Dr. Strangelove or: How I learned to stop worrying and love the Clinical Practice Guidelines

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DEPARTMENT OF OTOLARYNGOLOGY
GRAND ROUNDS PRESENTATION
MARCH 19, 2014
Objectives:

1. The participant should be able to identify the various levels of evidence and apply them to setting guideline recommendations.

2. The participant should know the Paradise criteria and indications for tonsillectomy related to these criteria.

3. The participant should understand the guideline recommendations for post-operative pain control.
How do we come up with Clinical Practice Guidelines?
IT MIGHT NOT BE SHAKESPEARE, BUT I JUST WROTE A PRETTY GOOD SONNET ABOUT BANANAS.
• The American Academy of Otolaryngology- Head and Neck Surgery Foundation (AAO-HNSF) has systemized the development of internal guidelines

• Published 8 multidisciplinary guidelines all within 12-18 months of conception

• Now on the 3rd edition of their Development Manual
What is a guideline?

- Evolving methodology
- Help Clinicians translate best evidence into best practice
- Promotes quality
  - Reducing healthcare variations
  - Improving Diagnostic Accuracy
  - Promoting Effective Therapy
  - Discouraging ineffective or harmful interventions
Why?

- Wide regional variations exist in managing conditions
- Wide variability within and between groups
Barriers to making valid, actionable guidelines

- Do not translate into measurable actions or activities
- Development inefficient and highly complex
- Gaps in evidence base may preclude guideline recommendations
The solution per AAO-HNSF is to produce quality-driven, evidence-based guidelines using efficient and transparent methodology for actionable recommendations with multidisciplinary applicability.
• Quality-driven:
  • places quality improvement at the forefront of guideline development. Uses current best evidence and multidisciplinary consensus to prioritize recommendations

• Evidence-based:
  • supporting all decisions with best available research evidence identified through systemic literature review

• Efficient:
  • Maximal use of available resources to create timely product, within 12-18 months
• Transparent methodology:
  • Explicit, reproducible, and applied methodology that can link recommendations to the level of evidence, benefit-harm-cost relationship, and roles of values and patient preferences

• Actionable:
  • tells the provider precisely what to do, to whom, and under what specific circumstance using unambiguous language

• Multidisciplinary:
  • all stakeholders are part of the developmental and implementation process
### Timetable for Guideline Development

<table>
<thead>
<tr>
<th>Month</th>
<th>Activity</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>Planning</td>
<td>Define topic, identify leadership, partner organizations and working group members</td>
</tr>
<tr>
<td>1-2</td>
<td>Stage 1 literature search</td>
<td>Identify existing guidelines and systematic reviews</td>
</tr>
<tr>
<td>3</td>
<td>Conference Call 1</td>
<td>Define purpose, timeline, scope</td>
</tr>
<tr>
<td>3-4</td>
<td>Stage 2 literature search</td>
<td>Identify RCTs</td>
</tr>
<tr>
<td>4</td>
<td>Conference Call 2</td>
<td>Refine scope and definitions, generate list of opportunities for QI</td>
</tr>
<tr>
<td>5</td>
<td>In-person meeting 1</td>
<td>Construct guideline of key action statements and profiles based on topic priorities</td>
</tr>
<tr>
<td>5-6</td>
<td>Stage 3 literature search</td>
<td>Identify best evidence to facilitate writing assignments</td>
</tr>
<tr>
<td>Month</td>
<td>Activity</td>
<td>Goals</td>
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<td>-----------------------------------------------------------------------</td>
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<tr>
<td>5-6</td>
<td>Writing Assignments</td>
<td>Write amplifying text for key action statements</td>
</tr>
<tr>
<td>7</td>
<td>In-person meeting 2</td>
<td>Refine key action statements, review amplifying text, revise and complete action statement profiles; finalize recommendation grades</td>
</tr>
<tr>
<td>7-8</td>
<td>Writing assignments</td>
<td>Revise and polish draft guideline</td>
</tr>
<tr>
<td>8</td>
<td>Appraising draft implementability</td>
<td>Appraisal of draft guideline clarity, quality and ability to be successfully implemented</td>
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<tr>
<td>9</td>
<td>Conference call 3</td>
<td>Review guideline appraisal report</td>
</tr>
<tr>
<td>10-11</td>
<td>Prerelease peer review</td>
<td>External review of draft guideline by representatives of target audiences</td>
</tr>
<tr>
<td>12</td>
<td>Public comment</td>
<td>Guideline draft released for period of public comment and review</td>
</tr>
<tr>
<td>13-14</td>
<td>Organizational board review and journal peer review</td>
<td>Review and approve guideline by board of directors with submission to journal for editorial peer review</td>
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</table>
How is this approach validated?

• “Simply inserting the word guideline in the title of a document does not make it so.”

• AGREE II (Appraisal of Guidelines Research & Evaluation II)
  • Methodologic framework for development
Agree or disagree?
• AGREE II uses the following attributes for quality guidelines
  • Explicit scope and purpose
  • Stakeholder involvement
  • Rigor of development
  • Clarity of presentation
  • Applicability
  • Editorial Independence
## Conference on Guideline Standardization (COGS) checklist

- 18 characteristics on COGS checklist

<table>
<thead>
<tr>
<th>No.</th>
<th>Characteristic</th>
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<tbody>
<tr>
<td>1</td>
<td>Overview material</td>
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<tr>
<td>2</td>
<td>Focus</td>
</tr>
<tr>
<td>3</td>
<td>Goal</td>
</tr>
<tr>
<td>4</td>
<td>Users/setting</td>
</tr>
<tr>
<td>5</td>
<td>Target population</td>
</tr>
<tr>
<td>6</td>
<td>Developer</td>
</tr>
<tr>
<td>7</td>
<td>Funding source</td>
</tr>
<tr>
<td>8</td>
<td>Evidence collection</td>
</tr>
<tr>
<td>9</td>
<td>Grading criteria</td>
</tr>
<tr>
<td>10</td>
<td>Evidence synthesis</td>
</tr>
<tr>
<td>11</td>
<td>Prerelease review</td>
</tr>
<tr>
<td>12</td>
<td>Update plan</td>
</tr>
<tr>
<td>13</td>
<td>Definitions</td>
</tr>
<tr>
<td>14</td>
<td>Recommendations and rationale</td>
</tr>
<tr>
<td>15</td>
<td>Benefits and harm</td>
</tr>
<tr>
<td>16</td>
<td>Patient preference</td>
</tr>
<tr>
<td>17</td>
<td>Algorithm</td>
</tr>
<tr>
<td>18</td>
<td>Implementation</td>
</tr>
</tbody>
</table>
What Guidelines Are Not

- Guidelines are not reimbursement policies
- Guidelines are not performance measures
- Guidelines are not legal precedents
- Guidelines are not intended for comprehensive management
- Guidelines are not for provider selection or public reporting
- Guidelines are not recipes for cookbook medicine
The Key Action Statement

• Cornerstone of Clinical Practice Guideline
• Describes the When, Who, “Must, should, or may”, Do What, and To Whom.
• “Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.”
“Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.”

- Aggregate evidence quality: Grade A, randomized controlled trials and multiple systematic reviews, for preventing postoperative nausea and vomiting; grade A, randomized controlled trials and 1 systematic review, for decreased pain and shorter time to oral intake

- Benefit: Decreased incidence of postoperative nausea and vomiting up to 24 hours posttonsillectomy, decreased times to first oral intake, and decreased pain as measured by lower pain scores and longer latency times to analgesic administration

- Harm: No adverse events in all randomized controlled trials except one, which reported increased hemorrhage as a secondary outcome unadjusted for other risk factors

- Cost: Direct cost of medication and indirect costs of drug administration

- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: Decreased postoperative pain, nausea, and vomiting are likely to result in increased patient satisfaction and decreased incidence of overnight hospital admission, associated with lower total health care costs compared with direct and indirect costs of drug administration

- Role of patient preference: None

- Intentional vagueness: None

- Exclusions: Patients with endocrine disorders who are already receiving exogenous steroids or in whom steroid administration may interfere with normal glucose-insulin regulation (e.g., diabetes)

- Policy level: Strong recommendation
What is the grade of evidence for a randomized controlled trial comparing two surgical techniques?

A. Grade A
B. Grade B
C. Grade C
D. Grade D
E. Grade X
Answer

- Grade B, includes RCTs and observational studies with dramatic effects or highly consistent results
# How to Assign the Aggregate Level of Evidence

<table>
<thead>
<tr>
<th>Grade</th>
<th>OCEBM Level</th>
<th>Treatment</th>
<th>Harm</th>
<th>Diagnosis</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>Systematic review of randomized trials</td>
<td>Systematic review of randomized trials, nested case-control studies, or observational studies with dramatic effect</td>
<td>Systematic review of cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Systematic review of inception cohort studies</td>
</tr>
<tr>
<td>B</td>
<td>2</td>
<td>Randomized trials or observational studies with dramatic effects or highly consistent evidence</td>
<td>Randomized trials, or observational studies with dramatic effects or highly consistent evidence</td>
<td>Cross-sectional studies with consistently applied reference standard and blinding</td>
<td>Inception cohort studies</td>
</tr>
<tr>
<td>C</td>
<td>3-4</td>
<td>Non-randomized or historically controlled studies, including case-control and observational studies</td>
<td>Nonrandomized controlled cohort or follow-up study (post-marketing surveillance) with sufficient numbers to rule out a common harm; case-series, case-control, or historically controlled studies</td>
<td>Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards</td>
<td>Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study</td>
</tr>
<tr>
<td>D</td>
<td>5</td>
<td>Case reports, mechanisms-based reasoning, or reasoning from first principles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>NA</td>
<td>Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Step 1 (Level 1*)</td>
<td>Step 2 (Level 2*)</td>
<td>Step 3 (Level 3*)</td>
<td>Step 4 (Level 4*)</td>
<td>Step 5 (Level 5)</td>
</tr>
<tr>
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<td>-----------------------------------------------------------------------------------</td>
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<tr>
<td>How common is the problem?</td>
<td>Local and current random sample surveys (or censuses)</td>
<td>Systematic review of surveys that allow matching to local circumstances**</td>
<td>Local non-random sample**</td>
<td>Case-series**</td>
<td>n/a</td>
</tr>
<tr>
<td>Is this diagnostic or monitoring test accurate? (Diagnosis)</td>
<td>Systematic review of cross sectional studies with consistently applied reference standard and blinding</td>
<td>Individual cross sectional studies with consistently applied reference standard and blinding</td>
<td>Non-consecutive studies, or studies without consistently applied reference standards**</td>
<td>Case-control studies, or 'poor or non-independent reference standard'**</td>
<td>Mechanism-based reasoning</td>
</tr>
<tr>
<td>What will happen if we do not add a therapy? (Prognosis)</td>
<td>Systematic review of inception cohort studies</td>
<td>Inception cohort studies</td>
<td>Cohort study or control arm of randomized trial*</td>
<td>Case-series or case-control studies, or poor quality prognostic cohort study**</td>
<td>n/a</td>
</tr>
<tr>
<td>Does this intervention help? (Treatment Benefits)</td>
<td>Systematic review of randomized trials or n-of-1 trials</td>
<td>Randomized trial or observational study with dramatic effect</td>
<td>Non-randomized controlled cohort/follow-up study**</td>
<td>Case-series, case-control studies, or historically controlled studies**</td>
<td>Mechanism-based reasoning</td>
</tr>
<tr>
<td>What are the COMMON harms? (Treatment Harms)</td>
<td>Systematic review of randomized trials, systematic review of nested case-control studies, n-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect</td>
<td>Individual randomized trial or (exceptionally) observational study with dramatic effect</td>
<td>Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**</td>
<td>Case-series, case-control, or historically controlled studies**</td>
<td>Mechanism-based reasoning</td>
</tr>
<tr>
<td>What are the RARE harms? (Treatment Harms)</td>
<td>Systematic review of randomized trials or n-of-1 trial</td>
<td>Randomized trial or (exceptionally) observational study with dramatic effect</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is this (early detection) test worthwhile? (Screening)</td>
<td>Systematic review of randomized trials</td>
<td>Randomized trial</td>
<td>Non-randomized controlled cohort/follow-up study**</td>
<td>Case-series, case-control, or historically controlled studies**</td>
<td>Mechanism-based reasoning</td>
</tr>
</tbody>
</table>
## How to Determine the Strength of Action for Key Guideline Statements

<table>
<thead>
<tr>
<th>Evidence Grade</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (high-quality)</td>
<td>Strong Recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>B (moderate quality)</td>
<td>Recommendation or strong</td>
<td>Option</td>
</tr>
<tr>
<td></td>
<td>recommendation</td>
<td></td>
</tr>
<tr>
<td>C (low quality)</td>
<td>Recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>D (very low quality)</td>
<td>Option</td>
<td>No recommendation</td>
</tr>
<tr>
<td>X (exceptional circumstance)</td>
<td>Recommendation or strong</td>
<td></td>
</tr>
<tr>
<td></td>
<td>recommendation</td>
<td></td>
</tr>
</tbody>
</table>
# Guideline Definitions for Evidence-Based Statements

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definition</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong Recommendation</td>
<td>Means benefits of the recommended approach clearly exceed the harms and quality of supporting evidence is excellent</td>
<td>Should follow strong recommendation unless clear and compelling rationale for alternative approach</td>
</tr>
<tr>
<td>Recommendation</td>
<td>Benefits exceed harms but quality of evidence is not as strong (B or C)</td>
<td>Generally follow recommendations but should remain alert to new information and sensitive to patient preference</td>
</tr>
<tr>
<td>Option</td>
<td>Either quality of evidence is suspect (C or D) or well-done studies show little clear advantage</td>
<td>Flexible in decision-making regarding appropriate practice; substantial role from patient preference</td>
</tr>
<tr>
<td>No recommendation</td>
<td>Both lack of evidence and unclear balance between benefit and harm</td>
<td>Little constraint in decision making and alert to new published evidence clarifying balance between benefit versus harm</td>
</tr>
</tbody>
</table>
What are the recent Clinical Practice Guidelines for Pediatric Otolaryngology?

- Clinical Practice Guideline: Tonsillectomy in Children
- Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children
- Clinical Practice Guideline: Tympanostomy Tubes in Children
Clinical Practice Guideline: Tonsillectomy in Children

- All clinicians in any setting interacting with children from 1 to 18 years old who may be a candidate for tonsillectomy

- Primary purpose to provide clinicians with evidence-based guidance in identifying children who are best candidates for tonsillectomy
• Secondary objectives:
  • Optimize perioperative management
  • Emphasize need for evaluation and intervention in special populations
  • Improve counseling and education of families
  • Highlight management options for patients with modifying factors
  • Reduce inappropriate or unnecessary variations in care
## Summary of Evidence-Based Statements

<table>
<thead>
<tr>
<th>Evidence-Based Statement</th>
<th>Statement Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical indication and planning</td>
<td></td>
</tr>
<tr>
<td>Watchful waiting</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Recurrent throat infection with documentation</td>
<td>Option</td>
</tr>
<tr>
<td>Tonsillectomy for recurrent infection with modifying factors</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Tonsillectomy for sleep-disordered breathing</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Tonsillectomy and polysomnography</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Outcome assessment for sleep-disordered breathing</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Perioperative care</td>
<td></td>
</tr>
<tr>
<td>Steroids</td>
<td>Strong Recommendation</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Strong Recommendation against</td>
</tr>
<tr>
<td>Postoperative care</td>
<td></td>
</tr>
<tr>
<td>Pain control</td>
<td>Recommendation</td>
</tr>
<tr>
<td>Posttonsillectomy hemorrhage</td>
<td>Recommendation</td>
</tr>
</tbody>
</table>
Key Action Statement 1

• Clinicians should recommend watchful waiting for recurrent throat infections if there have been fewer than 7 episodes in the past year or fewer than 5 episodes per year in the past 2 years or fewer than 3 episodes in the past 3 years.

• Recommendation based on RCTs with limitations and observational studies with preponderance of benefit over harm
Evidence Profile

• Aggregate Evidence Quality: Grade B, RCTs with minor limitations failing to show clinically important advantages of surgery over observation and Grade C, observational studies showing improvement with watchful waiting

• Benefit: Avoid unnecessary surgery with potential complications of vomiting, hemorrhage, pain, infection, or anesthesia problems

• Harm: waiting may result in delayed treatment in patients with unusually frequent and severe recurrent throat infections

• Cost: Potential direct cost of managing future throat infections

• Benefit-harm assessment: Preponderance of benefit over harm

• Value Judgment: consensus that tonsillectomy for recurrent throat infections should be limited to circumstances for which clinically important benefits are shown in RCTs; emphasis on avoiding harm related to surgery or anesthesia in condition that may be largely self-limited

• Role of patient preference: limited to specific unusual circumstances such as complications of tonsillitis or comorbidities

• Intentional vagueness: none

• Exclusions: Peritonsillar abscess, personal or family disease of rheumatic heart disease, Lemierre syndrome, severe infections requiring hospitalization

• Policy level: recommendation
• Despite multiple RCTs on tonsillectomy, data lacks on its effectiveness for sore throat

• Most evidence points to only a modest degree of improvement in the most severely and frequently affected children

• Watchful waiting is not inaction, rather close monitoring and accurate documentation
Which of the following does not meet the Paradise criteria?

A. A 6 y/o female with a history of 9 tonsil infections over the past year with supporting documentation from her Pediatrician.

B. A 12 y/o male with a history of 3 throat infections seen each time by his PCP for the past 3 years with documentation.

C. A 7 y/o female with 5 throat infections over the past 2 years with a record for each visit.

D. A 13 y/o female with 7 strep infections over the past year who stopped going to her PCP after the 4th infection.

E. None of the above, all meet the criteria.
Answer

- D, not substantial documentation to support diagnosis and recommendation for tonsillectomy
The Paradise Criteria

- 4 categories
- Frequency
  - 7 episodes in the past year
  - 5 episodes per year for 2 consecutive years
  - 3 episodes per year for 3 consecutive years
- Clinical Features (1 or more of the following)
  - Oral temp at least 38.5 C
  - Cervical lymphadenopathy (> 2cm or tender)
  - Tonsillar or pharyngeal exudate
  - Positive culture for group A Beta-hemolytic strep
- Treatment
  - Antibiotics administered at conventional dose
- Documentation
  - Each episode and its qualifying features substantiated by concurrent notation in a clinical record
Why wait?

• Less than 12 months, no good evidence to support tonsillectomy. Most RCTs required a minimum of 12 months of follow-up.

• Paradise et al observed children with recurrent throat infections finding high rate of spontaneous resolution over 12 months.

• Recommend 12-month period of observation prior to consideration of tonsillectomy.
Why wait?

- History more than 12 months
  - Possibility pts meeting Paradise criteria will spontaneously improve
  - Paradise et al: control group who met criteria for surgery: only averaged 1.17 episode in following year, 1.03 infection in second year, 0.45 episodes in third year
  - Multiple other studies relate similar data even when relaxing Paradise criteria in their control groups
Pharyngitis Burn Out?

- 2 case studies assessing natural history of recurrent pharyngotonsillitis

- Woolford et al found patients with history of 5 infections over 2 years and placed on waiting list over mean of 9 months, 27% no longer met criteria for surgery

- Prim et al found 18.6% of 623 pts had no recurrent pharyngotonsillitis within 6 months before scheduled surgery even after meeting Paradise criteria. Pts placed on waiting list of a mean of 10.8 months
Conclusions

- Watchful waiting may be beneficial to a larger population of patients with recurrent pharyngotonsillitis
- Proper observation and documentation are key to the decision process
- Developing a good relationship and having a frank discussion of the risks and benefits of tonsillectomy is important
Key Action Statement 2

• Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and one or more of the following: temperature >38.5°C, cervical adenopathy, tonsillar exudate or positive test for GABHS

• Option based on systematic reviews and randomized controlled trials with minor limitations, with a balance of benefit to harm
Evidence Profile

- Aggregate Evidence Quality: Grade B, well-designed RCTs with minor limitations; some Grad C observational studies

- Benefit: Modest reduction in frequency and severity of recurrent throat infection for up to 2 years after surgery, modest reduction in frequency of GABS for up to 2 years after surgery, improved disease-specific QoL

- Harm: risk and morbidity of tonsillectomy

- Cost: Direct cost of tonsillectomy, direct nonsurgical costs with indirect costs associated with recurrent infection

- Benefit-harm assessment: balance between benefit and harm

- Value Judgment: Importance of balancing the modest, short-term benefits of tonsillectomy in carefully selected children with recurrent throat infection against favorable natural history seen in control groups and potential for harm or adverse effects

- Role of patient preference: Large role for shared decision making in severely affected pts, given favorable natural history of recurrent throat infections and modest improvement associated with surgery, limited role in patients who do not meet strict indications for surgery

- Intentional vagueness: none

- Exclusions: none

- Policy level: option
Defining and Documenting “Throat Infection”

• When evaluating child, record subjective assessment of patient’s severity of illness:
  • Temp, pharyngeal +/- tonsillar erythema, tonsil size, tonsillar exudate, cervical adenopathy, test for GABS
  • Supportive data including work/school absence, spread of infection within the family, family history of rheumatic heart disease or glomerulonephritis
Efficacy and Effectiveness of Tonsillectomy for Recurrent Throat Infections

• Modest but statistically significant reduction in frequency of throat infection among severely affected individuals
Efficacy of Tonsillectomy for recurrent throat infection in severely affected children: results of parallel randomized and nonrandomized clinical trials

JL PARADISE, CD BLUESTONE, RZ BACHMAN ET AL
NEW ENGLAND JOURNAL OF MEDICINE 1984
• Emphasized documentation for each episode
• For sore throat of any degree of severity, tonsillectomy group experienced decrease of 1.9 episodes per year (not including the sore throat from surgery); Control group improved over time with only 3.1 annual events;
• No significant difference in the third year of follow-up
• For moderate or severe throat infections, tonsillectomy group experienced 0.1 episodes compared to control of 1.2 episodes. Rate reduction diminished over next year of followed and were no longer significant in 3 years
Tonsillectomy and Adenotonsillectomy for Recurrent Throat Infection in Moderately Affected Children

JL PARADISE, CD BLUESTONE, DK COLBORN
PEDIATRICS 2002
Subsequent study

Entrance criteria for history and/or documentation relaxed

Surgery groups with reduction rate of 0.8 and 0.7 episodes/year

Episodes of moderate to severe sore throat: control subjects in 2 arms experienced 0.3 episodes/year

No statistically significant difference in mean days with sore throat in first 12 months

Authors concluded modest benefit did not justify inherent risks, morbidity and costs
Tonsillectomy or Adenotonsillectomy versus Non-surgical Treatment for Chronic/recurrent Acute Tonsillitis

MJ BURTON, PP GLASZIOU
COCHRANE DATABASE SYSTEMATIC REVIEW 2009
- Pooled data from RCTs
- Tonsillectomy patients with 1.4 fewer episodes per year (with cost of 1.0 episode of sore throat for surgery)
- When only episodes of moderate/severe sore throat considered, surgery associated with only 0.2 fewer episodes in exchange for episode of sore throat from surgery
- 4 day reduction in number of sore throat days (21 vs 17)
Adenotonsillectomy for Upper Respiratory Infections: Evidence based?

BK VAN STAAIJK, EH VAN DEN AKKER, GJ VAN DER HEIJDEN, ET AL
ARCHIVES OF DISEASE IN CHILDHOOD
• Included 13 randomized and nonrandomized controlled studies

• Pooled estimated risk difference favoring tonsillectomy:
  • 1.2 fewer episodes of sore throat
  • 2.8 fewer days of school absence
  • 0.5 fewer episodes of upper respiratory infections per person-year

• Control groups showed significant spontaneous reduction in rate of recurrent infection
Further Results

• Most case series describing outcomes for patients on wait lists for tonsillectomy showed indications for surgery no longer present in large proportion of patients with a mean follow-up period of 3 years
Quality of Life

- Is there improved quality of life?
- Studies all suggest significant improvement in surgery patients
- Only 2 studies enrolled children exclusively
- Both had numerous methodological flaws
Counseling Family and Patient

- Advise of modest anticipated benefits of tonsillectomy weighed against natural history of resolution
- Per Guideline panel, no preponderance of benefit over harm; even for patients meeting strict Paradise criteria
Clinicians should assess the child with recurrent throat infection who does not meet criteria in Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergy/intolerance, PFAPA, or history of peritonsillar abscess.

**Recommendation** based on randomized controlled trials and observational studies with a preponderance of benefit over harm.
Evidence Profile

• Aggregate Evidence Quality: Grade B, RTCs with limitations for PFAPA, Grade C, observational studies for all other factors

• Benefit: Identifying factors that might otherwise have been overlooked which may influence decision to perform tonsillectomy and improve outcomes

• Harm: none

• Cost: none

• Benefit-harm assessment: preponderance of benefit over harm

• Value Judgment: None

• Role of patient preference: should be included

• Intentional vagueness: none

• Exclusions: none

• Policy level: Recommendation
Modifying Factors

- 3 categories
  - Exceptions to recognized criteria based on individual features of illness
  - Specific clinical syndromes including PFAPA or peri-tonsillar abscess
  - Poorly validated clinical indications including halitosis, febrile seizures and malocclusion
PFAPA

• Periodic Fever, Apthous Stomatitis, Pharyngitis, Adenitis
• Occurs primarily in children < 5 yrs old
• Lasts less than 5 days and recurs
• Steroid use leads to prompt termination
• 2 RCTs showed statistical improvement in patients undergoing tonsillectomy, however, control group pts improved as well
• Consider based on frequency, severity of illness, and child’s response to medical management
Peritonsillar Abscess

• Remains controversial

• 10-20% subsequent need for tonsillectomy in pts with peritonsillar abscess management with needle aspiration and/or I and D (Herzon et al, Schraff et al)

• “Quinsy” Tonsillectomy?
PANDAS

- Pediatric Autoimmune Neuropsychiatric Disorders associated with Streptococcal Infections
- Anecdotal evidence to support tonsillectomy in treatment
- Entity is poorly understood and role of tonsillectomy is uncertain and unproven
Poorly Validated Indications

- Chronic Tonsillitis, Febrile Seizures, Muffled Speech, Halitosis, Malocclusion, Tonsillar Hypertrophy, Cryptic Tonsils, Chronic Pharyngeal Carrier of GABSH
- Need a shared decision making process for each of these with understanding of risks/benefits
Clinicians should ask caregivers of children with sleep-disordered breathing and tonsil hypertrophy about comorbid conditions that may improve after tonsillectomy including growth retardation, poor school performance, enuresis, and behavioral problems.

Recommendation based on observational before-and-after studies with a preponderance of benefit over harm.
Evidence Profile

- Aggregate Evidence Quality: Grade C, before-and-after observational studies
- Benefit: improve decision making in children with SDB by identifying comorbid conditions associated with SDB which may improve with tonsillectomy
- Harm: None
- Cost: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value Judgment: Perception that potentially important comorbid conditions may be overlooked or not included in routine assessment of children with SDB; consensus that substantial evidence from before-and-after studies supports inquiring about these conditions
- Role of patient preference: Large role for caregiver education and shared decision making
- Intentional vagueness: none
- Exclusions: none
- Policy level: Recommendation
Sleep-Disordered Breathing

• PSG is gold standard for diagnosis of SDB
• Not necessary to perform in every child
• Presence or absence of snoring neither includes or excludes SDB
• Tonsillar size alone does not correlate with severity of SBD (Howard et al.)
  • Likely relationship of tonsil and adenoid size/volume, craniofacial anatomy, and neuromuscular tone
My tonsils are as big as golf balls. What do you suggest?

A four iron should do it!
Behavioral Problems with SDB

- Externalizing Behaviors: Aggression, Hyperactivity
- Internalizing Behaviors: Depression
- Known to increase risk in some children
- Leads to symptoms of ADHD
- Poor school performance secondary to problems with memory and attention
Behavioral Problems with SDB

- Improvement or resolution of behavioral problems following tonsillectomy
- Several studies show improvement significantly in both objective and subjective testing
- Improvement in behavior continues for at least 2 years after surgery
- Gozal found school performance improvement in tonsillectomy pts with SDB
SDB and Quality of Life

- Baldassari et al examined quality of life in children with sleep disordered breathing
- Found QoL similar to, or worse than, children with chronic diseases such as asthma or juvenile rheumatoid arthritis
Multiple studies show up to 50% of children with SDB have enuresis.

Basha et al showed 61% of children free of enuresis, 23% with decrease after surgery for SDB.

Studies show resolution rates increase proportionally as time following surgery increases.
SDB and Growth Retardation

• Important factor to consider in children with growth failure

• Bonuck et al performed systematic review and meta-analysis of height and weight changes after surgery for SDB

• Significant increase in height, weight, and growth biomarkers
Important Considerations

- Modifying factors do not affect every child to the same degree
- Only 30% to 40% of children with SBD by PSG score in abnormal range for hyperactivity
- Unknown but very small percentage have growth failure
- Severity of SDB does not correlate closely with the severity of behavioral or QoL scores
For the Clinician

- Elicit adequate sleep history in patients presenting with behavioral problems, decreased school performance, decreased QoL, enuresis, and growth failure
Pediatric Sleep Questionnaire

While sleeping, does your child...
1) snore more than half the time? 
Yes  No  Don't Know
2) sleeps snoring?  
Yes  No  Don't Know
3) snore loudly?  
Yes  No  Don't Know
4) have "heavy" or loud breathing? 
Yes  No  Don't Know
5) have trouble breathing, or struggle to breathe? 
Yes  No  Don't Know

Have you ever....
6) seen your child stop breathing during the night?  
Yes  No  Don't Know

Does your child...
7) tend to breathe through the mouth during the day?  
Yes  No  Don't Know
8) have a dry mouth on waking up in the morning?  
Yes  No  Don't Know
9) occasionally wet the bed?  
Yes  No  Don't Know
10) wake up feeling unrefreshed in the morning?  
Yes  No  Don't Know
11) have problems with sleepiness during the day?  
Yes  No  Don't Know

This child often...
12) does not seem to listen when spoken to directly?  
Yes  No  Don't Know
13) has difficulty organizing tasks and activities?  
Yes  No  Don't Know
14) is easily distracted by extraneous stimuli?  
Yes  No  Don't Know
15) fidgets with hands or feet or squirms in seat?  
Yes  No  Don't Know
16) is “in the go” or often acts as if “driven by a motor”?  
Yes  No  Don’t Know
17) interrupts or intrudes on others (e.g., butts into conversations or games)? 
Yes  No  Don’t Know

18) has a teacher or other supervisor commented that your child appears sleepy during the day? 
Yes  No  Don’t Know
19) is it hard to wake your child up in the morning? 
Yes  No  Don’t Know
20) does your child wake up with headaches in the morning? 
Yes  No  Don’t Know
21) did your child stop growing at a normal rate at any time since birth? 
Yes  No  Don’t Know
22) is your child overweight? 
Yes  No  Don’t Know

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Key Action Statement 5

- Clinicians should counsel caregivers about tonsillectomy as a means to improve health in children with abnormal polysomnography who also have tonsil hypertrophy and sleep-disordered breathing

- Recommendation based on observational before-and-after studies with preponderance of benefit over harm
Evidence Profile

- Aggregate Evidence Quality: Grade C, observational, before-and-after studies and meta-analysis of observational studies showing substantial reduction in prevalence of SDB and abnormal PSG after tonsillectomy

- Benefit: improved caregiver awareness of how tonsillectomy may benefit when PSG is abnormal including improved sleep, better nighttime and daytime functioning, improved functional health status, prevention or improvement of comorbid conditions

- Harm: potential anxiety to caregivers from counseling

- Cost: None

- Benefit-harm assessment: Preponderance of benefit over harm

- Value Judgment: Consensus that objectively documented SDB with PSG may warrant intervention even if not association with comorbid conditions; recognition that abnormal PSG encompasses broad range of values, with lack of evidence to support definitions of severity that correlate with surgical outcomes; concern that not treating children with abnormal PSG may lead to future morbidity or impaired health status

- Role of patient preference: Moderate; different caregivers may seek different levels of information

- Intentional vagueness: Uses abnormal PSG recognizing no consensus among groups regarding the exact criteria defining abnormal study

- Exclusions: none for counseling

- Policy level: Recommendation
SDB and PSG

- No consensus on definition of abnormal PSG
- Most sleep experts agree abnormal PSG in children if AHI >1 or pulse oximetry levels less than 92%
- While some feel AHI > 5 requires tonsillectomy, no evidence-based cutoff to indicate need and some with AHI < 5 may still be symptomatic
• Evaluation of oxygen desaturation as important as evaluation of AHI

• Children may have significant oxygen desaturation (<85%) despite low AHI

• Even mild oxygen desaturation can negatively affect academic performance
Results after Tonsillectomy

- No RCTs comparing tonsillectomy to other interventions
- Favorable short-term outcomes in many nonrandomized trials
- QoL improvements significantly improved on validated questionnaires for:
  - Sleep disturbance
  - Physical symptoms
  - Emotional symptoms
  - Hyperactivity
  - Daytime functioning
Other Outcome Improvement

- Pulmonary Hypertension normalizes after tonsillectomy based on Echo assessment
- School performance improved
- Health care utilization reduced
- Sleep parameters improved
  - PSG is often not normalized
Risk Factors for Recurrent or Persistent OSA

- Obesity
- Severe preoperative OSA
- Craniofacial and Neuromuscular anomalies
- Positive family history of OSA
- African American ethnicity
Clinicians should counsel caregivers and explain that SDB may persist or recur after tonsillectomy and may require further management.

Recommendation based on observational studies, case-control and cohort design, with a preponderance of benefit over harm.
Evidence Profile

- Aggregate Evidence Quality: Grade C, before-and-after observational studies and systematic reviewed

- Benefit: identify children who require further management of SDB; improve outcomes

- Harm: none

- Cost: Time spent in counseling

- Benefit-harm assessment: Preponderance of benefit over harm

- Value Judgment: Perception of inadequate counseling by physicians and under appreciation that SDB may persist or recur despite tonsillectomy

- Role of patient preference: limited

- Intentional vagueness: none

- Exclusions: none

- Policy level: recommendation
Resolution of SDB after Tonsillectomy

• Few patients undergo preoperative PSG and even fewer undergo postoperative PSG
• Meta-analysis revealed improvement in SDB in most children but only resolution in 60-70% of subjects
• Meta-analysis of 4 studies: only 10-25% of obese children with resolution of SDB after tonsillectomy
• Contrasted to the reported resolution in 70% to 80% of normal weight children
Repeat PSG?

• Postoperative caregiver reports of continued symptoms warrant further evaluation including PSG
Hypertrophic tonsils may contribute to SDB in children

SDB is often multifactorial

Obesity plays a key role in SDB in some children

PSG is considered the best test for diagnosing and measuring outcomes in children, but it is not necessary in all cases and access may be limited by availability of sleep laboratories and willingness of insurers and third-party payers to cover the cost

Tonsillectomy is effective for control of SDB in 60-70% of children with significant tonsillar hypertrophy

Tonsillectomy produces resolution of SDB in only 10-25% of obese children

Caregivers need to be counseled that tonsillectomy is not curative in all cases of SDB in children, especially in children with obesity
"Your tonsils don't look good, but that's okay. Who's going to be looking at them?"
Which of the following should never be administered to a patient undergoing tonsillectomy?

A. IV Dexamethasone
B. Ampicillin
C. IV Acetaminophen
D. IV/IM Ketorolac
Answer

- D, Ketorolac has been proven to increase the risk of bleeding in tonsillectomy patients. All of the other medications have indications.
Key Action Statement 7

-Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy

-Strong recommendation based on randomized controlled trials and systematic reviews of randomized controlled trials with a preponderance of benefit over harm
Evidence Profile

• Aggregate Evidence Quality: Grade A, randomized controlled trials and multiple systematic review for preventing PONV; Grade A, randomized controlled trials and 1 systematic review, for decreased pain and shorter times to oral intake

• Benefit: decreased incidence of PONV up to 24 hours posttonsillectomy, decreased time to first oral intake, decreased pain as measured by lower pain scores and longer latency times to analgesic administration

• Harm: no adverse events in all RCTs except one, reported increased hemorrhage rate as secondary outcome unadjusted for other risk factors

• Cost: Direct cost of medication and indirect cost of drug administration

• Benefit-harm assessment: Preponderance of benefit over harm

• Value Judgment: decreased PONV and postoperative pain likely to result in increased patient satisfaction and decreased incidence of overnight hospital admission, associated with lower total health care costs compared with direct and indirect costs of drug administration

• Role of patient preference: none

• Intentional vagueness: none

• Exclusions: Patients with endocrine disorders who are already receiving exogenous steroids or in whom steroid administration may interfere with normal glucose-insulin regulation (eg, diabetes)

• Policy level: Strong recommendation
Why do we give it?
PONV and Tonsillectomy

- Occurs independent of dissection technique and in 70% of children who do not get antiemetics
- Generally requires overnight hospitalization
- Associated with decreased patient satisfaction and increased use of resources
IV Dexamethasone

- Cochrane systematic review showed children receiving dexamethasone less likely to vomit than children receiving placebo (relative risk, 0.54) and more likely to advance diet on POD 1 (relative risk, 1.69)
- NNT = 4, to result in 1 fewer patient experiencing post-op emesis
- Most published studies use IV dexamethasone dose of 0.5 mg/kg; however, smaller doses may be as effective
Risks?

- All RCTs and systematic reviews except 1 found no evidence of increased risk
- Czarnetzki et al published in JAMA in 2008
- Randomized trial between placebo and 3 different weight-based doses of IV dexamethasone
- Found an increased risk of post-operative hemorrhage in all doses with dose-dependent increase in risk
- Hemorrhage was secondary outcome in their study
- When primary hemorrhage was excluded, lost significance
Key Action Statement 8

• Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy
  • *Strong recommendation against administering or prescribing based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm*
Evidence Profile

- Aggregate Evidence Quality: Grade A, randomized controlled trials and systematic reviews, showing no benefit in using perioperative antibiotics to reduce posttonsillectomy morbidity

- Benefit: Avoidance of adverse events related to antimicrobial therapy; including rash, allergy, GI upset, and induced bacterial resistance

- Harm: None

- Cost: None

- Benefit-harm assessment: Preponderance of benefit over harm

- Value Judgment: although panel recognizes antimicrobial therapy often used in perioperative management, practice is suboptimal given the lack of demonstrable benefits in RCTs plus well-documented potential adverse events and cost of therapy

- Role of patient preference: None

- Intentional vagueness: Panel advises against routine antimicrobial therapy, recognizing there may be individual circumstances in which use of antimicrobials for a given patient is deemed appropriate

- Exclusions: patients with cardiac conditions requiring perioperative antibiotics for prophylaxis; patients undergoing tonsillectomy with concurrent PTA

- Policy level: Strong recommendation
• Poll of practicing otolaryngologists: 79% continue to use antibiotics in patients undergoing tonsillectomy

• Cochrane review of 10 RCTs: no evidence to support a consistent, clinically important impact of antibiotics on reducing the main morbid outcomes of tonsillectomy

• Antibiotics with no impact on secondary hemorrhage or the severity of secondary hemorrhage (readmission, blood transfusion, return to OR)

• Risks of antibiotics: Allergy to Beta-lactams is 2% per course and anaphylaxis estimated in 0.01% to 0.05% of all PCN courses
Pain, Diet, and Activity

- No impact on pain in 5 of 7 trials
- No impact on analgesic use in 5 of 6 trials
- No impact on return to normal activity in 4 of 6 trials
- No impact on time to normal diet in 4 of 7 trials
- Benefits were only small when found
- Cochrane review concluded antibiotic use only with caution
• Burden on parents to get patient to try to swallow another liquid

• Additional load on caregivers in early post-op period – explains high dropout rate in many studies
Key Action Statement 9

• The clinician should advocate for pain management after tonsillectomy and educate caregivers about the importance of managing and reassessing pain.

• Recommendation based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm
Evidence Profile

- **Aggregate Evidence Quality:** Grade B, randomized controlled trials comparing analgesics after tonsillectomy, and Grade C, observational studies suggesting inadequate pain control and hydration after tonsillectomy.

- **Benefit:** Pain relief, improved and faster recovery; avoidance of complications from dehydration, inadequate food intake.

- **Harm:** adverse affects of specific analgesic preparations.

- **Cost:** Time spent by clinician advocating; direct cost of medications used.

- **Benefit-harm assessment:** Preponderance of benefit over harm.

- **Value Judgment:** Perception by the panel that pain control is often underemphasized and inadequately discussed after tonsillectomy; importance of engaging the caregiver and providing education about pain management and reassessment.

- **Role of patient preference:** Limited regarding advocacy; substantial role in choice of analgesic and method of reassessment.

- **Intentional vagueness:** none.

- **Exclusions:** none.

- **Policy level:** Recommendation.
Post-operative Pain Control

- Single dose of IV Dexamethasone is beneficial while antibiotics show no benefit of post-operative pain control
- No recommendation on the type of analgesic to use
- Advocate and educate prior to surgery and reinforce pain assessment and management prior to discharge
• Preoperative pain education for children valuable prior to tonsillectomy
• Introduce a numeric pain intensity scale to communicate pain experience
• Hydration important in post-operative pain control
• Studies are limited but show inadequate hydration at home for children undergoing tonsillectomy
Noncompliance among caregivers

- Significant contributing factor
- American data and European data similar regarding inadequacy of caregiver compliance
- Fortier et al found up to 24% of patients received either no pain medication or a single dose in the first postoperative day despite knowing the child was in severe pain
Topical Agents?

- Recent Cochrane review analyzed 6 trials including 400 children
- Unfortunately risk of bias was high in most studies, reporting quality was poor, and data was inadequate to permit conclusions
True or False

- Giving Acetaminophen with Codeine is safe in the general pediatric population as long as it is properly dosed in a weight-based manner.
Codeine

• Acetaminophen with codeine does not provide superior control of pain compared with acetaminophen only either at rest or with swallowing

• Codeine’s lack of efficacy may be due to substantial genetic variation in the activity of cytochrome P450 CYP2D6

• Ultra-rapid metabolism may put some children at risk
NSAIDs

• Cochrane review of nearly 1000 children from 13 RCTs found no significant difference of postoperative bleeding compared with placebo or other analgesics

• Toradol (Ketorolac) with rates of postoperative hemorrhage of 4.4% to 18%

• Avoid Toradol
PRN versus Time-Dependent Dosing

• 4 RCTs evaluated effectiveness of time-dependent dosing

• Each trial found children still experienced moderate pain

• When comparing hydrocodone PRN to acetaminophen on schedule, acetaminophen scheduled was more effective. Children still had moderate pain
When is pain worst?

- In the mornings
- Independent of dosing schedules
- Dehydration?
- Muscle spasms during the night?
- Does not improve even when given scheduled medications during the night
Pain Management
Conclusions

• Base the starting dose on patient’s weight
• Ensure adequate monitoring of pain levels
• Don’t use acetaminophen with codeine
• Educate caregivers on expected post-operative pain course
  • Education on the assessment of pain is important and may improve compliance
Clinicians who perform tonsillectomy should determine their rate of primary and secondary posttonsillectomy hemorrhage at least annually.

**Recommendation based on observational studies with a preponderance of benefit over harm**
Evidence Profile

• Aggregate Evidence Quality: Grade C, observational studies and large-scale audit, showing variability in postoperative hemorrhage rates and some association with surgical technique; Grade C, observational studies, showing hemorrhage as a consistent sequelae of tonsillectomy with heterogeneity among studies

• Benefit: Improve preoperative counseling for tonsillectomy; encourage quality improvement efforts

• Harm: None

• Cost: Administrative burden

• Benefit-harm assessment: Preponderance of benefit over harm

• Value Judgment: Perceived heterogeneity among clinicians regarding knowledge of their own hemorrhage rates after tonsillectomy; potential for clinicians to reassess their process of care and improve quality

• Role of patient preference: Limited

• Intentional vagueness: Specifics on determining the hemorrhage rate are left to the clinician

• Exclusions: None

• Policy level: Recommendation
• No recommendations on the surgical technique as prospective trials have lacked justifiable evidence in one regard to the other

• Understanding the rates can allow for communication of surgical risk during informed consent
Hemorrhage after Tonsillectomy

• Primary versus Secondary

• Primary Hemorrhage defined as within the first 24 hours

• Secondary Hemorrhage occurring more than 24 hours after surgery often between 5 to 10 days

• Rate of Primary Hemorrhage: 0.2-2.2%

• Rate of Secondary Hemorrhage: 0.1-3%
National Prospective Tonsillectomy Audit (NPTA)

- Performed in UK in 2005
- Investigated 33,921 pts undergoing tonsillectomy in the UK from 2003-2004
- Primary hemorrhage rate: 0.6%
- Secondary Hemorrhage rate: 3%
- Hot surgical techniques (Diathermy or coblation) increased risk of secondary hemorrhage 3-fold
National Prospective Tonsillectomy Audit (NPTA)

• Risk of secondary hemorrhage for cold steel dissection with bipolar diathermy versus cold steel operation with only ice packs/ties was 1.5 times higher

• No significant difference in primary hemorrhage rates based on surgical technique
National Prospective Tonsillectomy Audit (NPTA)

- Risk factors for posttonsillectomy bleed
  - Increased patient age
  - Male gender
  - History of recurrent tonsillitis
  - Previous Peritonsillar Abscess
Mowatt et al

- Systemic review of electrosurgery for tonsillectomy
- Risk of post-operative hemorrhage higher following hot techniques compared to cold dissection
- Meta-analysis revealed bipolar diathermy techniques with statistically significant lower odds of primary hemorrhage
- Hot techniques including monopolar diathermy and coblation with statistically significant higher rate of secondary hemorrhage
Is coblation worse?

- Cochrane review of coblation versus other surgical techniques
- 19 RCTs evaluated
- 9 trials included
- No significant difference in postoperative bleeding in comparing techniques
Do NSAIDs increase the risk?

- Cochrane review of 20 RCTs
- 13 RCTs with 955 children requiring surgical intervention for bleeding
- 7 RCTs with 471 children not requiring surgical intervention
- No significantly increased risk of bleeding following tonsillectomy with the use of NSAIDs
Conclusions

• Do not use cookie-cutter medicine
• Talk with the parents. Understand their concerns and formulate a plan together in the best interest of your patient
• Give the best care possible both in the OR and out
• Counsel the family on expected post-operative pain multiple times
Bibliography


