Quality Assessment of the Clinical Practice Guideline for Tympanostomy Tubes in Children

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Abstract

Objectives. To determine the association between the introduction of statements 6 and 7 in the 2013 clinical practice guideline (CPG) for tympanostomy tubes in children and the identification of preoperative middle ear fluid (acute otitis media / otitis media with effusion [AOM/OME]) in children undergoing bilateral myringotomy and tube (BMT) placement.

Study Design. Case series with chart review.


Subjects and Methods. Patients who underwent BMT for recurrent AOM were retrospectively reviewed. We examined 240 patients before (BG; 2012) and 240 patients after (AG; 2014) the introduction of the CPG.

Results. The baseline characteristics of the 2 groups were comparable. The total annual number of BMT placements performed at our institution decreased from 3957 (BG) to 3083 (AG). There was no significant increase in the rate of preoperative AOM/OME identification following CPG introduction (BG 78.3% vs AG 83.3%, P = .164). The rate of identification of AOM/OME in the operating room (OR) increased from 54.2% (BG) to 71.3% (AG, P < .001). The rate of identification of AOM/OME both in the clinic and in the OR increased from 55.1% (BG) to 71.3% (AG, P < .001). Cases with concordant clinic and OR AOM/OME occurred among younger children (P = .045), those with fewer episodes of AOM (P = .043), and those with shorter time between the clinic and OR dates (P = .008).

Conclusions. Following the introduction of the CPG, there was no change in the rate of identification of AOM/OME prior to recommending BMT placement in children with recurrent AOM. The lack of improved compliance with statements 6 and 7 may be related to multiple clinician- and patient-derived factors.

Keywords
tympanostomy tubes, clinical practice guidelines, recurrent acute otitis media, otitis media with effusion, pediatrics

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Bilateral myringotomy and tube (BMT) placement is a common procedure accounting for >20% of all ambulatory surgery performed among children aged <15 years in the United States.1 Recurrent acute otitis media (RAOM)—which is defined by at least 3 episodes of acute otitis media (AOM) over 6 months or by at least 4 episodes of AOM over 12 months—was shown to have negative consequences on childhood development,2,3 often resulting in increases in missed work and school time,4,5 antibiotic resistance,6,7 and health care expenditures.8,9 For children with RAOM, BMT was shown to reduce the prevalence of middle ear effusions (otitis media with effusion [OME]),10 improve hearing outcomes,11,12 and enhance disease-specific quality of life.13-15 The high frequency of BMT, therefore, is attributable to the high prevalence and associated morbidity of RAOM and demonstrated efficacy of BMT.1,16

There continues to be debate over the appropriate indications for BMT placement.17-20 To address this lack of consensus over indications for BMT placement, the American Academy of Otolaryngology—Head and Neck Surgery published an evidence-based clinical practice guideline (CPG) directing the treatment of children who are being considered for tympanostomy tube placement.21 It remains to be determined, however, whether and to what degree physicians adhere to the CPG recommendations. Furthermore, physician
and patient factors that may be contributing to or detracting from physician adherence to CPG recommendations remain unclear.

In this study, we investigated trends in physician practice at a single tertiary care children’s hospital with regard to BMT placement before and after introduction of the CPG. In particular, we examined the influence of key action statements 6 and 7 in the CPG on clinical practice, which recommend offering BMT for children who meet criteria for RAOM and who have evidence of unilateral or bilateral OME at the time of evaluation (statement 7) but not for children who lack OME in either ear at the time of evaluation (statement 6).21

To determine the association of these CPG recommendations with changes in clinical practice, we compared the number of patients with and without evidence of OME who underwent BMT placement before and after introduction of the CPG.

Methods
This study was approved by the University of Pittsburgh Institutional Review Board. A retrospective chart review was conducted of patients who underwent BMT for RAOM between 2012 and 2014 at the Children’s Hospital of Pittsburgh of the University of Pittsburgh Medical Center (CHP of UPMC; Pittsburgh, Pennsylvania). Exclusion criteria included prior BMT or other otorhinolaryngologic surgery, indications for BMT other than RAOM (including cleft palate), hearing or speech difficulties only, history of OME only, syndromes, or retraction-type ear disease (atelectasis or adhesive otitis media). Patients were also excluded if significant relevant sections of their medical records were incomplete.

The CPG for BMT placement in children was introduced July 2013,21 so medical records were queried from patients who received BMT in 2012 (before guidelines [BG]) and compared with those who underwent BMT in 2014 (after guidelines [AG]). Cases were identified in archived operating room (OR) schedules and enrolled according to the aforementioned criteria. To control for seasonal variation, 20 cases were randomly selected from each of the 12 months of the year in the BG and AG cohorts, resulting in a total of 480 cases (240 BG cases and 240 AG cases).

Following review of these medical records, a database was established to record the following variables for each patient: (1) demographics—age at time of tube placement and sex; (2) medical history—number of AOM events in the 6 months prior to surgery as reported by parent or guardian, antibiotic treatment of AOM, and antibiotic allergies; (3) family history of BMT or RAOM in a first- or second-degree relative; (4) preoperative visit—documented OME, laterality of OME, otalgia, and parental concerns for hearing or speech delay; (5) operative visit—time elapsed since preoperative visit, documented OME, laterality of OME; and (6) postoperative visit—tube patency and whether a postoperative audiogram was performed.

Statistical analyses were performed with SPSS 23 (IBM, Armonk, New York). P < .05 was considered significant. Independent samples t tests and Pearson’s chi-square tests were used to investigate whether members of a candidate list of covariates were associated with OME documentation at the preoperative evaluation and/or in the OR.

In terms of secondary outcome measures, AOM/OME concordance was calculated by dividing cases with AOM/OME at both the clinic appointment and in the OR at the time of BMT by cases with AOM/OME at either the clinic appointment or OR date. In this way, cases with dry middle ear spaces in both the clinic and the OR are excluded. The percentage of patients with AOM/OME at the clinic appointment and in the OR was determined by examining the intraoperative findings of children with AOM/OME in the clinic over time. The percentages of patients in the time groups (0-2, 2-4, 4-6, and >6 weeks) were compared with linear-by-linear association.

Results
The final data set contained 480 patients who underwent BMT for RAOM: 240 patients in the BG cohort and 240 patients in the AG cohort. There were no significant differences in patient demographics between the BG and AG groups (Table 1). Before introduction of the 2013 CPG, AOM/OME was documented at the time of initial clinic evaluation for 78.3% of patients who went on to receive BMT (BG group; Table 2). After introduction of the CPG, this percentage increased to 83.3%, which was not statistically significant (P = .164).

The agreement between AOM/OME documented at the time of clinic evaluation and at the time of BMT surgery was examined. In the BG group, 55.1% of patients exhibited agreement between the clinic and the OR, as opposed to 71.3% in the AG group (P < .001, AOM/OME concordance; Table 2).

Across the combined cohorts, the mean age of patients with concordant AOM/OME status in the clinic and OR was 1.7 years, as compared with 2.0 years for patients with discordant AOM/OME status (P = .045; Table 3). The mean length of time between clinic evaluation and time of surgery was shorter among those patients with concordant AOM/OME versus those patients with discordant AOM/OME (20.6 vs 26.2 days, P = .008). The percentage of patients who had fluid in clinic as well as intraoperatively decreased with increasing time elapsed between clinic and the OR (P = .020; Figure 1). Finally, the mean number of AOM episodes was fewer among concordant AOM/OME cases as opposed to discordant ones (4.25 vs 4.58, P = .043). In summary, patients who were more likely to have AOM/OME present at the time of clinic evaluation and at the time of surgery were generally younger, had fewer prior episodes of AOM, and experienced shorter lengths of time between clinic evaluation and BMT.

Discussion
The 2013 CPG for BMT placement provides clinicians with evidence-based recommendations on the indications for and
management of BMT, yet it is unclear to what degree these recommendations are being followed. Addressing this question is important in 2 respects. First, it is necessary to confirm that best care practices are being followed to optimize patient safety and ensure cost-effectiveness in health care spending on BMT, which is approximately $1.8 billion annually in the United States. Second, identifying patient- and/or physician-related factors that may create barriers to compliance with the CPG will aid in the future refinement of CPGs and the development of novel quality improvement strategies.

In this study, the main outcome measure of appropriately identifying middle ear fluid at the initial clinic visit prior to proceeding with BMT placement did not significantly change following introduction of the CPG (78.3% vs 83.3%, $P = .164$). Sajisevi and coauthors recently published a population-based analysis of adherence to the CPG before 2013 and found a remarkably similar adherence rate for statement 6 of 77.6%. A number of potential barriers to compliance may account for this discrepancy, and these barriers can be broadly grouped into patient- and physician-related factors.

In terms of patient-related factors, parental preference to proceed with BMT likely plays an important role in determining adherence/nonadherence to CPG recommendations. Examples include excessive missed work and/or school time, large geographic distance to specialty care (as is often the case in the catchment area of CHP of UPMC), apprehension over antibiotic exposure, and subjective speech and hearing concerns. Some of these factors may be
addressed through enhancements in patient education and doctor-patient communication, whereas others will require policy changes at the institutional/societal level.

Physician-related factors likely also contribute significantly to adherence/nonadherence. Cabana et al cited 7 major reasons why physicians fail to follow CPGs, including lack of awareness, lack of familiarity, lack of self-efficacy, lack of outcome expectancy, external barriers, lack of agreement with evidence, and inertia of previous practice. In the case of the CPG for BMT, lack of awareness and/or familiarity with the CPG is unlikely given the prominence of the American Academy of Otolaryngology—Head and Neck Surgery as well as the academic setting of this study. External barriers, such as appeasing the parental preferences outlined earlier, likely play an increasingly important role in the evolving era of medicine that ties reimbursement to consumer reviews. Lack of self-efficacy (ie, physician believes that he or she cannot perform guideline recommendations) and lack of outcome expectancy (ie, physician believes that performance of guideline recommendation will not lead to desired outcome) are unlikely in the context of BMT. The role of inertia from previous practice undoubtedly figures into the incomplete adherence to the CPG regardless of the practice setting.

In spite of these barriers, it is important to note that practice paradigms do not change instantaneously. While there was not a statistically significant increase in the proportion of patients undergoing BMT surgery at our institution who had AOM/OME documented at the time of preoperative evaluation, statements 6 and 7 of the CPG are nevertheless being followed in >80% of cases. Additionally, diffusion of knowledge throughout the community can be gradual, and a greater period may be required before the impact of the CPG on clinical practice can be accurately assessed.

Although the rate of AOM/OME identification at initial clinic evaluation has not significantly changed since introduction of the CPG, there has been a significant increase in the rate of AOM/OME identification in the OR at the time of surgery. Given that the CPG makes no recommendation regarding surgeon behavior in relation to AOM/OME documentation in the OR at the time of BMT, these changes may be reflective of surgeons becoming more selective in ways not fully captured by this study. This notion is also supported by a 22% overall decrease in the number of BMT procedures performed at our institution from 2012 (n = 3957) to 2014 (n = 3083) without a change in the overall number of pediatric otolaryngologists at CHOP of UPMC. This decrease in BMT performed may also be reflective of the continued decline in the overall incidence of AOM following the introduction of the pneumococcal 13 vaccine and changes to health insurance providers in the western Pennsylvania region.

It is interesting to note that when compared with discordant cases (eg, those with discrepant fluid status between clinic and OR), the concordant cases (eg, those with fluid in the preoperative clinic and OR settings) involved younger children, children with fewer prior AOM episodes, and those with shorter intervals between clinic evaluation and BMT (Table 3). The shorter interval between clinic and OR visits is fairly intuitive (the shorter the period between visits, the less likely it is that AOM/OME will clear prior to surgery). Figure 1 demonstrates that beyond 6 weeks, the likelihood of identifying AOM/OME in the OR for a child previously found to have AOM/OME in the clinic approaches the flip of a coin. This may, of course, either represent sustained AOM/OME or clearance of the middle ear with recurrent AOM/OME.

The observation that younger children are more likely to exhibit AOM/OME concordance is somewhat counterintuitive given that prior studies showed decreased sensitivity of otoscopic examination in identifying OME among children younger than 1 year. One potential account for younger age as a predictor of AOM/OME concordance is a bias on the part of the clinician to proceed to BMT more rapidly for younger patients, which might secondarily increase the probability of AOM/OME still being present at the time of surgery. Alternatively, examination of the middle ear space in clinic among infants may be more accurate than for the toddler, who is more effective in resisting examination in contradistinction to prior studies.

The finding that fewer episodes of AOM are seen in concordant versus discordant cases may relate to clinicians’ decisions to proceed with BMT in higher-frequency RAOM cases, regardless of AOM/OME status; that is, clinicians may think that BMTs are warranted for patients who have experienced a greater number of AOM episodes, regardless of whether those patients have active AOM/OME at the time of presentation. Definitive conclusions are challenging to draw, given the inherent inaccuracy of self-reporting the number of AOM episodes and the questionable clinical significance of 4.25 versus 4.58 AOM episodes.

Although the CPG makes no recommendation regarding AOM/OME documentation in the OR, the premise for statement 6 is that children without effusions have favorable

![Figure 1](image-url)

**Figure 1.** Percentage of children with AOM/OME in the OR who were found to have AOM/OME in clinic as stratified by time between clinic and OR dates. AOM, acute otitis media; OME, otitis media with effusion; OR, operating room.
eustachian tube function and a better intervention-free prognosis as compared with children with effusions. The observation of clear middle ear spaces at the time of surgery in a subset of children who were found to have effusions suggests that these children may have favorable eustachian tube function as well. This potential finding makes one question when the surgeon should examine the ear before and/or at the time of surgery. Statement 6 does not specify when the time of assessment for tube candidacy should be completed. One can argue that if the surgeon examines the ear preoperatively the day of surgery, those children with clear middle ears should not be recommended for tubes.

The retrospective nature of our study was a limitation in that we were unable to assess patient- and physician-derived factors for performing BMT against CPG guidelines. The fact that our study was performed at a single center was also a limitation. Various centers may adopt differing strategies to facilitate the adoption of CPGs, yielding varied levels of success. Future analyses of interdepartmental differences in physician behavior pertaining to the adoption of the CPG may reveal institution-level incentive structures that are more or less effective at facilitating CPG adherence.

Conclusion

Tympanostomy tube placement is the most common ambulatory surgery performed among children in the United States, and optimizing physician adherence to an evidence-based CPG is thus crucial for ensuring patient safety and cost-effectiveness in health care spending. Our retrospective single-institution review demonstrates that while >80% of BMT surgery takes place in accordance with the 2013 CPG recommendations outlined in statements 6 and 7, a significant number of procedures are taking place in the absence of AOM/OME documented at the preoperative visit. Adherence/nonadherence is likely related to multiple clinician- and patient-derived factors. To improve adherence rates, it will therefore be necessary to devise quality improvement strategies that further address these barriers.

Author Contributions

Joshua J. Sturm, designed study, collected data, analyzed data, wrote article, revised article; Phillip Huyett, designed study, collected data, analyzed data, revised article; Amber Shaffer, collected data, analyzed data, revised article; Dennis Kitsko, designed study, revised article; David H. Chi, designed study, revised article.

Disclosures

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References


