



A randomized study of four different types of tympanostomy ventilation tubes – One-year follow-up



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ARTICLE INFO

Article history:

Received 19 May 2016

Received in revised form

12 August 2016

Accepted 15 August 2016

Available online 17 August 2016

Keywords:

Ventilation tubes

Otorrhea

Tympanostomy tubes

Complications

Secretory otitis media

Extrusion

Material

ABSTRACT

Objective: To compare four different types of tympanostomy ventilation tubes (VT); long-shaft and short-shaft silicone tubes and long-shaft and short-shaft fluoroplastic tubes, regarding time to extrusion and events of otorrhea.

Methods: A prospective randomized controlled trial in children with bilateral recurrent acute otitis media or secretory otitis media; four hundred children were randomized to receive one type of VT in the right ear and another type in the left ear. Postoperatively the children were assessed every third month by an otolaryngologist to monitor the incidence of otorrhea and tube extrusion.

Results: Out of the 400 children, 22 were excluded during surgery. Mean age was 35.3 months. A majority (63.8%) were boys. Forty-eight children were lost to follow up during the first year. Significantly more short-shaft VTs were extruded after 12 months compared to long-shaft VTs, regardless of material. Significantly higher incidence of otorrhea was found in the fluoroplastic VT ears compared to the silicone ones, regardless of length of tube.

Conclusion: Long-shaft VTs last longer in the eardrum during the first year of treatment. Silicone tubes render a reduced risk of otorrhea during the first year of treatment.

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1. Introduction

Otitis media is one of the most common diseases during childhood, and more than seventy percent of all children experience at least one episode of otitis media [1]. Acute otitis media can be treated with antibiotics, but resolves most often spontaneously, which is also the case for secretory otitis media (SOM). Still a large number of children require tympanostomy ventilation tubes (VTs) to prevent recurrent acute otitis media (rAOM) and prolonged hearing impairment, respectively. VT insertion under general anesthesia is currently the most common surgical procedure performed in children. In Sweden, harboring almost ten million inhabitants, approximately ten thousand children receive VTs

annually [2]. A study from 2000 showed that 6.8% of North American children were treated with VTs by the age of three years [3].

There are numerous types of VTs with differences in shape and material. Unfortunately, there are very few randomized studies comparing the effects of different types of tubes. Knowledge about probable time to extrusion and complication rate is mainly based on retrospective, observational studies, with the obvious weaknesses that non-randomized studies render. A systematic review of the literature on VT treatment concluded that there is not enough evidence to determine whether the design or material of the VT has any impact on its duration or effect [2].

The present randomized study compares four different VTs with the aim to elucidate differences in duration and complication rate based on the basic features of the VT, i.e. shape and material. Two fundamentally different VT shapes were identified in the multitude of shapes on the market, and were thus tested: long-shaft single-flanged and short-shaft double-flanged. The two most commonly

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used materials were also identified, and tested: fluoroplastic and silicone.

The aim of the study was to decide if shape and/or material of VTs had had influence on extrusion rate or events of otorrhea during the first year after insertion.

2. Material and methods

Four hundred children between one and ten years of age, admitted into a tertiary referral ENT department in Stockholm for bilateral VT insertion for rAOM, SOM or a combination of both were included after informed consent by their caregivers.

Exclusion criteria were previous VT treatment, on-going acute otitis media, Downs's syndrome and craniofacial malformations such as cleft palate.

Four different types of tubes were tested (Fig. 1). Details are shown in Table 1.

1. Shepard VT (short-shaft double-flanged, fluoroplastic)
2. Donaldson VT (short-shaft double-flanged, silicone)
3. Long Armstrong VT (long-shaft single-flanged, silicone)
4. Straight VT (long-shaft single-flanged, fluoroplastic)

Using non-transparent consecutively numbered envelopes, 400 children were randomized to receive a specific combination of two different types of VT each. Statistical software was used to arrange the pre-randomization preparation, so that in each combination only one VT parameter (shape or material) differed in each patient.

The VTs were inserted in the anterior part of the tympanic membrane under general anesthesia. Surgery was performed at a teaching tertiary referral ENT unit in Stockholm. All surgeons at the unit, including young residents (with supervision when needed)

contributed to the study and performed the VT insertion. If the surgeon failed to insert the intended types of VT the patient was excluded from the study. After surgery, the children were examined by an otolaryngologist every three months, and at extra visits in between if the caregiver requested this, during one year or until six months had passed since the extrusion of the last remaining VT. At all postoperative examinations a form was filled out by the examiner indicating the presence of VT for each ear, purulent otorrhea, events of otalgia, observed VT occlusion, VT extraction, persistent perforation and presence of myringosclerosis.

The Regional Ethical Review Board in Stockholm approved this study (ref. 2008/69–31/3). The study was registered at ClinicalTrials.gov (NCT00809601).

2.1. Statistical analysis

A statistical power analysis indicated a need of a study population of four hundred children in order to answer the primary hypothesis (time to extrusion of VT) with 80% power at a 5% significance level.

For comparison between two groups, Chi2-test and Fisher's exact test was used for dichotomous variables and the Mann-Whitney *U* test was used for continuous variables. The data was analyzed using SPSS software, version 22.0.

3. Results

These are the results from the 1-year follow up.

Twenty-two (5.5%) of the children were withdrawn from the study during surgery due to various reasons, including insertion failures with the intended VT type or when an acute otitis media was detected at myringotomy. Thus 378 children continued within the

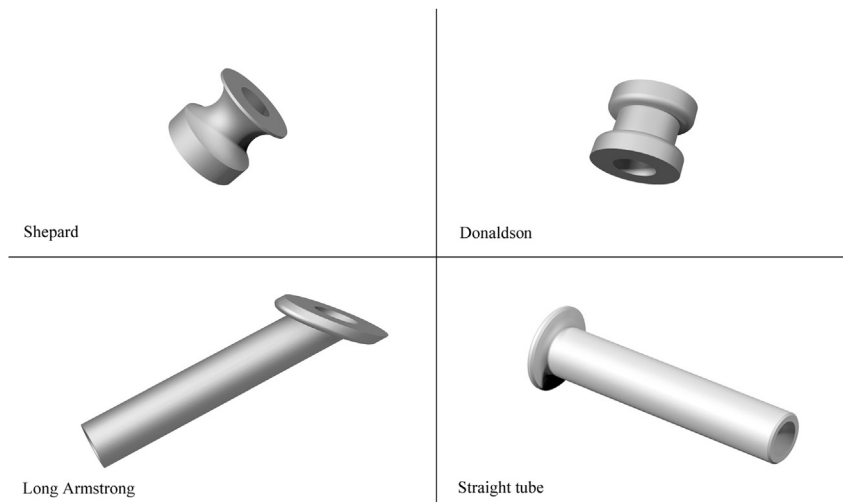


Fig. 1. Design of the four tested tubes. Provided by the retailer (Atos Medical AB, Hörby, Sweden).

Table 1

Measurements of each ventilation tube. Provided by retailer (Atos Medical AB, Hörby, Sweden).

	Material	Length	Inner diameter	Flange diameter	Weight
Shepard TT	fluoroplastic	2.2 mm ^a	1.10 mm	2.4 mm	9 g
Donaldson TT	silicone	2.2 mm ^a	1.10 mm	2.3 mm	9 g
Armstrong long TT	silicone	7.0 mm ^b	1.14 mm	2.6 mm	9 g
Straight TT	fluoroplastic	7.0 mm ^b	1.14 mm	2.7 mm	9 g

^a For double-flanged tubes the length refers to the distance between the flanges.

^b For single-flanged tubes the length refers to the distance from the flange to the outer end of the tube.

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