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A randomized study of four different types of tympanostomy ventilation tubes – Full-term follow-up

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ABSTRACT

Objective: To evaluate the impact of tympanostomy ventilation tube material (silicone vs fluoroplastic) and shape (short vs long) regarding time to extrusion, occurrence of otorrhea, occlusion, tube removal and occurrence of persistent perforation.

Methods and material: Four different types of ventilation tubes were used; Long Armstrong tubes, Donaldson tubes, Shepard tubes and straight tubes, representing four specific combinations of VT material (silicone or fluoroplastic) and shape (short, double flanged or long, single flanged). Four hundred children scheduled for bilateral tube insertion were included in a randomized trial. The patients received one type of tube in the right ear and another type in the left ear. The incidence of tube extrusion and complications were monitored postoperatively every third month by an otolaryngologist.

Results: Twenty-two children were excluded during surgery. Out of the studied 378 children the mean age was 35.3 months. 63.8% were boys. Short tubes extruded earlier than long tubes; hazard ratio (HR) 4.84 (95% CI 3.50–6.69, $p < 0.001$). Long Armstrong tubes were least prone to extrude. Silicone tubes resulted in significantly longer time to first infection in a VT ear, HR 1.68 (95% CI 1.03–2.76, $p = 0.039$). Donaldson tubes rendered the longest mean time to first infection ($p = 0.025$). Infections did not affect tube extrusion rates significantly ($p = 0.879$). No significant differences were found regarding tube occlusion, tube extraction or persistent perforation.

Conclusions: Long tubes are less prone to extrude early. Long Armstrong tubes have the least propensity to extrude early. Silicone tubes render significantly longer time to first infection. Donaldson tubes result in least infections. Infection does not affect extrusion rates significantly.

Level of evidence: 1b

1. Introduction

It has been estimated that more than seventy percent of all children experience at least one episode of acute otitis media [1]. Transmyringeal ventilation tube (VT) insertion is a treatment option for recurrent acute otitis media (rAOM) as well as for secretory otitis media (SOM) causing hearing impairment.

Insertion of VTs is one of the most common surgical procedures during childhood. It was reported that by the age of three, 6.8% of North American children had VTs inserted [2]. VT insertion may prevent rAOM and restore hearing impaired by SOM [3,4]. In 77% of children receiving VTs, the quality of life was improved [5].

Time to tube extrusion vary and VT treatment can result in complications: otorrhea; tube blockage; tympanosclerosis; and persistent tympanic membrane perforation [6]. Even though VTs are by far the most common implant in pediatric patients, the knowledge about the clinical outcomes of different types of VTs is sparse. There is a plethora of commercially available VTs, differing in design and material, but very few have been tested in randomized controlled trials (RCTs). A systematic review of the literature concluded that there is a lack of

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Table 1
Measurements of each ventilation tube. Provided by retailer (Atos Medical AB, Hörby, Sweden).

	Material	Length	Inner diameter	Flange diameter	Weight
Shepard VT	fluoroplastic	2.2 mm[a]	1.10 mm	2.4 mm	9 gr
Donaldson VT	silicone	2.2 mm[a]	1.10 mm	2.3 mm	9 gr
Armstrong long VT	silicone	7.0 mm[b]	1.14 mm	2.6 mm	9 gr
Straight VT	fluoroplastic	7.0 mm[b]	1.14 mm	2.7 mm	9 gr

[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.

evidence of whether the VT design or material have any impact on possible tube-associated complications [7].

The present study compared four different types of VTs. The hypotheses were that the two basic features of the VT, i.e. shape and material, cause different time to tube extrusion and different complication rates.

2. Material and methods

Children between one and ten years of age planned for bilateral VT insertion for rAOM or SOM were eligible for inclusion in the study. Exclusion criteria were previous VT treatment, on-going acute otitis media, Downs's syndrome and craniofacial malformations such as cleft palate. Informed consent was obtained from the caregivers.

Four hundred children were randomized by the use of non-transparent consecutively numbered envelopes to receive different types of VTs in each ear. Four different types of tubes were used representing four different combinations of the basic tube features; shape (short or long tubes) and material (fluoroplastic or silicone). Details are shown in Table 1. Statistical software was used to arrange the pre-randomization preparation, so that in each child only one parameter, i.e., shape or material, differed between the ears.

The VT insertions were performed under general anesthesia in an academic tertiary referral ENT department. All surgeons at the unit, including young residents (with supervision when needed) contributed to the study and performed the VT insertion. The VTs were inserted in the anterior portion of the tympanic membrane. At the end of surgery, three drops of oxytetracycline, hydrocortisone and polymyxin B (Terracortril with polymyxin B®, Pfizer) were installed in the inner part of the external ear canal. If the surgeon failed to insert the intended type of VT the patient was excluded from the study. The children were examined postoperatively by an otolaryngologist every third month, and at extra visits in between if the caregiver requested that, until six months had passed since the extrusion of the last remaining VT. Maximum follow-up time was set at 45 months. The otolaryngologist filled out a form at all postoperative examinations regarding presence of VT for each ear, purulent otorrhea, observed VT occlusion, VT extraction and persistent perforation.

Prior to study start, 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. Outcomes

Time to VT extrusion was measured as the time from surgery to the first observation of the whole VT inner flange appearing lateral to the tympanic membrane. Time to a first event of a complication and the total number of complications were also measured.

2.2. Power analysis

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

2.3. Statistical analyses

For descriptive statistics, categorical data are presented as frequencies and percentages, *n* (%), while discrete and continuous data are given as means and standard deviations (SDs). Differences between two independent groups were tested using Pearson's χ^2-test for categorical data and the Mann-Whitney *U* test for discrete and continuous data. To take the dependence between right and left ear on the same individual into account, time to VT extrusion, treated as interval-censored data, was analyzed using shared gamma frailty Cox regression models clustered on individuals. The models applied a penalized likelihood on the hazard function using splines with 8 knots and smoothing parameter $\kappa = 10000$. These regression models used either tube type, tube shape, tube material, or both tube shape and tube material as independent variables. The results are presented as hazard ratios (HRs) with accompanying 95% confidence intervals (CIs). Time to VT extrusion was illustrated graphically using Kaplan-Meier curves. Persistent perforation, defined as having a perforation lasting at least 90 days, was analyzed using Generalized Estimating Equations (GEE) logistic regression models with an independent working correlation matrix structure and within-subject effect for ears. These regression models used either tube type or both tube shape and tube material as independent variables. The statistical analyses were performed using IBM SPSS Statistics 24 and the R package 'frailtypack'. For all statistical analyses, a two-sided p-value < 0.05 was considered statistically significant.

3. Results

Out of the 400 children included in the study, twenty-two (5.5%) were withdrawn during surgery due to protocol violation or due to an acute otitis media finding at myringotomy. Thus, 378 children continued the study, 64.3% boys and 35.7% girls. The reason for VT insertion was rAOM in 44.7% of the children, SOM in 41.0% and a combination of rAOM and SOM in 14.3%. Mean age at surgery was 35.3 (SD 19.5) months for all children. The mean age at insertion for each type of VT is presented in Table 2 as well as the number of inserted VTs,

Table 2
Number of ventilation tubes of each type and mean age at insertion. Distribution of indication for surgery and gender for the different tube types.

	n	Mean age at surgery months (SD)	Indication for surgery (number of tubes)			Gender distribution (number of tubes)	
			rAOM	rAOM & SOM	SOM	Girls	Boys
Shepard VT	188	37.0 (19.9)	77 (41.0%)	31(16.5%)	80 (42.6%)	63 (33.5%)	125 (66.5%)
Donaldson VT	190	35.6 (19.6)	88 (46.3%)	24 (12.6%)	78 (41.1%)	64 (33.7%)	126 (66.3%)
Armstrong long VT	190	34.5 (19.9)	92 (48.4%)	23 (12.1%)	75 (39.5%)	72 (37.9%)	118 (62.1%)
Straight VT	188	34.7 (18.6)	81 (43.1%)	30 (16.0%)	77 (41.0%)	71 (37.8%)	117 (62.2%)

Abbreviations: rAOM - recurrent acute otitis media, SOM – secretory otitis media.