Topic Brief: Polysomnography in Children with Obstructive Sleep Disordered Breathing being considered for Tonsillectomy

Date: 06/04/2020
Nomination Number: 871

Purpose: This document summarizes the information addressing a nomination submitted on 7/30/2019 through the Effective Health Care Website. This information was used to inform the EPC Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: There is variation among medical society practice recommendations with regards to the necessity of performing polysomnography for all children with Obstructive Sleep Disordered Breathing (OSDB) for whom tonsillectomy is being considered.

Program Decision: The EPC Program will not develop a new systematic review because we did not find any primary studies addressing the concerns of this nomination

Key findings

- We did not find any completed or in-process systematic reviews that addressed polysomnography test characteristics to predict appropriateness of surgical vs. non-surgical treatment for children with OSDB, polysomnography effectiveness in improving sleep, behavioral, and health outcomes among children with OSDB, or harms associated with performing polysomnography among children with OSDB.
- No relevant primary studies were found that addressed the key questions in a limited feasibility search.

Background

- Obstructive Sleep Disordered Breathing (OSDB) is a clinical diagnosis characterized by obstructive abnormalities of the respiratory pattern or the adequacy of oxygenation/ventilation during sleep, which include snoring, mouth breathing, and pauses in breathing.[1]
- More than 300,000 tonsillectomies (with or without adenoidectomy) are performed annually in the United States for children less than 15 years of age.[2] About 80% of these surgeries are done to treat OSDB. OSDB can also be managed non-surgically through watchful waiting, continuous positive airway pressure, and other strategies.[3]
- Identifying children who require tonsillectomy vs. patients who can avoid surgery and its potential complications has been an ongoing challenge for health care providers.[4]

- Polysomnography, also called a sleep study, is a test used to diagnose sleep disorders. There is variation in recommendations of medical societies regarding the necessity of polysomnography. American Academy of Sleep Medicine recommends polysomnography for all children with OSDB for whom tonsillectomy is being considered[5] while American Academy of Otolaryngology–Head and Neck Surgery Foundation recommends polysomnography for high-risk children (less than 2 years of age or exhibit obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses).[6]

Nomination Summary

- The nominator is a sleep medicine physician who is interested in determining whether current evidence supports requiring all children being considered for tonsillectomy undergo a polysomnography.
- The nominator plans to use the report to inform update of clinical guidelines and health care policies.
- We worked with the nominator to formulate key questions and a scope that could help address the nomination while maintaining equipoise.

Scope

1. What are the test characteristics (sensitivity, specificity, and predictive value) of PSG for identifying children with OSDB who require tonsillectomy/adenotonsillectomy vs. children with OSDB who will respond to non-surgical management (i.e. watchful waiting, CPAP, etc.)?
2. What is the effectiveness of PSG in improving sleep, behavioral, and health outcomes among children with OSDB?
3. What are the harms associated with conducting PSG among children with OSDB?

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing and setting)

Questions	1. PSG Test Characteristics	2. PSG Effectiveness	3. PSG Harms
Population	Children 2 years old or older with suspected OSDB being considered for tonsillectomy/ adenotonsillectomy *Exclude: obese children; children with Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses*		
Interventions	PSG		
Comparators	No PSG		

Questions	1. PSG Test Characteristics	2. PSG Effectiveness	3. PSG Harms
Outcomes	**Sensitivity, specificity, positive/ negative predictive value** for identifying children with OSDB who need surgery vs. those who will respond to non-surgical management	**Sleep outcomes** • Apnea Hypopnea Index • Sleep quality measures (Obstructive Sleep Apnea-18, Clinical Assessment Score-15) • Pediatric Sleep Questionnaire 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** • Overdiagnosis/ overtreatment • Surgery-related harms • Re-admission or ER visit or ICU admission for postoperative pain, dehydration, post-tonsillectomy hemorrhage, or nausea and vomiting • Reoperation for primary or secondary post-tonsillectomy hemorrhage • Velopharyngeal insufficiency • 30-day mortality • Undertreatment/ delayed treatment • Non-surgical treatment-related harms
Timing	All timings		
Setting	All settings		

Abbreviations: PSG=polysomnography; OSDB=obstructive sleep-disordered breathing; ER=emergency room; ICU=intensive care unit; BMI=body mass index

Assessment Methods

See Appendix A.

Summary of Literature Findings

We did not find any completed or in-process systematic reviews that addressed polysomnography test characteristics to predict appropriateness of surgical vs. non-surgical treatment for children with OSDB, polysomnography effectiveness in improving sleep, behavioral, and health outcomes among children with OSDB, or harms associated with performing polysomnography among children with OSDB.

We did not find primary studies or in-progress clinical trials that address any of the key questions. Studies that do investigate test accuracy of polysomnography focused primarily on accuracy for diagnosing obstructive sleep apnea rather than the sleep test's ability to predict treatment outcomes.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

Due to lack of primary studies that address the key questions, a systematic review is deemed not feasible at this time.

Please see Appendix B for detailed assessments of the EPC Program selection criteria.

References

1. Lin J, Suurna M. Sleep Apnea and Sleep-Disordered Breathing. Otolaryngol Clin North Am. 2018 Aug;51(4):827-33. doi: 10.1016/j.otc.2018.03.009. PMID: 29779616. [https://www.ncbi.nlm.nih.gov/pubmed/29779616].

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3. Venekamp RP, Hearne BJ, Chandrasekharan D, et al. Tonsillectomy or adenotonsillectomy versus non-surgical management for obstructive sleep-disordered breathing in children. Cochrane Database Syst Rev. 2015 Oct 14(10):CD011165. doi: 10.1002/14651858.CD011165.pub2. PMID: 26465274. [https://www.ncbi.nlm.nih.gov/pubmed/26465274].

4. Yellon RF. Is polysomnography required prior to tonsillectomy and adenoidectomy for diagnosis of obstructive sleep apnea versus mild sleep disordered breathing in children? Laryngoscope. 2010 May;120(5):868-9. doi: 10.1002/lary.20883. PMID: 20422677. [https://www.ncbi.nlm.nih.gov/pubmed/20422677].

5. Aurora RN, Zak RS, Karippot A, et al. Practice parameters for the respiratory indications for polysomnography in children. Sleep. 2011 Mar 1;34(3):379-88. doi: 10.1093/sleep/34.3.379. PMID: 21359087. [https://www.ncbi.nlm.nih.gov/pubmed/21359087].

6. Mitchell RB, Archer SM, Ishman SL, et al. Clinical Practice Guideline: Tonsillectomy in Children (Update). Otolaryngol Head Neck Surg. 2019 Feb;160(1_suppl):S1-S42. doi: 10.1177/0194599818801757. PMID: 30798778. [https://www.ncbi.nlm.nih.gov/pubmed/30798778].

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years December 2016 to December 2019 on the key questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
  - AHRQ EHC Program https://effectivehealthcare.ahrq.gov/
  - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
  - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed from the last five years 2014-2019 on parts of the nomination scope not addressed by earlier identified systematic reviews. We reviewed a random sample of 200 identified titles and abstracts for inclusion and classified identified studies by key question and study design to estimate the size and scope of a potential evidence review.

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to December 17, 2019
Date searched: December 17, 2019
Searched by: Robin Paynter, MLIS

 # Searches (Number of Citations)
1 Sleep Apnea Syndromes/ (14345)
2 exp Sleep Apnea, Obstructive/ (19856)
3 ((obstruct* adj3 sleep* adj3 breath*) or OSDB).ti,ab,kf. (547)
4 (sleep* adj5 (apnea* or hypopnea* or apneahypopnea* or apnoea* or hypopnoea* or apnoeic)).ti,ab,kf. (36690)
5 ((hypertroph* or hyperplasia or obstructive) adj3 (tonsil* or adenoid* or adenotonsil* or adeno-tonsil*)).ti,ab,kf. (2694)
6 ((nighttime or sleep* or "night time") and (((breath* or airway*) adj5 (obstruct* or restric*)) or (mouth adj3 breath*))).ti,ab,kf. (4583)
7 or/1-6 (46557)
8 Adolescent/ or Child/ or Child, Preschool/ (2945068)
9 (adolescen* or child* or juvenile* or paediatr* or pediatr* or preschool* or pre-school* or school-age or teen* or toddler* or youth* or young).ti,ab,kf. (2101299)
10 or/8-9 (3779321)
11 polysomnography/ (20370)
12 (polysomnograph* or polysomnogram*).ti,ab,kf. (18535)
13 or/11-12 (27222)
14 and/7,10,13 (3602)
15 limit 14 to english language (3291)
16 15 not (obese or obesity or craniofacial or cranio-facial or "Down syndrome" or neuromuscular or neuro-muscular or "sickle cell" or mucopolysaccharidoses).ti. (2899)
17 (meta-analysis or systematic review).pt. (177594)
18 (meta-analy* or metaanaly* or ((evidence or systematic) adj3 (review or synthesis))).ti,ab,kf. (281909)
19 or/17-18 (303392)
20 and/16,19 (64)
21 limit 20 to yr="2016 -Current" (30)
22 (controlled clinical trial or randomized controlled trial).pt. (584630)
23 (control or controls or controlled or random* or trial).ti,ab,kf. (4344698)
24 or/22-23 (4466569)
25 and/16,24 (837)
26 limit 25 to yr="2014 -Current" (324)
27 limit 16 to yr="2014 -Current" (1112)
28 27 not (21 or 26) (772)

Search for Primary Studies (ClinicalTrials.gov)
https://clinicaltrials.gov/ct2/results?cond=&term=OSBD+OR+%28%28sleep*+OR+night+OR+nighttime+OR+nocturnal%29+AND+%28breathing+OR+apnea*+OR+hypopnea*+OR+apneahypopnea*+OR+apnoea*+OR+hypopnoea*+OR+apnoeic+OR+obstructive+OR+restriction%29%29&type=&rslt=&recrs=b&recrs=a&recrs=f&recrs=d&recrs=e&age_v=&age=0&gndr=&intr=polysomnography+OR+polysomnogram&titles=&outc=&spons=&lead=&id=&cntry=&state=&city=&dist=&locn=&strd_s=&strd_e=&prcd_s=&prcd_e=&sfpd_s=01%2F01%2F2016&sfpd_e=12%2F17%2F2019&lupd_s=&lupd_e=&sort=

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes, polysomnography is an intervention/test available in the United States.
1b. Is the nomination a request for an evidence report?	Yes, a systematic review is requested.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes, effectiveness is a focus of a review.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes, more than 300,000 tonsillectomies (with or without adenoidectomy) are performed annually in the United States for children less than 15 years of age. About 80% of these surgeries are done to treat OSDB.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. If polysomnography can predict response to surgical vs. non-surgical treatment, prescription of the appropriate treatment will be streamlined and unnecessary procedures and complications can be avoided.
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes, see 2b.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. The average cost for tonsillectomy ranges from $3,200 to $8,500.
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes, since we did not find any completed on in-process systematic review that addressed the key questions, a new review would not be duplicative.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes, there is variation in recommendations of medical societies regarding the necessity of polysomnography. American Academy of Sleep Medicine recommends polysomnography for all children with OSDB for whom tonsillectomy is being considered while American Academy of Otolaryngology–Head and Neck Surgery Foundation recommends polysomnography for high-risk children (less than 2 years of age or exhibit obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses).
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes, see 4a.

Selection Criteria	Assessment
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We did not find any primary studies or completed/ongoing clinical trials that addressed the key questions. Thus, we could not recommend a systematic review by the EPC Program.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Not done.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Not done.

Abbreviations: OSDB=Obstructive Sleep Disordered Breathing; EPC=Evidence-based Practice Center