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Phosphorylcholine-coated antibiotic tympanostomy tubes: Are post-tube placement complications reduced?

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Persistent tympanic membrane perforations

Summary

Objective: To determine if a phosphorylcholine (PC) antibacterial coating on standard Armstrong beveled tympanostomy tubes (TT) reduced the incidence of post-tube placement complications.
Methods: A prospective cohort aged 8–51 months received bilateral TTs for otitis media with effusion between July 2002 and February 2004 at a tertiary care pediatric hospital. Seventy children were randomized to receive a PC-coated TT in one ear and an uncoated TT in the other. Otologic examinations at prescribed intervals over two years post-operatively ascertained the status of sequelae. We analyzed the incidence of TT complications: otorrhea, premature extrusion, persistent tympanic membrane perforations, granulation tissue, and ventilation tube lumen obstruction.
Results: There was no statistical difference in the incidence of any of these sequelae between standard and PC-coated tympanostomy tubes ($p > 0.05$) during the 24-month-follow-up period. Results after 13 months of follow-up may have been affected by patients lost to follow-up and therefore a smaller sample size as the study continued.
Conclusions: This study found that there is no statistically significant difference in the incidence of complications between uncoated and PC-coated fluoroplastic Armstrong beveled TTs.

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1. Introduction

The insertion of tympanostomy tubes (TT) in children is one of the most common pediatric surgical procedures. Originally used to treat the mild to moderate conductive hearing loss (20—30 dB) associated with middle ear effusion (MEE), physicians also use TT to manage recurrent acute otitis media (AOM) [1,2]. Myringotomy with TT insertion (M&T) for young children suffering from middle ear effusion bilaterally for $\geq$3 months is a common practice [3]. A study published in 2000 noted 6.8% of American children had tubes inserted by the age of three, while other studies note up to two million American children per year receive the intervention [4]. Although the procedure is associated with various sequelae, it has been found to improve the quality of life in 80% of children who received the intervention in a study conducted by the American Society of Pediatric Otolaryngology. This improvement was based on physical symptoms, caregiver concerns, emotional distress, hearing loss, activity limits, and speech impairment [5]. For properly selected patients, the benefits of TT placement outweigh the possible associated complications.

Complications of TT include otorrhea, premature extrusion, persistent perforation, granulation tissue and retraction pocket formation with or without cholesteatoma, and tube blockage. The shape of the tube or the type of TT material may affect the development of these complications; this has resulted in the creation of tubes with differing shapes, lumen diameters, and construction materials, including various tube coatings. Phosphorylcholine (PC) coatings were developed by Biocompatibles Ltd. of the UK. The PC coating has undergone numerous safety tests including cytotoxicity, acute systemic toxicity, intracutaneous reactivity, pyrogenicity, and skin sensitization. This coating has been applied to several other medical applications including urology and coronary angioplasty. In these applications, the PC coating has been shown to be resistant to protein absorption, fibrinogen absorption, platelet adhesion, and bacterial absorption. Independent laboratory studies have shown that fluoroplastic TTs coated with PC resist bacterial attachment and subsequent biofilm formation. This technology has been licensed by Gyrus ENT for use on fluoroplastic Armstrong Beveled Grommet TTs. These coatings are applied using a controlled dipping process to an approximately 50—100 nm thickness.

We were interested in whether PC-coated TT could prevent some of the post-tube complications, including blockage, otorrhea and early extrusion. We compared the use of PC-coated Armstrong beveled tympanostomy tubes to regular Armstrong tubes.

2. Study objective

The purpose of this study was to compare the complication rates between uncoated fluoroplastic Armstrong beveled TTs and PC-coated fluoroplastic Armstrong TTs. Outcomes analyzed were otorrhea, premature extrusion, persistent tympanic membrane perforations, granulation tissue, and TT lumen obstruction.

3. Methods

A prospective cohort aged 8—51 months received bilateral TT placement for otitis media with effusion between July 2002 and February 2004 at Children's Hospital Boston, a tertiary care pediatric hospital. These candidates presented with otitis media with 3—4 months of prior medical intervention, consistent with AAO-HNS guidelines, but without prior tube placement. Seventy children were randomized to receive a PC-coated TT in one ear and an uncoated, conventional fluoroplastic TT in the other. The cohort's mean age was 19 months and ranged from 8 months to 51 months. Twenty-five patients were female (35.7%) and 45 were male (64.1%). Photodocumentation of the TTs after placement in the tympanic membrane at the time of surgery was obtained. Otologic examinations at prescribed intervals over two years post-operatively ascertained the status of sequelae. To determine post-operative middle ear status, patients were evaluated 3 weeks, 6 months, 10 months, 13 months, 17—19 months, and 21—24 months post-operatively. Documentation of the follow-up examinations was recorded on a standardized form assessing patient feedback, otomicroscopic examination, description of the tympanic membrane and middle ear condition, description of the tube, and at least one post-operative audiogram. A patient was considered to have successfully completed the study when both TTs had extruded, the tympanic membrane had healed or when the patient had completed his or her 21—24-month post-operative visit. This study was approved by the Children's Hospital Boston Institutional Review Board.

Relevant statistics were computed by a statistician in the Children's Hospital Boston Clinical Research Program. Each ear provided a binary outcome (complication or no complication), and these were compared using logistic regression models. The positive correlation between outcomes for a given patient (one for each ear) was accommodated by using a random intercept for the patient. Models were fit using the nonlinear mixed model procedure in SAS 9.1. Wald tests and confidence intervals were