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Impact of Otitis Media Severity on Children's Quality of Life

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Abstract

Objective—Children with otitis media (OM) suffer sleep disturbances, loss of appetite, earache, and behavioral problems. Our objective was to quantitate the average burden of OM and to compare the associated impact of tympanostomy tubes on infant health related quality of life (HR-QoL).

Study Design—Multi-institutional prospective cross-sectional study.

Setting—Otolaryngology, family practice, and pediatric clinics.

Subjects and Methods—Children ages 6 to 24 months of age with or without recurrent OM. Patient history, the PedsQL Infant QoL survey, and the 6-item child with OM survey (Otitis Media 6 [OM-6]) were collected from providers and parents.

Results—Data from 1208 patients were analyzed. Mean age was 14.7 months, and 54% were male. The mean OM-6 score of children with recurrent OM was 3.3, whereas similarly aged well-children had a mean OM-6 score of 2.5. The mean PedsQL Infant scores of recurrent OM patients were significantly worse than those of children from well-child visits. Worse OM-6 scores were correlated with poorer PedsQL Infant scores, Pearson $r = -0.581$ (1-12 months) and -0.558 (13-24 months), $P < .001$. Otolaryngology patients who were recommended to undergo ear tube placement had significantly poorer OM-6 scores and worse PedsQL Infant scores, whereas patients with prior tube placement had significantly better OM-6 and PedsQL Infant scores.

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Conclusion—Children with recurrent OM had significantly worse HR-QoL than similarly aged healthy children. Increased burden of OM strongly affected HR-QoL, and recommendation for tube placement was associated with increased disease burden and poorer HR-QoL. The presence of tympanostomy tubes was associated with better OM-6 and PedsQL Infant scores.

Keywords

acute otitis media; recurrent otitis media; otitis media with effusion; quality of life; tympanostomy tube; pressure equalization tube

Introduction

Otitis media (OM) is the most common medical problem in childhood; furthermore, the disease is often recurrent. Otitis media is the most frequent reason for physician visits, antibiotic use, and surgery for children in developed countries.[1] Most children have at least 1 episode of acute OM by the age of 3 years, with a peak incidence between 6 and 11 months of age.[2] Otitis media can result in a sensation of fullness, pain, and conductive hearing loss. Children with OM often have sleep disturbances, loss of appetite, and earache, as well as psychosocial impacts that can result in long-term behavioral and family problems.[3]

A 2005 study by Brouwer et al explored the effects of recurrent acute OM (AOM) on child health-related quality of life (HR-QoL). The study compared the HR-QoL in children ages 1 to 7 years with recurrent AOM to 4 reference populations. Children with recurrent AOM had poorer HR-QoL than children from the general population and children with mild-moderately severe chronic illness. Further, HR-QoL of children with 4 or more episodes of AOM in the preceding year was poorer than that of children with 2 to 3 episodes. They concluded that recurrent AOM has a considerable negative impact on the HR-QoL of children. Further, the study suggested that the effects are proportional to the severity of the condition.[4] Despite the debilitating nature of the AOM on HR-QoL, research and expert opinion vary on the effectiveness and indications for ear tube placement. A recent Comparative Effectiveness Review (CER) found insufficient evidence to suggest that ear tube placement improves HR-QoL in children with OM.[5]

The current study set out to expand and quantify the impact and predictability of the burden of OM on HR-QoL in children ages 6 to 24 months. We hypothesized that the greater the burden of OM in children, the worse the quality of life of the child. Further, we evaluated the associations of pressure equalization tubes on disease burden and HR-QoL, and the association of disease burden and HR-QoL in patients who were recommended to undergo myringotomy and tube placement.

Methods

Study Design and Participants

This was a multi-institutional prospective cross-sectional study conducted at 23 participating sites, including family practice, pediatrics, and otolaryngology clinics from January 2009 to February 2012. The otolaryngology sites were recruited through the BEST-ENT (Building Evidence for Successful Treatments in Otolaryngology) and CHEER (Creating Healthcare

Excellence through Education and Research) research networks who had established relationships with their pediatric and family practice colleagues.[6] The Washington University School of Medicine Human Research Protection Office provided institutional review board approval, allowing a waiver for written informed consent for study participants because they were not individually identified. However, individual physicians at participating sites signed informed consent forms because their practice information and names were identified.

The sole inclusion criterion was children ages 6 to 24 months with a chief complaint of recurrent or chronic OM, who presented to participating pediatric otolaryngology (Peds Oto) sites for evaluation and treatment. Children were recruited from family practice or pediatric (PCP) sites during well-child visits to serve as controls without recurrent or chronic OM. Exclusion criteria were (1) children < 6 months old or > 24 months old; (2) caregivers who were unable to provide consent; and (3) caregivers who were unable to complete the survey forms in English.

Participating sites recruited interested caregivers of the eligible patients at the time they were seen. Caregivers who chose to participate were given a packet of survey instruments to complete either during their visit or later with a mail-in option.

Background Data

A demographics form, a family information form, overall health, and OM history form were filled out by the parent/caregiver (hereinafter referred to as caregiver). Data collected from these surveys included family income, parental insurance status, mother's and father's educational level, age, sex, ethnicity of the child, day care attendance status, and parental reports on number of OM episodes (over 1- and 3-month time periods) and the perceived problems in the child from these episodes.

A physician-completed patient history form was collected from participating sites. Data collected included an assessment of the child's current condition, including number of visits in the last 1- and 3-month time periods with a diagnosis of AOM, comorbidities, presence of ear tubes, and candidacy for tube placement.

Outcomes Assessed

To assess the HR-QoL of the children at the time of participation, several validated tools were used. The Otitis Media 6 (OM-6) survey is a 6-item, disease-specific tool that is a valid and reliable measure of HR-QoL of children with OM as completed by caregivers.[7] It represents the domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns. The median survey score from the validation study was 2.8 (range, 1-7).[7] Elevated OM-6 scores correlate to increased burden of disease and impact of otitis media on the child.[7] The OM-6 survey has previously been used as a disease-specific QoL measure in cross-sectional studies and has been shown to correlate well with global QoL measures.[8-10]

The PedsQL Infant Impact Module is a validated instrument that measures overall HR-QoL and disease-specific symptoms in infants ages 1 to 24 months.[11] The module uses 2 forms—

1 for children ages 1 to 12 months and another for children ages 13 to 24 months. The module encompasses the impact of all pediatric health conditions on overall child HR-QoL. The domains of physical, emotional, social, and cognitive functioning as well as communication and worry are measured, as well as daily activities and relationships.[11] The PedsQL scoring results in a scale of 1 to 100 with higher scores indicating better HR-QoL.[8,11] The median scores from the validation study for infants < 12 months of age were 82.47, 79.47, and 68.02 for healthy, acutely ill, and chronically ill patients, respectively. The mean scores from the validation study for infants 13 to 24 months of age were 85.55, 82.15, and 69.87 for healthy, acutely ill, and chronically ill patients, respectively.

Sample Size Estimation

Based on an estimated true correlation of 0.3 of the PedsQL with OM-6, a 2-sided alpha of .001, and 80% power, we calculated that 1400 subjects would be required for this study. We had planned to recruit at least 2000 subjects in order to have an adequate number of completed data forms for analysis.

Data Management and Analysis

The surveys were collected, and data were input into a password-protected Microsoft Access database. No direct patient identifiers were recorded into the database; surveys were entered by “packet ID” in order to link to corresponding physician forms. Incomplete data forms were omitted from analysis. Data analysis was then performed to allow comparison between the average burden of OM (OM-6) and the impact on overall patient HR-QoL (PedsQL Infant Impact), as well as caregiver perception of the frequency of the child’s illness (Family Information and Health History Form) to the physician-reported diagnosis. All statistical analyses were conducted using SPSS software version 20 (IBM Corporation, Armonk, New York, USA). Bivariate analysis was performed using the independent *t* test for dichotomous predictor variables, analysis of variance for categorical predictor variables, and Pearson’s correlation for continuous predictor variables. Statistical significance was set at a 2-tailed alpha level of $P < .05$.

Results

Demographics and Health History

A total of 2413 children from 23 participating sites were enrolled in the study (Figure 1). Patients with a completed physician form and who completed at least 1 of the patient forms were included in the data analysis (n = 1208). Incomplete individual forms were excluded from analysis. Patients were then subdivided based on site of enrollment. The majority, 84.6%, of patients were enrolled by Peds Oto practices, and 15.4% were enrolled by PCP clinics (Table 1). The majority (86%) were White, whereas 9% were African American, and 60% of mothers had attained a bachelor’s degree or greater, with no differences between practice types.

Analysis of the survey responders from Peds Oto clinics versus PCP clinics revealed no significant difference in race or in the education level of the mother. Responders from Peds Oto sites recruited children who were on average older by 3 months at the time of survey

response. Further, there were more caregivers with private or employer-sponsored insurance in the PCP group, and more caregivers with Medicaid in the Peds Oto group, $P < .01$. Further, the caregivers from Peds Oto had significantly different reported income. Peds Oto had significantly more families with income less than $20,000 and with income greater than $100,000. Conversely, Peds Oto had significantly fewer families with income between $40,000 and $80,000. In addition, a higher proportion of patients from Peds Oto sites were enrolled in day care as compared to patients from PCP clinics.

Next, the caregiver- and provider-diagnosed episodes of AOM over 1- and 3-month time periods were examined in both the well-child visits from PCP clinics and the recurrent OM group from Peds Oto sites. It is not surprising that the Peds Oto patients had significantly more caregiver-reported and physician-diagnosed episodes of AOM as compared to healthy controls over 1- and 3-month time periods (Table 2). Consistent with prior studies, caregiver perception of the number of episodes of AOM was significantly higher than the episodes diagnosed by a physician following examination over 1- and 3-month time periods[12] (Table 2).

To further confirm the role of the well-child PCP visits as controls, we determined the presence or absence of tubes and the presence or absence of a recommendation by a provider to undergo bilateral myringotomy and tube placement in both the PCP and Peds Oto groups. As expected, the healthy well-child responders from PCP sites were far less likely to have undergone prior placement of ear tubes. Similarly, the responders from PCP sites were far less likely to receive a recommendation to undergo placement of ear tubes (Table 3).

OM-6 and PedsQL Infant Scores

To determine the disease-specific burden of OM on the child, we compared the mean OM-6 scores in the PCP and Peds Oto groups. It is not surprising that patients enrolled by a Peds Oto practice had a significantly higher mean OM-6 score as compared to healthy same age-group patients from PCP clinics, $P < .001$ (Table 4).

Similarly, we compared overall HR-QoL with PedsQL Infant Impact scores, divided into 6-12 months and 13-24 months age groups for analysis (Table 4). The mean PedsQL Infant score for children ages 6 to 12 months at a Peds Oto practice was 74.56, significantly worse than that for well children ages 6 to 12 months evaluated at a PCP, 82.64, $P < .001$. Furthermore, the Peds Oto score was worse than the mean of 79.47 from the validation study for age-matched acutely ill children.[11] Similarly, the mean PedsQL Infant score for children ages 13 to 24 months at a Peds Oto practice was 78.92, significantly worse than that for well children ages 13 to 24 months from PCP visits, 86.82 ($P < .001$), and worse than the mean of 82.15 from the validation study for age-matched acutely ill children.[11]

Next, the relationship between physician-diagnosed episodes of OM and OM-6/PedsQL scores was examined. An increasing number of diagnosed episodes of OM over 1 and 3 months was significantly correlated with an increased OM-6 score ($r = 0.35$ and 0.39, respectively, $P < .001$ for both). Furthermore, increased numbers of OM episodes (at both 1 and 3 months) were significantly correlated with poorer Peds-QL Infant scores ($r = -0.35$,

−0.36 for the 6-12 month age group, respectively; and −0.23, −0.27 for the 13-24 month age group, respectively; $P < .001$ for all analyses).

Information regarding hearing loss was obtained from the physician-completed patient history form. The mean OM-6 score was significantly elevated in patients with a documented conductive hearing loss. Similarly, mean PedsQL Infant scores were significantly worse in patients with documented conductive hearing loss (Table 5).

Next, the relationship between the average burden of OM (OM-6 as proxy) and overall HR-QoL (PedsQL Infant) in Peds Oto patients was examined. There was a moderately strong correlation between increasing disease-specific impact of OM and poorer HR-QoL, Pearson $r = 0.58$ (1-12 months) and 0.56 (13-24 months), respectively, $P < .001$ (Figures 2A and 2B). Thus, when the Pearson r values are squared ($r^2 = 0.34$ and 0.31, respectively), they show that OM explained approximately one-third of the variance in the PedsQL Infant scores.

Provider Tube Recommendation and Prior Tube Placement

Mean OM-6 and PedsQL Infant scores were calculated based on provider recommendations to undergo ear tube placement (patients with tubes in place were excluded). As Table 4 shows, the mean OM-6 score in patients evaluated at Peds Oto sites (3.50) was significantly worse in patients who were recommended to undergo ear tube placement versus those who were not (2.74), $P < .001$. Similarly, for both age groups, the mean PedsQL Infant scores were significantly worse in Peds Oto patients who were recommended to undergo placement of ear tubes. These trends were similar in the patients from the PCP sites but were not statistically significant for PedsQL Infant scores or OM-6 scores (Table 4).

The association of prior tube placement and OM-6 and PedsQL Infant Impact scores is shown in Table 4. The mean OM-6 score in patients at a Peds Oto site was significantly better in patients who had previously undergone placement of ear tubes (2.84) than in those who had not (3.42), $P < .001$. For both age groups, the mean PedsQL Infant scores were significantly better in Peds Oto patients who had previously undergone placement of ear tubes. It is interesting that patients from PCP sites with prior tube placement did not have significantly different OM-6 scores and HR-QoL.

Discussion

The present study examined disease-specific and overall HR-QoL measures related to OM in children ages 6 to 24 months. Our findings suggest that the burden of OM is strongly correlated with overall HR-QoL—as the impact of disease increased, HR-QoL decreased. Further, the results suggested that patients with poorer disease-specific and overall QoL received a recommendation to undergo ear tube placement. Finally, patients with ear tubes in place reported higher disease-specific and overall HR-QoL scores.

Elevated (worse) OM-6 scores, a proxy for evaluating the disease-specific burden of OM on children, strongly correlated with poorer overall HR-QoL, as determined by PedsQL Infant scores. Similar to prior studies, these results implied that the burden of disease, not just the presence or absence of disease, was an important factor in HR-QoL.[4] It is not surprising that

patients with more diagnosed episodes of OM over a 1- or 3-month time period or documented conductive hearing loss had significantly worse OM-6 scores and correspondingly worse PedsQL Infant scores. These findings suggest that routine use of the OM-6 survey could assist providers in determining overall impact of OM on a child's HR-QoL.

Physician recommendation for the placement of tubes was significantly related to poorer disease-specific and overall QoL. This finding suggests that surgical treatment for OM may be appropriately reserved for patients with greater disease burden and poorer HR-QoL. It is interesting that the presence of pressure equalization tubes in patients with recurrent OM was associated with significantly better disease-specific and overall HR-QoL. Similar to prior studies, OM-6 disease-specific scores appeared better in patients who had ear tubes placed.[13,14] The present study revealed OM-6 scores in Peds Oto patients with prior tube placement ~0.6 lower (better) as compared to those without prior tube placement. This difference is less than the previously reported decreases of 1.61 and 1.65 in the prior studies but still reflects ~0.5 standard deviation population difference.[13,14] The cross-sectional nature of the current study likely is responsible for the lesser difference, whereas the prior studies reported change scores of the same patient preand post-placement of tubes. The current results support a previous report that suggested an association between ear tube placement and higher overall HR-QoL but were not statistically significant.[15] Finally, the results contrasted with a recent Comparative Effectiveness Review and Cochrane Review that did not find correlation of placement of ear tubes with changes in HR-QoL.[5,16]

Although promising, the better HR-QoL (PedsQL scores higher by about 7 points) in children with ear tubes did not match levels similar to similarly aged well children. In contrast, the scores only reached a point similar to the reported means of acutely ill children from the PedsQL validation studies. Further, although the apparent improvement in the overall HR-QoL scores in patients with ear tubes was statistically significant, it did not meet the minimal clinically important difference threshold of 0.5 standard deviations typically applied in HR-QoL studies.[17,18] It is clear that additional studies are needed to further assess the impact of tube placement on overall HR-QoL in patients with recurrent OM.

The present study has several limitations. First, it is a cross-sectional study and represents a snapshot in time. A prospective longitudinal study using the OM-6 and PedsQL Infant Module prior to and after treatment for recurrent OM would be ideal to evaluate the direct effect of ear tubes on HR-QoL. Because the OM-6 survey was not designed to provide comparative data across different patient populations, conclusions using these comparisons may not be generalizable. Improved control groups, increased number of participants, and prospective analysis could help control for these potential confounders. In addition, responder or self-selection bias may have influenced the results in unknown ways. We were unable to use nearly half of the surveys collected due to incomplete data collection, as shown in Figure 1. More than half of the children in this study had mothers who were college graduates, which is higher than the 37% of women in the United States overall.[19]

Conclusion

In this large, prospective cross-sectional study conducted across multiple institutions, disease-specific QoL of young children with OM strongly correlated with HR-QoL. Findings suggest that patients with increased burden of disease and worse HR-QoL received recommendations to undergo ear tube placement. Furthermore, the placement of tubes was associated with better disease-specific and overall QoL in patients with recurrent OM. The results of the current study can provide a basis from which to evaluate the impact of tympanostomy tube guidelines on QoL as translated into clinical practice.

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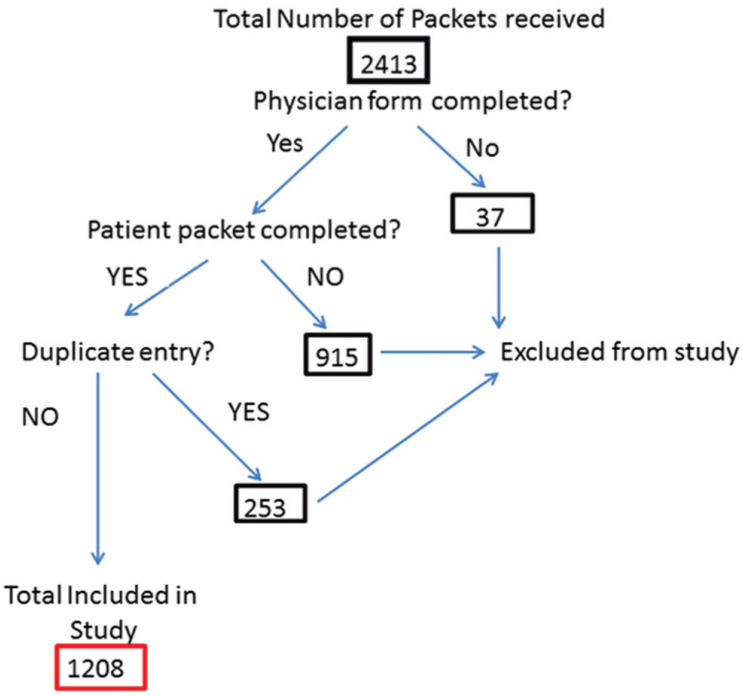

Figure 1.
Flowsheet of included participants for the study.

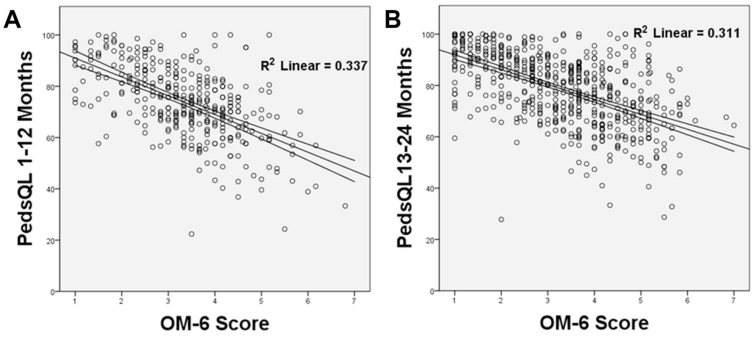

Figure 2.

PedsQL Infant Impact scores and Otitis Media 6 (OM-6) scores (A) for children 6 to 12 months old and (B) for children 13 to 24 months old.

Table 1

Demographics of 1208 Children Participating in the Study.

	All Sites	Peds Oto Sites	PCP Sites	*P* Value
Age, Mean (SD)	14.7 (4.5)	15.2 (4.3)	12.2 (4.9)	< .001
Sex, n (%)				.002
Male	652 (54.0)	564 (55.7)	88 (44.9)	
Female	556 (46.0)	448 (44.3)	108 (55.1)	
Ethnicity, n (%)				.02
Hispanic	54 (6.0)	53 (6.9)	1 (0.8)	
Non-Hispanic	845 (94.0)	718 (93.1)	127 (99.2)	
Total	899	771	128	
Income, n (%)				< .001
<$20,000	160 (14.3)	142 (15.0)	18 (10.5)	
$20,000-$39,999	170 (15.2)	148 (15.6)	22 (12.9)	
$40,000-$59,999	134 (12.0)	99 (10.4)	35 (20.5)	
$60,000-$79,999	194 (17.3)	154 (16.2)	40 (23.4)	
$80,000-$99,999	166 (14.8)	137 (14.5)	29 (17.0)	
$100,000 or higher	292 (26.1)	265 (28.0)	27 (15.8)	
Other	3 (0.3)	3 (0.3)	0 (0.0)	
Total	1119	948	171	
Day care, n (%)				< .001
Yes	603 (61.2)	573 (62.2)	30 (46.2)	
No	383 (38.8)	348 (37.8)	35 (53.8)	
Total	1006	921	65	
Insurance status, n (%)				< .001
None	3 (0.3)	1 (0.1)	2 (1.1)	
Medicaid	299 (26.2)	275 (28.5)	24 (13.6)	
Private or employer sponsored	776 (68.1)	630 (65.4)	146 (83.0)	
Other government insurance	62 (5.4)	58 (6.0)	4 (2.3)	
Total	1140	964	176	

Abbreviations: PCP, family practice or pediatric; Peds Oto, pediatric otolaryngology.

Table 2

Caregiver- and Physician-Reported/Diagnosed Episodes of Acute Otitis Media at Pediatric Otolaryngology (Peds Oto) and Family Practice or Pediatric (PCP) Sites.

	Caregiver	Physician	*P* Value	Caregiver	Physician	*P* Value
Site	1 month	1 month		3 month	3 month	
Peds Oto, Mean (SD), n	1.36 (1.06), 894	1.14 (0.99), 941	< .001	3.03 (1.91), 889	2.67 (1.79), 927	< .001
PCP, Mean (SD), n	0.75 (0.58), 64	0.24 (0.51), 179	< .001	1.22 (0.98), 61	0.44 (0.94), 178	< .001
P value	< .001	< .001		< .001	< .001	

Table 3

Presence or Absence of Tubes and Recommendation for Tube Placement.

	All Sites	PCP	Peds Oto
Presence of tubes			
Yes, n (%)	190 (17)	12 (6)	186 (20)
No, n (%)	943 (83)	192 (94)	773 (80)
Physician recommendation for tube placement			
Age 6-12 months			
For, n (%)	249 (60)	3 (2)	249 (81)
Against, n (%)	166 (40)	128 (98)	57 (19)
Age 13-24 months			
For, n (%)	407 (75)	6 (8)	420 (86)
Against, n (%)	137 (25)	66 (92)	69 (14)

Abbreviations: PCP, family practice or pediatric; Peds Oto, pediatric otolaryngology.

Table 4

OM-6 and PedsQL Infant Impact Scores by Type of Practice and History of Tubes.

Overall	OM-6	*P* Value	PedsQL 1-12 Mo	*P* Value	PedsQL 13-24 Mo	*P* Value
Peds Oto, Mean (SD), n	3.30 (1.25), 922		74.56 (14.00), 384		78.92 (13.81), 621	
PCP, Mean (SD), n	2.52 (1.28), 85	< .001	82.64 (13.59), 74	< .001	86.82 (10.93), 132	< .001
Peds Oto sites						
Recommendation for tube placement						
Yes, Mean (SD), n	3.50 (1.22), 642		72.13 (14.60), 249		77.83 (13.82), 420	
No, Mean (SD), n	2.74 (1.19), 91	< .001	79.91 (12.04), 57	< .001	82.16 (11.66), 69	.014
Presence of prior tubes						
Yes, Mean (SD), n	2.84 (1.23), 178		78.21 (11.00), 67		81.24 (14.62),	125
No, Mean (SD), n	3.42 (1.23), 707	< .001	73.47 (14.53), 296	.003	78.39 (13.60), 477	.050
PCP sites						
Recommendation for tube placement						
Yes, Mean (SD), n	2.98 (1.26), 8		70.60 (17.91), 3		74.92 (13.90), 6	
No, Mean (SD), n	2.47 (1.52), 74	.389	84.27 (11.94), 128	.317	87.90 (10.23), 66	.071
Presence of prior tubes						
Yes, Mean (SD), n	3.23 (1.35), 9		77.57 (16.05), 7		70.48 (14.71), 5	
No, Mean (SD), n	2.41 (1.25), 75	.119	84.50 (11.92), 126	.301	88.00 (9.72), 69	.055

Abbreviations: OM-6, Otitis Media 6; PCP, family practice or pediatric; Peds Oto, pediatric otolaryngology; PedsQL, PedsQL Infant Impact Module.

Table 5

Conductive Hearing Loss and OM-6 and PedsQL Infant Impact Scores.

Hearing	OM-6	*P* Value	PedsQL 1-12 Mo	*P* Value	PedsQL 13-24 Mo	*P* Value
Normal, Mean (SD), n	2.51 (1.09), 328		78.50 (14.4), 160		82.12 (12.8), 239	
Conductive hearing loss, Mean (SD), n	3.06 (1.04), 160	< .001	71.97 (12.3), 65	.002	76.85 (14.4), 107	.001

Abbreviations: OM-6, Otitis Media 6; PedsQL, PedsQL Infant Impact Module.