Tympanostomy tube sequelae in children with otitis media with effusion: a three-year follow-up study

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Key words: otitis media, otitis media with effusion, otitis media with effusion/surgery, ear, middle/surgery, middle ear ventilation, child.

Summary

Tympanostomy tube (TT) insertion is one of the most frequently performed procedures in otolaryngology. Otorrhea, tympanosclerosis, retraction, perforation, and cholesteatoma are complications reported in the literature after its application. **Aim**: To determine the incidence and the type of TT insertion sequelae/complications in children presenting with recurrent otitis media and chronic otitis media with effusion undergoing myringotomy and tube placement. **Study Design**: prospective cohort study. **Material and Method**: A total of 75 children (150 ears) aged 11 months to 10 years were regularly followed up for up to 38 months after TT insertion. **Results**: Incidence of sequelae/complications: otorrhea - 47.3% of the ears; perforation - 2.1%; retractions - 39.7%; tympanosclerosis - 23.3%. Average length of stay: 12.13 months. Mean age at initial tube placement of children not requiring a second set of tubes = 35.9 months and mean age at initial tube insertion of children requiring an additional set of tubes = 25.6 months (P=0.04). TT stayed longer in the ears that had more episodes of otorrhea (P=0.01). TT insertion with adenoidectomy was associated with a smaller number of otorrhea episodes (P=0.02) **Conclusions**: Otorrhea was the most frequently found complication. TT placement with adenoidectomy was associated with fewer otorrhea episodes. TT extruded later in those ears that had more episodes of otorrhea. Younger age at the time of the initial tube placement is associated with higher incidence of additional tube placement. One in six patients will probably require a second set of ventilation tubes.

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INTRODUCTION

Since the reintroduction of ventilation tubes (VT) by Armstrong in 1954, myringotomy with VT insertion has been established as an effective treatment approach for otitis media with effusion (OME)[1]. OME is a middle ear inflammation in which there is retro-tympanic liquid collection, without signs or symptoms of acute infection and integral tympanic membrane [2]. It is normally considered a direct continuation of the inflammatory process that takes place during prolonged and recurrent episodes of acute otitis media (AOM), which is confirmed not only by that fact that all cases of OME follow an episode of AOM, but also because of experimental studies in animals [3]. There are approximately 2.2 million episodes of OME diagnosed every year in the United States, causing expenses of nearly US$4 billion [4]. Currently, myringotomy with insertion of ventilation tubes is one of the two most common surgical procedures in North-American children and the main reason for children to take general anesthesia [5]. Even though considered a simple procedure with significant benefits, VT insertion may present undesirable consequences. Tympanic membrane and middle ear sequelae in children with OME treated with VT have been reported many times in the literature. In many occasions, it is difficult to separate sequelae resulting from the disease from those resultant from treatment. Complications in insertion of VT include otorrhea, tympanosclerosis, tympanic membrane perforation, retractions and cholesteatomas [6, 7].

The identification of previously non-existing changes in the tympanic membrane (incidence) requires a prospective study with regular and appropriate follow-up. Differently from prevalence, data of incidence allow risk estimates for the development of sequelae during a specific period of time in those subjects that did not have it in the onset of the study.

Thus, we tried to determine types and incidences of sequelae/complications related with ventilation tube in a cohort of children with OME (children with recurrent otitis media and otitis media with chronic effusion), submitted to myringotomy and VT insertion and regularly followed up.

MATERIAL AND METHOD

We conducted a cohort longitudinal prospective study with sub-individual data (ears).

Seventy-five children with diagnosis of OME, coming from the pediatric clinic of Otorhinolaryngology, Porto Alegre, were enrolled in the study during the period of June 2001 to October 2002, and they were followed up until July 2004. It included patients that were aged 11 months to 10 years, who had had middle ear effusion for six weeks or more (OME), with diagnosis of recurrent otitis media - ROM (three or more episodes of AOM within six months) or chronic otitis media with effusion - COME (persistence of effusion for over three months) that presented indication of myringotomy and ventilation tube insertion. The first author (MBRP) has performed the clinical follow-up of all selected cases for a minimum period of six weeks before the surgery. Immittanciometry was made, when necessary, to confirm the presence of effusion in cases of ROM and all patients with diagnosis of COME were assessed with audiometry and immittanciometry. We performed pneumatic otoscopy under video-endoscopic vision, in all patients, 24 hours before the surgical procedure to confirm the absence of signs and symptoms of acute infection. The patients that presented, at the time of the surgery, AOM, upper airway infections, current use of antibiotics or history of conclusion of treatment less than 7 days before, were excluded.

The surgical act was performed under general anesthesia. Middle ear effusion was aspirated with an Alden-Senturia collector (*Alden-Senturia collector*®, Storz Instruments, St. Louis, USA), because it had been included in a study about the presence of bacteria in middle ear effusion of children with OME [8]. Short-term ventilation tubes, made of silicone, measuring 1.2 x 2.6 mm, type Donaldson (*Medicone*®, Pomp Produtos Hospitalares, Cachoeirinha, Brazil) were placed on the anterior-inferior quadrant of the TM.

Patients were examined with videoendoscopy in the following intervals: 7 and 30 days after surgery and then within 45-60 days or at any time if there were any complications. We assessed the time VT remained in place, frequency of otorrhea, perforations and other structural TM changes after extrusion of VT and number of episodes of AOM and OME after the extrusion of the VT.

Quantitative variables (age, duration of follow-up, and stay of VT) were described as mean (± standard deviation) and qualitative variables (surgical indication, type of surgery, occurrence of otorrhea, tympanosclerosis, retraction, perforation, AOM and OME after extrusion of VT), were presented by absolute and percentage frequency.

The analysis of data was conducted by Kolmogorov-Smirnov test (K-S). Out of the total quantitative variables, only VT time of stay had to be submitted to logarithmic transformation to be assessed by analysis of variance, considering its asymmetry. The comparison of means was carried out with analysis of variance (ANOVA) and comparisons of proportion of chi-square. The level of significance adopted was = 0.05.

Research data were stored in a database using the software MS Excel®, version 2002 for Windows XP. The statistical package we employed was Statistical Package for Social Sciences (SPSS®), version 11.0[9].

The research protocol was approved by the Research Ethics Committee, Research and Post-Graduation Group at Hospital de Clínicas de Porto Alegre. Written post-informed consent was collected from all parents or guardians. The