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Variables associated with repeated ventilation tube insertion in healthy non-syndromic children☆

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ABSTRACT

Objectives: The objectives of this study was to determine variables associated with rVT insertions for rAOM and/or OME in otherwise healthy children.
Methods: This was designed as a retrospectively controlled cohort study. Patients were identified from a prospectively collected surgical database. Eligible subjects were those who had undergone rVT and a consecutive concurrent control group who received only one ventilation tube (VT). Exclusion criteria included craniofacial abnormalities and syndromes. Demographics, tympanic membrane characteristics, parental smoking, breast-feeding history, large day-care attendance, and soother use was collected.
Results: Over a period of 10 years, 59 patients underwent rVT (5.6%). 180 children who underwent VT were included in the control group. There was no difference in gender distribution ($p = 1$, 1.73:1 vs. 1.76:1), mean age ($p = 0.69$, 4.7 ± 3.33 vs. 4.4 ± 3.17) or chronic rhinitis ($p = 0.36$, OR 1.376, 95% CI: 0.69–2.74). The rVT group was associated significantly more with a smoking parent ($p = 0$, OR 61.8, 95% CI 21.26–176.07), large day care attendance ($p = 0$, OR 23.39, 95% CI: 8.637–57.54), breast feeding <3months ($p = 0$, OR −0.074, 95% CI: 0.028–0.331), soother use ($p = 0$, OR 21.49, 95% CI: 7.81–55.87), and tympanic membrane atelectasis ($p < 0.0005$). The same factors were also found to be significant upon multiple regression analysis ($p < 0.05$).
Conclusions: Otherwise healthy children with rAOM and/or OME are at a greater risk of rVT if they attend large day cares, were not breast fed for ≥3 months, if their tympanic membranes were atelectatic and most significantly if their parents smoke.

1. Introduction

Myringotomy and ventilation tube insertion (VT) is currently the most frequently performed surgical procedure on children in North America, with over 600,000 cases annually in the US [1], with one in 15 children (6.8%) undergoing VT by the age of three years [2–4]. The indications for VT include persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy [1,5,6], but the rates of VT insertion vary amongst differing geographic regions, possibly representing differing exposures to environmental factors [7].

Currently there is evidence in the literature that one in five children will require a subsequent insertion of VT [1]. Both Marchica et al. and Boston et al. concluded that the existence of craniofacial abnormalities, young age, as well as syndromic diagnosis increased the likelihood of recurrent otitis media and re-insertion of ventilation tubes (rVT) in children [8,9].

However, the evidence on the burden in non-syndromic children where the financial and social impact on the health care system is well documented is less well described [1]. Environmental factors such as day care attendance, parental smoking, and history of pacifier use as well as breast-feeding have been theorized and often listed as risk factors but never proven to be a cause for additional tube insertion [1,2,6]. Therefore, it is our goal to conduct a cohort study of a prospectively collected database to delineate any possible risk factors for additional ventilation tube insertion in an otherwise healthy pediatric population.

☆ This study was presented as a poster by at the 2014 Spring Combined Otolaryngology Society Meeting in Las Vegas, Nevada on May 14th–18th, 2014.

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2. Method

This study was designed as a retrospective cohort study based on a single surgeon's practice at the Stollery Children's Hospital, University of Alberta, Edmonton, Canada. Eligible patients were identified from a prospectively kept surgical database, which contains demographic, record of urgency, anesthetic mode, diagnoses (indication of surgery and up to six Otolaryngological and non-Otolaryngological procedures), all procedures performed (up to six), complications, and special instrumentation information. Verification of eligibility and the remainder of required variables were established from the records of the private practice and the hospital. Ethics approval was granted by the University of Alberta's Health Research Ethics Board (HREB: Pro00042754).

Eligible children ($\leq$17 years old) were those who had undergone VT insertion using a 1.14 mm Donaldson tympanostomy tube (Summit Medical Inc, MN, US) for recurrent acute otitis media (rAOM), and/or otitis media with effusion (OME). The 2004 American Academy of Otolaryngology clinical practice guidelines for VT insertion [10] was used for all patients. Candidates for surgery according to the guideline included children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damages to the tympanic membrane or middle ear. Children with OME of any duration who are at risk are candidates for earlier surgery [10]. Patients were included if they were followed up for a minimum of one year or until resolution of symptoms of rAOM and/or OME after extrusion of tubes, and were healthy otherwise. The children were then allocated to the rVT group, if they had undergone two or more VT procedures, and to the control group if they had undergone only one.

Children were excluded if the indication of surgery was not rAOM, or OME if they had undergone another concomitant otologic surgery (tympanoplasty, or tympanomastoidectomy), if they were syndromic, harbored a cleft palate, a craniofacial diagnosis, dysmorphic features, immune deficiency, ciliary dyskinesia, cystic fibrosis or another general diagnosis that puts the patient at risk of rVT.

The control group was collected from a concomitant period to the procedures of the rVT group, in order to minimize the confounding effect of season, and period of experience.

3. Data collection

Variables of interest identified as potential risk factors for rVT (as identified by prior literature [1,6,8,9]) were collected from the prospective database. They included:

a) Age at time of initial VT insertion
b) Gender
c) Parental smoking – defined as a smoking parent living in the household (whether they asserted that they smoke inside or outside the residence)
d) Large day care attendance – defined as day care attendance with >10 children per group
e) History of breast feeding >3 months in duration as a protective mechanism
f) History of pacifier use during infancy
g) Documentation of atelectasis – defined as grades II–IV Sade atelectasis on intraoperative microscopy [11]
h) Follow up duration
i) Other concomitant surgeries

This information was collected prospectively by the senior surgeon (HE) in a special patient information sheet during the clinic visit, and operating room session. Review of the hospital and private medical records was then completed and cross-checked to ensure data accuracy and possible rVT insertion by a different surgeon in the same region. The exclusion criteria were then applied to give a final data set for analysis.

4. Follow-up

All patients were followed up by the primary surgeon for a minimum duration of one year after last VT insertion. Follow-up dates up to January 2014 were recorded.

5. Statistical analysis

Descriptive statistics were used for patients' parameters (mean, range, standard deviation). Variables of interest were documented into sub-types of binary, ordinal, and continuous categorical data. Binary data included: gender, large day care attendance, history of breast-feeding >3 months in duration, and history of pacifier use during infancy. Continuous data included the age at time of initial VT. The ordinal data included documentation of atelectasis in the operating room. These variables were analyzed initially using a bivariate analysis to determine the association of the variables with rVT (and 95% CI were calculated). Those found to be statistically significant were then included in a multivariate regression model to determine the significant predictors of rVT (dependent variable). The level of significance was accepted as $p < 0.05$. Analyses were performed with SPSS Statistics 20.0 (SPSS Inc, Chicago, IL).

6. Results

Four hundred and twenty eight patients received VT insertion by the senior author (HE) between January 2002 and January 2012 (Fig. 1). One hundred and fifty-four of these patients received rVT insertion during this same time period. Eighty-seven patients were excluded: seventy-nine patients were diagnosed with craniofacial and or congenital syndromes, three patients had concomitant tympanoplasty at the time of rVT, and five patients received concomitant tympanomastoidectomy. Of the 79 patients diagnosed with craniofacial or congenital syndromes: 30 had Down syndrome, ten had Pierre-Robin's sequence, five had CHARGE syndrome, six had chromosomal abnormalities, five had fetal alcohol syndrome, three had Achondroplasia, five patients had cystic fibrosis, six patients had ciliary dyskinesia and nine patients had other syndromes. Finally, 59 healthy non-syndromic children who received rVT were included. Of the final 59 patient included in the data analysis, 21 patients had concomitant adenoidectomy and three patients had tonsillectomy at the time of rVT.

One hundred and eighty patients met the inclusion criteria as a control group. Ninety-four patients were excluded: eighteen patients were diagnosed with craniofacial syndromes and or congenital syndromes, twenty nine patients had a VT insertion not for rAOM or OME, eighteen patients had concomitant tympanoplasty at the time or VT, and twenty-nine patients received concomitant tympanomastoidectomy. Of the 180 patients who met inclusion criteria as a control group, 40 patients had concomitant adenoidectomy and nine patients had tonsillectomy at the time VT.