Quality-of-Life Outcomes After Surgical Intervention for Otitis Media

Michele Richards, MD; Carla Giannoni, MD

**Objective:** To assess the change in disease-specific quality of life in children with recurrent acute otitis media and/or chronic otitis media with effusion treated with surgical intervention.

**Design:** Prospective questionnaire-based outcome study.

**Setting:** An academic pediatric otolaryngology practice.

**Participants:** Consecutive series of 123 children referred for surgical treatment of recurrent acute otitis media and/or chronic otitis media with effusion.

**Intervention and Methods:** Surgery included bilateral myringotomy and tympanostomy tube placement either alone or with adenoidectomy. An otitis media disease-specific questionnaire was administered before and after surgical intervention.

**Main Outcome Measures:** Comparison of the mean percentage change in total ear symptom score between presurgery and postsurgery scores at 1 and 6 months after surgery.

**Results:** The mean percentage change in total ear symptom score was a 74.5% improvement ($P<.001$) at the 1-month follow-up and a 59.8% improvement ($P<.001$) at the 6-month follow-up. Parental worry related to the child's ear problems was also significantly decreased, with a mean otitis media disease-specific questionnaire score of 3.43 ($P<.001$) at 1 month and 2.64 ($P<.001$) at 6 months after surgery. When caregivers were asked if they would have their child undergo tympanostomy tube placement if they had to make the decision again, 91% and 84% responded yes at the 1- and 6-month follow-up, respectively.

**Conclusions:** The disease-specific quality of life of children with recurrent acute otitis media and/or chronic otitis media with effusion with appropriate surgical indications significantly improved after surgical intervention. The amount of parental worry concerning their children's ear problems also significantly improved following surgery, and most caregivers would opt again for tube placement.


**Otitis Media** is one of the most common childhood diseases resulting in physician office visits in the United States today. It affects approximately two thirds of all children by the age of 3 years, and one third of these children will have at least 3 episodes of otitis media before their third birthday. Otitis media accounts for approximately 25 to 30 million office visits per year and results in an estimated annual cost of $3 billion to $5 billion including medical and surgical treatment.

Chronic otitis media with effusion (COME) is defined as a middle ear effusion without pain, redness, or bulging of the tympanic membrane. It occurs most commonly between the ages of 2 and 4 years as documented by tympanograms. The exact prevalence of COME is unknown, but in approximately 10% of children with an episode of acute otitis media (AOM), a middle ear effusion is still present at 3 months. The presence of bilateral middle ear effusions is frequently associated with a conductive hearing loss in the range of 20 to 25 dB.

Acute otitis media is defined as inflammation of the middle ear associated with the signs of an acute infection including an erythematous, bulging tympanic membrane, and the presence of a middle ear effusion and symptoms including pain, fever, and/or irritability. It affects children most commonly between the ages of 6 and 18 months, with a younger age at first episode associated with an increased risk of recurrent acute otitis media (RAOM). Many other risk factors have been documented, including sex (male sex), race (Native American), season (fall...
PATIENTS AND METHODS

STUDY DESIGN

This study was designed as a prospective questionnaire study evaluating otitis media–related symptoms before surgery and 1 and 6 months after surgery. Demographic data were also obtained at each questionnaire administration.

POPULATION

The study population consisted of a convenience sample of children referred to the University of Florida pediatric otolaryngology clinic, Gainesville, for surgical treatment of RAOM and/or COME. Inclusion criteria included (1) age younger than 16 years, (2) a diagnosis of RAOM as defined by 3 or more episodes of AOM over the past year or a diagnosis of COME defined as the presence of middle ear effusion in 1 or both ears for 3 months or longer, (3) child’s primary caregiver present to complete the survey, and (4) children presenting to the practice of a single pediatric otolaryngologist. Exclusion criteria included (1) presentation to the other physicians within the University of Florida otolaryngology group, (2) previous ear surgery other than myringotomy and/or tympanostomy tube placement, (3) tympanostomy tubes already present at presentation, (4) tympanic membrane perforation, and (5) primary caregiver not present or unable to read and understand English.

METHODS

An expanded version of Rosenfeld’s previously validated otitis media quality-of-life survey, the Otitis Media–6 (OM-6), was used to assess disease-specific quality of life.¹¹ The questionnaire was expanded into individual variables to allow for analysis of each specific variable. It also included demographic data at each administration. The questionnaire, the Otitis Media Outcome–22 (OMO-22), used in this study is presented in the Figure. It is a 22-item questionnaire based on a 7-point Likert scale with associated demographic questions. The questionnaire can be divided into a physical, emotional, hearing loss, speech, and social symptoms subsets. This study was approved by the institutional review board of the University of Florida. The primary caregiver of the child consented to participate in the study and received the questionnaire at a presurgery visit, and again at the 1- and 6-month follow-up appointments. If the patient did not show for the scheduled appointment, the questionnaire was sent with a self-addressed stamped envelope to the home address. Three attempts were made to contact the caregiver to fill out the follow-up questionnaire for each follow-up time.

Surgical treatment consisted of bilateral myringotomy and tympanostomy tube placement (BMT) alone for those children younger than 3 years without a history of previous tympanostomy tubes. Adenoidectomy was added to the procedure for those children undergoing their second set of tympanostomy tubes and/or for children older than 3 years with COME. Other indications for adenoidectomy included chronic rhinorhea with associated rhinosinusitis or chronic mouth breathing with associated snoring.

VALIDATION OF INSTRUMENT

The validity of this expanded version of Rosenfeld’s OM-6 questionnaire, the OMO-22, was also evaluated. Test-retest reliability and internal consistency. A subset of 10 patients filled out the questionnaire at 2 separate times prior to surgery. A paired t test showed no significant difference in total ear scores between the 2 presurgery questionnaires (P = .41), demonstrating a stable clinical condition. The overall internal consistency measured by the overall Cronbach α coefficient was .85, suggesting a high degree of correlation between the items. The α coefficients for each item ranged from .83 to .85.

The ability of the questionnaire to adequately measure ear-related symptoms and quality of life was also evaluated. The discriminant validity was assessed by comparing the total ear scores of children with RAOM and/or COME with a cohort of 10 children without a significant history of ear problems. The mean total ear score of the children with RAOM and/or COME was 49.1, while the mean total ear score of the control children was 6.4, with a t test demonstrating a significant difference (P = .001). Attempts were also made to evaluate the concurrent validity or to compare this questionnaire with a gold standard such as the Short Form–36 (SF-36) Health Survey. The only validated global health survey with standardized norms currently available for use in a young pediatric population is the Child Health Questionnaire. Unfortunately, this questionnaire is designed for use in children 5 years and older. The mean age of the children in this study is only 2 years 4 months. An attempt was made to have caregivers fill out both the OMO-22 and the Child Health Questionnaire, but the number of items that were not applicable to this age group was significant, rendering any comparisons invalid.

Significant responsiveness to change was found with the OMO-22. The percentage change in the total ear symptom scores changed a mean of 74.5% (95% confidence interval [CI], 66.3%-82.5%) between presurgery and 1 month postsurgery. The percentage change in the total ear symptom scores also changed a mean of 59.8% (95% CI, 49.4%-70.1%) between presurgery and 6 months’ postsurgery.

DATA COLLECTION AND ANALYSIS

The children’s history, physical examination findings, audiometric data, diagnosis, and the information concerning the surgical procedure and findings were obtained from the patients’ medical records. The data were entered into a database using Paradox (Borland International, Scotts Valley, Calif) software and verified. The SAS 8.1 (SAS Institute Inc, Cary, NC) statistical program was used to perform all statistical calculations. Significance testing between times was performed using paired t tests for parametric data with equal distributions and the Mann-Whitney test for nonparametric data. P < .05 was considered statistically significant.

In the literature, many researchers have examined the possible benefits of various treatments of both RAOM and COME. Current recommendations are based on analysis of treatment efficacy from multiple outcome perspec-
tives including effusion resolution, a decline in the number of infections, improvements in hearing, and the effects of otitis media on language development, academic performance, and behavior. These standard clinical outcome measures have generally demonstrated benefits of treatment, including surgical therapies, in properly selected patient populations.9 The current recommendations suggest that tympanostomy tubes are the appropriate treatment for children with persistent effusions for more than 3 months and hearing loss in spite of antimicrobial therapy.4,6,10 Currently accepted guidelines suggest that the placement of tympanostomy tubes is indicated after more than 4 episodes of AOM per year as well.5,10

The need to demonstrate the benefits of specific treatments has become more important in health care because managed care and primary payers have begun to demand documentation of the appropriateness of health care interventions. Tympanostomy tube placement is the second most common surgical procedure performed on children after circumcision.4 Few studies evaluating patient-specific quality-of-life outcomes in the surgical treatment of otitis media have been completed. While standard objective measures have demonstrated a benefit in general, there is little evidence available today that the surgical treatment of RAOM or COME improves quality of life.

Quality-of-life issues related to otitis media include such factors as physical symptoms (fever, otalgia, and otorrhea), emotional symptoms (irritability, poor appetite, decreased activity, restlessness, and apathy), hearing loss (decreased response to verbal commands, talking louder, and turning up the television, radio, or video game television), speech symptoms (decrease in articulation, pronunciation, and understandability and speech delay), social symptoms (number of days infection required patient to stay home from school or day care and days of work lost by parents owing to child’s illness), and parents’ emotional symptoms (amount of worry caused by child’s infections, negative effect on parent’s mood, and negative effect on parent’s competence level). Evaluating the effects on quality of life and subjective assessment of tube placement for RAOM and COME is an important feature of documenting the benefits of the treatment along with the more frequently examined objective measures.
or more episodes of AOM during the year prior to tube placement (81%) and 5 or more physician visits because of ear infections (87%). Thirty-nine percent of the children missed 5 or more days because of ear infection, and 43% of the caregivers reported missing 5 or more days from work because of their child's ear infections. Table 3 gives the diagnosis and surgery demographics for the study population.

Prior to the placement of tympanostomy tubes, more than 50% of the caregivers reported that they had been worried, concerned, or inconvenienced by their child's ear infections all of the time, while another 21% reported worrying most of the time, 16% a good part of the time, 7% a small part of the time, and 3% none of the time. This improved tremendously at the 1- and 6-month follow-up, with only 1% and 7% reporting being worried, concerned, or inconvenienced all the time by their child's ear infections, respectively. The mean change in OMO-22 score for parental worry was a decrease of 3.43 (with responses scaled from 0-6) at 1-month follow-up and 2.64 at the 6-month follow-up with a significant P value of less than .001.

The caregivers were asked on the follow-up questionnaires, “Would you have your child undergo ear tube placement if you had to make the decision again?” At the 1-month follow-up, 74 of 80 caregivers responded to this question, with 67 (91%) answering yes, 1 (1%) responding no, and 6 (8%) unsure. At the 6-month follow-up, all 68 caregivers responded to this question, with 57 (84%) answering yes, 3 (4%) answering no, and 8 (12%) unsure.

The questionnaire can be divided into the following 5 subgroups: physical symptoms, hearing and vestibular symptoms, speech symptoms, emotional effects, and social effects. As demonstrated in Table 4, all subgroups of the OMO-22 improved after surgical intervention. The physical symptoms and emotional effects subgroups improved the most. The mean total score of the OMO-22 prior to surgical intervention was 49.1. The mean total score was 11.6 at 1-month follow-up and 15.6 at the 6-month follow-up. The individual scores for each variable for presurgery, 1-month follow-up, and 6-month follow-up are listed in Table 5. The mean percentage change in the total ear symptom score was a 74.5% improvement at 1-month follow-up and 59.8% at the 6-month follow-up. The percentage change in total ear symptom score was significant at both the 1-month and 6-month follow-up visits.
The type of surgery that the children underwent did not influence their mean total score percentage change. At 1-month follow-up, a 70.6% (95% CI, 59.9%-81.4%) improvement was noted in children undergoing BMT alone and an 84.2% (95% CI, 77.9%-90.5%) improvement was noted in children undergoing BMT and adenoidectomy. At the 6-month follow-up, the percentage change was 55.6% (99% CI, 42.7%-68.6%) for BMT alone and 70.7% (99% CI, 53.0%-88.3%) for BMT and adenoidectomy. These differences were not statistically significant by the Mann-Whitney test for nonparametric data.

Health care today is characterized by increasing pressure to document the effectiveness and appropriateness of specific disease treatments to provide patients with cost-effective, quality medical care. While many studies have evaluated the benefits of tympanostomy tube placement based on objective measures, little research has been done to assess subjective patient responses as they relate to quality of life. Patient-based measurements of symptoms, functional status, social and emotional consequences of disease and its treatment, and satisfaction with care are expanded outcome measures used in outcomes research. These outcome measures are determined by health-related quality-of-life assessments.

In reviewing the published literature, we found 5 studies specifically examining otitis media treatment outcomes as they relate to quality of life and otitis-specific functional health status. Alsarraf et al developed and tested several new instruments to assess otitis health status, although their instruments were not included in the published report. The Otitis Media Functional Sta-

### Table 4. Scores for the 5 Otitis Media Outcome–22 Questionnaire Subgroups

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Presurgery</th>
<th>1-mo Follow-up</th>
<th>6-mo Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical symptoms</td>
<td>12.5 (11.6-13.4)</td>
<td>2.7 (2.0-3.5)†</td>
<td>4.2 (3.2-5.2)†</td>
</tr>
<tr>
<td>Hearing and vestibular symptoms</td>
<td>9.4 (7.4-10.8)</td>
<td>1.8 (1.1-2.5)†</td>
<td>2.6 (1.3-3.9)†</td>
</tr>
<tr>
<td>Speech symptoms</td>
<td>7.3 (5.6-8.7)</td>
<td>2.6 (1.5-3.8)†</td>
<td>4.0 (2.6-5.4)‡</td>
</tr>
<tr>
<td>Emotional effects</td>
<td>12.9 (11.5-14.4)</td>
<td>2.6 (1.7-2.9)†</td>
<td>3.4 (2.3-4.5)‡</td>
</tr>
<tr>
<td>Social effects</td>
<td>7.0 (5.9-8.6)</td>
<td>1.9 (0.9-2.9)†</td>
<td>1.4 (0.8-2.0)†</td>
</tr>
<tr>
<td>Total Ear Score</td>
<td>49.1 (44.8-53.4)</td>
<td>11.6 (8.5-14.6)†</td>
<td>15.6 (11.6-19.6)†</td>
</tr>
</tbody>
</table>

*Data are mean (95% confidence interval) score.†P<.001.‡P<.05.

### Table 5. Scores for Individual Variables of the Otitis Media Outcome–22 Questionnaire*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Presurgery</th>
<th>1-mo Follow-up</th>
<th>6-mo Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear pain</td>
<td>4.0 (3.6-4.3)</td>
<td>0.6 (0.4-0.9)†</td>
<td>1.2 (0.9-1.5)†</td>
</tr>
<tr>
<td>Ear tugging</td>
<td>4.2 (3.8-4.1)</td>
<td>1.1 (0.8-1.4)†</td>
<td>1.1 (0.8-1.5)†</td>
</tr>
<tr>
<td>Otorrhea</td>
<td>1.3 (0.9-1.7)</td>
<td>0.6 (0.3-0.8)†</td>
<td>1.0 (0.8-1.5)§</td>
</tr>
<tr>
<td>Fever</td>
<td>3.1 (2.8-3.5)</td>
<td>0.4 (0.2-0.6)‡</td>
<td>0.9 (0.6-1.2)†</td>
</tr>
<tr>
<td>Poor balance</td>
<td>1.7 (1.4-2.1)</td>
<td>0.4 (0.2-0.6)†</td>
<td>0.3 (0.1-0.5)†</td>
</tr>
<tr>
<td>Difficulty hearing</td>
<td>2.3 (1.9-2.7)</td>
<td>0.3 (0.1-0.4)‡</td>
<td>0.7 (0.3-1.0)†</td>
</tr>
<tr>
<td>Frequently says &quot;what&quot;</td>
<td>1.8 (1.4-2.2)</td>
<td>0.4 (0.2-0.6)§</td>
<td>0.6 (0.3-1.0)‡</td>
</tr>
<tr>
<td>Television played excessively loud</td>
<td>1.5 (1.1-1.7)</td>
<td>0.3 (0.1-0.5)‡</td>
<td>0.5 (0.2-0.8)‡</td>
</tr>
<tr>
<td>Frequently doesn’t respond to verbal commands</td>
<td>2.1 (1.7-2.5)</td>
<td>0.4 (0.2-0.6)†</td>
<td>0.6 (0.3-0.8)‡</td>
</tr>
<tr>
<td>Delayed speech</td>
<td>1.8 (1.4-2.3)</td>
<td>0.7 (0.4-1.0)†</td>
<td>1.0 (0.6-1.5)†</td>
</tr>
<tr>
<td>Poor pronunciation</td>
<td>1.8 (1.4-2.3)</td>
<td>0.7 (0.4-1.0)†</td>
<td>1.2 (0.7-1.6)§</td>
</tr>
<tr>
<td>Difficult to understand</td>
<td>1.7 (1.4-2.1)</td>
<td>0.6 (0.3-0.9)‡</td>
<td>0.8 (0.5-1.1)†</td>
</tr>
<tr>
<td>Unable to repeat words clearly</td>
<td>1.8 (1.4-2.2)</td>
<td>0.6 (0.3-1.0)†</td>
<td>1.0 (0.6-1.4)†</td>
</tr>
<tr>
<td>Irritable</td>
<td>3.5 (3.2-3.9)</td>
<td>0.7 (0.5-0.9)‡</td>
<td>0.9 (0.6-1.2)†</td>
</tr>
<tr>
<td>Frustrated</td>
<td>2.8 (2.4-3.2)</td>
<td>0.5 (0.3-0.7)‡</td>
<td>0.8 (0.5-1.1)†</td>
</tr>
<tr>
<td>Sad</td>
<td>1.4 (1.1-1.7)</td>
<td>0.2 (0.1-0.3)‡</td>
<td>0.2 (0.2-0.4)‡</td>
</tr>
<tr>
<td>Restless</td>
<td>3.0 (2.6-3.4)</td>
<td>0.7 (0.4-0.9)‡</td>
<td>0.8 (0.5-1.2)‡</td>
</tr>
<tr>
<td>Poor appetite</td>
<td>2.2 (1.9-2.6)</td>
<td>0.5 (0.3-0.9)‡</td>
<td>0.6 (0.4-0.9)‡</td>
</tr>
<tr>
<td>Limited playing</td>
<td>1.3 (1.0-1.6)</td>
<td>0.3 (0.1-0.5)‡</td>
<td>0.2 (0.0-0.9)‡</td>
</tr>
<tr>
<td>Limited sleeping</td>
<td>2.9 (2.4-3.2)</td>
<td>0.9 (0.5-1.2)‡</td>
<td>0.7 (0.5-1.0)‡</td>
</tr>
<tr>
<td>Doing things with family and/or friends limited</td>
<td>1.2 (0.9-1.5)</td>
<td>0.4 (0.1-0.6)‡</td>
<td>0.3 (0.1-0.5)‡</td>
</tr>
<tr>
<td>Attending school or day care limited</td>
<td>1.7 (1.3-2.0)</td>
<td>0.3 (0.1-0.6)‡</td>
<td>0.2 (0.1-0.3)‡</td>
</tr>
<tr>
<td>Total Ear Score</td>
<td>49.1 (44.8-53.4)</td>
<td>11.6 (8.49-14.8)†</td>
<td>15.6 (11.7-19.6)†</td>
</tr>
<tr>
<td>Mean % change</td>
<td>...</td>
<td>74.5 (66.5-82.5)†</td>
<td>59.8 (49.4-70.1)†</td>
</tr>
</tbody>
</table>

*Data are mean (95% confidence interval) score unless otherwise specified.†P<.001.‡P<.05.§P>.05 (not statistically significant).
Rosenfeld et al. performed a study using the OM-6 examining the short-term impact of tympanostomy tube placement on children’s quality of life. This study demonstrated little change in quality of life before tympanostomy tube placement and a significant short-term post-surgery improvement with an average follow-up of 34 days. Physical symptoms, caregiver concerns, emotional distress, and hearing loss improved the most. Otorrhea and lack of satisfaction with surgical decision were associated with poorer outcomes.

Rovers et al. studied the effect of treatment on quality of life in children with COME aged between 1 and 2 years. Children were randomized to watchful waiting or BMT, and quality of life was measured using a Dutch language general quality of life questionnaire, the TNO-AZL Infant Quality-of-Life questionnaire and a psychological test (the Erickson parent-child interaction scales). They did not find a significant difference between the watchful waiting vs BMT placement. This study is limited by several factors, including the lack of a disease-specific questionnaire. It also lacked evidence that the quality-of-life questionnaire used was sensitive to changes in disease state (responsiveness to change).

Facione evaluated 61 children with COME and retrospectively compared the 12-month period prior to tube placement with the 12-month post-surgery period. She found decreases in health care visits and antibiotic use after tympanostomy tube placement with or without adenoidectomy and suggested that ventilation tubes improve the overall quality of life of children with COME. This study is limited by its retrospective nature, lack of validation of the questionnaire used in the study, and the absence of specific quality-of-life variables. No studies evaluating long-term benefit of tympanostomy tubes were identified, and only 1 study included adenoidectomy when clinically indicated in the surgical treatment for RAOM and/or COME.

The present study suggests that (1) there is a significant improvement in the quality of life of children with either RAOM or COME and in their parents’ response to surgical treatment and (2) this improvement persists for an extended period after surgical therapy. Prior to surgical treatment, the caregivers and children were making significant numbers of physician office visits that required absence from school or day care for the children and absence from work for the parents. The caregivers’ amount of worry declined significantly from 52% of the caregivers being worried, concerned, or inconvenienced by their children’s ear infections all of the time to 1% and 7% at 1 and 6 months after surgery, respectively. The improvement in worry about their children, as well as the possibility of increased work productivity and decreased absenteeism, may improve the quality of life of the parents. This is supported by the fact that most caregivers (91% at 1-month and 84% at 6-month follow-up) would elect to proceed with surgical intervention if they had to make the choice again.

More important, there was a statistically significant improvement in the mean percentage change of the total ear score on the OMO-22, with a 74.5% improvement at the 1-month follow-up and a 59.8% improvement at the 6-month follow-up. Only 3 children were reported to have an increase in total ear scores corresponding to an increase in symptoms at the 1-month follow-up, and only 7 children had an increase in total ear scores at the 6-month follow-up. Statistically significant improvement in all 5 subgroups of otitis media-related symptoms was noted, especially in the physical symptoms and emotional effects subsets. This suggests that, overall, surgical treatment when appropriately indicated resulted in a significant improvement in disease-specific quality of life for these children.

The present study does have several limitations. First, otitis media is a disease primarily of early childhood and, therefore, the questionnaire must be administered to the caregivers, not the child. It is possible that the caregivers’ perceptions may not accurately represent the children’s actual state of health. For example, Rosenfeld et al demonstrated that parents’ perceptions of their children’s hearing abilities do not correlate with actual hearing loss, although they can still play an important role in assessing quality-of-life issues. Although this may be regarded as a limitation, proxy use in assessing quality of life in pediatric patients is common. Proxies may even be preferable in many circumstances because the caregiver will be the one making all medical decisions concerning the child. Children also frequently lack the language skills necessary for quality-of-life assessment, making proxy use a necessity.

Second, quality-of-life surveys and questionnaire-based outcome studies depend on the accuracy of the respondents’ answers. In the questionnaire format, bias or inaccuracy in self-reporting is always a possibility. In the present study, the parents are asked to recall information over the previous year on the presurgery questionnaire. Parents’ recall for such questionnaire items may not be completely accurate. This is a limitation common to questionnaire-based studies, as well as patient-provided medical histories.

This study had a less than 70% response rate at the 6-month follow-up. This is typical for questionnaire-based studies, and responses from 60% to 80% are typically considered excellent. The basic characteristics of the nonresponders were similar to responders in terms of age, sex, number of ear infections, number of physician visits, and total ear scores at presurgery assessment. It would be expected that those children who were not followed up likely had less problems and, therefore, lower total ear scores after surgical intervention for their otitis media because they did not seek medical care for continued complaints or follow-up as recommended.

The patient population in this study could also be a confounding factor. The parents and their children in this study had been bothered enough by the episodes of otitis media to seek the medical attention of a specialist.
This may result in parents perceiving their children’s otitis media as more of a problem than a similar group of parents who did not seek a specialist’s care for their children. Since the present study was designed to assess the effects of surgical intervention for RAOM and/or COME on quality-of-life issues and because only children who seek specialist care will receive surgical intervention, the patient population should not impact on this study directly as a confounding factor.

This study is designed as an observational study with repeated measures instead of the gold standard of a randomized, controlled, double-blind prospective study. It would be unethical and inappropriate to randomly assign patients to receive surgical intervention vs a sham operation in accordance with the Declaration of Helsinki because the well-being of the subject should take precedence over the interests of science, and the risks to the subject outweigh the importance of the objective.22 Even randomly assigning children to receive surgical vs nonsurgical medical treatment is ethically questionable because this would preclude providing children with the standard of care available in this country for the treatment of RAOM or COME, which again could outweigh the benefit of the study. Using patients as their own control prevents differences in individuals’ extent of disease from confounding the study, but it does not take into account an individual’s own variance in extent of disease. It will not account for improvements in or worsening of the disease state that could occur throughout the natural course of the disease. While children, in general, tend to outgrow RAOM and COME over time, it would be highly improbable to see such significant differences over a short period of 1 to 6 months.

Another limitation of this study is the lack of a validated global quality-of-life survey for children younger than 5 years with which to compare the OMO-22. Ideally, the disease-specific outcomes assessment tool used in this study would have been compared with a global health outcomes assessment device, such as the SF-36 Health Survey used in adults. Unfortunately, there is not currently a global quality-of-life standard available at this time for use in young children. Further research needs to be completed in assessing global quality-of-life measures in young children. Validated measures of disease-specific quality-of-life surveys, such as the OMO-22, need to be compared with this global measure. This comparison would further allow for assessment of the impact of RAOM and COME on children’s lives and help to determine when a specific treatment is truly beneficial in improving the quality of life of these children.

CONCLUSIONS

The mean percentage change in the total ear symptom scores significantly improved both at 1 and 6 months after surgical intervention for RAOM and/or COME in patients with standard surgical indications for tympanostomy tube placement with or without adenoidectomy. Most caregivers were satisfied with the outcome of the surgical intervention and would make the same decision for their children to undergo treatment again.

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REFERENCES