	1652 (2.1)	NR
	Clark 2004[90]	131577	500	NR	NR	500 (0.38)	NR	500 (0.38)
	Duval 2015[82]	39906	935	NR	NR	935 (2.3)	NR	463 (1.2)
	Kvarner 2009[127]	34955	157	NR	NR	157 (0.45)	157 (0.45)	NR
	Colclasure 1990[111]	2011	36	7 (0.35)	29 (1.4)	0 (0)	12 (0.60)	7 (0.35)
	Crysdale 1986[114]	7974	199	199 (2.5)	NR	NR	0	NR
	Herdman 1986[115]	2400	13	13 (0.54)	0	NR	NR	0
	Lannigan 1993[109]	4386	25	25 (0.6)	NR	NR	NR	18 (0.41)
	Liu 2001[107]	1438	134 (evaluations for PTH in 112 children)	9 (0.63)	125 (9)	NR	60 (4.2)	20 (1.4)
	Padia 2015[83]	15953	1187	NR	NR	1187 (7.4)	NR	413 (2.6)

Totals								
All arms	NA	1147321	23661 (2.1)	957 (0.08)	1422 (0.12)	21282 (1.9)	8342 (0.73)	4694 (0.41)
OSDB	NA	44318	597 (1.4)	149 (1.4)	183 (1.6)	265 (0.80)	155 (1.4)	214 (0.50)
Throat Infection	NA	4056	187 (4.6)	NR	150 (6.3)	37 (2.2)	NR	2 (0.13)
Mixed	NA	449923	8771 (1.95)	344 (1.2)	518 (1.8)	7909 1.9()	5600 (3.1)	395 (1.1)
Unspecified	NA	649024	14106 (2.2)	464 (1.3)	571 (2.4)	13071 (2.1)	2587 (0.58)	4083 (0.78)

*The authors of this study reported bleeding rates on children with recurrent throat infection and OSDB in further publications.
N=Number; NR=Not Reported; OSDB=Obstructive Sleep Disordered Breathing; PTH=Post-Tonsillectomy Hemorrhage

Other Harms

Table H-8. Revisits for pain, nausea, or dehydration reported in case series, database, or registry studies

Technique	Indication Author, Year	Total Arm N	Pain Revisits/ Readmissions, n (%)	Dehydration Revisits/ Readmissions, n (%)	PONV Revisits/ Readmissions, n (%)	Mixed/Other Revisits/ Readmissions, n (%)
Coblation tonsillectomy	**Mixed**					
	Walner 2012[95]	1,918	NR	29 (1.5)	NR	NR
Unspecified Tonsillectomy	**Mixed**					
	Elinder 2016[121-123]	18,712	NR	NR	NR	Unplanned contact of health care provider 2,180 (11.6)
	Mahant 2014 [84, 85]	139,715	1060 (0.8)	Revisit for dehydration and vomiting 3,011(2.2)	NR	NR
	Edmonson 2015[79]	35,085	Acute post-op pain 354 (6.9) Throat pain 224 (4.2)	311 (7.6)	PONV 118 (0.37) Vomiting alone 106 (0.3)	NR
	Mills 2004[102]	4,853	NR	NR	Vomiting requiring admission overnight 107 (2.7)	Rehydration or analgesia 24 (0.5)
	Achar 2015[94]	3,527	NR	NR	NR	ER visit for pain relief, poor oral intake, fever, and NV 346 (9.8)
	Not Specified					
	Mahadevan 2016[117]	5,400	74 (1.37)	4 (0.07)	32 (0.59)	Fever or Drug Reaction 2 (.03)
	Bhattacharyya 2014[80]	79,520	1,180 (1.5)	NR	7503 (1.4)	Fever/ NV/ Dehydration 1,765 (2.2)
	Duval 2015[82]	39,906	NR	898 (2.3)	NR	NR
	Colclasure 1990[111]	2,011	NR	2 (0.05) [Not specific to	NR	NR

Technique	Indication Author, Year	Total Arm N	Pain Revisits/ Readmissions, n (%)	Dehydration Revisits/ Readmissions, n (%)	PONV Revisits/ Readmissions, n (%)	Mixed/Other Revisits/ Readmissions, n (%)
				age group]		
	Granell 2004[103]	1,243	NR	Poor oral intake 2 (0.2)	NR	NR
Totals	**(N studies)**					
	All (11)	331890	2668 (0.11)	4257 (1.9)	7760 (6.2)	4317 (3.8)
	Coblation total tonsillectomy (1)	1,918	NR	29 (1.5)	NR	NR
	Unspecified tonsillectomy (10)	329972	2668 (0.11)	4228 (1.9)	7760 (6.2)	4317 (3.8)

ER=Emergency Room; N=Number; NR=Not Reported; NV= Nausea and Vomiting; PONV=Postoperative Nausea and Vomiting

Table H-9. Other harms reported in case series and database studies

Author Study Design RoB	Indication	Intervention	Total Arm N	Harms of Intervention N (%)	Mortality N (%)	VPI N (%)
Odhagen 2016[131] Registry Low	OSDB, Throat Infection	Total or partial tonsillectomy (unspecified)	Total: 11741 Partial: 15794	Total tonsillectomy Total reoperations 75 (0.6) Reoperation for airway obstruction 49 (66.2) Reoperation for Infection 11 (14.9) Reoperation for Other cause 14 (18.9) Partial tonsillectomy Total reoperation 609 (3.9) Reoperation for airway obstruction	NR	NR

Author Study Design RoB	Indication	Intervention	Total Arm N	Harms of Intervention N (%)	Mortality N (%)	VPI N (%)
				501 (82.3) Reoperation for Infection 73 (12) Reoperation for Other cause 35 (5.7)		
Mahadevan 2016[117] Case Series Moderate	Not Specified	Tonsillectomy (unspecified)	5,400	NR	Died within 1 month of tonsillectomy due to ventricular fibrillation, not direct link to tonsillectomy surgery 1(.01)	NR
Raol 2016[93] Database Low	Not Specified	Tonsillectomy (unspecified)	40,591	Respiratory failure 383 (0.94)	Children's Teaching Hospital (n=10,220) ≤10 (0.09) Non-Children's Teaching Hospital (n=20,176) ≤10 (0.04) Nonteaching Hospital (n=8,235) ≤10 (0.12)	NR
Lavin 2015[132] Database Low	OSDB	Tonsillectomy (unspecified)	21,434 (899 Obese, 20535 Non-obese) Weighted N	Obese T&A patients respiratory complications 146 (16.2) Obese T&A patients major respiratory complications (pulmonary insufficiency or respiratory failure) 45 (5.04) Non-obese T&A patients respiratory	No deaths in obese T&A patients 0 (0)	NR

Author Study Design RoB	Indication	Intervention	Total Arm N	Harms of Intervention N (%)	Mortality N (%)	VPI N (%)
				complications 1984 (9.7) Non-obese T&A major respiratory complications (pulmonary insufficiency or respiratory failure) 617(3.0)		
Shay 2015[81] Case Series Low	Not Specified	Tonsillectomy (unspecified)	36,221	NR	2(0.005)	NR
Walner 2012[95] Database/Registry Moderate	OSDB, Throat Infection	Coblation total tonsillectomy	1,918	NR	0(0)	NR
Tweedie 2012[133] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	1,735	Postoperative desaturation or pulmonary edema or lung collapse 13 (0.75) Postoperative aspiration 2 (0.12) Malignany hyperpyrexia 1 (0.06)	0(0)	NR
Sarny 2011[125, 126] Database/Registry Low	Not Specified	Tonsillectomy (unspecified)	9,405	NR	0(0)	NR
Bhattacharyya 2010[134] Database/Registry Moderate	Not Specified	Tonsillectomy (unspecified)	535,949	Airway obstruction NR (0.04)	NR	NR
Jones 2007[101] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy, (unspecified)	2,554	NR	NR	61(2.7)
Granell 2004[103] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	1,243	NR	0(0)	NR

Author Study Design RoB	Indication	Intervention	Total Arm N	Harms of Intervention N (%)	Mortality N (%)	VPI N (%)
Windfuhr 2001[104-106] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	2,567	NR	1(0.04)	NR
Peters 1999[119] Case Series Moderate	Not Specified	Tonsillectomy including Adenotonsillectomy (unspecified)	1,508	NR	0(0)	NR
Herdman 1986[115] Case Series Moderate	Not Specified	Tonsillectomy (unspecified)	2,400	NR	0(0)	NR
Kristensen 1984[135] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	1,150	0(0)	0(0)	NR
Carmody 1982[116] Case Series Moderate	Not Specified	Tonsillectomy (unspecified)	3,756 (1649 0-19 yrs)	NR	0(0)	NR

Studies of Perioperative or Postoperative Medications

Bleeding-Related Harms

Table H-10. Bleeding-related outcomes in comparative study arms evaluating perioperative medications

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
Steroid	**Mixed**								
	Gallagher 2012[136]	Dexamethasone, 0.5 mg/kg (injection)	154	17	2 (1)	NR	15 (9.7)	3 (1.9)	3 (1.9)
	Czarnetzki 2008[137]	Dexamethasone, 0.5 mg/kg (IV)	52	12	NR	NR	12 (24)	NR	4 (8)
	Czarnetzki 2008[137]	Dexamethasone, 0.05 mg/kg (IV)	53	6	NR	NR	6 (11)	NR	3 (6)
	Czarnetzki 2008[137]	Dexamethasone, 0.15 mg/kg (IV)	54	2	0	0	2 (4)	NR	1 (2)

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
	Hanasono 2004[138]	Cold tonsillectomy+ dexamethasone, 1 mg/kg (IV)	44	1	NR	NR	1 (2.3)	1 (2)	NR
	Aysenur 2014[139]	Dexamethasone sodium phosphate, 1 mg/kg (infiltration)	20	0	0	0	0	0	0
	Hermans 2012[140]	Dexamethasone, 0.15 mg/kg (IV)	46	0	NR	NR	0	NR	0
	Hermans 2012[140]	Dexamethasone, 0.5 mg/kg (IV)	44	0	NR	NR	0	NR	0
	Aouad 2012[141]	Methylprednisolone, 2.5 mg/kg (IV)	78	0	0	0	0	0	0
	Aouad 2012[141]	Dexamethasone, 0.5 mg/kg (IV)	75	0	0	0	0	0	0
	Hanasono 2004[138]	Hot tonsillectomy+ dexamethasone, 1 mg/kg (IV)	62	0	NR	NR	0	0	NR
	Unspecified								
	Elhakim 2003[142]	Dexamethasone, 0.5 mg/kg (IV)	55	0	NR	0	NR	NR	NR
	Alajmi 2008[143]	Dexamethasone, 1mg/kg (IV)	42	0	NR	0	NR	0	NR
	Kaan 2006[144]	Dexamethasone	32	0	NR	NR	NR	NR	0
NSAIDs	**Throat infection**								
	Abdel-Ghaffar 2015[145]	Lornoxicam in one tonsil , 8 mg (infiltration)	34	0	NR	NR	NR	0	0
	Unspecified								
	Solanki 2012[146]	Diclofenac, 2 mg/kg (rectal)	25	3	NR	NR	3 (12)	NR	NR
	Moss 2014[147]	Ibuprofen, 10 mg/kg (IV)	73	2	NR	NR	2 (3)	0	1 (1.4)
	Lee 2009[148]	Ketorolac, preoperative, 1 mg/kg (IV)	24	1	NR	NR	1 (4)	NR	NR
	Keidan 2004[149]	Ketoroloc, 1 mg/kg^{-1} (IV)	25	0	NR	NR	0	NR	NR
	Lee 2009[148]	Ketorolac, perioperative, 1	26	0	NR	NR	0	NR	NR

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
		mg/kg (IV)							
	Kedek 2005[150]	Ibuprofen, 10 mg/kg (oral)	20	0	NR	NR	0	NR	NR
Non-NSAID Analgesics	**Unspecified**								
	Lee 2009[148]	Propacetamol, perioperative, 30 mg/kg (IV)	26	0	NR	NR	0	NR	NR
	Keidan 2004[149]	Fentanyl, 2 $\mu g/kg^{-1}$(IV)	32	0	NR	NR	0	NR	NR
	Lee 2009[148]	Propacetamol, preoperative, 30 mg/kg (IV)	26	0	NR	NR	0	NR	NR
Anesthetic	**Mixed**								
	Aysenur 2014[139]	Levobupivacaine with epinephrine, ND (infiltration)	20	0	0	0	0	0	0
	Unspecified								
	Safavi 2012[146]	Bupivacaine (0.25%), 5 mL (infiltration)	25	4	NR	NR	4 (16)	NR	NR
Placebo	**Throat infection**								
	Abdel-Ghaffar 2015[145]	peritonsillar saline in other tonsil (infiltration)	34	0	NR	NR	NR	0	0
	Abdel-Ghaffar 2015[145]	bilateral peritonsillar saline (infiltration)	68	0	NR	NR	NR	0	0
	Mixed								
	Gallagher 2012[136]	placebo (saline), 0.5 mg/kg (injection)	151	13	2 (1)	NR	11 (7.3)	5 (3.2)	1 (0.6)
	Czarnetzki 2008[137]	Placebo (saline), NR (IV)	54	2	NR	NR	2 (4)	NR	0
	Hermans 2012[140]	Placebo (saline), 0.5 mL/kg (IV)	44	1	NR	NR	1 (2)	NR	1 (2)
	Hanasono 2004[138]	Cold tonsillectomy+placebo, 1 mg/kg (IV)	57	1	NR	NR	1 (1.8)	1 (1.8)	NR

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH	Primary PTH n (%)	Secondary PTH n (%)	Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
	Aysenur 2014[139]	Saline, ND (infiltration)	20	0	0	0	NR	0	0
	Hanasono 2004[138]	Hot tonsillectomy+placebo, 1 mg/kg (IV)	56	0	NR	NR	0	0	NR
	Unspecified								
	Alajmi 2008[143]	Placebo, 5 mL (IV)	38	3	NR	3 (7.9)	NR	3 (7.9)	NR
	Moss 2014[147]	Placebo (normal saline), 10 mg/kg (IV)	65	1	NR	NR	1 (2)	NR	0
	Elhakim 2003[142]	Placebo (saline), 0.5 mg/kg (IV)	55	0	NR	0	NR	NR	NR
	Kaan 2006[144]	Placebo (saline), 0.5 mg/kg (IV)	30	NR	NR	NR	NR	NR	0
Totals	**(N arms)**								
	All arms	NA	1839	69 (3.8)	4 (0.7)	3 (0.66)	51 (5.9)	13 (1.4)	14 (1.2)
	Steroids (14)	NA	811	38 (4.7)	2 (0.61)	0 (0)	36 (7.1)	4 (0.84)	11 (1.8)
	Placebo (12)	NA	672	21 (3.3)	2 (0.89)	3 (1.8)	16 (3.6)	9 (2.1)	2 (0.43)
	NSAIDs (7)	NA	227	6 (2.6)	NR	NR	5 (2.96)	0 (0)	1 (0.93)
	Anesthetics (2)	NA	45	4 (8.9)	0 (0)	0 (0)	4 (8.9)	0 (0)	0 (0)
	Non-NSAID Analgesics (3)	NA	84	0 (0)	NR	0 (0)	0 (0)	NR	NR

N=Number; NR=Not Reported; NSAID=Nonsteroidal Anti-Inflammatory Drug; PTH=Post-Tonsillectomy Hemorrhage

Table H-11. Bleeding-related outcomes in comparative study arms evaluating postoperative medications for pain

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH, n	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
NSAIDs	**Throat infection**								
	Stage 1988[151]	Acetylsalicylic acid (Oral, dose not specified)	423	18	5 (1.2)	13 (3.1)	NR	NR	8 (2)
	Mixed								
	Ozkiris 2012[152]	Ibuprofen, 30 mg/kg/day (Oral)	115	6	NR	NR	6 (5.21)	NR	1 (1)
	Unspecified								
	Murto 2015[153]	Celecoxib, 6 mg/kg preoperative and 3 mg/kg post-op (Oral)	141	8	NR	NR	8 (5.7)	8 (5.7)	3 (2.1)
Non-NSAID analgesics	**Throat infection**								
	Stage 1988[151]	Acetaminophen (Oral)	409	9	7 (1.7)	2 (0.49)	NR	NR	3 (1)
	Mixed								
	Ozkiris 2012[152]	Metamizole sodium, 0.4 mg/kg/day (Oral)	115	4	NR	NR	4 (3.47)	NR	0
	Ozkiris 2012[152]	Acetaminophen, 40 mg/kg/day (Oral)	110	4	NR	NR	4 (3.63)	NR	0
	Unspecified								
	Lalicevic et al. 2004[154]	Benzydamine hydrochloride oral rinse, 20 mg/kg (Oral)	138	6	NR	NR	6 (4.3)	NR	NR
Steroids	**Mixed**								
	Park 2015[155]	Prednisolone, 0.25 mg/kg/day (Oral)	69	2	NR	NR	2 (2.5)	NR	NR
	Macassey et	Prednisolone	91	11	NR	NR	11 (12)	1 (1)	NR

Drug class	Indication Author, Year	Intervention	Total Arm N	Total PTH, n	Primary PTH n (%)	Secondary PTH n (%)	Other/ Undefined PTH n (%)	Nonoperative Readmission or Revisit for PTH n (%)	Reoperation for PTH n (%)
	al. (2012)[156]	syrup, 0.5 mg/kg (Oral)							
Other	**Unspecified**								
	Lalicevic 2004[154]	Salvia officinalis oral rinse, 20 mg/kg (Oral)	140	6	NR	NR	6 (4.3)	NR	NR
No treatment/ Placebo	**Throat infection**								
	Macassey 2012[156]	Placebo syrup, 0.5 mg/kg (Oral)	102	13	NR	NR	13 (12)	1 (1)	NR
	Park 2015[155]	No Prednisolone	69	2	NR	NR	2 (2.5)	NR	NR
	Unspecified								
	Murto 2015[153]	Placebo	141	8	NR	NR	8 (5.7)	8 (5.7)	2 (1.4)
Totals	**(N arms)**								
	All arms (13)	NA	2063	97 (4.7)	12 (1.4)	15 (1.8)	70 (5.7)	18 (3.8)	17 (1.2)
	NSAIDs (3)	NA	679	32 (4.7)	5 (1.2)	13 (3.1)	14 (5.5)	8 (5.7)	12 (1.8)
	Non-NSAID analgesics (4)	NA	772	23 (3.0)	7 (1.7)	2 (0.49)	14 (3.9)	NR	3 (0.47)
	Steroids (2)	NA	160	13 (8.1)	NR	NR	13 (8.1)	1 (1.1)	NR
	Other (1)	NA	140	6 (4.3)	NR	NR	6 (4.3)	NR	NR
	No treatment/ Placebo (3)	NA	312	23 (7.4)	NR	NR	23 (7.4)	9 (3.7)	2 (1.4)

N=Number; NR=Not Reported; NSAID=Nonsteroidal Anti-Inflammatory Drug; PTH=Post-Tonsillectomy Hemorrhage

Other Harms

Table H-12. Revisits or readmissions for pain, dehydration, and PONV reported in comparative study arms addressing perioperative agents

Drug Class	Author	Perioperative Agent	Total Arm N	N Pain Revisits, (%)	N Dehydration Revisits, (%)	N PONV Revisits, (%)
Steroids	Gao[157]	Dexamethasone (IV)	78	0 (0)	NR	0
	Gao[157]	Dexamethasone (infiltration)	78	0 (0)	NR	0
	Hanasono[138]	Dexamethasone	61	NR	1 (1.6)	NR
	Alajmi[143]	Dexamethasone	42	0 (0)	0	0
	Elhakim[142]	Dexamethasone	20	0 (0)	0	0
NSAIDs	Oztekin[158]	Diclofenac	20	0 (0)	0	0
Anesthetic	*El-Fattah[159]	Propofol	80	0 (0)	0	0
Placebo/no agent	Hanasono[138]	Placebo	56	NR	0	NR
	Sukhani[160]	Placebo	49	NR	NR	ER or hospital admit for vomiting and poor oral intake 1 (2)
	Alajmi[143]	Placebo	38	Readmitted for throat pain/dysphagia 4 (10.5)	NR	NR
	Oztekin[158]	No perioperative agent	20	0 (0)	0	0
Totals	**(N arms)**					
	All arms (11)	NA	542	4 (1.1)	1 (0.33)	1 (0.26)
	Steroids (5)	NA	279	0	1 (1.6)	0
	NSAIDs (1)	NA	20	0	0	0
	Anesthetic (1)	NA	80	0	0	0
	Placebo (4)	NA	163	4 (6.9)	0	1 (1.4)

*Indication for surgery in these arms was throat infection; indication not specified in all other arms
N=Number; NR=Not Reported; NSAID=Nonsteroidal Anti-Inflammatory Drug

Rescue Medications

Table H-13. Need for rescue analgesics and anti-emetics reported in studies addressing perioperative medications

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
Steroids						
Gao 2015[157] RCT 5-10 low	G1: Intravenous dexamethasone, 0.5mg/kg (IV) (78) G2: Local infiltration dexamethasone, 0.5mg/kg (infiltration) (78) G3: Control (no dexamethasone)(79)	sharp dissection technique with cautery hemostasis	mCHEOPS score > 4 assessed by anesthesiologist Vomiting > 2 times in 2 minutes	From PACU to 24 hrs post-op	**Doses of IV fentanyl needed, mean(μg) ± SD** G1: 14.2 ± 12 G2: 9.4 ± 6.8 G3: 23.1 ± 17.5 **Number of patients needing 2nd injection of fentanyl,** G1: 9/44 (20.5) G2: 0/32 (0) G3: 17/60 (28.3) **Doses of IV metoclopramide, mean ± SD** G1: 1.9 ± 0.5 G2: 2.3 ± 0.9 G3: 4.1 ± 1.2	G1 vs. G3, p < 0.01 G2 vs. G3, p < 0.01 G1 vs. G2, p = 0.002 G1 vs. G3, p = NR G2 vs. G3, p = NR G1 vs. G2, p = NR G1 vs. G3, p < 0.001 G2 vs. G3, p < 0.001 G1 vs. G2, p < 0.001
Aysenur 2014[139] RCT 3-14 moderate	G1: Dexamethasone sodium phosphate, 1 mg/kg (infiltration) (20) G2: Levobupivacaine with epinephrine (infiltration) (20) G3: Saline	A standard dissection and snare technique	Upon Request NA	POD0 POD1	**Number of analgesic interventions needed (paracetamol suspension) – POD0,** G1: 2.5±0.5 G2: 2.8±0.3 G3: 3.5±0.5 **Number of analgesic interventions needed (paracetamol**	G1 vs. G2, p<0.05 G1 vs. G3, p<0.05 G2 vs. G3, p <0.05 G1 vs. G2, p<0.05 G1 vs. G3, p<0.05

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
	(infiltration) (20)				**suspension) – POD1,** G1: 2±0.3 G2: 2.6±0.5 G3: 3.3±0.4	G2 vs G3, p = ns
				POD2	**Number of analgesic interventions needed (paracetamol suspension) – POD2,** G1: 1.9±0.3 G2: 2.5±0.5 G3: 3.2±0.4	G1 vs. G2, p<0.05 G1 vs. G3, p<0.05 G2 vs G3, p < 0.05
				POD3	**Number of analgesic interventions needed (paracetamol suspension) – POD3,** G1: 1.9±0.3 G2: 2.4±0.6 G3: 3.1±0.3	G1 vs. G2, p<0.05 G1 vs. G3, p<0.05 G2 vs G3, p < 0.05
				POD7	**Number of analgesic interventions needed (paracetamol suspension) – POD7,** G1: 1.4±0.6 G2: 2.2±0.4 G3: 2.6±0.4	G1 vs. G2, p<0.05 G1 vs. G3, p<0.05 G2 vs G3, p < 0.05

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
Faiz 2013[161] RCT 4-13 moderate	G1: Dexamethasone, 0.1 mg/kg (IV) (42) G2: Acetaminophen, 15 mg/kg (IV) (42)	Unspecified tonsillectomy	Objective pain score ≥5 Appearance of vomiting	post-op (Ward)	**N needing IV meperidine (mg), (%)** G1: 7 (17) G2: 5 (12) **N needing IV ondansetron (mg), (%)** G1: 0 (0) G2: 1 (2)	G1 vs. G2, p = 0.533 G1 vs. G2, p = 0.314
Hermans 2012[140] RCT 2-18 low	G1: Dexamethasone, 0.15 mg/kg (IV) (46) G2: Dexamethasone, 0.5 mg/kg (IV) (44) G3: Placebo (saline), 0.5 mL/kg (IV) (44)	Cold dissection	CHEOPS score >7 or VAS score ≥3 Vomiting and/or retching without expulsion of gastric content	From PACU until discharge from hospital	**N needing IV morphine (µg), (%)** G1: 20 (43.5) G2: 16 (36) G3: 23 (52) **N needing IV tramadol (mg), (%)** G1: 17 (37) G2: 18 (40) G3: 23 (52) **N needing IV alizapride (mg), (%)** G1: 5 (10.9) G2: 5 (11.4) G3: 22 (50) **N needing IV tropisetron (mg), (%)** G1: 1 (2.2) G2: 1 (2.3) G3: 3 (7)	G1 vs. G2 vs. G3, p = 0.321 G1 vs. G2 vs. G3, p = 0.331 G1 vs. G2 vs. G3, p = 0.005 G1 vs. G2 vs. G3, p = 0.578
Aouad 2012[141] RCT 2-12 low	G1: Methylprednisolone, 2.5 mg/kg (IV) (78) G2: Dexamethasone, 0.5 mg/kg (IV) (75)	Electrocautery	Wong-Baker faces pain score >6 Upon request	From PACU to 24 hrs post-op From PACU to 24 hrs post-op	**N needing single dose of IV morphine (mg), (%)** G1: 3 (3.8) G2: 3 (4) **Doses of IV paracetamol (mg), median (range)**	G1 vs. G2, p = NR G1 vs. G2, p = 0.26

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
			Recurrent vomiting >2 episodes less than 5 minutes apart	From PACU to 24 hrs post-op	G1: 2 (0-4) G2: 3 (1-4) **N needing IV ondansetron (mg), (%)** G1: 1 (1) G2: 2 (3)	G1 vs. G2, p = 0.62
Khani 2009[162] RCT 4-12 low	G1: Dexamethasone, 0.5 mg/kg (IV) (33) G2: Placebo (saline), 0.5 mg/kg (IV) (33)	Unspecified tonsillectomy with or without adenoidectomy	"Faces" pain scale (unspecified) Vomiting > 2 times	8 hrs post-op PACU	**Patients needing IV morphine (µg),** G1: 5 (15.1) G2: 16 (48.4) **Patients needing IV metoclopramide (mg),** G1: 6 (18.1) G2: 17 (51.5)	G1 vs. G2, p < 0.05 G1 vs. G2, p <0.001
Alajmi 2008[143] RCT 5-18 moderate	G1: Dexamethasone, 1mg/kg (IV) (42) G2: Placebo, 5 mL (IV) (38)	Cold dissection	When patient complained of pain Vomiting > 2 times	PACU to 24 hrs post-op 6 hrs post-op	**Patients needing oral Profinal (mg),** G1: 6 (14) G2: 18 (47) **N needing oral metoclopramide (mL), (%)** G1: 2 (4.8) G2: 25 (65.8)	G1 vs. G2, p = 0.001 G1 vs. G2, p<0.001
Czarnetzki 2008[137] RCT 2-17 moderate	G1: Dexamethasone, 0.05 mg/kg (IV) (53) G2: Dexamethasone, 0.15 mg/kg (IV) (54) G3:	Total tonsillectomy with dissection (cold dissection, hot dissection, or combination)	VAS pain score ≥ 3, CHEOPS pain score ≥8, revised Faces Pain Scale ≥3 Unspecified	PACU Within 24 hrs post-op	**N needing IV morphine (mg) in PACU, (%)** G1: 42 (78) G2: 36 (79) G3: 37 (67) G4: 42 (78) **N needing oral ibuprofen (mg), (%)** G1: 20 (38) G2: 23 (43)	G1 vs. G2 vs. G3 vs. G4, p = 0.42 G1 vs. G2 vs. G3 vs. G4, p = 0.01

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
	Dexamethasone, 0.5 mg/kg (IV) (52) G4: Placebo (saline) (IV) (54)			Within 24 hrs post-op	G3: 20 (38) G4: 35 (65) **N needing IV ondansetron (µg), (%)** G1: 4 (8) G2: 3 (5.6) G3: 2 (4) G4: 11 (20)	G1 vs. G2 vs. G3 vs. G4, p = 0.04
Kim 2007[163] RCT 2-7 moderate	G1: Dexamethasone, 0.0625 mg/kg (IV) (24) G2: Dexamethasone, 0.125 mg/kg (IV) (25) G3: Dexamethasone, 0.25 mg/kg (IV) (23) G4: Dexamethasone, 0.5 mg/kg (IV) (25) G5: Dexamethasone, 1 mg/kg (IV) (24)	Electrocautery	Objective pain score ≥6 for 2 consecutive 5 minute intervals or if the patients articulated that their throat hurt NA	0-24 hours post-op	**Need for IV morphine (mg) (up to 24 hrs),** G1: NR G2: NR G3: NR G4: NR G5: NR	G1 vs. G2 vs. G3 vs. G4 vs. G5, p > 0.05
Kaan 2006[144] RCT 4-12 low	G1: Dexamethasone, 0.5 mg/kg (IV) (32) G2: Placebo (saline), 0.5 mg/kg	Cold dissection	"Faces" scale pain score >3 Retching or vomiting more than once in 3	PACU 2 hrs post-op	**N needing IV meperidine (mg), (%)** G1: 8 (25) G2: 12 (40) **N needing oral paracetamol (mg, 2**	G1 vs G2, p = NR G1 vs G2, p = NR

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
	(IV) (30)		minutes If vomiting was not under control in 20 minutes, ondansetron was given		**hrs), (%)** G1: 6 (19) G2: 4 (13)	
				3 hrs post-op	**N needing oral paracetamol (mg, 3 hrs), (%)** G1: 11 (34) G2: 17 (57)	G1 vs G2, p = NR
				4 hrs post-op	**N needing oral paracetamol (mg, 4 hrs), (%)** G1: 12 (38) G2: 7 (23)	G1 vs G2, p = NR
				5 hrs post-op	**N needing oral paracetamol (mg, 5 hrs), (%)** G1: 3 (9) G2: 2 (7)	G1 vs G2, p = NR
				1-8 hrs post-op	**N needing IV ondansetron (mg), (%)** G1: 0 (0) G2: 0 (0)	G1 vs G2, p = NR
				1-8 hrs post-op	**N needing IV metoclopramide (mg), (%)** G1: 6 (19) G2: 10 (33)	G1 vs G2, p = NR
Samarkandi 2004[164] 2-12 moderate	G1: Dexamethasone, 0.5 mg/kg (IV) (29) G2: Placebo (normal saline), 0.5 mg/kg (IV) (31)	Electrocautery	Unspecified (Rectal acetaminophen given to all children) Vomiting occurring less than 5 minutes apart or with persistent distressing emetic symptoms (Early=PACU,	PACU	**N needing suppository acetaminophen (mg, immediate), (%)** G1: 10 (37) G2: 17 (54.8)	**Need for analgesia,** G1 vs G2, p = 0.275
				Ward	**N needing suppository acetaminophen (mg, late), (%)**	

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
			Late=Ward)	PACU	G1: 17 (63) G2: 14 (45.1) **N needing IV metoclopramide (mg), (%)** G1: 7 (24.1) G2: 15 (48.4)	G1 vs G2, p =0.09
Elhakim 2003[142] RCT 4-11 low	G1: Dexamethasone, 0.5 mg/kg (IV) (55) G2: Placebo (saline), 0.5 mg/kg (IV) (55)	Electrocautery	CHEOPS pain score >7 or children who were crying during two consecutive five-minute observation periods until the child was comfortable More than two episodes of vomiting (repeatedly one to two minute period)	PACU to 24 hrs post-op	**Doses of IV pethidine needed, mean(mg) ± SD** G1: 0 ± 0 G2: 0.6 ± 0.1 (n=9) **Patients needing IV metoclopramide (mg, early), n (%)** G1: 6 (11) G2: 2 (4) **Patients needing IV metoclopramide (mg, late), n (%)** G1: 6 (11) G2: 0 (0) **Total patients needing IV metoclopramide (mg), n (%)** G1: 2 (4) G2: 12 (22)	G1 vs G2, p = NR G1 vs. G2, p < 0.001
NSAID						
Moss 2014[147] RCT 6-17 moderate	G1: Ibuprofen, 10 mg/kg (IV) (73) G2: Placebo (normal saline), 10 mg/kg (IV) (65)	Electrocautery	VAS pain score rating >30 mm NA	PACU PACU	**Doses of IV fentanyl needed, mean (µg doses) ± SD** G1: 1.6±1.3 G2: 1.9±1.06 **N needing IV fentanyl (µg), (%)** G1: 61 (84)	G1 vs. G2, p = 0.021 G1 vs. G2, p = 0.068

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
				24-28 hrs post-op	G2: 61 (94) **N needing more than 1 dose of IV fentanyl (µg), (%):** G1: 31 (42) G2: 40 (62)	G1 vs. G2, p=0.028
Abdel-Ghaffar 2012[165] RCT 8-18 moderate	G1: IV lornoxicam, 8 mg (20) G2: Infiltration lornoxicam, 8 mg (20) G3: Placebo (saline), 12 mL (20)	Unspecified tonsillectomy	VRS pain score ≥2 NA	Within 24 hrs post-op	**Doses of injection diclofenac needed, mean(mg) ± SD** G1: 44.73 ± 9.31 G2: 69.8 ± 38.71 G3: 87.8 ± 24.4 **N needing 3 rescue doses of injection diclofenac (%):** G1: 0 (0) G2: 9 (45) G3: 12 (60)	G1 vs. G3, p < 0.000 G2 vs. G3, p = NS G1 vs. G2, p < 0.009 G1 vs. G3: p=0.000 G2 vs G3: NS G1 vs. G2: p=0.01
Solanki 2012[146] RCT 1-15 moderate	G1: Diclofenac, 2mg/kg (rectal) (25) G2: Bupivacaine (0.25%), 5 mL (instillation) (25)	Unspecified tonsillectomy	NA Unspecified	PACU to 24 hrs post-op	**Patients needing injection ondansetron (units),** G1: 2 (8) G2: 2 (8)	G1 vs G2, p = NR
Yegane Moghaddam 2012[166] RCT 10-25 low	G1: Diclofenac, 1.0 mg/kg (rectal) (30) G2: Gabapentin, 20 mg/kg (oral) (30) G3: Placebo (30)	Unspecified tonsillectomy	Pain felt in recovery room or ward and VAS pain score >4 NA	PACU and Ward	**Doses of injection meperidine, mean(mg) ± SD** G1: 16.66 ± 8.95 G2: 14.16 ± 6.97 G3: 33.4 ± 13.97	G1 vs. G3, p = 0.004 G2 vs. G3, p = 0.001 G1 vs. G2, p=0.59
Rhendra 2010[167] 5-12 moderate	G1: Sodium diclofenac, 1 mg/kg (rectal) (65) G2: Viscous lignocaine, 2%, 4	Cold dissection	Patient complained of intolerable pain and VAS score (0-100 mm) assessment (unspecified)	0.5 hrs post-op 2 hrs post-op	**Doses of IV pethidine needed 0.5 hrs post-op, mean(units) ± SD** G1: 0.16 ± 0.13 G2: 0 ± 0 **Doses of IV pethidine**	G1 vs. G2, p = 0.301 G1 vs. G2, p = 0.023

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
	mg/kg (topical) (65)		NA		**needed 2 hrs post-op, mean(units) ± SD** G1: 0.11 ± 0.32 G2: 0.02 ± 0.12	
				12 hrs post-op	**Doses of IV pethidine needed 12 hrs post-op, mean(units) ± SD** G1: 0.46 ± 0.59 G2: 0.65 ± 0.59	G1 vs. G2, p = 0.061
				24 hrs post-op	**Doses of IV pethidine needed 24 hrs post-op, mean(units) ± SD** G1: 0.11 ± 0.22 G2: 0.25 ± 0.53	G1 vs. G2, p = 0.068
Antila 2006[168] RCT	G1: ketoprofen, 2 mg/kg (IV) (15) G2: tramadol, 1 mg/kg (IV) (15) G3: placebo (saline), (IV) (15)	Standard adenotonsillectomy	On patient demand	0 to 24 hrs post-op	**N needing fentanyl mean ±SD,** G1: 5.5 ± 5 G2: 7.6 ± 7.1 G3: 9.4 ± 10	G1 vs. G2, p = 0.035 G1 vs G3, p = 0.049 G2 vs G3, p=NR
Bhattacharya 2005[169] RCT 8-12 moderate	G1: Diclofenac, 2 mg/kg (rectal) (25) G2: Pethidine, 0.5 mg/kg (IV) (25)	Unspecified tonsillectomy or adenoidectomy	VAS score > 40 mm or on patient demand NA	Ward (1 hr post-op to following morning)	**Doses of oral paracetamol needed, mean(mg) ± SD** G1: 350 ± 0.2 G2: 500 ± 0.5 **N needing 2nd dose of rescue oral paracetamol (mg) (%)** G1: 5 (20) G2: 6 (24)	G1 vs G2, p <0.05 G1 vs. G2: p=NR
Kedek 2005[150] 5-12 moderate	G1: Ibuprofen syrup, 10 mg/kg (20) G2: Lidocaine infiltration, 0.5%, 10 mg/kg (20)	Unspecified adenotonsillectomy	VAS score >4 NA	1 hrs post-op – 6 hrs post-op	**Doses of syrup paracetamol needed, mean(mg doses) ± SD** G1: 4.1 ± 1.41 G2: 3.8 ± 1.15	G1 vs G2, p = ns

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
Oztekin 2002[158] RCT 5-14 moderate	G1: Diclofenac, 1 mg/kg (rectal) (20) G2: No Rx (20)	Unspecified tonsillectomy with or without adenoidectomy	Children had any throat pain (unspecified) NA	PACU WARD (PACU+WARD)	**Doses of infusion morphine (µg) needed in PACU, mean (SD)** G1: 130.33 ± 11.26 G2: 169.92 ± 9.22 **Doses of infusion morphine (µg) needed in Ward, mean (SD)** G1: 50.80 ± 11.38 G2: 87.77 ± 10.55 **Total doses of infusion morphine (µg) needed, mean (SD)** G1: 181.13 ± 19.15 G2: 257.68 ± 16.04	G1 vs. G2, p = 0.012 G1 vs. G2, p = 0.021 G1 vs. G2, p = 0.009
Anti-emetics						
Bolton 2007[170] 6 mos-12 years low	G1: Odansetron, 0.1 mg/kg (injection) (273) G2: Metoclopramide, 0.5 mg/kg (injection) (284)	Unspecified tonsillectomy with or without adenoidectomy	Post-op every four hours (P.R.N.) NA	post-op (unspecified)	**Doses of oral codeine needed, mean(mg) SD** G1: 1.4 ± 1.5 G2: 1.7 ± 1.7	G1 vs G2, p = NR
Fujii 2003[171] RCT 4-10 low	G1: Ramosetron, 3 µg/kg (IV) (20) G2: Ramosetron, 6 µg/kg (IV) (20) G3: Ramosetron, 12 µg/kg (IV) (20) G4: Placebo, NR	Unspecified tonsillectomy with or without adenoidectomy	NA Retching and/or vomiting ≥2 episodes within 48 hours	PACU-48 hrs post-op	**N needing IV metoclopramide (mg), (%)** G1: 5 (25) G2: 0 (0) G3: 0 (0) G4: 5 (25)	G1 vs. G4, p = ns G2,G3 vs. G4, p=0.024

Author, Year Study Design Age range	Intervention Groups (N)	Surgical Technique	Criteria for using rescue analgesia/rescue anti-emetics	Assessment Timepoint	Rescue Analgesic Needed, N (%) or mean ± SD Rescue Anti-emetic Needed, N (%) or mean ± SD	Group Differences
	(IV) (20)					
Holt 2000[172] RCT 2-14 low	G1: Tropisetron, 0.2 mg/kg – 5 mg/kg (IV) (35) G2: Placebo (IV) (36)	Unspecified tonsillectomy or adenotonsillectomy	NA Vomiting >2 times and clinician discretion	PACU-24 hrs post-op	**Patients needing IV metoclopramide (mg),** G1: 1 (3) G2: 12 (33)	G1 vs G2, p <0.01

G = Group; hrs= Hours; IV = Intravenous; kg = Kilograms; mCHEOPS = modified Eastern Ontario Children's Hospital Pain Scale; mg = Milligrams; N= Number; NA = Not Applicable; NR = Not Reported; NS = Not Significant; PACU = Post-Anesthesia Care Unit; POD = Post-Op Day; PRN = As Needed ("pro re nata"); RCT = Randomized Controlled Trial; SD = Standard Deviation; µg = Micrograms; VAS = Visual Analog Scale; VRS = Visual Rating Scale

Table H-14. Time to return to normal activity associated with perioperative medications

Author, Year Age Study Design RoB	Drug Class	Intervention	Time to return to normal activity, n/N (%) or mean ± SD (n)	Outcome measure (e.g., mean days)
Giannoni et al. (2002)[173] 3-15 RCT moderate	Perioperative steroid + analgesics	Dexamethasone and ropivacaine + clonidine, 1.0 mg/kg (IV) and 0.15 mL/kg + 1 ug/kg	Time to return to normal activity, 7.74 ± 2.49 (25)	Mean days
Giannoni et al. (2002)[173] 3-15 RCT moderate	Placebo + analgesics	Placebo (saline) and ropivacaine + clonidine, 0.25 mL/kg (IV) and 0.15 mL/kg + 1 ug/kg	Time to return to normal activity, 6.38 ± 2.24 (25)	Mean days

IV = intravenous; RCT = Randomized Controlled Trial; µg = Micrograms

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Appendix I. Summary of Existing Systematic Reviews

Table I-1. Existing reviews of surgical interventions for OSDB/SDB (7 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
Song et al. 2016[1]	Tonsillectomy or Adenotonsillectomy (T&A); OSA in children	• Children <18 years • Prospective studies • Literature search database inception to 2015 • Included studies published 1996 to 2014	• Neurocognitive function • AHI	19 studies with 898 children	• There was a reduction in AHI after T&A in children with SDB across studies • Improvement in neurocognitive function and IQ after T&A • Decreased effectiveness of T&A in older children suggests a threshold age when neurocognitive deficits become irreversible
De Luca Canto et al. 2015[2]	Adenotonsillectomy (AT); OSA in children	• Children 0 to 18 years • Clinical studies with postop evaluation within 3 weeks after AT • Literature search up to 2015 • Included studies published 1987 to 2015	• Postop complications that required intervention including respiratory, hemorrhage, pain, NV, refusal to drink, inadequate oral intake, dehydration, fever, dysphagia, cardiac	23 studies with 13537 children	• Most frequent postop complication was respiratory compromise at 9.4% followed by secondary hemorrhage at 2.6% and primary hemorrhage at 2.4% • Children with OSA have 5 times more respiratory complications after AT than children without OSA (across only 4 studies with 9394 children) • Bleeding is more likely to occur among children without OSA compared to children with OSA (across only 4 studies with 9394 children)
Lee et al. 2015[3]	Adenotonsillectomy (T&A); OSA in obese and non-obese children	• Children <18 years • Obese and non-obese children with OSA • RCTs, retrospective observational case series, NRCTs • Literature search published up to 2014 • Included studies 1994 to 2014	• PSG parameters • Residual OSA postop	51 studies with 3413 children	• Residual OSA remained in ~1/2 the children especially those with severe OSA and obesity after T&A • Postop improvements in non-obese exceeded obese children • Postop T&A saw increased sleep efficiency, slow wave sleep, oxygen saturation, spontaneous arousals

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
					• Postop T&A saw decreased REM and non-REM AHI, number and severity of respiratory events, and total arousals • T&A postop saw a prominent decrease in AHI by 12.4 events/hr
Van et al. 2015[4]	Adenotonsillectomy (T&A); OSA in children	• Children 0 to 14 years • Children with OSA • RCTs, observational • Literature search 1995 to 2014 • Included studies published	• BMI • Weight percentiles	6 studies with 729 children	• Evidence for significant weight gain in short term following T&A in children with OSA regardless of initial weight status
Venekamp et al. 2015[5]	Tonsillectomy or adenoidectomy; OSDB in children	• Children 2 to 16 years with OSDB • RCTs • Literature search from database inception to 2015 • Included studies published 2004 to 2014	Primary • Disease-specific quality of life • Adverse events, complications and morbidity • Intraoperative and postoperative bleeding • Postoperative infection, dehydration, and pain Secondary • Generic quality of life • Respiratory events • Cardiovascular complications • Neurocognitive performance, attention, behavior, school performance, absence from school and weight changes	3 studies with 562 children Study 1: 453 children with mild to moderate OSAS (adenotonsillectomy vs. no surgery) Study 2: 29 children with symptoms/signs of OSDB (adenotonsillectomy vs. no surgery) Study 3: 80 children with Down Syndrome or mucopolysaccharidosis and mild to moderate OSAS (adenotonsillectomy vs. CPAP)	• Only 3 included studies • Disease-specific QoL mean scores were lower (better or fewer symptoms) at 7 months after adenotonsillectomy compared to watchful waiting in one study (CHAT Trial) • Mean OSAS QoL at 12 months did not differ significantly between adenotonsillectomy vs. CPAP(Sudarsan Trial) • Mean ESS score did not differ at 6 months, but was lower in adenotonsillectomy group at 12 months in one study (Sudarsan Trial) • 15 children (3%) had a serious adverse event (CHAT Trial)
Walton et al.	Intracapsular	• Children <16 years	• Postop pain	16 studies with	• Secondary hemorrhage rate

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
2015[6]	tonsillectomy or Total tonsillectomy; SDB in children	• Children with SDB • RCTs • Included studies published 1999 to 2010	• Analgesic use • Recovery time • Diet • Bleeding rate • Infection • Regrowth rate requiring further surgical intervention	1312 participants (699 in the partial tonsillectomy group and 635 in the TT group)	and number of days until pain free were superior in the IT group than the TT group • Formal meta-analysis was not conducted due to lack of raw data reporting within individual studies
Wang et al. 2015[7]	Tonsillectomy or Tonsillotomy; SDB in children	• Children birth to 18 years • Sleep disordered breathing • Studies compared tonsillotomy and tonsillectomy directly • Prospective studies • Literature search up to 2014 • Included studies published 1999 to 2014	• Operation time, secondary postop bleeding, pain-free days, PSG outcomes, QoL, immune function, rate of SBD recurrence	10 studies with 1029 children	• Tonsillotomy had lower hemorrhage rate, shorter operation time, and more pain-free days over tonsillectomy • No significant difference in QoL, Postop immune function, and resolving obstructive symptoms

AHI= Apnea Hypopnea Index ; BMI=Body Mass Index; CPAP=Continuous Positive Airway Pressure; OSA=Obstructive Sleep Apnea; OSAS= Obstructive Sleep Apnea Syndrome ; PSG=Polysomnography; QoL=Quality of Life; RCT=Randomized Controlled Trials; SDB=Sleep Disordered Breathing; TT=Total Tonsillectomy

Table I-2. Existing reviews of surgical interventions for tonsillitis/throat infections (2 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
Burton et al. 2014[8]	Tonsillectomy or adenotonsillectomy; Chronic/recurrent acute tonsillitis	• Children and adults with diagnosed recurrent acute tonsillitis or chronic tonsillitis • RCTs • Literature search up to 2014 • Included studies with children published 1984 to 2010	Primary • Number/severity of episodes of tonsillitis/sore throat • Number of days with sore throat • Morbidity/mortality of surgery (include complications and no. days with postop pain from surgery) Secondary • Consumption of antibiotics, analgesics • Absence/time off work/school • QoL	5 studies with 987 children only; 3 studies with 196 adults only	• Demonstrated moderate reduction in number of episodes of sore throat during first year postop
Georgalas et al. 2014[9]	Tonsillectomy; Acute recurrent or Chronic throat infections	• RCTs, Published systematic reviews of RCTs • Literature search 1966 to 2014 • Included SRs published 2001 to 2010	• Episodes of tonsillitis or sore throat • Time off school or work • Surgery: bleeding (intraoperative and postop) • Surgery: postop pain (includes analgesia use)	15 studies/SRs	• Findings that tonsillectomy is more beneficial in children with severe symptoms, and only modestly beneficial for children with low incidence of tonsillitis • Diathermy is associated with reduced rates of primary bleeding, but increased rates of secondary bleeding

RCT=Randomized Controlled Trials; SR=Systematic Review

Table I-3. Existing reviews of surgical approach or technique (5 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
Acevedo et al. 2012[10]	Tonsillotomy or Tonsillectomy	• Children and adults • RCTs, Observational • Literature search 2010 to 2011 • Included studies published 1999 to 2010	Primary • Postop bleeding rate • Rate of dehydration requiring medical care Secondary • Days of analgesic use • Days to return to normal diet • Est. intraoperative blood loss	39 studies with 14707 children and adults	• Tonsillotomy had lower postop bleeding rate, postop dehydration rate requiring medical care, reduced days of analgesic use, and reduced days to return to normal diet • No clinically significant difference in intraoperative blood loss • Subgroup analysis suggests that coblation technique confers more of an advantage than microdebrider for postop complications • Data not sufficient to assess tonsil regrowth rates
Jeyakumar et al. 2011[11]	Adenotonsillectomy (T&A) or Tonsillectomy	• Children 0 to 10 years • Children of normal weight or overweight • Prospective studies • Literature search 1970 to 2009 • Included studies published 1988 to 2009	• Postop BMI vs. control group BMI • % of weight gain greater than expected postop • Change in weight pre-op to postop	9 studies with 795 children	• A large number of normal weight and overweight children gained a greater than expected amount of weight after T&A
Alexiou et al. 2011[12]	Tonsillectomy (Vessel Sealing Systems (VSS) (e.g., LigaSure Vessel Sealing System,Thermal Welding System,BiClamp)) or Harmonic Scalpel or Coblation (e.g., Cold Steel (CS), Electrocautery Dissection (EC))	• Children and Adults • RCTs • Literature search database inception to 2010 • Included studies published 2001 to 2011	• Operative time • Intraoperative and Postop bleeding (primary and secondary) • Postop pain	33 studies with 3139 patients (11 studies with children only; 8 studies with adults only; 14 studies with mixed population)	• VSS group postop bleeding was significantly less than Conventional techniques in 792 patients • Postop pain was significantly less on the 1st and 7th days in the VSS group in 740 patients • No difference in outcomes between Coblation and CS/EC groups • Included studies with weak evidence maintaining a lower threshold for inclusion in meta analysis
Mösges et al. 2011[13]	Tonsillectomy (Coblation)	• Children and Adults • RCTs, prospective studies	• Postop hemorrhage (primary and	24 studies with 796 patients (461	• Postop hemorrhage rate for children is 2.9%

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
		• Literature search dates NR • Included studies published 2001 to 2009	secondary)	children and 335 adults)	• Primary hemorrhage rate for children was 1% and secondary hemorrhage rate was 6.2% postop
Pinder et al. 2011[14]	Tonsillectomy (Dissection or Diathermy)	• Children and Adults • RCTs • Literature search from 1966 to 2010 • Included studies published 1997 to 2000	Primary • Intraoperative blood loss • Primary and secondary hemorrhage Secondary • Pain control with need of analgesia and use of validated pain scores • Time before resuming normal activities • Operating time	2 studies with 254 children and adults	• No difference in rate of secondary postop bleeding overall • Studies demonstrated increased pain in diathermy group compared to dissection group

CS=Cold Steel, EC=Electrocautery Dissection, RCT=Randomized Controlled Trials; T&A= Adenotonsillectomy, VAS=Visual Analog Scale, VSS= Vessel Sealing Systems

Table I-4. Existing reviews of perioperative medications (9 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
Bellis et al. 2014[15]	Dexamethasone (Tonsillectomy)	• Children up to 18 years • RCTs and quasi-RCTs • During perioperative period (24 hrs prior, during procedure, or 24 hrs postop) • Included studies published 1991-2012	• Hemorrhage rate	61 studies with 13933 children	• No significant increase in risk of post-tonsillectomy hemorrhage • Clinical heterogeneity was noted across studies • Inadequate evidence due to majority of studies not designed to investigate post-tonsillectomy hemorrhage with use of dexamethasone • Overall ROB was high or unclear for all RCTs
Plante et al. 2012[16]	Dexamethasone or Prednisolone (Tonsillectomy)	• Adults and children • RCTs • Literature search 1947 to 2011 • Included studies published	Primary • Incidence of postop bleeding Secondary • Incidence of admission for	29 studies with 2674 patients (19 studies with children only, 6 studies with adults only, 4 studies	• Administration of steroids did not increase the incidence of bleeding postop • The incidence of admission due to bleeding did not increase in steroid group compared to

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
		1991 to 2011	bleeding episodes • Operative interventions for bleeding episodes • Red blood cell transfusion • Mortality	included mixed population)	control group • The incidence for operative re-intervention for bleeding was significantly increased in the steroid group compared to control group; with a significant increase of re-interventions in children (8 studies) but not in adults (4 studies) • No dose effect was observed • Dexamethasone was used in 28 studies and Prednisolone used in 1 study
Shargorodsky et al. 2012[17]	Dexamethasone (Tonsillectomy or Adenotonsillectomy)	• Children ≤18 years • RCTs • Dexamethasone administration preop or intraoperatively • Literature search from 1990 to 2010 • Included studies published 1991 to 2009	• Primary and secondary hemorrhage	12 studies with 1180 children	• No significant association between dexamethasone at any dose and bleeding compared to placebo • No significant association between increasing dosage and bleeding • Doses on 0.4 to 0.6 mg/kg showed significantly increased odds of bleeding compared to placebo
Geva et al. 2011[18]	Dexamethasone (Tonsillectomy)	• Children and Adults • RCTs • Literature search up to 2009 • Included studies published 1991 to 2008	• Intraoperative and postop bleeding • Bleeding requiring reoperation	14 studies with 1429 children and adults (11 studies with 1166 children only, 3 studies with 263 adults only)	• No significant increase in postop bleeding between patients receiving dexamethasone and control patients across mixed population • Younger patients receiving dexamethasone resulted in a statistically nonsignificant decrease in the risk of postoperative bleeding
Steward et al. 2011[19]	Dexamethasone (Tonsillectomy)	• Children 9 months to 18 years • RCTs • Literature search up to 2010 • Included studies published 1991 to 2009	• Number of children experiencing emesis during 24 hrs postop • Number of children return to solf/solid diet by day 1 postop • Pain at 24 hrs	19 studies with 1756 children	• ROB in included studies was not formally assessed • Statistically significant reduction in emesis during the 1st 24 hrs postop compared to placebo group • Statistically significant increase

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
			measured by VAS		in the number of children return to soft/solid diet 1 day postop compared to placebo • Statistically significant improvement in postop pain compared to placebo using VAS as measurement
Chan et al. 2014[20]	Ketorolac (NSAID) (Tonsillectomy)	• Children and Adults • RCTs, retrospective case-control studies • Literature search from 1970 to 2013 • Included studies published 1995 to 2004	• Postop hemorrhage	10 studies with (7 studies with children only, 2 studies with mixed population, 1 study adults only)	• Children under 18 are not at statistically significantly increased risk for postop hemorrhage with ketorolac use
Lewis et al. 2013[21]	NSAIDs (Tonsillectomy or Adenotonsillectomy)	• Children up to and including 16 years • RCTs • Literature search from database inception to 2012 • Included studies published 1995 to 2011	• Bleeding • Postop complications	15 studies with 1101 children	• Use of NSAIDs was associated with a non-significant increase in the risk of bleeding requiring surgical intervention • NSAIDs did not significantly alter the number of perioperative bleeds requiring non-surgical intervention • NSAIDs benefit a reduction of vomiting • Insufficient evidence to exclude an increased risk of bleeding when NSAIDs are used
Riggin et al. 2013[22]	NSAIDs (Tonsillectomy)	• Children and adults who underwent tonsillectomy • RCTs • Literature search from database inception to 2012 • Included studies published 1984 to 2012	• Postop hemorrhage • Secondary hemorrhage • Bleeding requiring readmission, reoperation, or tranexamic acid	36 studies with 1747 children and 1446 adults	• No increased risk of bleeding in those using NSAIDs after tonsillectomy • Use of NSAIDs in children was not associated with increased risk of general bleeding, most severe bleeding, secondary hemorrhage, readmission or need of reoperation due to bleeding • In pediatrics population, overall odds ratio of bleeding was lower than general population (including adults) and not

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
					significant
Dhiwakar et al. 2012[23]	Antibiotics (Tonsillectomy or Adenotonsillectomy)	• Children and adults undergoing tonsillectomy or adenotonsillectomy • RCTs • Antibiotic administration 48 hrs pre-op, intraoperatively, postop • Literature search from database inception to 2012 • Included studies published 1986 to 2008	• Pain • Consumption of analgesia • Secondary hemorrhage • Fever • Time to resume normal diet/activities • Adverse events (e.g., rash, anaphylaxis, candidiasis, diarrhea)	10 studies with 1035 children and adults	• No evidence to support clinically important impact of antibiotics in reducing pain , need for analgesia, and secondary hemorrhage rates • No significant reduction in pain with antibiotics • Mostly not shown to be effective in reducing need for analgesics • Not associated with reduction in significant secondary hemorrhage rates • Antibiotics reduced the proportion of patient with fever

AHI=Apnea-Hypopnea Index, AT=Adenotonsillectomy, CPAP= Continuous positive airway pressure, CS=Cold Steel, EC=Electrocautery Dissection, ESS=Epworth Sleepiness Scale, NSAIDs=Non-steroidal anti-inflammatory drugs, OSDB=Obstructive sleep-disordered breathing, QoL=Quality of life, RCTs=Randomized controlled trials, ROB=Risk of bias, RR=Pooled Relative Risk, SBD=Sleep disordered breathing, T&A= Adenotonsillectomy, VAS=Visual Analog Scale, VSS= Vessel Sealing Systems

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