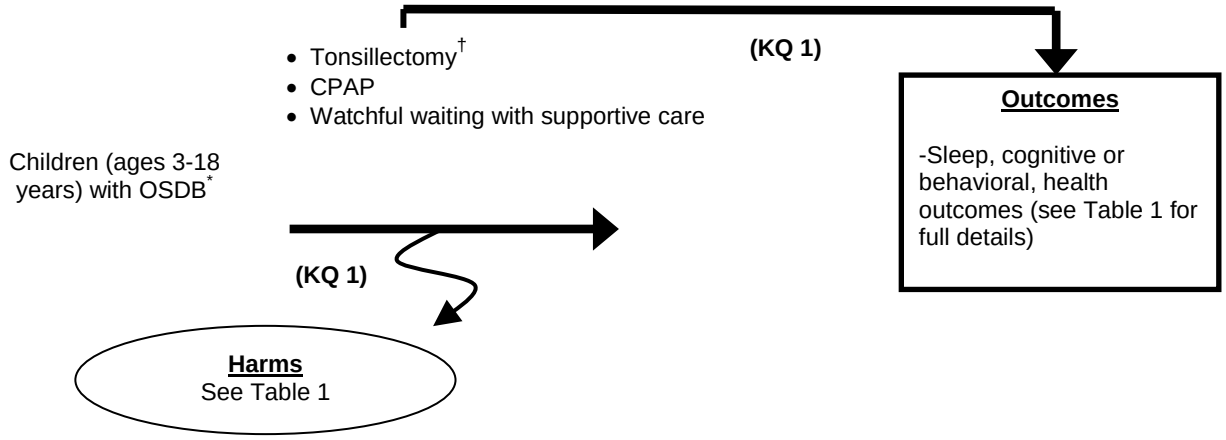
Appendix A. Analytic Frameworks

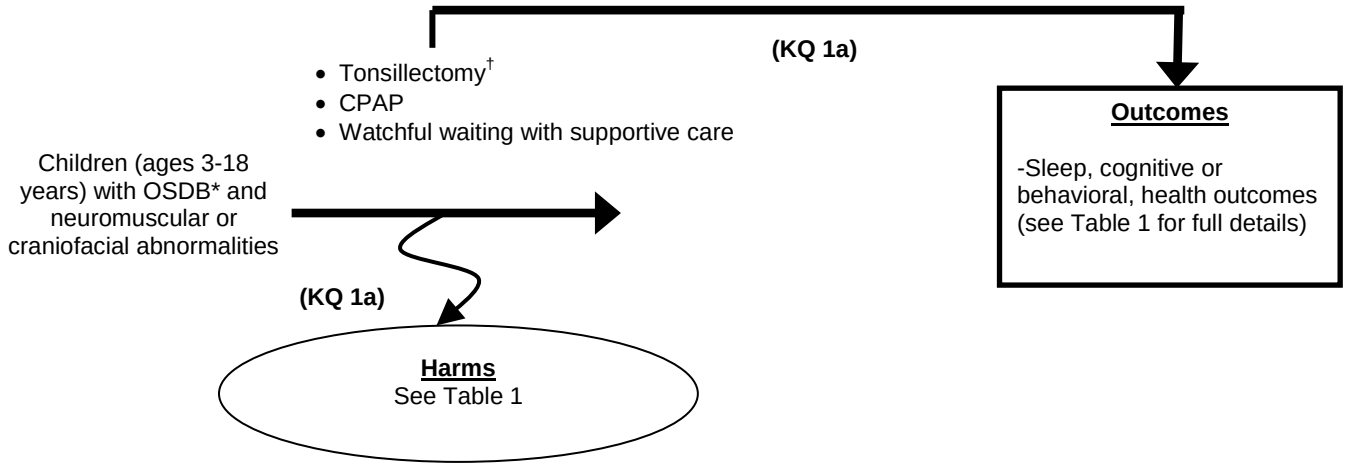
Figure A-1. Analytic framework for Key Question 1



*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)

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

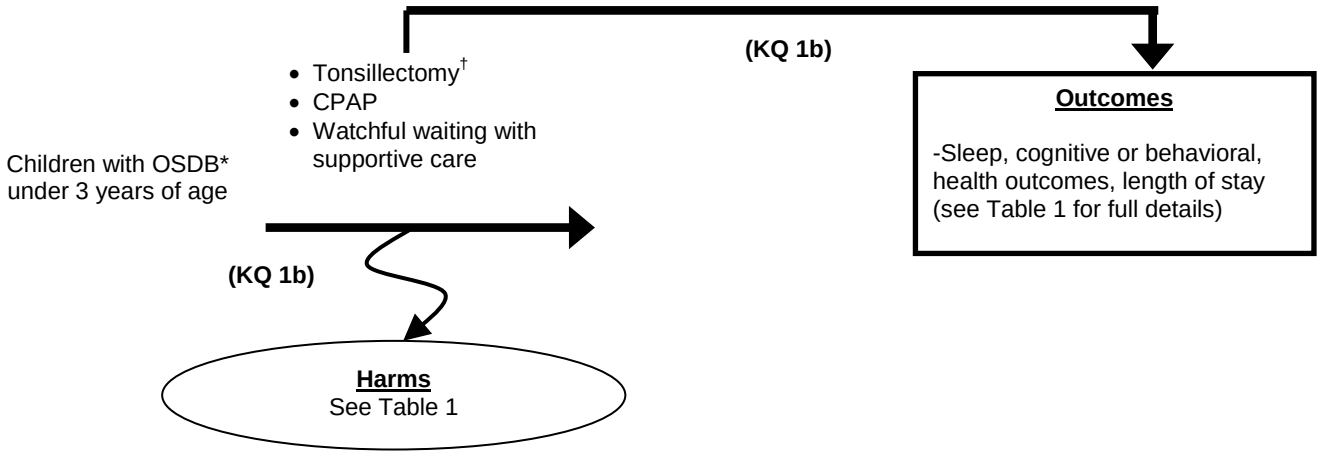
Figure A-2. Analytic framework for Key Question 1a



*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)

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

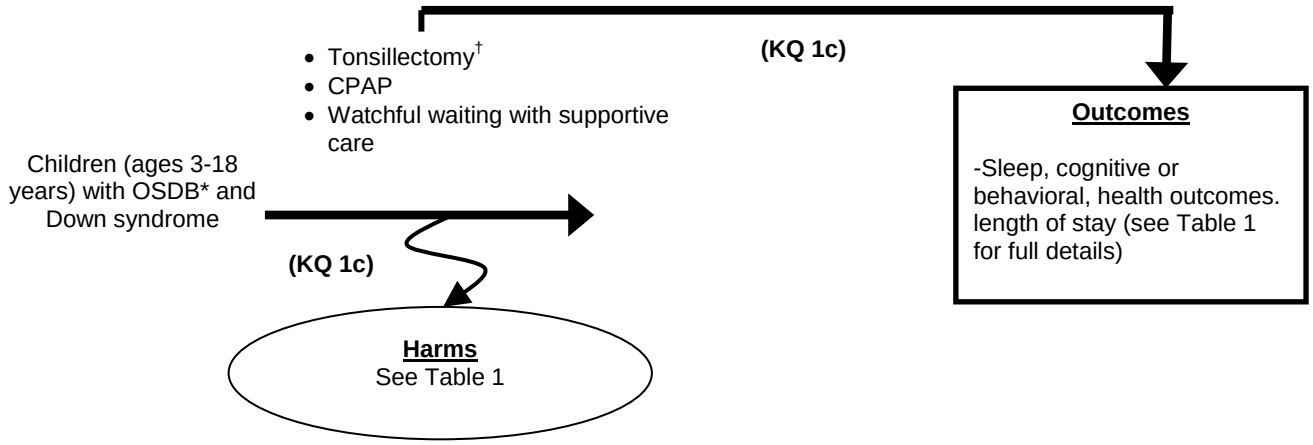
Figure A-3. Analytic framework for Key Question 1b



*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)

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

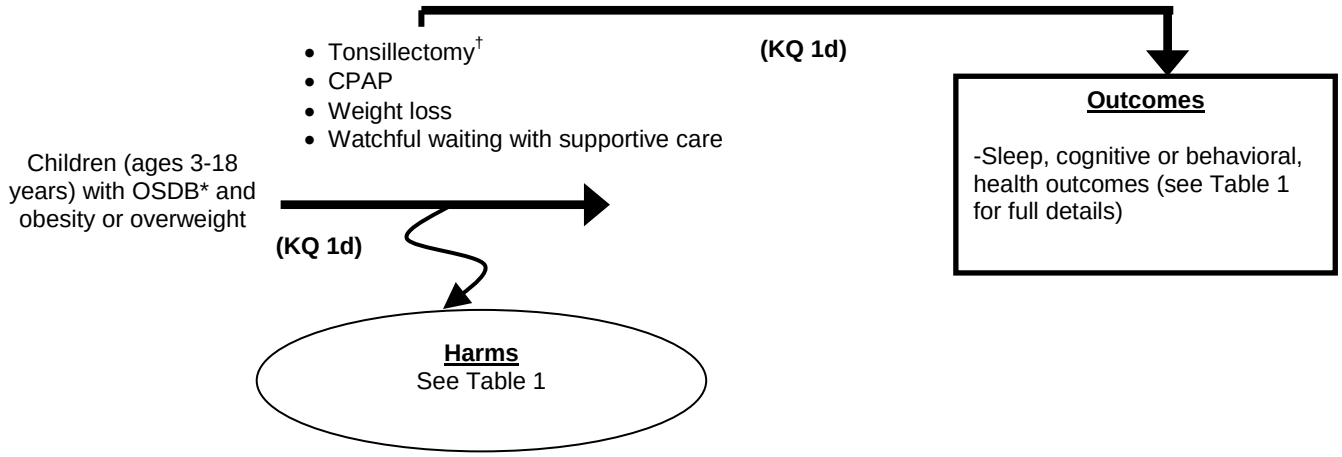
Figure A-4. Analytic framework for Key Question 1c



*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)

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

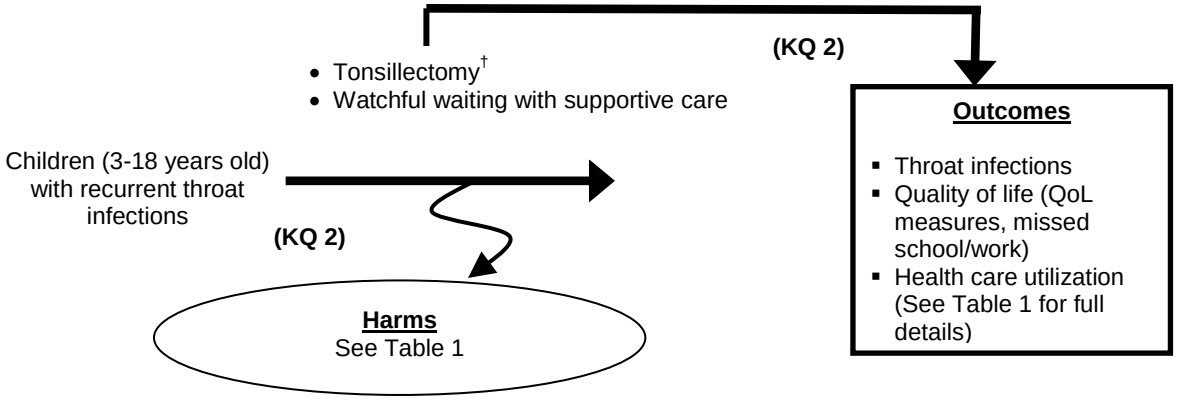
Figure A-5. Analytic framework for Key Question 1d



*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)

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

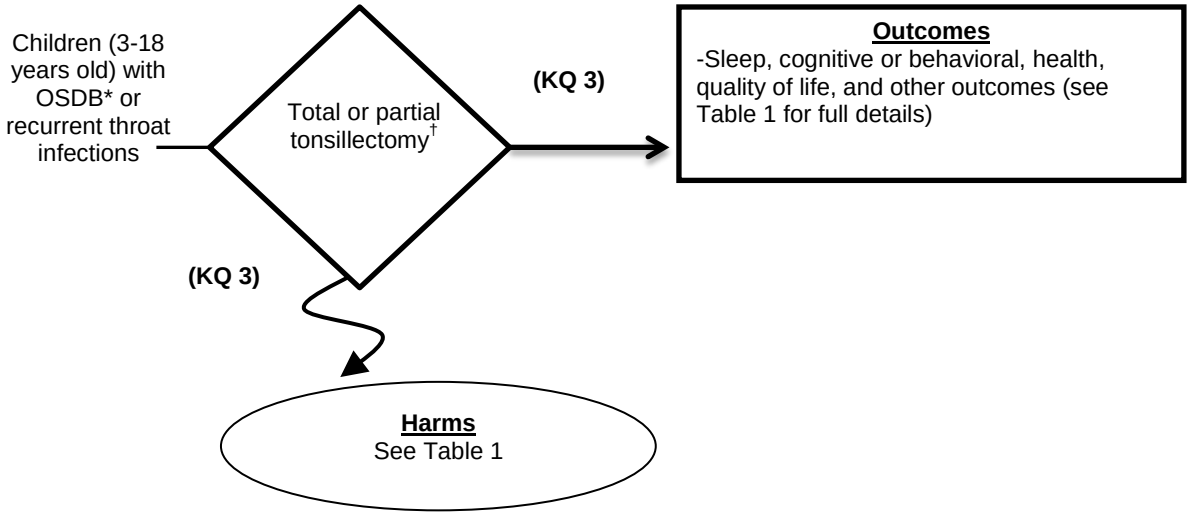
Figure A-6. Analytic framework for Key Question 2



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

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

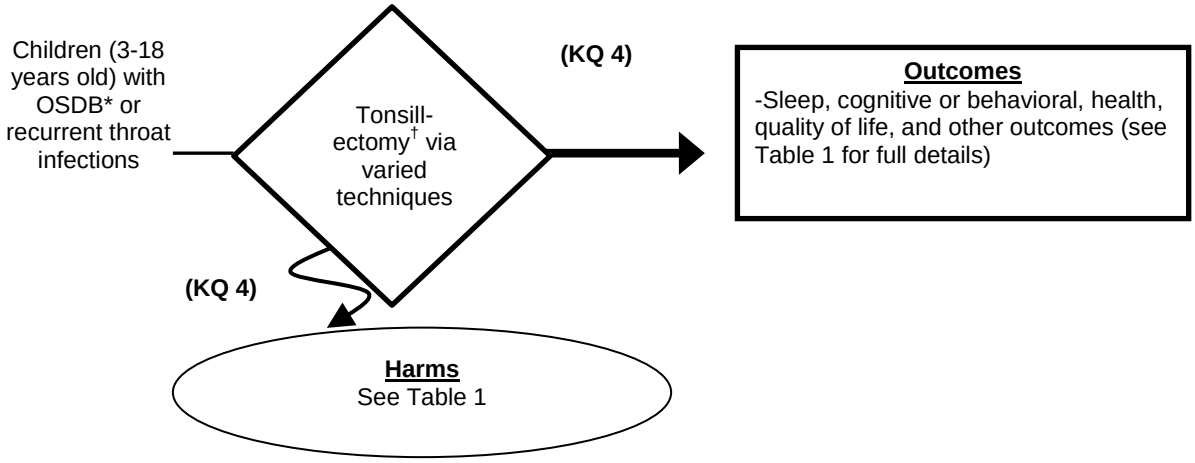
Figure A-7. Analytic framework for KQ3



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

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

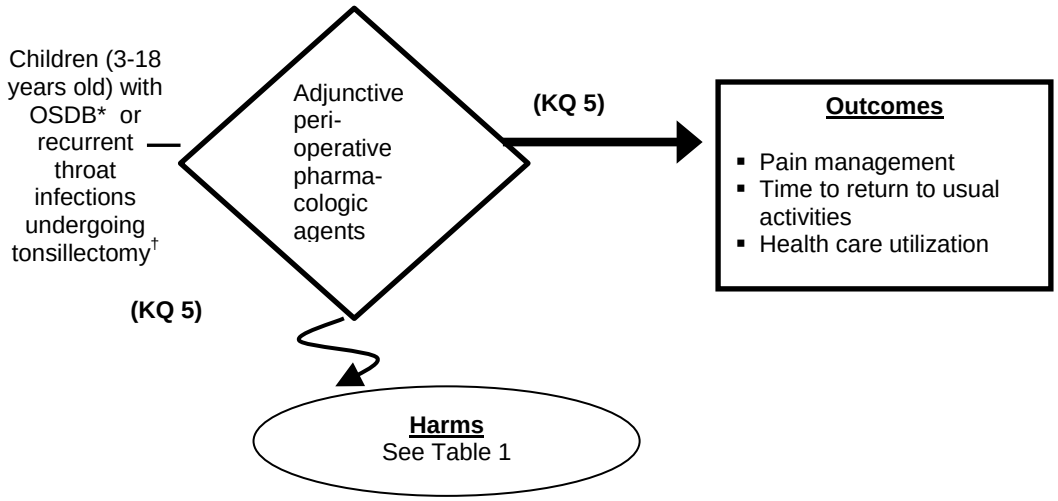
Figure A-8. Analytic framework for KQ4



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

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

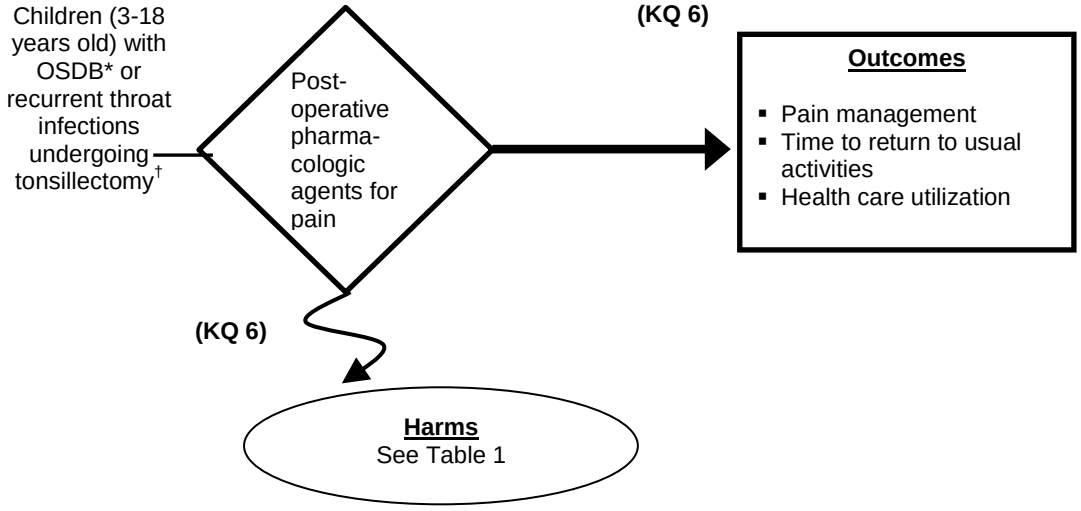
Figure A-9. Analytic framework for KQ5



*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).

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

Figure A-10. Analytic framework for KQ6



*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).

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

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. Screening and Risk of Bias Assessment Forms

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 measurem ent 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?				
Performa nce 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?				

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. Smith B, Strahle J, Garton H, et al. 198 The Association Between Chiari Malformation Type-1 and Tethered Spinal Cord in Children. Neurosurgery. 2015 Aug;62 Suppl 1, CLINICAL NEUROSURGERY:232. doi: 10.1227/01.neu.0000467162.36537.f8. PMID: 26182044. X-1

2. Tsou YA, Lin CD, Hsu HY, et al. Association of beta-Lactam-Sensitive Haemophilus influenzae Type B with Adenoid Biofilm Formation in Patients with Adenoidectomy Surgery. Surg Infect (Larchmt). 2015 Jul 14doi: 10.1089/sur.2014.069. PMID: 26171604. X-1

3. Choi JH, Yoon HC, Kim TM, et al. The immediate effect of adenotonsillectomy on Eustachian tube function in children. Int J Pediatr Otorhinolaryngol. 2015 Jun 28doi: 10.1016/j.ijporl.2015.06.025. PMID: 26169069. X-1, X-5

4. Ni K, Zhao L, Wu J, et al. Th17/Treg balance in children with obstructive sleep apnea syndrome and the relationship with allergic rhinitis. Int J Pediatr Otorhinolaryngol. 2015 Jun 28doi: 10.1016/j.ijporl.2015.06.026. PMID: 26166452. X-1, X-5

5. Glenn C, Cheema AA, Safavi-Abbasi S, et al. Spinal cord detethering in children with tethered cord syndrome and Chiari type 1 malformations. J Clin Neurosci. 2015 Jul 9doi: 10.1016/j.jocn.2015.05.023. PMID: 26165471. X-1

6. D'Souza JN, Schmidt RJ, Xie L, et al. Postoperative nonsteroidal anti-inflammatory drugs and risk of bleeding in pediatric intracapsular tonsillectomy. Int J Pediatr Otorhinolaryngol. 2015 Jul 2doi: 10.1016/j.ijporl.2015.05.042. PMID: 26164211. X-5

7. Erdim I, Akcay T, Yilmazer R, et al. Is Metabolic Syndrome Associated With Obstructive Sleep Apnea in Obese Adolescents? J Clin Sleep Med. 2015 Jun 22 PMID: 26156956. X-1

8. Certal V, Silva H, Carvalho C, et al. Model for prediction of pediatric OSA: Proposal for a clinical decision rule. Laryngoscope. 2015 Jul 7doi: 10.1002/lary.25438. PMID: 26154921. X-1

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Appendix E. Methods for Meta-Analyses

Model Specification

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.

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

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:

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

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.

The models were fit using the No U-turn Sampler (NUTS, 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 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
Murto, 2015[1]	Yes	Yes	Yes	No	Yes	Yes or no indication of lack of fidelity	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Gao, 2015[2]	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[3]	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[4]	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[5]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	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
Elbadawey, 2015[6]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Amin, 2014[7]	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[8]	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[9]	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[10]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of lack of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Moss, 2014[11]	Unclear	Yes	Yes	Yes	Yes	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
Aydin, 2014[12]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of lack of fidelity	NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Gabr, 2014[13]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Quante, 2014[14-19]	Yes	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Ericsson, 2014[20, 21]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Faiz, 2013[22]	Yes	Yes	Yes	Yes	No	Yes or no indication of lack of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Merry, 2013[23]	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[24]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of lack of	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
						fidelity								
Basuni, 2013[25]	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[26]	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[27]	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[28]	No	No	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Beriat, 2013[29]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Matin, 2013[30]	Unclear	Unclear	Yes	No	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Unclear	Yes	Yes	High
Muhammad, 2013[31]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication	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
						of fidelity								
Gallagher, 2012[32]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Frampton, 2012[33]	No	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Hermans, 2012[34]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Low
Havel, 2012[35]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Aouad, 2012[36]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Macassey, 2012[37]	Yes	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Yilmaz, 2012[38]	Unclear	Unclear	Yes	Unclear	Yes	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
Safavi, 2012[39]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Paramasivan, 2012[40]	Unclear	Unclear	Yes	Unclear	NA	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Chang, 2012[41]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Kemal, 2012[42]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Hamza, 2012[43]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High
Al-Shehri, 2012[44]	Unclear	Unclear	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Abdel-Ghaffar, 2012[45]	Yes	Unclear	Yes	Yes	No	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Beriat, 2012[46]	Unclear	Unclear	Yes	Unclear	Unclear	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
Omrani, 2012[47]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Salama, 2012[48]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Matin, 2012[49]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Moghaddam, 2012[50]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Solanki, 2012[51]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Stelter, 2012[52, 53]	No	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Parker, 2011[54]	No	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Roje, 2011[55,70]	Yes	Unclear	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								
Babademez, 2011[56]	Unclear	No	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Jones, 2011[57]	Unclear	No	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Ferri, 2011[58]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	No	Yes	Yes	Yes	Yes	Moderate
Haraldsson, 2011[59]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
D'Eredita, 2010[60]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ferreira, 2010[61]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Pruegsanusak, 2010[62]	Unclear	Unclear	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Rhendra Hardy, 2010[63]	No	No	Yes	Yes	Yes	Yes or no indication	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
						of fidelity								
Lock, 2010[64-66]	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Karaman, 2009[67]	No	No	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Unclear	No	Unclear	High
D'Eredita, 2009[68]	Yes	Yes	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Unclear	Unclear	Moderate
Parker, 2009[69]	Yes	Yes	Yes	Yes	Yes	Unclear	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stephens, 2009[71]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Erdem, 2009[72]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Wilson, 2009[73]	Unclear	Unclear	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	No	Unclear	High
Hesham, 2009[74]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication	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
						of fidelity								
Khani, 2009[75]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Bhattacharya, 2009[76]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	Yes	Yes	Moderate
Lee, 2009[77]	Unclear	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Czarnetzki, 2008[78]	Unclear	Unclear	Yes	NA	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Sezen, 2008[79]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Erdem, 2008[80]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Lee, 2008[81]	Yes	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	No	Yes	No	Yes	Yes	Yes	No	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
Chimona, 2008[82]	Unclear	Unclear	Yes	NA	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
D'Agostino, 2008[83]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Korkmaz, 2008[84]	Unclear	No	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Davis, 2008[85]	Yes	Yes	Yes	Yes	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Chang, 2008[86]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Hegazy, 2008[87]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Alajmi, 2008[88]	No	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Skoulakis, 2007[89]	Unclear	Unclear	Yes	Yes	Yes	Yes or no	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
						indication of fidelity								
Bukhari, 2007[90]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Bolton, 2007[91]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Mitic, 2007[92]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Park, 2007[93]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Kim, 2007[94]	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Shapiro, 2007[95]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Salomone, 2007[96]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	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
Lister, 2006[97]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Antila, 2006[98]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Coticchia, 2006[99]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Leaper, 2006[100]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Sobol, 2006[101]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Derkay, 2006[102]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Parsons, 2006[103]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High
Kamal, 2006[104]	Unclear	Unclear	Yes	Unclear	No	Yes or no	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
						indication of fidelity								
Kaan, 2006[105]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ericsson, 2006[106]	Yes	No	Yes	No	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	No	Yes	Yes	Yes	Moderate
Hussain, 2006[107]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Ericsson, 2006[106, 108, 109]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Ragab, 2005[110]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	High
Kutluhan, 2005[111]	Unclear	No	Unclear	No	Unclear	Yes or no indication of fidelity	Unclear	Yes	No	Unclear	Unclear	Unclear	Unclear	High
Oko, 2005[112]	Unclear	Yes	Yes	Yes	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
Kirazli, 2005[113]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Kedek, 2005[114]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	Moderate
Chang, 2005[115]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	Yes	Yes	Moderate
Bhattacharya, 2005[116]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Lister, 2005[97]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Abdul Monem, 2005[117]	Unclear	Unclear	Yes	Yes	Unclear	Yes or no indication	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Collison, 2004[118]	No	No	Yes	No	Unclear	Unclear	Yes or NA	NA	Yes	Yes	Yes	Yes	Yes	High
Samarkandi, 2004[119]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Unclear	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
Chan, 2004[120]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	No	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
D'Eredita, 2004[121]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Unclear	Moderate
Hanasono, 2004[122]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Low
Celiker, 2004[123]	Yes	Yes	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Goldstein, 2004[124]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Lalicevic, 2004[125]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stoker, 2004[126]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Keidan, 2004[127]	Unclear	Unclear	Yes	Yes	Yes	Yes or 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
						indication of fidelity								
van Staaij, 2004[128-130]	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Yes	No	Yes	Yes	Yes	Yes	High
Fujii, 2003[131]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Perkins, 2003[132]	Unclear	No	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Elhakim, 2003[133]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Low
Willging, 2003[134]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Stoker, 2003[135]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Oztekin, 2002[136]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	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
Sukhani, 2002[137]	Unclear	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Kothari, 2002[138]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Shah, 2002[139]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Raut, 2002[140]	Yes	Unclear	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Giannoni, 2002[141]	Yes	Yes	Yes	Yes	No	No	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Kokki, 2002[142]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Paradise, 2002[143_a]	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Paradise, 2002[143_b]	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Young, 2001[144]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication	Unclear	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
						of fidelity								
Densert, 2001[145]	Unclear	Unclear	Yes	Unclear	Unclear	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	High
Walker, 2001[146]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Temple, 2001[147]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Bergler, 2001[148]	Unclear	Unclear	Yes	Unclear	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Fujii, 2001[149]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Fujii, 2001[150]	Unclear	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Nunez, 2000[151]	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
Pizzuto, 2000[152]	Yes	Yes	Yes	Unclear	No	Yes or no indication of fidelity	Yes or NA	Yes	Unclear	Yes	Yes	Yes	Yes	Moderate
Holt, 2000[153]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Jensen, 2000[154]	Yes	Yes	Yes	Yes	Yes	Yes or no indication of fidelity	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Low
Romsing, 1998[155]	Unclear	Unclear	Yes	Yes	No	Unclear	Yes or NA	Yes	No	Yes	Yes	Yes	Yes	High
Stage, 1988[156]	No	Unclear	Yes	Unclear	Yes	Unclear	Yes or NA	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Paradise, 1984[157_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 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
Koshy, 2015[158]	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	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
Chettri, 2014[159]	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[160]	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[161]	Yes	Yes	Yes, appropriate	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Yes, valid and reliable measure used for	Yes, valid and reliable measure used	Yes or study accounts for imbalance	Partially: some variables taken into account	Yes, all important outcome(s)	Yes, same length of follow-up or	Not applicable: no loss to follow-up or 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 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
							all outcomes of interest		between groups through a post hoc approach such as multivariate analysis	or adjustment achieved to some extent	reported	remedied through analysis	follow-up was not considered to be high	
Moriniere, 2013[162]	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	Moderate
Ozkiris, 2012[163]	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	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	Not applicable: no loss to follow-up or loss to follow-up was not	Low

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 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
							of interest					analysis	considered to be high	
Ozkiris, 2012[164]	Yes	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	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
Ragab, 2011[165]	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[166]	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

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 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
Lock, 2010[64-66]	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	Yes or study accounts for imbalance between groups through a post hoc approach such as multivariate analysis	Cannot determine	Yes, all important outcome (s) reported	Yes, same length of follow-up or remedied through analysis	Yes	Moderate
Brigance, 2009[167]	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[168]	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	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 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
													to be high	
Vlastos, 2008[169]	Yes	Yes	Yes, appropriate	Yes, accounts for variations	No, not blinded	Yes, valid and reliable measure used	Partially, valid and reliable measures used for some 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	Moderate
Fernandes, 2008[170]	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[171]	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

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 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
Tarasiuk, 2004[172]	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
Chau, 2004[173]	No, criteria vary	Cannot Determine	Cannot determine or no description of the derivation of the comparison group	Cannot determine	No, not blinded	Yes, valid and reliable measure used	Cannot determine or measurement approach not reported	No, valid and reliable measure not used	No or cannot determine	No, not taken into account	Yes, all important outcome(s) reported	No, different length of follow-up	Cannot determine	High
Silveira, 2003[174]	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	Low

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 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
Dualibi, 2002[175]	Yes	Cannot Determine	Cannot determine or no description of the derivation of the comparison group	Cannot determine	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	Cannot determine	Yes, all important outcome(s) reported	Yes, same length of follow-up or remedied through analysis	Cannot determine	High
Nawasreh, 2000[176]	Yes	Cannot Determine	Cannot determine or no description of the derivation of the comparison group	Cannot determine	No, not blinded	Cannot determine or measurement approach not reported	Cannot determine	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	Not applicable: no loss to follow-up or loss to follow-up was not considered to be high	High
Paradise, 1984[157_b]	Partially: some, but not all criteria, applied to all groups or not clearly stated if some criteria are	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 important 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 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
	applied to all 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
Padia, 2015[177]	No	Yes	Yes	Yes	Moderate
Achar, 2015[178]	Yes	Yes	Unclear	Yes	Moderate
Edmonson, 2015[179]	Yes	Yes	Yes	Yes	Low
Bangiyev, 2015[180]	Unclear	Unclear	Unclear	Yes	High
Lavin, 2015[181]	Yes	Yes	Yes	Yes	Low
Duval, 2015[182]	Yes	Yes	Yes	Yes	Low
Suzuki, 2014[183]	Yes	Yes	Unclear	Yes	Moderate
Mahant, 2014[184, 185]	Yes	Yes	Yes	Yes	Low
Bhattacharyya, 2014[186, 187]	Yes	Yes	Yes	Yes	Low
Sarny, 2013[188, 189]	Yes	Yes	Yes	Yes	Low
Hultcrantz, 2013[190, 191]	Yes	Yes	Yes	Yes	Low
Walner, 2012[192]	Yes	Yes	Unclear	Yes	Moderate
Perkins, 2012[193]	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
Tweedie, 2012[194]	Yes	Yes	Unclear	Yes	Moderate
Tomkinson, 2012[195, 196]	Yes	Yes	Yes	Yes	Low
Hessen, 2011[197]	Yes	Yes	Yes	Yes	Low
Bhattacharyya, 2010[198]	Yes	Yes	Unclear	Yes	Moderate
Kim, 2010[199]	Yes	Yes	Unclear	Yes	Moderate
Gooda, 2010[200]	Yes	Yes	Unclear	Yes	Moderate
D'Agostino, 2009[201]	Yes	Yes	Unclear	Yes	Moderate
Kvaerner, 2009[202]	Yes	Yes	Yes	Yes	Low
Arnoldner, 2008[203]	Yes	Yes	Unclear	Yes	Moderate
Lowe, 2007[204]	Yes	Yes	Yes	Yes	Low
Abou-Jaoude, 2006[205]	Unclear	Unclear	Unclear	Yes	High
Zhao, 2006[206]	Unclear	Unclear	Unclear	Yes	High
Tomkinson, 2005[207]	Yes	Yes	Yes	Yes	Low
Clark, 2004[208]	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
Mills, 2004[209]	Yes	Yes	Unclear	Yes	Moderate
Granell, 2004[210]	Yes	Unclear	Yes	Yes	High
Windfuhr, 2002[211, 212]	Yes	Yes	Unclear	Yes	Moderate
Liu, 2001[213]	Yes	Yes	Unclear	Yes	Moderate
Lannigan, 1993[214]	Yes	Yes	Unclear	Yes	Moderate
Colclasure, 1990[215]	Yes	Yes	Unclear	Yes	Moderate
Chowdhury, 1988[216]	Yes	Yes	Unclear	Yes	Moderate
Carithers, 1987[217]	Yes	Yes	Unclear	Yes	Moderate
Crysdale, 1986[218]	Yes	Yes	Unclear	Yes	Moderate
Herdman, 1986[219]	Yes	Yes	Unclear	Yes	Moderate
Kristensen, 1984[220]	Yes	Yes	Unclear	Yes	Moderate
Capper, 1984[221]	Unclear	Yes	Unclear	Yes	High
Yuan, 1984[222]	No	Yes	No	Yes	High
Carmody, 1982[223]	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 14 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 (4), Brazil (2), Israel (2), Australia (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 and United Kingdom and patients were selected from otolaryngology 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 (15) included children with OSDB (typically based on clinical diagnosis vs. PSG). Indication was mixed in 2 studies and not specified in one. 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), 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). Fourteen studies did not specify indication; the surgical indication was throat infection in 9 studies and OSDB in 7 studies. 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 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 (37) 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 (31) 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 (6). 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 (2), New Zealand (2), Canada (2) Jordan (1), Serbia (1), Korea (1), Egypt (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 for Key Questions 4 and 5

Key Questions 3 and 4

Bleeding-Related Harms in Comparative Studies

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	0	2 (5.4)	0	NR	NR
	Paramasivan 2012[2]	50	1	1 (2)	0	0	NR	NR
	D'Eredita 2009[3]	74	1	NR	NR	1 (1)	1 (1)	NR
	Throat Infection							
	Salama 2012[4]	75	3	NR	3 (10)	0	NR	NR
	Elbadawey 2015[5]	40	1	NR	1 (2.5)	0	NR	NR
	Hegazy 2008[6]	40	0	0	0	0	0	0
	Temple 2001[7]	18	0	0	0	0	0	0
	Di Renzo 2008[8]	21	0	0	0	0	0	0
	Mixed							
	Stoker 2004[9]	44	3	NR	NR	3 (7)	NR	1 (2)
	Omrani 2012[10]	47	2	1 (2.12)	1 (2.12)	NR	NR	NR
	Chimona 2008[11]	30	1	NR	NR	1 (3)	NR	NR
	Roje 2011[12, 13]	50	1	NR	NR	1 (2)	NR	NR
	D'Eredita 2010[14]	32	1	NR	NR	1 (3)	1 (3)	NR
	Mitic 2007[15]	20	0	0	0	0	0	0
	Unspecified							
	Parker 2009[16]	35	2	NR	NR	2 (6)	NR	2 (6)
	Shapiro 2007[17]	23	1	0	0	1 (4.3)	NR	1 (4.3)

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 (%)
	Parker 2011[18]	40	1	NR	NR	1 (3)	NR	1 (3)
	Matin 2013[19]	100	0	0	0	0	0	0
	Shah 2002[20]	17	0	0	0	0	0	0
Cold Dissection	**OSDB**							
	Salomone 2007[21]	50	7	NR	7 (14)	0	NR	NR
	Ericsson 2009[22, 23]	32	2	NR	NR	2 (6)	2 (6)	NR
	Paramasivan 2012[2]	50	1	1 (2)	0	0	NR	NR
	Korkmaz 2008[24]	41	1	NR	NR	1 (2)	NR	1 (2)
	Aydin 2014[25]	40	0	0	0	0	0	0
	Skoulakis 2007[26]	15	0	0	0	0	0	0
	Chaidas 2013,[27]	51	0	0	0	0	0	0
	Beriat 2013[28]	45	0	0	0	0	0	0
	Throat Infection							
	Paradise et al.(2002)[29]	203	7	0	7 (2)	0	5 (1.6)	NR
	Raut 2002[30]	32	5	1 (3)	4 (12.5)	0	NR	NR
	Frampton 2012[31]	100	3	NR	3 (3)	0	NR	NR
	Elbadawey 2015[5]	40	1	NR	1 (2.5)	0	NR	NR
	Sezen 2008[32]	25	0	0	0	0	0	0
	Frampton 2012[31]	100	0	0	0	0	0	0
	Di Renzo 2008[8]	21	0	0	0	0	0	0
	Chettri 2014[33]	40	0	0	0	0	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 (%)
	Mixed							
	D'Eredita 2014[34]	285	15	NR	15 (5.3)	0	15 (5.3)	NR
	Omrani 2012[10]	47	7	2 (4.26)	5 (10.64)	0	NR	NR
	Haraldsson 2007[35]	49	2	NR	2 (4.1)	0	NR	NR
	Roje 2009[12, 13] RCT Low	50	2	NR	NR	2 (4)	NR	NR
	Ozkiris 2012 [36]	99	2	NR	2 (2)	0	NR	NR
	Chimona 2008[11]	30	1	NR	NR	1 (3)	NR	NR
	Nunez 2000[37]	25	1	NR	1 (3.8)	0	NR	NR
	Hultcrantz 2004[38-40]	43	1	NR	NR	1 (2)	NR	NR
	Gabr 2014[41]	20	0	0	0	0	0	0
	Collison2004[42]	28	0	0	0	0	0	0
	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)	NR
	Parker 2009[16]	35	2	NR	NR	2 (6)	NR	NR
	Hesham 2009[45]	69	1	NR	1 (1.33)	0	NR	NR
	Silveira 2008[46] 3-13	28	1	NR	1 (3.6)	0	NR	1 (3.6)
	Shapiro 2007[17]	23	0	0	0	0	0	0
	Young 2001[47]	23	0	0	0	0	0	0
	Pruegsanusak 2010[48]	20	0	0	0	0	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 (%)
Electrocautery	**OSDB**							
	Moriniere 2013[49]	105	8	NR	8 (7.6)	0	NR	NR
	Coticchia 2006[50]	10	0	0	0	0	0	0
	Lister 2006[51]	25	0	0	0	0	0	0
	Salomone 2007[21]	50	0	0	0	0	0	0
	Throat Infection							
	Leaper 2006[52]	101	21	0	21 (21)	0	11(11)	2 (2)
	Raut 2002[30]	18	4	1 (5.5)	3 (16.6)	0	NR	NR
	Ragab 2011[53]	91	3	2 (2.2)	1 (1.1)	0	NR	NR
	Ragab 2011[53]	921	2	1 (1.1)	1 (1.1)	0	NR	NR
	Temple 2001[7]	20	0	0	0	0	0	0
	Chettri 2014[33]	40	0	0	0	0	0	0
	Mixed							
	D'Eredita 2014[34]	285	12	NR	12 (4.2)	0	12 (4.2)	NR
	Ozkiris 2012[36]	102	6	NR	6 (5.9)	0	NR	NR
	Haraldsson 2007[35]	49	3	NR	3 (6.1)	0	NR	NR
	D'Eredita 2010[14]	32	2	NR	NR	2 (6)	2 (6)	NR
	Stoker 2004[9]	45	2	NR	NR	2 (4)	NR	2 (4)
	Nunez 2000[37]	22	2	NR	2 (8.3)	0	NR	NR
	Perkins 2003[54]	42	0	0	0	0	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 (%)
	D'Eredita 2004[55]	28	0	0	0	0	0	0
	Mitic 2007[15]	20	0	0	0	0	0	0
	Unspecified							
	Walker 2001[56]	75	9	0	9 (12)	0	6 (8)	3 (4)
	Hesham 2009[45]	71	4	NR	4 (5.33)	0	NR	1 (1.33)
	Willging 2003[57]	59	3	NR	NR	3 (5)	NR	1 (2)
	Derkay 2006[58]	150	2	0	0	2 (1.3)	NR	2 (1.3)
	Al-Shehri 2012[59]	93	2	NR	NR	2 (2.2)	NR	NR
	Shah 2002[20]	17	1	0	0	1 (6)	NR	1 (6)
	Parker 2011[18]	40	1	NR	NR	1 (3)	NR	1 (3)
	Silveira 2008[46]	29	1	1 (3.4)	NR	0	NR	NR
	Chan 2004,[60]	28	1	NR	1 (4)	0	1 (4)	NR
	Young 2001[47]	23	0	0	0	0	0	0
	Chang 2012[61]	33	0	0	0	0	0	0
	Park 2007[62]	21	0	0	0	0	0	0
Harmonic Scalpel	**Throat Infection**							
	Leaper 2006[52]	103	24	0	24 (23)	0	9 (9)	4 (4)
	Salama 2012[4]	75	1	0	1 (3.3)	0	1 (3.3)	NR
	Unspecified							
	Oko 2005[43]	61	9	1 (2)	8 (13)	0	NR	NR
	Willging 2003[57]	61	6	NR	NR	6 (10)	NR	3 (5)

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 (%)
	Walker 2001[56]	97	5	0	5 (5.2)	0	5 (5.2)	1 (1)
Laser	**Throat Infection**							
	Hegazy 2008[6]	40	1	NR	1 (2.5)	0	NR	NR
	Elbadawey 2015[5]	40	0	0	0	0	0	0
	Mixed							
	D'Eredita 2004[55]	30	0	0	0	0	0	0
	Unspecified							
	Kothari 2002[44]	79	9	9 (11.3)	NR	0	9 (11.3)	3 (3.7)
Molecular Resonance	**OSDB**							
	D'Eredita 2009[3]	74	0	0	0	0	0	0
	Mixed							
	D'Eredita 2014[34]	287	2	NR	2 (1)	0	NR	NR
	D'Eredita 2010[14]	32	0	0	0	0	0	0
	Unspecified							
	Chang 2012[61]	33	0	0	0	0	0	0
Thermal Welding	**OSDB**							
	Aydin 2014[25]	40	0	0	0	0	0	0
	Throat Infection							
	Sezen 2008[32]	25	0	0	0	0	0	0
	Mixed							
	Ozkiris 2012[36]	104	5	NR	5 (4.8)	0	NR	NR
	Chimona 2008[11]	30	0	0	0	0	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 (%)
Unspecified/ Other Techniques	**OSDB**							
	Vlastos 2008[63] Unspecified tonsillectomy	780	11	NR	NR	11 (1.4)	NR	11 (1.4)
	Marcus 2013[64-70] Unspecified tonsillectomy	212	5	0	0	5 (2.4)	5 (2.4)	NR
	Throat Infection							
	Orvidas et al.2006[71] Unspecified tonsillectomy	145	5	0	0	5 (3.4)	NR	2 (1.4)
	Van Staaij 2004[72] Unspecified tonsillectomy	194	7	7 (4)	0	0	3 (2)	2 (1)
	Unspecified							
	Al-Shehri 2012[59] Unspecified tonsillectomy	97	6	NR	NR	6 (6.2)	NR	6 (6.2)
	Bukhari 2007[73] Electrocautery and cold dissection (left or right tonsil)	100	2	2 (2)	NR	0	NR	NR
Totals	**(N arms)**							
	All arms (107)	8069	280 (3.5)	31 (0.71)	177 (3.0)	70 (0.88)	92 (2.8)	53 (1.4)
	Electrocautery (31)	2645	89 (3.4)	5 (0.19)	71 (3.0)	13 (0.49)	32 (3.8)	13 (1.5)
	Cold dissection (34)	1892	73 (3.9)	5 (0.56)	55 (3.5)	11 (0.71)	26 (2.5)	3 (0.52)
	Harmonic scalpel (5)	397	45 (11.3)	1 (0.30)	38 (11.3)	6 (1.5)	15 (5.5)	8 (3.1)
	Unspecified/ other technique (6)	1528	36 (2.4)	9 (1.4)	0	27 (1.8)	8 (2.0)	21 (1.7)
	Coblation (19)	793	20 (2.5)	2 (0.54)	7 (1.6)	11 (1.5)	2 (0.62)	5 (1.4)
	Laser (4)	189	10 (5.3)	9 (6.0)	1 (0.91)	0	9 (6.0)	3 (2.0)
	Thermal welding (4)	199	5 (2.5)	0	5 (2.5)	0	0	0
	Molecular resonance (4)	426	2 (0.47)	0	0	2 (0.47)	0	0

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**							
	Moriniere 2013 [49]	88	3	2 (2)	1 (1)	0	3 (3)	1 (1)
	Ericsson 2009[22, 23]	32	2	NR	NR	2 (6)	2 (6)	NR
	Chang 2008[74]	34	NR	NR	NR	NR	NR	0
	Coticchia 2006 [50]	13	NR	NR	NR	NR	0	NR
	Throat infection							
	Stelter 2012 [75_1437]	14	0	0	0	0	0	0
	Mixed							
	Hultcrantz 2004[38-40]	49	2	NR	NR	2 (4)	NR	NR
	Chan 2004[60]	27	NR	0	NR	NR	0	NR
Cold dissection	**OSDB**							
	Skoulakis 2007[26]	15	0	0	0	0	0	0
	Chaidas 2013 [27]	50	0	0	0	0	0	0
	Korkmaz 2008[24]	40	1	NR	NR	1 (3)	NR	1 (3)
	Unspecified							
	Park 2007[62]	19	0	0	0	0	0	0
Laser	**OSDB**							
	Havel 2012[76] (diode laser)	21	0	0	0	0	0	0
	Havel 2012[76] (CO_2 laser)	21	0	0	0	0	0	0
	Throat infection							
	Stelter 2010[75, 77]	12	0	0	0	0	0	0
Microdebrider	**OSDB**							
	Lister 2006[51]	25	0	0	0	0	0	0
	Beriat 2013 [28]	37	0	0	0	0	0	0

	Mixed							
	Gabr 2014[41]	20	0	0	0	0	0	0
	Unspecified							
	Pruegsanusak 2010 [48]	20	1	0	0	1 (5)	1 (5)	NR
	Derkay 2006 [58]	150	1	0	0	1 (1)	NR	1 (1)
Other/ Unspecified	**OSDB**							
	Vlastos 2008 [63]	243	1	0	0	1 (0.41)	NR	NR
Totals	**(N arms)**							
	All arms (20)	930	11 (1.2)	2 (0.26)	1 (0.14)	8 (0.93)	6 (1.4)	3 (0.55)
	Coblation (7)	257	7 (2.7)	2 (1.6)	1 (0.98)	4 (2.2)	5 (2.9)	1 (0.74)
	Microdebrider (5)	252	2 (0.79)	0	0	2 (1.2)	1 (0.98)	1 (0.43)
	Cold dissection (4)	124	1 (0.81)	0	0	1 (2.5)	0	1 (0.81)
	Other/Unspecified (1)	243	1 (0.41)	0	0	1 (0.41)	0	0
	Laser (3)	54	0	0	0	0	0	0

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[58]	150	NR	5 (3.3)	NR
	Beriat 2013[28]	37	0	0 (0)	NR
Coblation	Chang 2008[74]	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[78]	50	1 (2)	NR	NR	NR
	D'Eredita 2004[55]	30	NR	0	NR	NR
Electrocautery	**OSDB**					
	Derkay 2006[58]	150	NR	4 (2.6)	NR	NR
	Chang 2005[79]	49	0 (0)	1 (2)	0	NR
	Throat Infection					
	Walker 2001[56]	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[9]	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[18]	40	NR	1 (2.5)	NR	NR
	D'Eredita 2010[14]	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[55]	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[17]	23	0 (0)	NR	0	NR
	Not Specified					
	Oko 2005[43]	61	NR	1 (1.6)	NR	NR
	Shapiro 2007[17]	23	NR	0	NR	NR
Coblation	**OSDB**					
	Chang 2008[74]	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 [3]	78	NR	0	NR	NR
	Stoker 2004[9]	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[17]	24	0	0	0	NR
Harmonic Scalpel	**Mixed**					
	Walker 2001[56]	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[3]	79	NR	0	NR	NR
Unspecified tonsillectomy	**OSDB**					
	Marcus 2013[64-70]	212	NR	7 (3.3)	NR	NR
	Van Staaij et al. 2004[72, 80, 81]	151	NR	NR	5 (3)	NR
	Orvidas 2006[71]	145	NR	2 (1.4)	NR	NR
	Brigance 2009[82]	61	NR	Hospitalization due to poor oral intake 1 (1.6)	NR	NR
	Goldstein 2004[83]	21	NR	0 (0)	0	NR
Totals	**(N arms)**					
	All arms (38)	3030	45 (1.5)	40 (1.3)	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 (5)	590	NR	10 (1.7)	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[84] Low	0-24 Mixed CA hospital discharge database-return visits within 30 days postop	35085	1719	NR	NR	1719 (4.9)	426 (1.2)	NR
Bhattacharyya 2015[85, 86] Low	<18 years (mean=7.5 years) Not specified CA, IA, FL, NY ER and ambulatory surgery and ER databases-return visits within 14 days postop	79520	1652	NR	NR	1652 (4.7)	NR	NR
Duval 2015[87] 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[88] Moderate	1-18 Unspecified Hospital system database-return visits within 21 days post-same-day tonsillectomy	15950	413	NR	NR	413 (2.6)	NR	NR
Mahant 2014[89, 90] 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[91] Moderate	≤15 years OSDB Japanese national inpatient database-7 years	31934	160	NR	NR	160 (0.50)	NR	160 (0.50)
Tomkinson 2012[92, 93] Low	<12 years Unspecified Wales Surgical Instrument Surveillance Programme Database-5 years	8414	176	58 (0.7)	118 (1)	0	53 (0.63)	37 (0.44)
*Tomkinson 2005[94] Low	<12 years Unspecified Patient Episode Database for Wales-return visits within 28 days post-tonsillectomy	6730	225	53 (0.79)	172 (3)	0	153 (2.3)	41 (0.61)
Clark 2004[95] Low	0-14 Unspecified Hospital Episode Statistics for England-4 years	131577	500	NR	NR	500 (0.38)	NR	500 (0.38)
Case Series								
Achar 2015[96] Moderate	0-17 Mixed Single institution ER chart review of 5 years	3527	222	NR	222 (6.3)	0	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 (%)
Walner 2012[97] Moderate	1-18 Mixed Single institution chart review of 7 years	1918	87	5 (0.5)	82 (4)	0	NR	31 (1.6)
Perkins 2012[98] Moderate	6.90±4.02 (mean yrs±SD) Mixed Single institution chart review of 7 years	9023	212	48 (0.5)	164 (2)	0	109 (1.2)	103 (1.1)
Kim 2010[99] Moderate	≤15 years Mixed Single institution chart review of 3 years	1109	33	0	33 (3)	0	3 (0.27)	2 (0.18)
Gooda 2010[100] Moderate	5-15 Throat infection Chart review of 8 years	1500	9	NR	NR	9 (0.6)	NR	2 (0.13)
D'Agostino 2009[101] Moderate	2-13 Mixed Single institution chart review of 5 years	3306	59	NR	59 (1.8)	0	NR	15 (0.45)
Arnolder 2008[102] Moderate	1-15 Mixed Single institution chart review for 13 years	3657	54	NR	NR	54 (1.5)	NR	54 (1.5)
Mills 2004[103] Moderate	9 months-17 years Unspecified	4853	209	46 (0.9; 95% CI: 0.68% to 1.22%)	163 (3; 95% CI: 2.8% to 3.9%)	0	NR	49 (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 (%)
	Single institution chart review of admitted or re-admitted patients over 9 years							
Granell 2004[104] Moderate	0-14 Mixed Single institution chart review of 6 years	1243	84	78 (6)	6 (0.48)	0	NR	36 (2.9)
Windfuhr 2001[105-107] Moderate	6 months-14 years Mixed Single institution chart review of 12 years	2567	41	27 (1)	14 (0.54)	0	NR	41 (1.6)
Liu 2001[108] 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)	0	60 (4.2)	20 (1.4)
Lannigan 1993[109] Moderate	3-13 Unspecified Single institution chart review of 4 years	4386	25	25 (0.6)	0 (0)	0 (0)	0 (0)	NR
Colclasure 1990[110] 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[111] Moderate	“Pediatric” (under 4 -over 12) Mixed Single institution chart review	6842	171	90 (1.3)	81 (1.2)	0	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 (%)
	of 13 years							
Carithers 1987[112] Moderate	1-23 (mean=6.3) Mixed Single institution chart review of 1 year	2563	78	30 (1.2)	48 (1.9)	0	NR	NR
Crysdale 1986[113] Moderate	≤2 -17 Unspecified Single institution chart review of 4 years	7974	199	199 (2.5)	0	0	NR	NR
Herdman 1986[114] Moderate	≤14 years Unspecified Single institution chart review of 7 years	2400	13	13 (0.54)	0	0	0	0
Kristensen 1984[115] Moderate	0-12 Mixed Single institution chart review of 5 years	522	11	NR	NR	11 (2.1)	NR	11 (2.1)
Carmody 1982[116] Moderate	0-19 Not specified Single institution chart review of 5 years	1649	13	10 (0.61)	3 (0.18)	0	NR	NR
Registries								
Hultcrantz 2014[117, 118] Low	2-18 OSDB Swedish National Registry for Tonsil Surgery-data at 30 days and 6 months postop	10820	304	NR	NR	304 (2.8)	155 (1.4)	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 (%)
Soderman 2011[119] Low	0-19 years Mixed Swedish National Tonsil Register-11 years	40322	431	NR	NR	431 (1.1)	NR	NR
Sarny 2011[120, 121] Low	1-18 Mixed Nationwide data collection for 12 months	3372	283	NR	NR	283 (8.4)	NR	47 (1.4)
Kvarner 2009[122] Low	≤16 years Unspecified Norwegian Patient Registry-7 years	34955	157	NR	NR	157 (0.45)	157 (0.45)	NR
Lowe 2007[123-125] Low	<5 to 15 years Mixed UK National Tonsillectomy Audit-1 year	21063	575	NR	NR	575 (3)	NR	NR
Totals								
All studies	NA	661851	13402 (2.02)	698 (1.1)	1319 (1.8)	11385 (1.8)	5356 (2.0)	1648 (0.62)
Database studies	NA	488831	9962 (2.03)	111 (0.73)	290 (1.9)	9561 (2.0)	4814 (2.5)	1201 (0.55)
Case series	NA	79925	2078 (2.6)	587 (1.5)	1029 (6.8)	74 (0.02)	392 (0.21)	540 (0.25)
Registry studies	NA	110532	1750 (1.6)	NR	NR	1750 (1.6)	312 (0.68)	47 (0.10)

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)	Perkins 2012[98] Moderate	9023	195	NR	NR	195 (2.2)	NR	NR
	Gooda 2010[100] Moderate	1500	9	NR	NR	9 (0.6)	NR	2 (0.13)
	Kim 2010[99] Moderate	1109	33	0	33 (3)	NR	3 (0.27)	2 (0.18)
	Lowe 2007[123-125] Low	6161	363	NR	NR	363 (5.9)	NR	NR
	Liu 2001[108] Moderate	1438	134 (evaluations for PTH in 112 children)	9 (0.63)	125 (9)	NR	60 (4.2)	20 (1.4)
Cold dissection (total tonsillectomy)	Hultcrantz* 2014[117, 118] Low	3945	192	NR	NR	192 (4.9)	118 (3)	NR
	Perkins 2012[98] Moderate	9023	1	NR	NR	1 (0.01)	NR	NR
	Arnolder 2008[102] Moderate	3657	54	NR	NR	54 (1.5)	NR	54 (1.5)
	Lowe 2007[123-125] Low	5176	181	NR	NR	181 (3.5)	NR	NR
	Windfuhr 2001[105-107] Moderate	2567	41	27 (1)	14 (0.54)	NR	NR	41 (1.6)
	Carmody 1982[116] Moderate	1649	13	10 (0.61)	3 (0.18)	0	NR	NR
Coblation (total tonsillectomy)	Walner 2012[97] Moderate	1918	87	5 (0.5)	82 (4)	NR	NR	31 (1.6)
	Perkins 2012[98] Moderate	9023	15	NR	NR	15 (0.17)	NR	NR
Other techniques	Hultcrantz* 2014[117, 118] Coblation-partial Low	1602	20	NR	NR	20 (1.2)	13 (1.2)	NR
	Perkins 2012[98]	9023	1	NR	NR	1 (0.01)	NR	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 (%)
	PlasmaKnife total tonsilectomy Moderate							
	Sarny 2011[120, 121] Total tonsillectomy-unspecified Low	2080	255	NR	NR	255 (12.3)	NR	87 (4.2)
	Sarny 2011[120, 121] Partial tonsillectomy-unspecified Low	1292	28	NR	NR	28 (2.2)	NR	11 (0.85)

*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[96]	459	28	NR	28 (6.1)	NR	NR	NR
	Suzuki 2014[91]	31934	160	NR	NR	160 (0.50)	NR	160 (0.50)
	Hultcrantz 2014[117, 118]	10820	304	NR	NR	304 (2.8)	155 (1.4)	NR
	Perkins 2012[98]	1141	105	NR	NR	105 (9.2)	NR	NR
Recurrent throat infection	Achar 2015[96]	2398	150	NR	150 (6.3)	NR	NR	NR
	Perkins 2012[98]	158	28	NR	NR	28 (17.7)	NR	NR
Mixed	Achar 2015[96]	564	37	NR	37 (6.6)	NR	NR	NR
	Perkins 2012[98]	330	65	NR	NR	65 (19.7)	NR	NR
Other (not specified)	Achar 2015[96]	106	7	NR	7 (0.20)	NR	NR	NR
	Perkins 2012[98]	71	14	NR	NR	14 (19.7)	NR	NR

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[97]	1918	NR	29 (1.5)	NR	NR
Unspecified Tonsillectomy	**Mixed**					
	Mahant 2014 [89, 90]	139715	1060 (0.8)	Revisit for dehydration and vomiting 3011(2.2)	NR	NR
	Edmonson 2015[84]	35085	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
	Achar 2015[96]	3527	NR	NR	NR	ER visit for pain relief, poor oral intake, fever, and NV 346 (9.8)
	Not Specified					
	Bhattacharyya 2014[85]	79520	1180 (1.5)	NR	7503 (1.4)	Fever/ NV/ Dehydration 1765 (2.2)
	Duval 2015[87]	39906	NR	898 (2.3)	NR	NR
	Mills 2004[103]	4853	NR	NR	Vomiting requiring admission overnight 107 (2.7)	Rehydration or analgesia 24 (0.5)
	Colclasure 1990[110]	2011	NR	2 (0.05) [Not specific to age group]	NR	NR
	Granell 2004[104]	1243	NR	Poor oral intake 2 (0.2)	NR	NR
Totals	**(N arms)**					
	All (9)	307778	2594 (1.0)	4253 (1.9)	7728 (6.5)	2135 (2.4)

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 total tonsillectomy (1)	1918	NR	29 (1.5)	NR	NR
	Unspecified tonsillectomy (8)	305860	2594 (1.0)	4224 (1.9)	7728 (6)	2135 (2.4)

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 Agent N (%)	Mortality N (%)	VPI N (%)
Lavin 2015[126] 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 45(5.04) Non-obese T&A patients respiratory complications 1984(9.7) Non-obese T&A patients respiratory failure/pulmonary insufficiency 617(3.0)	No deaths in obese T&A patients 0 (0)	NR
Shay 2015[86] Case Series Low	Not Specified	Tonsillectomy (unspecified)	36,221	NR	2(0.005)	NR
Walner 2012[97] Database/Registry Moderate	OSDB, Throat Infection	Coblation total tonsillectomy	1,918	NR	0(0)	NR
Tweedie 2012[127] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	1,735	NR	0(0)	NR
Sarny 2011[120, 121] Database/Registry Low	Not Specified	Tonsillectomy (unspecified)	9,405	NR	0(0)	NR

Author Study Design RoB	Indication	Intervention	Total Arm N	Harms of Agent N (%)	Mortality N (%)	VPI N (%)
Bhattacharyya 2010[128] Database/Registry Moderate	Not Specified	Tonsillectomy (unspecified)	535,949	Airway obstruction NR(0.04)	NR	NR
Granell 2004[104] Case Series Moderate	Not Specified	Tonsillectomy (unspecified)	1,243	NR	0(0)	NR
Windfuhr 2001[105-107] Case Series Moderate	OSDB, Throat Infection	Tonsillectomy (unspecified)	2,567	NR	1(0.04)	NR
Herdman 1986[114] Case Series Moderate	Not Specified	Tonsillectomy (unspecified)	2,400	NR	0(0)	NR
Kristensen 1984[115] 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

Key Questions 5 and 6

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[129]	Dexamethasone, 0.5 mg/kg (injection)	154	17	2 (1)	0	15 (9.7)	3 (1.9)	3 (1.9)
	Czarnetzki 2008[130]	Dexamethasone, 0.5 mg/kg (IV)	52	12	0	0	12 (24)	NR	4 (8)
	Czarnetzki 2008[130]	Dexamethasone, 0.05 mg/kg (IV)	53	6	0	0	6 (11)	NR	3 (6)

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 (%)
	Czarnetzki 2008[130]	Dexamethasone, 0.15 mg/kg (IV)	54	2	0	0	2 (4)	NR	1 (2)
	Hanasono 2004[131]	Cold tonsillectomy+ dexamethasone, 1 mg/kg (IV)	44	1	0	1 (2.3)	0	1 (2)	0
	Aysenur 2014[132]	Dexamethasone sodium phosphate, 1 mg/kg (infiltration)	20	0	0	0	0	0	0
	Hermans 2012[133]	Dexamethasone, 0.15 mg/kg (IV)	46	0	0	0	0	0	0
	Hermans 2012[133]	Dexamethasone, 0.5 mg/kg (IV)	44	0	0	0	0	0	0
	Aouad 2012[134]	Methylprednisolone, 2.5 mg/kg (IV)	78	0	0	0	0	0	0
	Aouad 2012[134]	Dexamethasone, 0.5 mg/kg (IV)	75	0	0	0	0	0	0
	Hanasono 2004[131]	Hot tonsillectomy+ dexamethasone, 1 mg/kg (IV)	62	0	0	0	0	0	0
	Unspecified								
	Nawasreh 2000[135]	Dexamethasone, 1 mg/kg (IV)	62	2	0	2 (3.2)	0	NR	NR
	Elhakim 2003[136]	Dexamethasone, 0.5 mg/kg (IV)	55	0	0	0	0	0	0
	Alajmi 2008[137]	Dexamethasone, 1mg/kg (IV)	42	0	0	0	0	0	NR
	Kaan 2006[138]	Dexamethasone	32	0	0	0	0	0	0
NSAIDs	**Throat infection**								
	Abdel-Ghaffar 2015[139]	Lornoxicam in one tonsil , 8 mg (infiltration)	34	0	0	0	0	0	0
	Unspecified								
	Solanki 2012[140]	Diclofenac, 2 mg/kg (rectal)	25	3	NR	NR	3 (12)	NR	NR
	Moss 2014[141]	Ibuprofen, 10 mg/kg (IV)	73	2	NR	NR	2 (3)	0	1 (1.4)
	Lee 2009[142]	Ketorolac, preoperative, 1	24	1	NR	NR	1 (4)	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)							
	Keidan 2004[143]	Ketoroloc, 1 mg/kg^{-1} (IV)	25	0	0	0	0	0	0
	Lee 2009[142]	Ketorolac, perioperative, 1 mg/kg (IV)	26	0	0	0	0	0	0
	Kedek 2005[144]	Ibuprofen, 10 mg/kg (oral)	20	0	0	0	0	0	0
Non-NSAID Analgesics	**Unspecified**								
	Lee 2009[142]	Propacetamol, perioperative, 30 mg/kg (IV)	26	0	0	0	0	0	0
	Keidan 2004[143]	Fentanyl, 2 µg/kg^{-1}(IV)	32	0	0	0	0	0	0
	Lee 2009[142]	Propacetamol, preoperative, 30 mg/kg (IV)	26	0	0	0	0	0	0
Anesthetic	**Mixed**								
	Aysenur 2014[132]	Levobupivacaine with epinephrine, ND (infiltration)	20	0	0	0	0	0	0
	Unspecified								
	Safavi 2012[140]	Bupivacaine (0.25%), 5 mL (infiltration)	25	4	NR	NR	4 (16)	NR	NR
Placebo	**Throat infection**								
	Abdel-Ghaffar 2015[139]	peritonsillar saline in other tonsil (infiltration)	34	0	0	0	0	0	0
	Abdel-Ghaffar 2015[139]	bilateral peritonsillar saline (infiltration)	68	0	0	0	0	0	0
	Mixed								
	Gallagher 2012[129]	placebo (saline), 0.5 mg/kg (injection)	151	13	2 (1)	NR	11 (7.3)	5 (3.2)	1 (0.6)
	Czarnetzki 2008[130]	Placebo (saline), NR (IV)	54	2	0	0	2 (4)	NR	0
	Hermans	Placebo (saline), 0.5 mL/kg	44	1	0	0	1 (2)	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 (%)
	2012[133]	(IV)							
	Hanasono 2004[131]	cold tonsillectomy+placebo, 1 mg/kg (IV)	57	1	1 (1.8)	0	0	1 (1.8)	NR
	Aysenur 2014[132]	Saline, ND (infiltration)	20	0	0	0	0	0	0
	Hanasono 2004[131]	hot tonsillectomy+placebo, 1 mg/kg (IV)	56	0	0	0	0	0	0
	Unspecified								
	Alajmi 2008[137]	Placebo, 5 mL (IV)	38	3	0	3 (7.9)	0	3 (7.9)	NR
	Nawasreh 2000[135]	Placebo (distilled water)(IV)	58	2	0	2 (3)	NR	2 (3)	0
	Moss 2014[141]	placebo (normal saline), 10 mg/kg (IV)	65	1	0	0	1 (2)	0	0
	Elhakim 2003[136]	Placebo (saline), 0.5 mg/kg (IV)	55	0	0	0	0	0	0
	Kaan 2006[138]	Placebo (saline), 0.5 mg/kg (IV)	30	NR	NR	NR	NR	NR	0
Totals	**(N arms)**								
	All arms	NA	1959	73 (3.7)	5 (0.27)	8 (0.47)	60 (3.2)	17 (1.1)	14 (0.83)
	Steroids (15)	NA	873	40 (4.6)	2 (0.23)	3 (0.34)	35 (4.0)	4 (0.61)	11 (1.4)
	Placebo (13)	NA	730	23 (3.2)	3 (0.43)	5 (0.91)	15 (0.80)	13 (0.85)	2 (0.12)
	NSAIDs (7)	NA	277	6 (2.6)	0	0	6 (2.6)	0	1 (1.4)
	Anesthetics (2)	NA	45	4 (8.9)	0	0	4 (16)	0	0
	Non-NSAID Analgesics (3)	NA	84	0	0	0	0	0	0

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	Acetylsalicylic	423	18	5 (1.2)	13 (3.1)	0	NR	8 (2)

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 (%)
	1988[145]	acid (Oral, dose not specified)							
	Mixed								
	Ozkiris 2012[146]	Ibuprofen, 30 mg/kg/day (Oral)	115	6	0	0	6 (5.21)	NR	1 (1)
	Unspecified								
	Murto 2015[147]	Celecoxib, 6 mg/kg preoperative and 3 mg/kg post-op (Oral)	141	8	0	0	8 (5.7)	8 (5.7)	3 (2.1)
Non-NSAID analgesics	**Throat infection**								
	Stage 1988[145]	Acetaminophen (Oral)	409	9	7 (1.7)	2 (0.49)	0	NR	3 (1)
	Mixed								
	Ozkiris 2012[146]	Metamizole sodium, 0.4 mg/kg/day (Oral)	115	4	0	0	4 (3.47)	NR	0
	Ozkiris 2012[146]	Acetaminophen, 40 mg/kg/day (Oral)	110	4	0	0	4 (3.63)	NR	0
	Unspecified								
	Lalicevic et al. 2004[148]	Benzydamine hydrochloride oral rinse, 20 mg/kg (Oral)	138	6	0	0	6 (4.3)	NR	NR
Steroids	**Mixed**								
	Park 2015[149]	Prednisolone, 0.25 mg/kg/day (Oral)	69	2	0	0	2 (2.5)	NR	NR
	Macassey et al. (2012)[150]	Prednisolone syrup, 0.5 mg/kg (Oral)	91	11	0	0	11 (12)	1 (1)	NR
Other	Unspecified								
	Lalicevic	Salvia officinalis	140	6	0	0	6 (4.3)	NR	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 (%)
	2004[148]	oral rinse, 20 mg/kg (Oral)							
No treatment/ Placebo	**Throat infection**								
	Macassey 2012[150]	Placebo syrup, 0.5 mg/kg (Oral)	102	13	0	0	13 (12)	1 (1)	NR
	Park 2015[149]	No Prednisolone	69	2	0	0	2 (2.5)	NR	NR
	Unspecified								
	Murto 2015[147]	Placebo	141	8	0	0	8 (5.7)	8 (5.7)	2 (1.4)
Totals	**(N arms)**								
	All arms (13)	NA	2063	97 (4.7)	12 (0.)	15 (0.)	70 ()	18 (0.)	17 (0.)
	NSAIDs (3)	NA	679	32 (4.7)	5 (1.2)	13 (3.1)	14 (2.6)	8 (5.7)	12 (1.8)
	Non-NSAID analgesics (4)	NA	772	23 (3.0)	7 (1.7)	2 (0.49)	14 (1.8)	NR	3 (1.3)
	Steroids (2)	NA	160	13 (8.2)	NR	NR	13 (8.1)	NR	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, Year	Perioperative Agent	Total Arm N	N Pain Revisits, (%)	N Dehydration Revisits, (%)	N PONV Revisits, (%)
Steroids	Gao[151]	Dexamethasone (IV)	78	0 (0)	NR	0
	Gao[151]	Dexamethasone (infiltration)	78	0 (0)	NR	0
	Hanasono[131]	Dexamethasone	61	NR	1 (1.6)	NR
	Alajmi[137]	Dexamethasone	42	0 (0)	0	0
	Elhakim[136]	Dexamethasone	20	0 (0)	0	0
NSAIDs	Oztekin[152]	Diclofenac	20	0 (0)	0	0
Anesthetic	*El-Fattah[153]	Propofol	80	0 (0)	0	0
Placebo/no agent	Hanasono[131]	Placebo	56	NR	0	NR
	Sukhani[154]	Placebo	49	NR	NR	ER or hospital admit for vomiting and poor oral intake 1 (2)
	Alajmi[137]	Placebo	38	Readmitted for throat pain/dysphagia 4 (10.5)	NR	NR
	Oztekin[152]	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[151] 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[132] 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 suspension) – POD1,** G1: 2±0.3	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)				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
Faiz 2013[155] 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 vs. G2, p = 0.533 G1 vs. G2, p = 0.314

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
					G1: 0 (0) G2: 1 (2)	
Hermans 2012[133] 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)	dissection technique combined with electrocoagulation when judged necessary by the surgeon.	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[134] RCT 2-12 low	G1: Methylprednisolone, 2.5 mg/kg (IV) (78) G2: Dexamethasone, 0.5 mg/kg (IV) (75)	electrodissection technique (for recurrent tonsillitis) or microdebrider-assisted partial tonsillectomy (for obstructive tonsils)	Wong-Baker faces pain score >6 Upon request Recurrent vomiting >2 episodes less than 5 minutes apart	From PACU to 24 hrs post-op 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: 2 (0-4) G2: 3 (1-4) **N needing IV ondansetron (mg), (%)**	G1 vs. G2, p = NR G1 vs. G2, p = 0.26 G1 vs. G2, p = 0.62

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
					G1: 1 (1) G2: 2 (3)	
Khani 2009[156] 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[137] RCT 5-18 moderate	G1: Dexamethasone, 1mg/kg (IV) (42) G2: Placebo, 5 mL (IV) (38)	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[130] RCT 2-17 moderate	G1: Dexamethasone, 0.05 mg/kg (IV) (53) G2: Dexamethasone, 0.15 mg/kg (IV) (54) G3: Dexamethasone, 0.5 mg/kg (IV) (52) G4: Placebo (saline) (IV) (54)	Classic complete 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 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) G3: 20 (38) G4: 35 (65) **N needing IV ondansetron (µg), (%)**	G1 vs. G2 vs. G3 vs. G4, p = 0.42 G1 vs. G2 vs. G3 vs. G4, p = 0.01 G1 vs. G2 vs. G3 vs. G4, p = 0.04

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
					G1: 4 (8) G2: 3 (5.6) G3: 2 (4) G4: 11 (20)	
Kim 2007[157] 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[138] RCT 4-12 low	G1: Dexamethasone, 0.5 mg/kg (IV) (32) G2: Placebo (saline), 0.5 mg/kg (IV) (30)	sharp dissection tonsillectomy technique	"Faces" scale pain score >3 Retching or vomiting more than once in 3 minutes If vomiting was not under control in 20 minutes, ondansetron	PACU 2 hrs post-op 3 hrs post-op	**N needing IV meperidine (mg), (%)** G1: 8 (25) G2: 12 (40) **N needing oral paracetamol (mg, 2 hrs), (%)** G1: 6 (19) G2: 4 (13) **N needing oral paracetamol (mg, 3**	G1 vs G2, p = NR 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
			was given		**hrs), (%)** G1: 11 (34) G2: 17 (57)	
				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[158] 2-12 moderate	G1: Dexamethasone, 0.5 mg/kg (IV) (29) G2: Placebo (normal saline), 0.5 mg/kg (IV) (31)	electrodissection	Unspecified (Rectal acetaminophen given to all children) Vomiting occurring less than 5 minutes apart or with persistent distressing emetic symptoms (Early=PACU, Late=Ward)	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), (%)** G1: 17 (63) G2: 14 (45.1)	
				PACU	**N needing IV metoclopramide (mg), (%)**	G1 vs G2, p =0.09

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
					G1: 7 (24.1) G2: 15 (48.4)	
Elhakim 2003[136] RCT 4-11 low	G1: Dexamethasone, 0.5 mg/kg (IV) (55) G2: Placebo (saline), 0.5 mg/kg (IV) (55)	electrodissection	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[141] 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 24-28 hrs post-op	**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) G2: 61 (94) **N needing more than 1 dose of IV**	G1 vs. G2, p = 0.021 G1 vs. G2, p = 0.068 G1 vs. G2, p=0.028

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
					fentanyl (µg), (%): G1: 31 (42) G2: 40 (62)	
Abdel-Ghaffar 2012[159] 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[140] 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[160] 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[161] 5-12 moderate	G1: Sodium diclofenac, 1 mg/kg (rectal) (65) G2: Viscous lignocaine, 2%, 4 mg/kg (topical) (65)	blunt and snare dissection technique	Patient complained of intolerable pain and VAS score (0-100 mm) assessment (unspecified) NA	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 needed 2 hrs post-op, mean(units) ± SD**	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
				12 hrs post-op 24 hrs post-op	G1: 0.11 ± 0.32 G2: 0.02 ± 0.12 **Doses of IV pethidine needed 12 hrs post-op, mean(units) ± SD** G1: 0.46 ± 0.59 G2: 0.65 ± 0.59 **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 = 0.061 G1 vs. G2, p = 0.068
Antila 2006[162] 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[163] 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[144] 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[152] 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[164] 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[165] 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[166] 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)[167] 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)[167] 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

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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 mucopolysaccharid osis 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 Type of Surgical Interventions (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 Medical Interventions for Tonsillectomy (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 1991 to 2011	Primary • Incidence of postop bleeding Secondary • Incidence of admission for bleeding episodes • Operative interventions for bleeding episodes • Red blood cell transfusion • Mortality	29 studies with 2674 patients (19 studies with children only, 6 studies with adults only, 4 studies included mixed population)	• 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 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

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
					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 measured by VAS	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 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

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	# Included Studies	Key Findings
					• 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 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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