

ORIGINAL RESEARCH

# Quality of life after tonsillectomy in children with recurrent tonsillitis

**Nira A. Goldstein, MD, Michael G. Stewart, MD, MPH, David L. Witsell, MD, MHS, Maureen T. Hannley, PhD, Edward M. Weaver, MD, MPH, Bevan Yueh, MD, MPH, Timothy L. Smith, MD, MPH, Laura J. Orvidas, MD, and the TO TREAT Study Investigators, Brooklyn and New York, NY; Durham, NC; Seattle, WA; Portland, OR; Rochester, MN**

**OBJECTIVE:** To describe changes in disease-specific and global quality of life (QOL) for children with recurrent or chronic tonsillitis at 6 months and 1 year after tonsillectomy using two validated instruments, the Tonsil and Adenoid Health Status Instrument (TAHSI) and the Child Health Questionnaire-PF28 (CHQ-PF28).

**STUDY DESIGN AND SETTING:** A multicenter, prospective observational outcomes study.

**RESULTS:** Ninety-two children, mean age (SD) 10.6 (3.4) years, enrolled with follow-up available for 58 children at 6 months and 38 children at 1 year. The children showed significant improvements in all subscales of the TAHSI including airway and breathing, infection, health care utilization, cost of care, eating and swallowing (all  $P < 0.001$ ), and behavior ( $P = 0.01$ ). Significant improvements were also found on several subscales of the CHQ-PF28, such as general health perceptions, physical functioning, parental impact, and family activities (all  $P < 0.001$ ).

**CONCLUSION/SIGNIFICANCE:** This uncontrolled study provides prospective evidence of improved disease-specific and global QOL in children after tonsillectomy.

© 2008 American Academy of Otolaryngology–Head and Neck Surgery Foundation. All rights reserved.

Recurrent and chronic infections of the tonsils and adenoid continue to be a common problem, and adenotonsillectomy (T&A) remains a commonly performed surgical procedure. Although there have been many reports on the effectiveness of T&A in children with recurrent tonsillitis, most authors have examined only changes in a few objective measures of health status such as the number of episodes of tonsillitis but have not measured additional patient-based outcomes.<sup>1-3</sup> The indications for T&A remain poorly defined and controversial.<sup>4,5</sup>

This controversy persists because the actual benefits of T&A are unclear when compared against observation and medical treatment of infections. Paradise et al<sup>2</sup> in a simul-

taneous randomized ( $n = 91$ ) and nonrandomized ( $n = 96$ ) trial of tonsillectomy with or without adenoidectomy vs nonsurgical therapy of severely affected children (seven or more documented episodes of tonsillitis in the year before enrollment, five or more episodes in each of the 2 preceding years, or three or more in each of the 3 preceding years) found a significant decrease in the number and severity of infections in the surgical groups during the first 2 years of follow-up. The differences in the third year favored the surgical group but were not statistically significant. In addition, the number of episodes of infection in the control group also decreased in each follow-up year. In a follow-up study of children less severely affected, the incidence of tonsillitis was significantly lower in the surgical group during each of the 3 follow-up years, but the rates of moderate or severe infection in the control children were low, less than one episode per year.<sup>3</sup> The authors concluded that surgery was not indicated for children not severely affected.

The current clinical guidelines from the American Academy of Otolaryngology–Head and Neck Surgery, which were developed using consensus of expert opinion, recommend tonsillectomy for children with three or more documented tonsil infections per year.<sup>6</sup> In Japan, the consensus indication is four episodes in each of 2 successive years.<sup>7</sup> These guidelines are less stringent than the numbers recommended by Paradise and colleagues most likely because of the belief by the otolaryngology community that children's overall general health and quality of life (QOL) are affected by recurrent tonsillitis and that parents and patients report significant reductions in infection and improvements in general health after tonsillectomy even when performed in children with less severe disease.

Stewart et al<sup>8</sup> measured the health status of 55 children with either recurrent tonsillitis or sleep-disordered breathing by using a validated global QOL instrument, the Child

Received September 2, 2006; accepted December 27, 2006.

Health Questionnaire version PF28 (CHQ-PF28). Children with tonsil and adenoid disease showed significantly lower scores on several CHQ-PF28 subscales including general health, physical functioning, behavior, bodily pain, and parental impact as compared with healthy normal children. Scores for the children with tonsil and adenoid disease were generally comparable to scores for children with asthma and juvenile rheumatoid arthritis, although the subscales related to emotional impact, behavior, and parental impact of the child's disease were worse for the children with tonsil and adenoid disease. Other studies on the QOL effects of tonsil and adenoid disease have focused on tonsil and adenoid hypertrophy causing sleep-disordered breathing.<sup>9-15</sup>

Conlon et al<sup>16</sup> reported that parents of 80 children who underwent tonsillectomy for recurrent tonsillitis carried a 100% satisfaction rating 1 year after the procedure, and 90% of the parents believed that their child's general health had improved. Wolfensberger et al<sup>17</sup> also reported a 91% parent satisfaction rating 1 year after tonsillectomy performed in 576 children with 88% of the surgeries performed for treatment of recurrent tonsillitis. Although these studies support the effectiveness of tonsillectomy for improving satisfaction and health status, they lacked validated measurement of QOL.

Although there are several instruments to assess global QOL in children, there are only three instruments that measure disease-specific health status in children with tonsil and adenoid disease.<sup>9,10,18</sup> Only one of the pediatric instruments, the Tonsil and Adenoid Health Status instrument (TAHSI), addresses recurrent or chronic infections.<sup>18</sup> This instrument has been shown to be valid, reliable, and responsive to clinical change. Disease-specific health status instruments are useful because they are usually more sensitive than global instruments to subtle changes in health status that are nevertheless important to patients and providers. Because tonsil and adenoid disease affects children over a wide age range and with different communication skills, the parent who is the primary caretaker is surveyed as a proxy for the affected child, and the instrument is designed for parental completion.

Thus, we tested the hypothesis that children who undergo tonsillectomy with or without adenoidectomy for treatment of chronic or recurrent tonsillitis would have significantly improved disease-specific QOL as measured by the TAHSI 6 months and 1 year after the procedure in a prospective observational outcomes study. Additionally, we hypothesized that children would have improved global QOL (as measured by the CHQ-PF28), reduced episodes of pharyngitis/sore throat, and fewer physician visits for pharyngitis/sore throat.

## METHODS

### Study Design

The study was named TO TREAT (Tonsillitis Outcomes: Toward Reaching Evidence in Adults and Tots) by the

AAOHNS Foundation. It is a multicenter, prospective observational study designed and supervised by a steering committee. The study was coordinated by the Duke Clinical Research Institute (DCRI) under contract with The Academy Foundation. Study coordination included data entry and maintenance, patient follow-up and data collection, and statistical analysis. Sites were enrolled voluntarily through an announcement on the academy's website. If the participating site was an academic center, institutional review board approval was obtained from their own institution. Institutional review board approval for community physicians was obtained from Duke University through an unaffiliated investigator agreement. Informed consent was obtained from the child's parent or caretaker.

The initial study design was to enroll children scheduled for tonsillectomy with or without adenoidectomy for treatment as well as control children defined as patients scheduled for surgery and enrolled in the study but either awaiting surgery, denied coverage by the insurance carrier, rescheduled for other reason, or children whose parents refused surgery and opted for observation or medical management. During the enrollment period, too few control patients were enrolled to allow a statistical comparison between surgical and control patients so only the tonsillectomy patients were included in the final analysis.

### Patient Sample

Children, aged 2 to 16 years, were recruited if they had three or more documented infections of the tonsils despite adequate medical therapy in the year before enrollment, three or more courses of antibiotic therapy for tonsillitis in the year before enrollment, or chronic tonsillitis as defined by 3 months of sore throat with or without halitosis not responding to beta-lactamase-resistant antibiotics. Diagnosis of a tonsil infection required documentation by a physician visit and/or a positive streptococcal culture. Children were required to be American Society of Anesthesiologists class I to III. Exclusion criteria were as follows: immunodeficiency, craniofacial syndrome, sickle cell disease, non-English-speaking parent or caretaker, children undergoing adenoidectomy alone, children undergoing tonsillectomy for sleep-disordered breathing or sleep apnea alone, suspected tonsil malignancy, quinsy tonsillectomy for peritonsillar abscess, partial tonsillectomy, tonsillectomy for halitosis alone, tonsillectomy used as an approach to another procedure, pregnancy, moving away from the treating physicians in the year after enrollment, and psychiatric comorbidity. The enrollment period was October 2003 through May 2005, and a convenience sample was recruited at each institution.

### Treatment

All techniques of tonsillectomy (cold knife, bovie electrocautery, bipolar electrocautery, Coblation, harmonic scalpel, and so on) were permitted as long as all the palatine tonsil tissue was removed in one procedure.

## Completion of Questionnaires

Parents or caretakers completed the TAHSI and CHQ-PF28 at enrollment before tonsillectomy and 6 and 12 months after surgery. Parents also completed questionnaires describing the number of sore throats, antibiotic courses, doctor visits, and days missed from school and daycare in the preceding 6 months. If surgery was delayed more than 2 months after enrollment, parents completed another set of surveys within 1 week of the surgical procedure. Enrollment questionnaires were mailed to the DCRI for data entry, and patients were contacted by the DCRI for completion of follow-up surveys. Patients were contacted by mail at least three times and called up to five times for follow-up. Data on clinical diagnosis were collected from patients who did not meet eligibility criteria.

The TAHSI consists of 18 items divided into six subscales (airway and breathing, infection, health care utilization, eating and swallowing, cost of care, and behavior).<sup>18</sup> Each item is scored using a 5-point ordinal scale that assesses the severity of specific symptoms scored as follows: 0, not a problem; 1, very mild problem; 2, moderate problem; 3, fairly bad problem; and 4, severe problem. Items were summed to obtain each subscale raw score. As described previously, the subscale raw score is converted to a score ranging from 0 (minimum score) to 100 (maximum score).<sup>18</sup>

The CHQ, released in 1997, is a valid, reliable, and responsive instrument designed to assess the physical and psychosocial well-being of pediatric patients.<sup>19</sup> There are four different versions of the CHQ; three were designed for parental completion, and of these, the version with lowest respondent burden is the CHQ-PF28, which contains 28 items. The CHQ-PF28 contains 12 subscales that measure constructs, or dimensions, of overall health status. The subscales consist of the following: (1) physical functioning, (2) role/social limitations because of emotional/behavioral problems, (3) role/social limitations because of physical problems, (4) bodily pain/discomfort, (5) behavior, (6) mental health, (7) self-esteem, (8) general health perceptions, (9) parental impact (emotional), (10) parental impact (time), (11) family activities, and (12) family cohesion.

The CHQ-PF28 was scored and broken down into subscales (range, 0-100) using published algorithms.<sup>19</sup> These scores were compared with the scores from published tables of normal population data that were obtained from parents of healthy children.

## Sample-Size Estimation

The sample-size estimation was calculated assuming that both study and control patients would be recruited. Based on validation data for the TAHSI, mean (SD) scores on the infection subscale before and after tonsillectomy were 36.16 (30.96) and 2.42 (5.35).<sup>18</sup> To establish a significant difference of 20 points (ie, the control patients reduce to 22 and the surgical patients reduce to 2), with an alpha error of 0.05 and 90% power and assuming a pooled standard deviation

of 15, we would need 13 patients in each group. We assumed that the control group would have lower accrual than the surgery group so our sample size was targeted at that group. If enrollment was 1:3 (control:surgery), then 52 total patients would be needed to achieve 90% power. Assuming a lost-to-follow-up rate of as high as 25%, we planned to enroll 70 patients. The pediatric and adult arms of TO TREAT enrolled patients simultaneously and enrollment continued until the target adult recruitment was reached. Because the pediatric recruitment proceeded more rapidly, the pediatric target enrollment was exceeded. In addition, pediatric enrollment continued after the first 70 patients with an attempted emphasis on enrolling control patients. At 92 patients, with only five controls, the study was discontinued and analyzed as an uncontrolled study.

## Statistical Analysis

Comparison of patient demographics and baseline TAHSI scores between the children whose parents completed the 6-month surveys and the children whose parents did not return the 6-month surveys was performed by using the Fisher exact test for categorical variables and the Wilcoxon signed rank test, a nonparametric paired-comparison test, for continuous variables. An exact test of the binomial proportion was used to compare the frequency (increased vs decreased) of throat infections at baseline and at the 6-month and 1-year follow-up. A likelihood ratio  $\chi^2$  test was used to compare the days missed from daycare/school and doctor visits at baseline and at follow-up and the Fisher exact test was used to compare antibiotic use and persistent halitosis at baseline and follow-up. Comparison of baseline and follow-up TAHSI and CHQ-PF28 scores was performed by using the Wilcoxon signed rank test. Comparison of CHQ-PF28 scores with population normals was performed using reported means, and a calculated 95% confidence interval from the study population. If the 95% confidence interval from the study population did not contain the published mean score for the healthy population, then the difference between groups was statistically significant (ie,  $P < 0.05$ ).

## RESULTS

Overall, 19 practice locations representing a wide geographic area across the United States participated in the study: Ada, OK; Baltimore, MD; Birmingham, AL; Brooklyn, NY; Chesapeake, VA; Davidson, NC; Durham, NC; Houston, TX; Jackson, MS; Kansas City, KS; Knoxville, TN; Liverpool, NY; Milwaukee, WI; Mount Pleasant, SC; Naples, FL; Placerville, CA; Palmyra, PA; Rochester, MN; and Wilmington, NC. Eight sites were academic medical centers, and 11 represented private practices. Ninety-two children initially entered the study.

The mean (SD) age of the patients was 10.6 (3.4) years; there were 34 (37%) boys and 58 (63%) girls. The

**Table 1**  
**Impact of tonsillectomy on the frequency and severity of tonsillitis during the prior 6 months**

Variable	No. (%) Baseline (n = 92)	No. (%) 6 months (n = 58)	No. (%) 1 year (n = 38)
<b>Episodes of sore throat</b>			
None	0	18 (31.0)	8 (21.1)
<1 per month	0	0	4 (10.5)
1 per month	36 (39.1)	35 (60.3)	24 (63.2)
2 to 4 per month	40 (43.5)	4 (6.9)	2 (5.3)
1 per week	1 (1.1)	0	0
2 per week	3 (3.3)	0	0
>2 per week	12 (13.0)	0	0
Unknown	0	1 (1.7)	0
<i>P</i> value*	—	<0.001	<0.001
<b>Child school/daycare days missed because of sore throat</b>			
<1	5 (5.4)	43 (74.1)	28 (73.7)
1 to 5 days	33 (35.9)	14 (24.1)	8 (21.1)
6 to 10 days	27 (29.3)	1 (1.7)	1 (2.6)
>10 days	27 (29.3)	0	0
Unknown	0	0	1 (2.6)
<i>P</i> value†	—	<0.001	<0.001
<b>Child doctor visits because of sore throat</b>			
None	0	19 (32.8)	8 (21.1)
1	4 (4.3)	28 (48.3)	23 (60.5)
2 to 6	64 (69.6)	6 (10.3)	5 (13.2)
7 to 10	19 (20.7)	0	0
>10	5 (5.4)	0	0
Unknown	0	5 (8.6)	2 (5.3)
<i>P</i> value†	—	<0.001	<0.001
<b>Child antibiotic use</b>			
None	0	49 (84.5)	32 (84.2)
1	6 (6.5)	9 (15.5)	6 (15.8)
2	11 (12.0)	0	0
3	20 (21.7)	0	0
>3	55 (59.8)	0	0
Unknown	0	0	0
<i>P</i> value‡	—	<0.001	<0.001
<b>Persistent halitosis</b>			
No	45 (48.9)	55 (84.8)	33 (86.8)
Yes	47 (51.1)	3 (5.2)	5 (13.2)
Unknown	0	0	0
<i>P</i> value‡	—	<0.001	<0.001

\*Exact test of the binomial proportion comparing baseline with the 6-month and 1-year follow-up.

†Likelihood ratio  $\chi^2$  test.

‡Fisher exact test.

racial distribution was as follows: white, 70 (76%); black, 15 (16%); Hispanic, 5 (5%); and Asian, 2 (2%). Treatment allocation was T&A in 82 (89%) patients, tonsillectomy alone in 5 (5%) patients, and observation or medical therapy alone in 5 (5%) patients. Follow-up data are not presented for the nonsurgical patients. Of the 87 tonsillectomy patients, 6-month follow-up was available for 58 (66.7%) patients and 1-year follow-up was available for 38 (43.7%) patients. There were no significant differences in patient age and baseline TAHSI scores between the children with the 6-month follow-up and the children lost to follow-up (data not shown). Significantly more girls ( $P = 0.02$ ) and nonwhite chil-

dren ( $P = 0.04$ ) had the 6-month follow-up as compared with the children lost to follow-up.

The mean (SD) number of episodes of tonsillitis in the year before enrollment was 5.3 (1.8). Parents reported the children had significantly fewer sore throats, antibiotic courses, days missed from daycare/school, and doctor visits 6 months and 1 year after tonsillectomy (Table 1). Persistent halitosis was found in 51.1% of the children at enrollment but only 5.2% of the children at 6 months and 13.2% of the children at 1 year, showing a significant improvement.

The baseline and change TAHSI scores are presented in Table 2. Infection, health care utilization, cost of care, and airway and breathing were the highest-rated subscales fol-



**Table 2**  
Impact of tonsillectomy on TAHSI scores

Subscale	Baseline mean (SD)* (n = 92)	6-month change mean (SD)† (n = 58)	P value‡	1-year change mean (SD)† (n = 38)	P value‡
Airway and breathing	31.5 (25.4)	27.3 (25.4)	<0.001	27.4 (25.0)	<0.001
Infection	66.4 (22.9)	61.5 (26.0)	<0.001	63.3 (24.3)	<0.001
Health care utilization	59.8 (21.5)	54.4 (25.3)	<0.001	53.9 (26.4)	<0.001
Eating and swallowing	14.8 (22.1)	11.0 (27.6)	<0.001	13.8 (24.5)	<0.001
Cost of care	44.0 (34.0)	37.3 (34.6)	<0.001	32.1 (34.9)	<0.001
Behavior	13.0 (27.9)	5.9 (32.3)	0.16	13.5 (30.8)	0.01

\*Scale 0 to 100. Higher scores indicate poorer QOL.

†Baseline score minus follow-up score (smaller scores indicate better disease-specific health status). Larger magnitude change scores indicate greater improvement.

‡Wilcoxon signed rank test on change from baseline.

lowed by eating and swallowing and behavior. Although the enrollment criteria was recurrent infection, significant improvements were found for all of the subscale change scores except behavior at 6 months and all of the subscale change scores at 1 year.

The baseline and change CHQ-PF28 scores are presented in Table 3. Subscales most affected were general health perceptions, family impact, behavior, bodily pain/discomfort, and family activities. Comparison of the baseline mean subscale scores with that of healthy children showed significantly lower scores, indicating poorer QOL, for all subscales except for mental health, self-esteem, and family cohesion (Table 4). After tonsillectomy, improvements in global QOL were found for all of the subscales change

scores at 6 months and 1-year follow-up with most improvements being statistically significant (Table 3).

## DISCUSSION

Although there are several prospective outcomes studies showing improvements in disease-specific and global QOL after T&A for children with sleep-disordered breathing,<sup>9,11-15</sup> this is the first study evaluating children with recurrent or chronic tonsillitis using validated QOL instruments. Scores on the disease-specific instrument, the TAHSI, were significantly improved 6 months and 1 year

**Table 3**  
Impact of tonsillectomy on CHQ-PF28 subscale scores

Subscale	Baseline mean (SD)* (n = 92)	6-month change mean (SD)† (n = 58)	P value‡	1-year change mean (SD)† (n = 38)	P value‡
Physical functioning	81.3 (23.6)	-15.3 (24.4)	<0.001	-16.1 (24.5)	<0.001
Role/social limitations					
Emotional/behavioral	85.2 (26.5)	-12.2 (24.9)	<0.001	-12.3 (27.5)	0.01
Physical	79.0 (31.0)	-20.0 (29.6)	<0.001	-25.6 (32.5)	<0.001
Bodily pain/discomfort	69.5 (27.5)	-15.4 (27.3)	<0.001	-12.1 (29.6)	0.02
Behavior	64.3 (19.3)	-10.8 (14.2)	<0.001	-13.0 (15.5)	<0.001
Mental health	80.5 (18.1)	-2.1 (19.6)	0.66	-3.0 (19.5)	0.54
Self-esteem	84.2 (20.1)	-3.3 (24.3)	0.67	-4.6 (19.0)	0.32
General health perceptions	61.7 (18.4)	-14.2 (19.7)	<0.001	-12.0 (19.6)	<0.001
Parental impact					
Emotional	64.0 (28.2)	-19.1 (26.3)	<0.001	-21.5 (33.4)	<0.001
Time	69.7 (31.2)	-24.0 (31.6)	<0.001	-20.9 (37.6)	<0.001
Family activities	67.7 (26.8)	-23.1 (28.1)	<0.001	-23.7 (28.4)	<0.001
Family cohesion	72.7 (22.9)	-7.4 (20.0)	0.005	-5.3 (15.9)	0.04

\*Scale 0 to 100. Lower scores indicate worse QOL.

†Baseline score minus follow-up score (higher scores indicate better global QOL). Larger magnitude change scores indicate greater improvement.

‡Wilcoxon signed rank test on change from baseline.

**Table 4**  
**Mean CHQ-PF28 subscale scores for children with recurrent tonsillitis and healthy children**

Subscale	Children with recurrent tonsillitis (n = 92)*	Healthy children (n = 391)†
Physical functioning	81.3 (76.5-86.1)	95.0‡
Role/social limitations		
Emotional/behavioral	85.2 (79.8-90.7)	92.5‡
Physical	79.0 (72.6-85.4)	93.7‡
Bodily pain/discomfort	69.5 (63.8-75.2)	81.3‡
Behavior	64.3 (60.3-68.3)	70.8‡
Mental health	80.5 (76.8-84.2)	79.7
Self-esteem	84.2 (80.1-88.3)	80.1
General health perceptions	61.7 (58.0-65.5)	74.0‡
Parental impact		
Emotional	64.0 (58.2-70.0)	81.3‡
Time	69.7 (63.3-76.1)	88.4‡
Family activities	67.7 (62.2-73.2)	91.1‡
Family cohesion	72.7 (68.0-77.4)	72.4

\*Scale 0 to 100. Lower scores indicate worse QOL. Values are mean (95% confidence intervals).

†Values are means.

‡Statistically significant difference ( $P < 0.05$ ).

after surgery. Even though children were recruited for the study based on their history of recurrent infection, children also showed improvement in the airway and breathing, eating and swallowing, and behavior subscale scores, in addition to the infection and health care subscale scores. Previous reports have also documented a high incidence of sleep-disordered breathing in children undergoing T&A for treatment of recurrent tonsillitis with subsequent improvement of obstructive symptoms postoperatively.<sup>20</sup>

The global QOL scores were significantly poorer at enrollment for most subscales compared with the scores obtained from a healthy pediatric patient population, confirming the significant QOL impact of recurrent tonsillitis. Our scores were similar to those obtained by Stewart et al<sup>8</sup> in their study using the CHQ-PF28 to study global QOL in children with tonsil and adenoid disease; however, that study also included children with hypertrophy and sleep-disordered breathing. The scores obtained in both studies were generally comparable to those seen in children with two chronic diseases, asthma and juvenile rheumatoid arthritis.

In addition, in the present study, we found significant improvement in the bodily pain/discomfort and physical functioning subscales with the resolution of tonsil infections after T&A. The children also showed significant improvements in most other areas including general health perceptions, role/social limitations, behavior, parental impact, and family activities.

Although prior studies have focused on reduction in the episodes of tonsillitis after T&A, our results show improvements in the overall health status and QOL in affected children. Caretaker opinions concerning QOL and health care status are critically important in assessing treatment outcomes and patient satisfaction.<sup>16,17</sup> Our results agree

with the earlier studies reporting high rates of parent satisfaction 1 year after the procedure.

Although the trial was designed to be a controlled study comparing children undergoing tonsillectomy with children observed or treated medically, we were unable to recruit enough control patients. There are likely several reasons for this, including referral patterns of children evaluated in the otolaryngology offices. In other words, by the time the children were referred to the otolaryngologist, the parents were convinced that tonsillectomy was needed. There is also potential bias among otolaryngologists who believe that T&A is effective and are more likely to recommend it to patients over observation. The study was also subject to additional selection bias because a convenience rather than a consecutive sample was recruited. To fully assess the efficacy of T&A in improving QOL, a controlled trial, preferably randomized, would be needed. However, we believed that a randomized trial would be quite difficult to implement because many parents would be unwilling to accept randomization; therefore, we chose an observational design in an attempt to enroll patients that did not have surgery as a comparison group. However, unfortunately we were unable to enroll enough patients to allow a comparative analysis.

Our entry criteria for this study included children who were less severely affected, using the criteria from prior studies, because we believed that many otolaryngologists and parents were using similar criteria in their decision making for elective tonsillectomy. Our entry criteria were consistent with the current clinical guidelines from the American Academy of Otolaryngology–Head and Neck Surgery.<sup>6</sup> Nevertheless, the children enrolled had, on average, more infections per year than the minimum

required for entry. After tonsillectomy, parents reported significantly fewer sore throats, antibiotic courses, and doctor visits. It is interesting to speculate on the potential reasons that prior studies showed nonsignificant reductions in the actual number of infections after tonsillectomy. Perhaps the criteria from prior studies were too stringent (eg, requiring a positive culture), and actual infections were undercounted because exact criteria were not met. In this study, we purposely chose less stringent clinical criteria in an attempt to ensure that all infections were counted and to match true clinical practice. However, we recognize that this could result in a bias in the other direction in which the number of infections is overestimated, perhaps from noninfectious episodes such as allergy.

Although reduction in the absolute number of infections is important, global QOL is also an important outcome. After tonsillectomy, we found significant improvements in QOL in these children. Of course, the placebo effect of intervention must be considered. However, the improvements were so striking that it seems unlikely that treatment-placebo effect is the entire explanation. In addition, we observed significant improvement in objective outcomes (eg, number of sore throats, physician visits, and courses of antibiotics), which should be less prone to the placebo effect. Alternative explanations are regression to the mean or the natural history of the disease. Regression to the mean could explain the reduction in the number of infections because this variable was an entry inclusion criterion; however, this phenomenon would not explain improvement in every other outcome variable. Again, a control group would be very helpful, but the changes seen were large, consistent across all outcomes, and stable over time, which all indicate it is unlikely that they were not caused by the impact of tonsillectomy in these children with recurrent tonsillitis.

An important limitation of this study is the loss to follow-up. It is possible that follow-up was available only on patients with the most improvement, thus biasing our outcomes measurements. However, baseline TAHSI scores between patients followed and patients lost to follow-up were not significantly different.

In summary, children with recurrent or chronic tonsillitis showed significant improvements in disease-specific and global QOL after T&A as measured by validated instruments. Furthermore, they experienced fewer infections, doctor visits, and courses of antibiotics after T&A. Recommendations for tonsillectomy should be based on evaluation of the child's overall health status and QOL and not just the number of culture-documented tonsil infections. Further controlled studies are recommended to corroborate these results.

## ACKNOWLEDGMENTS

We thank Tanya Darrow and Tasha Carmon of the Duke Clinical Research Institute for study coordination and data entry, Jack Shostak, BS, MBA, of

the Duke Clinical Research Institute for statistical consultation, and Margaretha L. Casselbrant, MD, PhD, for assistance with protocol design. TO TREAT Study Investigators: Michael Belmont, MD, Daniel Bruegger, MD, Beth Burghardt, MD, C. Ron Cannon, MD, Stephen Conley, MD, Valerie Flanery, MD, John Fornadley, MD, Paul Gidley, MD, Nira A. Goldstein, MD, Howard Hessian, MD, Mark J. Hoy, MD, Greg Hulka, MD, Patrick Kane, MD, Joseph Kerschner, MD, Jon Langford, MD, L. Frederick Lassen, MD, Roger Levin, MD, Pamela Nicklaus, MD, Laura Orvidas, MD, Michael Y. Parker, MD, Nalin Patel, MD, Reginald M. Rice, Jr, MD, Richard Scher, MD, Andrew Shapiro, MD, Richard Waguespack, MD, Derrick Wallace, MD, Robert Weatherly, MD, Julie Wei, MD, James Williams, MD, and David L. Witsell, MD.

## AUTHOR INFORMATION

From the Division of Pediatric Otolaryngology, SUNY Downstate Medical Center, Brooklyn, NY (Dr Goldstein); Department of Otorhinolaryngology, Weill Cornell Medical College, New York, NY (Dr Stewart); Division of Otolaryngology–Head and Neck Surgery, Department of Surgery, Duke University School of Medicine, Durham, NC (Dr Witsell); American Academy of Otolaryngology–Head and Neck Surgery Foundation (Drs Witsell and Hannley); VA Puget Sound Healthcare System, and the Department of Otolaryngology–Head and Neck Surgery, University of Washington School of Medicine, Seattle, WA (Drs Weaver and Yueh); Department of Otolaryngology, Oregon Health and Science University, Portland, OR (Dr Smith); and Department of Otorhinolaryngology, Mayo Clinic, Rochester, MN (Dr Orvidas).

Presented at the Annual Meeting of the American Academy of Otolaryngology–Head and Neck Surgery, Toronto, Canada, September 19, 2006.

Corresponding author: Nira A. Goldstein, MD, Department of Otolaryngology, SUNY Downstate Medical Center, 450 Clarkson Avenue, Box 126, Brooklyn, NY 11203.

E-mail address: ngoldstein@downstate.edu.

## FINANCIAL DISCLOSURE

**Michael Stewart** is a consultant for Schering-Plough Corporation; **Timothy Smith** is a scientific consultant for Acclarent, Inc.

Supported by the National Center for the Promotion of Research in Otolaryngology at the American Academy of Otolaryngology–Head and Neck Surgery Foundation, which was partially funded by a generous unrestricted grant from the Schering-Plough Corporation.

## REFERENCES

1. McKee WJE. A controlled study of the effects of tonsillectomy and adenoidectomy in children. *Br J Prev Soc Med* 1963;17:49–69.
2. Paradise JL, Bluestone CD, Bachman RZ, et al. Efficacy of tonsillectomy for recurrent throat infections in severely affected children: results of parallel randomized and nonrandomized clinical trials. *N Engl J Med* 1984;310:674–83.
3. Paradise JL, Bluestone CD, Colborn DK, et al. Tonsillectomy and adenotonsillectomy for recurrent throat infection in moderately affected children. *Pediatrics* 2002;110:7–15.
4. Burton MJ, Towler B, Glasziou P. Tonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis. *Cochrane Database Syst Rev* 1999;3:CD001802.
5. Discolo CM, Darrow DH, Koltai PJ. Infectious indications for tonsillectomy. *Pediatr Clin North Am* 2003;50:445–58.

6. Clinical indicators tonsillectomy, adenoidectomy, adenotonsillectomy. *Am Acad Otolaryngol Head Neck Surg*. Available at: <http://entnet.org/practice/products/indicators/tonsillectomy.html>. Accessed August 17, 2006.
7. Fujihara K, Koltai PJ, Hayashi M, et al. Cost-effectiveness of tonsillectomy for recurrent acute tonsillitis. *Ann Otol Rhinol Laryngol* 2006;115:365–9.
8. Stewart MG, Friedman EM, Sulek M, et al. Quality of life and health status in pediatric tonsil and adenoid disease. *Arch Otolaryngol Head Neck Surg* 2000;126:45–8.
9. de Serres LM, Derkay C, Astley S, et al. Measuring quality of life in children with obstructive sleep disorders. *Arch Otolaryngol Head Neck Surg* 2000;126:1423–9.
10. Franco RA Jr, Rosenfeld RM, Rao M. Quality of life for children with obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2000;123:9–16.
11. de Serres LM, Derkay C, Sie K, et al. Impact of adenotonsillectomy on quality of life in children with obstructive sleep disorders. *Arch Otolaryngol Head Neck Surg* 2002;128:489–96.
12. Flanary VA. Long-term effect of adenotonsillectomy on quality of life in pediatric patients. *Laryngoscope* 2003;113:1639–44.
13. Mitchell RB, Kelly J, Call E, et al. Long-term changes in quality of life after surgery for pediatric obstructive sleep apnea. *Arch Otolaryngol Head Neck Surg* 2004;130:409–12.
14. Stewart MG, Glaze DG, Friedman EM, et al. Quality of life and sleep study findings after adenotonsillectomy in children with obstructive sleep apnea. *Arch Otolaryngol Head Neck Surg* 2005;131:308–14.
15. Tran CD, Nguyen CD, Weedon J, et al. Child behavior and quality of life in pediatric obstructive sleep apnea. *Arch Otolaryngol Head Neck Surg* 2005;131:52–7.
16. Conlon BJ, Donnelly MJ, McShane DP. Improvements in health and behaviour following childhood tonsillectomy: a parental perspective at 1 year. *Int J Pediatr Otorhinolaryngol* 1997;41:155–61.
17. Wolfensberger M, Jaury J-A, Linder T. Parent satisfaction 1 year after adenotonsillectomy of their children. *Int J Pediatr Otorhinolaryngol* 2000;56:199–205.
18. Stewart MG, Friedman EM, Sulek M. Validation of an outcomes instrument for tonsil and adenoid disease. *Arch Otolaryngol Head Neck Surg* 2001;127:29–35.
19. Landgraf JM, Abetz L, Ware JE. *Child Health Questionnaire (CHQ): A User's Manual*. 1st ed. Boston: The Health Institute, New England Medical Center; 1996.
20. Stradling JR, Thomas G, Warley AR, et al. Effect of adenotonsillectomy on nocturnal hypoxaemia, sleep disturbance, and symptoms in snoring children. *Lancet* 1990;335:249–53.