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Quality of life improvement after pressure equalization tube placement in Down syndrome: A prospective study

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ABSTRACT

Objective: To evaluate quality-of-life changes after bilateral pressure equalization tube placement with or without adenoidectomy for the treatment of chronic otitis media with effusion or recurrent acute otitis media in a pediatric Down syndrome population compared to controls.
Study design: Prospective case-control observational study.
Methods: The OM Outcome Survey (OMO-22) was administered to both patients with Down syndrome and controls before bilateral tube placement with or without adenoidectomy and at an average of 6–7 months postoperatively. Thirty-one patients with Down syndrome and 34 controls were recruited. Both pre-operative and post-operative between-group and within-group score comparisons were conducted for the Physical, Hearing/Balance, Speech, Emotional, and Social domains of the OMO-22.
Results: Both groups experienced improvement of mean symptom scores post-operatively. Patients with Down syndrome reported significant post-operative improvement in mean Physical and Hearing domain item scores while control patients reported significant improvement in Physical, Hearing, and Emotional domain item scores. All four symptom scores in the Speech domain, both pre-operatively and post-operatively, were significantly worse for Down syndrome patients compared to controls ($p \leq 0.008$).
Conclusions: Surgical placement of pressure equalizing tubes results in significant quality of life improvements in patients with Down syndrome and controls. Problems related to speech and balance are reported at a higher rate and persist despite intervention in the Down syndrome population. It is possible that longer follow up periods and/or more sensitive tools are required to measure speech improvements in the Down syndrome population after pressure equalizing tube placement ± adenoidectomy.

1. Introduction

Otitis media (OM) is one of the most common medical conditions of childhood [1].

There is a high rate of otolaryngologic conditions in Down Syndrome (DS) children including chronic otitis media with effusion (COME) and recurrent acute otitis media (RAOM). Hearing loss, primarily conductive, is common in DS with up to an 81% prevalence [2,3].

The treatment of middle ear pathology in DS patients with pressure equalization (PE) tubes continues to be debated due to the frequent need for multiple PE tube placement, the perception of an increased rate of complications with multiple interventions, and controversy regarding the efficacy of tubes in resolving hearing loss. In a retrospective study by Iino et al., the authors reported that up to 40% of DS patients had persistent conductive hearing loss at 6 weeks after surgical management along with increased rates of recurrent effusions, otorrhea, perforation, and cholesteatoma [4]. A subsequent prospective study reported that DS children with COME who were treated by PE tube placement had significant resolution of hearing loss, with only 2% showing persistent hearing loss at one year [3]. A prior retrospective study by our group of OM in DS patients found that following PE tube placement, the post-operative hearing was normal or near normal for the better hearing ear in 85.9% of the patients and bilaterally in 71% of the patients [5]. The majority (63.7%) of patients required two or more sets of tubes during the follow up period, and complications were significantly increased if the patient received three or more sets of tubes [5]. Although PE tube placement is the standard primary treatment for COME or RAOM in otherwise healthy children, some have

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suggested that the lack of improvement with intervention in DS argues for conservative management rather than surgery.

The effect of chronic ear disease and hearing loss extends beyond audiometric measures. The impact in the pediatric population has been noted in language and cognitive development, social interactions, behavior, family stress and quality of life (QOL) [6–10]. Although the impact of OME on child development is debated, multiple studies demonstrate an improvement in health-related quality of life after PE tube placement in OME [9,11].

Quality of life in DS patients with COME, and change in quality of life measures and otologic outcomes after PE tube placement in this population requires further study. DS children report decreased baseline quality of life when compared with healthy controls including lower measures in the areas of gross motor skills, autonomy, social functioning and cognitive functioning [12]. Measuring otitis media quality-of-life outcomes may help set appropriate expectations and document benefits of treatment that have previously been overlooked. A validated tool for measuring OM outcomes has been described using a 22-item questionnaire titled the Otitis Media Outcome-22 (OMO-22) [11]. Using this QOL tool, Richards and Giannoni [11] reported a 74.5% improvement in total ear symptom score at 1-month follow-up and 59.8% improvement at 6-month follow-up in non-DS children receiving ear tubes.

The goal of this prospective case-control observational study is to measure quality of life change in DS patients receiving PE tubes with or without adenoidectomy compared to a control group.

2. Materials and methods

2.1. Study design

The study was approved by the institutional review board of Oregon Health & Science University. The study population consisted of DS and non-DS children referred to the Oregon Health & Science University (OHSU) pediatric otolaryngology clinic for surgical treatment of RAOM and/or COME. The inclusion criteria for controls included (1) age younger than 16 years, (2) a diagnosis of RAOM as defined by 4 or more episodes of AOM in the past 6 months or 3 episodes of AOM in 3 months, or a diagnosis of COME defined as the presence of middle ear effusion in 1 or both ears for 3 months or longer, and (3) child's primary caregiver present to complete the survey. Inclusion criteria for the DS population included a clinical or chromosomal diagnosis of DS as well as meeting the above mentioned criteria. Exclusion criteria for this study included (1) previous ear surgery other than myringotomy and/or PE tube placement, (2) PE tubes already present at presentation, (3) tympanic membrane perforation, and (4) primary caregiver not present or unable to read and understand either English or Spanish. Additional exclusion criteria for the control group include syndromic diagnosis, cleft palate, cholesteatoma, developmental or intellectual disability, craniofacial deformity, immune deficiency, or other medical condition leading to predilection for prolonged ear disease.

Sample size estimations were determined using historical data provided by Richards et al. [11] and based on the relative proportion (%) of improvement between independent case and control subjects, with a 1:1 ratio, assuming a two-tailed Z-test, 80% power (1-β), and a 0.050 error probability. A total sample size of 40 subjects would be adequate to detect a relative improvement difference of 40% on OM-22 total scores between cases ($n = 20$) and controls ($n = 20$). Over 30 patients in each group were recruited to the study allowing for an anticipated response rate at follow-up of less than 100%.

2.2. Outcome measures

The OMO-22 was administered to study participants before bilateral PE tube placement with or without adenoidectomy, and again at least 2 months post-operatively. The OMO-22 is a validated QOL tool designed to assess the disease-specific quality of life in patients suffering from RAOM and/or COME using 22 questions based on a 7-point Likert scale, with additional accompanying demographic questions (Appendix 1) [11]. The symptom severity questions in the OMO-22 can be divided into 5 symptom domains: Physical, Hearing and Balance, Speech, Emotional, and Social. The questions can be assessed individually, or one can assess the total symptom severity in each domain. The range of scores in each domain is Physical: 0–30, Hearing and Balance 0–24, Speech 0–24, Emotional 0–30, and Social 0–24; total possible score of 0–132.

The questionnaire and introduction letter were prepared in both Spanish and English per the fluency of the primary caregiver. The primary caregiver of the child consented to participate in the study and received the questionnaire at a pre-operative clinical visit or on the day of the surgery. The questionnaire was administered again at a post-operative visit at least 2 months following surgery, or by mail. If no response was obtained following two mailed surveys, three attempts to reach the primary caregiver and complete the survey by phone were made.

Surgical treatment consisted of bilateral PE tube placement alone for those children younger than 3 years without a history of previous PE tubes. Adenoidectomy was added to the procedure for some children undergoing their second set of PE tubes and/or for children older than 4 years with COME; the indication for adenoidectomy was for improvement of Eustachian tube dysfunction.

2.3. Data management and statistical analysis

Clinical data including patient history, age, sex, diagnosis, and surgical procedure notes were obtained from the OHSU electronic medical record system (Epic Systems, Madison, WI). This information as well as the pre-operative and post-operative questionnaire answers was entered into a database, and the SPSS v.22.0 (IBM Corp., Armonk, NY) program was used for statistical analysis. Both pre-operative and post-operative between group and within group score comparisons were conducted using independent t-testing and matched pair t-testing for all parametric, normally distributed data. Mann-Whitney U and Wilcoxon signed rank testing equivalents were used for all nonparametric data distributions, when applicable. To compare the magnitude of individual postoperative change, while accounting for variation in preoperative status, relative mean improvement (RMI) percentages were calculated for OMO-22 total scores using the formula: [(postoperative change (Δ) scores/preoperative scores) x 100]. Average RMI values were reported for both DS and non-DS individual scores. All comparisons were reported using a Type I error probability (p-value) at the 0.050 level of significance.

3. Results

A total of 31 DS patients and 34 controls were enrolled in the study between September 2013 and June 2015. Follow-up information was obtained for 20 DS patients and 23 controls, with a follow up rate of 65% and 68% respectively. The average age at surgery for the DS cohort was 3.8 years (range 9 months–13.3 years) and an average time to follow up 6.8 months. For the control cohort, the average age at surgery was 4.4 years (range of 4 months–12.4 years) and an average time to follow-up 7 months. The range of days from the time of the pre-op questionnaire to intervention for the Down syndrome group ($n = 20$) was 0–42 days