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Ventilation tube non-function due to blockage in children: the frequency, course and effect on hearing. A prospective cohort study

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Main Article

Dr M Merven takes responsibility for the integrity of the content of the paper

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Abstract

Objective. To assess the effect on hearing of non-functioning ventilation tubes due to blockage during the first six months post-operatively, using UK national guidelines.
Method. A prospective, observational study was conducted on 37 children who underwent bilateral ventilation tube insertion. Air and bone conduction thresholds were measured before and following surgery, and at one, three and six months post-operatively. Tube non-function was assessed by tympanometry supported by otoscopy.
Results. Post-operatively, an average of 21 per cent of ventilation tubes were non-functioning. Ears with non-functioning tubes had significantly ($p = 0.0001$) poorer mean air conduction thresholds than functioning tubes, with a magnitude of 6 dB HL. Ears with otorrhoea were most affected (15 per cent). At any one visit, the air–bone gap was closed to 10 dB or less in 76 per cent of ears. Non-functioning tubes reduced this to 56 per cent. Compared with tympanometry, otoscopy underdiagnosed tube non-function due to blockage by 22 per cent.
Conclusion. Non-functioning of ventilation tubes occurs frequently and can be missed on otoscopy. Although it is associated with poorer air conduction thresholds, the magnitude of this difference is unlikely to warrant further intervention unless there is otorrhoea or recurrence of bilateral hearing impairment.

Introduction

Otitis media with effusion (OME) is the most common cause of hearing loss in children. A meta-analysis of randomised, controlled trials has shown that short-stay ventilation tubes improve hearing to a greater extent than natural resolution. This benefit occurs primarily during the first six months after ventilation tube insertion, and in children with persistent OME and hearing loss of more than 25 dB HL.[1]

The commonest clinical complication of ventilation tubes is non-function due to blockage. In the immediate post-operative period, the tubes can become blocked with blood, and thereafter with crusts of middle-ear secretions or pus.

The most cited article on ventilation tube obstruction rates is the meta-analysis by Kay *et al.*, published in 2001.[2] The overall blockage rate (blockage type not defined) was only 7 per cent (confidence interval = 6.1–7.7) in 17 studies, with a range of 0–37 per cent.

To date, the only prospective study, controlled for time, that has reported ventilation tube non-function due to blockage with extrusion is the Medical Research Council's Trial of Alternative Regimens for Glue Ear Treatment ('TARGET' trial, published in 2003).[3] In that study, tube non-function due to blockage was determined by a combination of otoscopy and tympanometry. The overall rates of non-function due to blockage and extrusion were 21 per cent (68 of 327) at 3 months, 45 per cent (148 of 325) at 6 months, 82 per cent (259 of 316) at 12 months, 92 per cent (281 of 304) at 18 months and 97 per cent (291 of 300) at 24 months. Separate data were not presented for non-function due to blockage separated from extrusion, nor did the study report non-function due to blockage and extrusion immediately post-operation or at one month. Furthermore, the effect on hearing of tube non-function due to blockage was not reported separately from the effect of tube extrusion.

Objectives

This study evaluated children after bilateral ventilation tube insertion, in the immediate post-operative period, and at one, three and six months, in order to: (1) assess the rates of tube non-function due to blockage, via a combination of tympanometry and otoscopy; and (2) report the effect of tube non-function on air conduction thresholds averaged over 0.5, 1, 2 and 4 kHz and air–bone gaps at 0.5, 1 and 2 kHz.

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Materials and methods

Study design

A prospective, time-controlled study was conducted of hearing in children who underwent bilateral ventilation tubes insertion to treat persistent otitis media with effusion (OME). Children aged 4–13 years, admitted for myringotomy and ventilation tube insertion for persistent bilateral OME, were assessed on admission for study eligibility.

Otoscopy confirmed bilateral OME, and children were then assessed using pure tone audiometry (air and bone conduction) and tympanometry. Immediately following surgery and prior to hospital discharge, each child had repeat tympanometry and audiometry. Out-patient return appointments were scheduled for one month, three months and six months post-operatively for otoscopy, tympanometry and audiometry, performed in that order.

Study setting

The study was conducted at the Otorhinolaryngology Department of Tygerberg Hospital, a tertiary academic hospital in Cape Town, South Africa, between March 2011 and March 2013.

Eligibility criteria

Children (aged 4–13 years) diagnosed with bilateral OME via otoscopy were considered eligible for inclusion in the study if: they had type B or type C tympanograms, and hearing loss was at least 20 dB HL on pure tone audiometry, with an air–bone gap of 10 dB or more, in both ears, when scheduling for surgery. Children due to undergo ventilation tube insertion, as per routine guidelines, were assessed on the day of surgery for inclusion in the study. Children who were unable to undergo audiometry because of developmental delay or mental disability were excluded.

Audiometry

Audiometry was carried out with calibrated instruments in a sound-treated room. Air conduction thresholds were assessed at 0.5, 1, 2 and 4 kHz in each ear. The bone conduction thresholds were assessed at 0.5, 1 and 2 kHz in each ear, with masking as required. The audiograms were obtained by a senior trained audiologist using play audiometry as needed.

Tympanometry

Tympanometry was performed on all children, using a pressure range of +200 to −400 daPa, with a Grason-Stadler (GSI) TympStar™ machine. The tympanograms were classified by a senior audiologist, according to the Jerger classification, as type A, B or C.[4]

Surgery

Surgery was performed under general anaesthesia by one of three surgeons on rotation over a six-month period. Antero-inferior myringotomy was performed in the pars tensa, and the middle-ear fluid was carefully suctioned until no more ear 'glue' appeared. Reuter bobbin fluoroplastic ventilation tubes were inserted. At the end of the procedure, tube patency was achieved by suction of any blood or fluid. If bleeding occurred, irrigation with saline was performed. No drops were routinely administered at the end of surgery. Adenoidectomy was performed at the surgeon's discretion.

Outcome evaluation

Tube function

All ventilation tubes were assessed and classified as being functional, non-functional or extruded, at one, three and six months, based on both otoscopy and tympanometry.

Otoscopy

If ventilation tubes were blocked, it was noted whether this was due to blood, crusts or pus. Infection was considered present if there was also pus in the external ear canal.

Tympanometric assessment of tube function

Assessment used the following criteria. Repeated failure to obtain a seal was taken as an indication of a patent ventilation tube. If a type B tympanogram was obtained, the external canal volume was measured. An external canal volume of 1.3 ml or greater was taken to indicate patency of the tube (such a large volume in this age group is unlikely in the presence of an intact drum). If an external canal volume of between 0.9 and 1.3 ml was obtained, it was compared to the external canal volume recorded prior to surgery. An increased volume of 0.4 ml or more was taken to indicate a patent ventilation tube.[3,5]

Where tympanometry suggested non-function but there was no otoscopic evidence of ventilation tube obstruction, the tube was classified as being non-functioning. The reference standard of tympanometry as the 'gold standard' was chosen because it is an objective measure. It indicates mechanically physical blockage and therefore the lack of ventilation. Otoscopy only suggests that air blockage could be possible. It is also the authors' experience that one seldom sees through the ventilation tube into the middle ear.

Audiometry

This was performed following surgery, prior to discharge from hospital, and then at one month, three months and six months post-operatively.

Management of infected ears

When the ears were infected (i.e. there was presence of pus in the external auditory canal), ears were either dry mopped or micro-suctioned, depending on the child's tolerance to micro-suction. In addition, topical antibiotic drops (Octin™ (ofloxacin 3 mg/ml)) were administered three times a day, with dry mopping for two weeks, and the child reviewed in one month. The treatment was repeated as required.

Statistical analysis

A mixed model, repeated measures analysis of variance was used to compare continuous measurements over different time points and between groups. The children were treated as random effects, and group and time were considered as fixed effects. For comparing whether ears were functional or not (a binary outcome), generalised estimating equations with binomial as underlying distribution were used. In order to determine whether the proportion of functional ears changed over time, the Stuart–Maxwell chi-square test was used. When analysing the rate of spontaneous resolution of blocked

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ventilation tubes, the chi-square test and Rao–Scott correction were used.

Ethical considerations

Ethical approval for the study was obtained from the Health Research Ethics Committee of the University of Stellenbosch. Signed consent for surgery was obtained in the hospital's routine manner. In addition, the principle investigator (MM) obtained written informed consent from the primary caregiver for each child included in the study, and obtained written assent from all study participants aged seven years and older.

Results

Children

Forty-one eligible children were scheduled for bilateral ventilation tube insertion. At the time of surgery, four children had only one tube inserted. In three children, the otitis media with effusion (OME) had resolved in one ear, and in one child there was a perforation due to an episode of 'acute otitis media'. These children are not included in the analysis.

Thus, 37 children (74 ears) were included in the study. Twenty-three were boys and 14 were girls, with a mean age at surgery of 78 months (range, 4–13 years). Nine (24 per cent) of these children had previously undergone adenoidectomy and 12 (32 per cent) had previously had ventilation tubes inserted.

The hearing in one ear on the morning of surgery had improved to be less than 20 dB HL in 8 of the 37 children (11 per cent). These ears still had a ventilation tube inserted and were included in the analysis. This was considered valid as audiometry is not routine clinical practice on the day of surgery to exclude natural resolution. The 'dry tap' rate was 0 per cent.

At ventilation tube insertion, 17 children (46 per cent) underwent concurrent adenoidectomy. No child had tonsillectomy performed.

All the 37 children attended at least 1 post-operative follow-up appointment. Eighty-nine per cent of children were evaluated after surgery, prior to discharge from hospital. Seventy per cent attended the one-month visit, 81 per cent attended the three-month visit and 76 per cent attended the six-month visit.

Tube function

In the immediate post-operative period, only 68 per cent (45 of 66) of ventilation tubes were functioning; the other 32 per cent were blocked, most frequently with blood. Thereafter, the percentage of ears with non-functioning tubes remained roughly constant, at 27 per cent at one month, 15 per cent at three months and 23 per cent at six months (an average of 21 per cent had non-functioning tubes over one, three and six months) (Table 1). There was no statistical difference between these percentages ($p = 0.4$).

All ears with otorrhoea had non-functioning ventilation tubes on tympanometry. Where tympanometry suggested non-function but there was no otoscopic evidence of tube obstruction, the tube was considered non-functional. This occurred in five ears at one month (35 per cent), two ears at three months (22 per cent) and one ear at six months (8 per cent). In one ear (2 per cent) at the three-month visit, otoscopy suggested tube blockage, but tympanometry indicated patency.

Sensitivity and specificity of diagnostic methods

When tympanometry, as an objective measure, was used as the gold standard to diagnose ventilation tube non-function or patency, the sensitivity of otoscopy was 80 per cent and the specificity was 99 per cent. In other words, otoscopy underdiagnosed tube non-function, but if it did suggest blockage then it was correct.

Resolution of tube blockage

The rate of spontaneous resolution of ventilation tube non-function from immediately post-operation to one month post-operation (i.e. 60 per cent; 9 of 15) was similar to the rate of resolution from one month to three months post-operation (i.e. 62 per cent; 8 of 13). Between three and six months, the rate of resolution was lower, at 17 per cent (1 of 6). However, this difference was not statistically significant because of the small numbers ($p = 0.13$).

Ventilation tube extrusion was less common, occurring in 7 per cent of ears (4 of 60) at three months and 13 per cent of ears (7 of 56) at six months.

Otorrhoea

Over the three post-operative visits (at one, three and six months), otorrhoea accounted for 15 per cent of the non-functioning ventilation tubes. Tube infection occurred in four ears at one month. In three of those ears, infection had resolved with treatment at three months. In one ear, the otorrhoea persisted from the one-month assessment to the six-month assessment, despite treatment. At the six-month visit, otorrhoea was present in five ears.

Effects of adenoidectomy on tube function

Regarding the ventilation tube function at one, three and six months post-operatively in relation to adenoidectomy, there were three groups: (1) those who had undergone adenoidectomy previously (42 ears) – the non-function rate in this group of ears was 19 per cent; (2) those who underwent concurrent adenoidectomy with ventilation tube insertion (76 ears) – the non-function rate in this group of ears was 25 per cent; and (3) those who had never undergone adenoidectomy (50 ears) – the non-function rate in this group of ears was 18 per cent. Analysis revealed no statistically significant difference between these three groups ($p = 0.31$).

The infection rate was similar in all three groups; namely, 4 per cent of ears in group 1, 6 per cent in group 2 and 5 per cent in group 3.

Tube function analysed by child

Table 2 shows the ventilation tube function rates analysed by child. At any single time point, both tubes were functional in a maximum of 64 per cent of children. Non-function in both tubes occurred on average in 14 per cent (range, 4–24 per cent) of children over the four follow-up periods.

Audiometry

Air conduction thresholds

Prior to surgery, the mean air conduction threshold was 32 dB HL (standard deviation (SD) = 11), with a range of 11–53 dB HL. There was a statistically significant improvement ($p = 0.0001$) from baseline at all time intervals after surgery

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Table 1. Analysis of ventilation tube function over time

Visit	Available ears	Tube functioning	Tube non-functioning	Tube infected	Tube extruded
Pre-operation	74 (100)	N/A	N/A	N/A	N/A
Immediately post-op*	66 (89)	45 (68)	21 (32)	0	0
1 month post-op	52 (70)	38 (73)	14 (27)	4 (8)	0
3 months post-op	60 (91)	47 (78)	9 (15)	1 (2)	4 (7)
6 months post-op	56 (76)	36 (64)	13 (23)	5 (9)	7 (13)
Average (1, 3 & 6 months post-op)	76%	72%	21%	6%	6%

The data report on the number (and percentages) of ears seen at each visit (unless indicated otherwise), and the state of the ventilation tube in those ears at each visit. *The children's first post-operative visit prior to discharge from hospital. N/A = not applicable; post-op = post-operation

Table 2. Analysis of ventilation tube function by child

Visit	Children (*n*)	Both tubes functional	One tube functional	Both tubes non-functional
Immediately post-op*	33	21 (64)	4 (12)	8 (24)
1 month post-op	26	15 (58)	8 (30)	3 (12)
3 months post-op	30	19 (63)	10 (33)	1 (4)
6 months post-op	28	12 (43)	12 (43)	4 (14)

The data report on the number (and percentages) of children seen at each visit (unless indicated otherwise), and the state of both of their ventilation tubes at each visit. *The children's first post-operative visit prior to discharge from hospital. Post-op = post-operation

(17 dB HL immediately post-operation, 15 dB HL at one month, 13 dB HL at three months and 15 dB HL at six months) (Table 3).

When analysed over all visits, ears with functioning ventilation tubes had significantly better thresholds ($p = 0.0001$) by 6 dB compared with those without (mean difference, 13 *vs* 19 dB HL). The difference was significant at all visits. At any one visit, an air conduction threshold of 20 dB HL or greater was more likely in children with non-functioning tubes. This was most significant at the six-month visit, where 62 per cent of ears with non-functioning tubes had thresholds of 20 dB or greater, compared to 6 per cent of ears with functioning tubes.

Figure 1 shows graphically the changes in air conduction thresholds over time in the different groups. The thresholds of ears with functioning ventilation tubes are consistently better than those with non-functioning tubes. The difference in thresholds shows a trend to increase at the six-month visit; however, this was not statistically significant. The thresholds for the ears with extruded tubes lie are better than for non-functioning tubes but worse than for functioning tubes.

Bone conduction thresholds

The mean pre-operative bone conduction threshold in the 74 ears was 8.3 dB HL (SD = 4.9), with a range of −5 to 21 dB HL. Following ventilation tube insertion, the mean bone conduction threshold improved from 8.3 dB HL to 6 dB HL, but this difference was not significant.

Air–bone gaps

Table 4 gives the mean pre-operative air–bone gaps and distribution in 10 dB bins, along with the post-intervention data. There was a significant ($p = 0.0001$) lessening in the magnitude of the air–bone gap from the pre-operative assessment to all post-operative assessments. Prior to surgery, the mean air–bone gap was 24 dB (SD = 11); this fell to 11 dB post-operatively (prior to hospital discharge), 8 dB at one month, 7 dB at three months and 10 dB at six months.

Prior to surgery, 89 per cent of ears had an air–bone gap of 11 dB or greater (11 per cent had an air–bone gap of 10 dB or lower). Following surgery, the percentages of ears with an air–bone gap of 10 dB or lower were: 56 per cent immediately post-operatively, 77 per cent at one month, 80 per cent at three months and 64 per cent at six months. Overall at one, three and six months, 76 per cent of ears had an air–bone gap of 10 dB or lower. In ears with non-functioning ventilation tubes, those percentages decreased to: 64 per cent at one month, 45 per cent at three months and 55 per cent at six months. Regarding functioning tubes, those percentages were significantly better: 82 per cent at one month, 85 per cent at three months and 67 per cent at six months.

There was a statistically significant relationship between air–bone gap and ventilation tube patency at all visits ($p = 0.004$). The air–bone gap at one month in ears with functioning tubes was 7.6 dB, versus 9.5 dB in ears with non-functioning tubes; at three months this was 6.2 dB versus 10.8 dB, and at six months it was 8.4 dB versus 13.4 dB.

Infection rate and its effects on hearing

In total over the three post-operative visits, 6 ears 8 per cent developed otorrhoea. Otorrhoea was present in four ears (8 per cent) at one month, in one ear (2 per cent) at three months, and in five ears (9 per cent) at six months (Table 1).

Ears with otorrhoea were classified in the 'non-functional' group because pus was impairing ventilation tube function and tympanometry measurements showed type B tympanograms with reduced ear canal volumes. There were too few ears with otorrhoea to determine statistical significance, but the trend showed poorer hearing in ears with otorrhoea compared to those ears with non-functioning tubes without otorrhoea.

The mean air conduction threshold (Table 3) in ears with infection was 27 dB HL, compared to 14 dB HL in ears with non-functioning ventilation tubes without infection at one month; these thresholds were 22.5 dB HL versus 17 dB HL at three months, and 32 dB HL versus 16 dB HL at six months. The numbers were too small to show statistical significance.

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Table 3. Air conduction thresholds

Visit	Ears (total *n*)	AC threshold (dB)		Ears with AC thresholds ≥20 dB HL (*n* (%))
		Mean	SD	
Pre-op on day of surgery				
– Total ears	74	32.2	10.8	64 (86)
Post-op on day of surgery				
– Total ears	66	16.6	6.1	21 (32)
– Functioning VTs	45	15.1	5.9	10 (22)
– Non-functioning VTs	21	19.8	5.4	11 (24)
1 month post-op				
– Total ears	52	14.7	6.1	7 (13)
– Functioning VTs	38	13.6	4.8	3 (8)
– Non-functioning VTs	14	17.9	8.2	4 (29)
– Non-functioning VTs with otorrhoea	4	27	8.6	3 (75)
– Non-functioning VTs without otorrhoea	10	14	4.3	1 (10)
– Extruded VTs	0			0
3 months post-op				
– Total ears	60	12.7	4.9	7 (12)
– Functioning VTs	47	11.6	4.3	3 (6)
– Non-functioning VTs	9	17.5	5.7	4 (44)
– Non-functioning VTs with otorrhoea	1	22.5	N/A	1 (100)
– Non-functioning VTs without otorrhoea	8	17	5.8	3 (38)
– Extruded VTs	4	15.3	2.1	0
6 months post-op				
– Total ears	56	15.2	8.4	12 (21)
– Functioning VTs	36	12.5	6.2	2 (6)
– Non-functioning VTs	13	22	10.6	8 (62)
– Non-functioning VTs with otorrhoea	5	32	4.9	5 (63)
– Non-functioning VTs without otorrhoea	8	16	8.7	3 (27)
– Extruded VTs	7	16.8	7.3	2 (29)

The data report on the mean hearing thresholds (air conduction) for each group of ears (grouped according to pre- and post-operative visits and according to the state of the ventilation tube at those visits). The last column reports the number of ears with thresholds of 20 dB HL or more at each visit. AC = air conduction; SD = standard deviation; pre-op = pre-operation; post-op = post-operation; VT = ventilation tube; N/A = not applicable

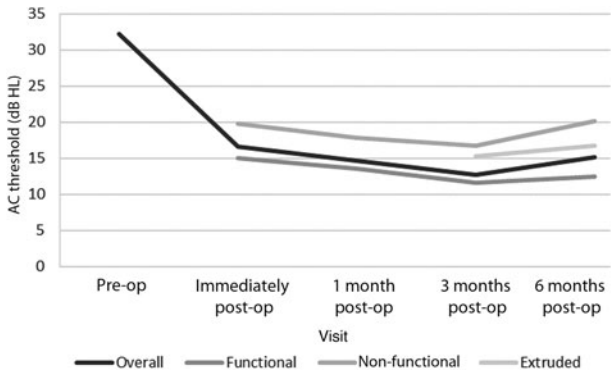


Fig. 1. Demonstrates the change in hearing threshold over time in ears grouped according to the state of tube function. AC = air conduction threshold; pre-op = prior to ventilation tube insertion; post-op = post-operative, prior to hospital discharge

Similarly, the air–bone gap (Table 4) was mostly worse in ears with infection compared to those ears with non-functioning ventilation tubes without infection: 16.8 dB versus 6.5 at one month, 7.5 dB versus 11 dB at three months, and 20 dB versus 9.3 dB at six months. In ears with non-functioning tubes and without otorrhoea, 56 per cent (45–64 per cent) had an air–bone gap of 10 dB or lower. The presence of otorrhoea decreased this to 36 per cent (25–100 per cent). Again, the numbers were too small to show statistical significance.

When ears with otorrhoea were excluded, the difference between the mean air conduction in ears with non-functioning ventilation tubes (but not infected) compared to those with functioning tubes (also not infected) was reduced to 3.5 dB (from 6 dB), but the difference was statistically significant ($p = 0.043$).

Ears with extruded tubes

There were six children who had one ear with an extruded ventilation tube, and one child with both tubes extruded. They comprised a total of 11 visits (4 ears at three months and 7 ears at six months). The mean air conduction threshold

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Table 4. Mean ABG at each visit and distribution in 10 dB bins

Visit	Ears (total *n*)	ABG (dB)		Number (%) of ears with ABG of:			
		Mean	SD	≤10 dB	11–20 dB	21–30 dB	30+ dB
Pre-op on day of surgery							
– Total ears	74	24	11	8 (11)	20 (27)	22 (30)	24 (32)
Post-op on day of surgery							
– Total ears	66	11	6	37 (56)	22 (33)	7 (11)	0
– Functioning VTs	45	9.8	5.6	26 (57)	18 (39)	2 (4)	0
– Non-functioning VTs	21	12.6	6.7	11 (55)	4 (20)	5 (25)	0
1 month post-op	52	8.1	5	40 (77)	10 (19)	2 (4)	0
– Total ears							
– Functioning VTs	38	7.6	3.6	31 (82)	7 (18)	0	0
– Non-functioning VTs	14	9.5	7.9	9 (64)	3 (21)	2 (15)	0
– Non-functioning VTs with otorrhoea	4	16.8	9	1 (25)	1 (25)	2 (50)	0
– Non-functioning VTs without otorrhoea	10	6.5	5.5	8 (80)	2 (20)	0	0
– Extruded VTs	0	N/A	N/A	0	0	0	0
3 months post-op	60	6.7	5.2	48 (80)	10 (16)	2 (4)	0
– Total ears							
– Functioning VTs	47	6.2	4.8	40 (85)	6 (13)	1 (2)	0
– Non-functioning VTs	9	10.8	6.2	4 (45)	4 (45)	1 (10)	0
– Non-functioning VTs with otorrhoea	1	7.5	N/A	1 (100)	0	0	0
– Non-functioning VTs without otorrhoea	8	11	6.4	3 (38)	4 (50)	1 (12)	0
– Extruded VTs	4	3.7	1.9	4 (100)	0	0	0
6 months post-op	56	9.5	8	36 (64)	14 (25)	5 (9)	1 (2)
– Total ears							
– Functioning VTs	36	8.4	5.8	24 (67)	10 (28)	2 (5)	0
– Non-functioning VTs	13	13.4	11.4	7 (55)	3 (23)	2 (15)	1 (7)
– Non-functioning VTs with otorrhoea	5	20	13.1	2 (40)	1 (20)	1 (20)	1 (20)
– Non-functioning VTs without otorrhoea	8	9.3	7.9	5 (62)	2 (25)	1 (13)	0
– Extruded VTs	7	8.3	9	5 (72)	1 (14)	1 (14)	0

The data report on the mean pre-operative air–bone gaps and distribution in 10 dB bins along with the post-intervention data. ABG = air–bone gap; SD = standard deviation; pre-op = pre-operation; post-op = post-operation; VT = ventilation tube; N/A = not applicable

in ears with extruded tubes was 15.3 dB HL at three months and 16.8 dB HL at six months.

Effects of previous ventilation tubes

There was no statistically significant difference in air conduction and air–bone gap between the group with a history of previous ventilation tubes and the group without.

Audiometry findings by child

This was not analysed in detail, but we can report on hearing in the 5 of 37 children (14 per cent) who had bilateral non-functioning ventilation tubes at one or more of the follow-up visits. Only two of these children had hearing thresholds of 20 dB HL or greater in both ears. One of those children had bilateral otorrhoea that required topical treatment. The other child had recurrence of bilateral OME, which required a new set of grommets.

Effects of adenoidectomy on hearing

Regarding the ears with functioning ventilation tubes, adenoidectomy did not have a significant effect on the air conduction results. The mean air conduction threshold over the one-, three- and six-month visits for the ears of children who had concurrent adenoidectomy was 12.7 dB HL. For those who underwent adenoidectomy previously or had no adenoidectomy, the mean air conduction threshold was 12 dB HL.

If both functioning and non-functioning ventilation tubes were included, again, adenoidectomy did not have a significant effect on hearing. For the ears of children who had concurrent adenoidectomy, the mean air conduction threshold was 14.6 dB HL. For those who had previous adenoidectomy, the mean air conduction threshold was 13 dB HL. For those who had no previous adenoidectomy, the mean air conduction threshold was 14.5 dB HL.

Discussion

Synopsis of key findings

The improvement in air conduction thresholds following bilateral ventilation tube insertion in our study is similar to that reported in a Cochrane meta-analysis.[1] Our study adds to

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information on the effect of tube function on air conduction thresholds and air–bone gaps at one, three and six months post-operatively.

The following points reflect the novel findings. First, prior to discharge on the day of operation, 32 per cent of ventilation tubes were non-functioning because of blood or ear 'glue'.

Second, at any post-operative visit (at one, three or six months), 21 per cent of ventilation tubes were non-functioning (range, 15–27 per cent). In approximately 30 per cent of ears, tube non-function was due to pus and in the rest it was a result of crusts. Spontaneous resolution of non-function occurred frequently (60 per cent from immediately post-operation to one month, 62 per cent from one month to three months, and 17 per cent from three months to six months).

Third, otoscopy under-diagnosed ventilation tube non-function by 22 per cent (8 of 36), if tympanometry is taken as the reference standard.

Fourth, the sensitivity of otoscopy to diagnose non-function due to blockage was 80 per cent and specificity was 99 per cent, if tympanometry is used as the gold standard.

Fifth, ears with non-functioning ventilation tubes had a significantly ($p = 0.0001$) poorer mean air conduction threshold compared with functioning tubes, with a magnitude of 6 dB. When ears with otorrhoea were excluded, this difference was reduced to 3.5 dB, but the finding was still statistically significant ($p = 0.043$).

Sixth, at any one visit, the air–bone gap was closed to 10 dB or lower in 76 per cent of ears (range, 64–80 per cent). Ventilation tube non-function reduced these percentages significantly, to 56 per cent ($p = 0.004$), with a range of 45–64 per cent, compared to 79 per cent (range, 67–85 per cent) of ears with functioning tubes that had an air–bone gap of 10 dB or lower. The presence of otorrhoea decreased this to 36 per cent (25–100 per cent). Ears with extruded tubes had an air–bone gap of 10 dB or lower in 82 per cent of cases (range, 71–100 per cent).

Seventh, when looking at the effect of adenoidectomy (comparing those who underwent concurrent adenoidectomy, those who had previously undergone adenoidectomy and those who had never undergone adenoidectomy), the ventilation tube function in ears of children who underwent concurrent adenoidectomy tended to be worse than in the other two groups (but this was not statistically significant). The mean hearing (air conduction threshold) was similar in all three groups.

Study strengths and weaknesses

This was a prospective study designed to describe the effect of a non-functioning ventilation tube on hearing in children with persistent bilateral otitis media with effusion (OME). Results of the air conduction threshold and air–bone gaps, reported to UK national guidelines, show clearly that non-functioning tubes have a significant detrimental effect on hearing in children with OME. The retention of patients in follow up was reasonable, with all children attending at least one follow-up appointment. The surgery was performed by trainees, but this is common in many countries. A minor weakness is the lack of power to show statistical differences in hearing between visits and in spontaneous resolution rates because of small numbers.

This study reports only one type of ventilation tube: the Reuter bobbin tube. However, there is no current evidence that the design or material of a ventilation tube has an impact on tube function.[6]

No drops were routinely used post-operatively to reduce post-operative otorrhoea. This could be viewed as a weakness; however, the Cochrane review by Syed *et al.*, published in 2013, concludes that 'the use of an intervention to prevent postoperative ear discharge should be restricted to those at a high risk of this discharge'.[7] At the outset, the presented cohort was not seen as a 'high risk' group according to the authors.

Comparison with other studies and reviews

Tube obstruction rates

In this study, the non-function rates are for fluoroplastic Reuter bobbin ventilation tubes. At three and six months, the rates of 15 per cent and 23 per cent are much higher than those reported in the study by Kay *et al.* in 2002, where the mean rate was 7 per cent.[2] Our rates are more in line with the Medical Research Council Trial of Alternative Regimens for Glue Ear Treatment data at three months, where the rate of non-function was 21 per cent (this trial did not differentiate blocked from extruded tubes, but one does not expect many to have been extruded at three months).[3]

Hearing with ventilation tubes

The hearing in children with ventilation tubes has been the subject of meta-analyses of randomised, controlled trials, by Rovers *et al.* in 2005[8] and Browning *et al.* in a Cochrane review in 2010.[1] To date, the only prospective study to report the combined non-function rate of blockage along with extrusion, controlled for time, is the Medical Research Council Trial of Alternative Regimens for Glue Ear Treatment trial.[3] Air conduction thresholds averaged between ears in children with functioning ventilation tubes in that trial were identical to this study at three months (both 12 dB HL). At six months, these thresholds were similar also (13 dB HL and 12 dB HL).

As yet, no study has reported the air–bone gaps according to the UK national guidelines; hence, no comparison can be made.

Effects of adenoidectomy on hearing

In 2012, the Medical Research Council Multicentre Otitis Media Study Group (Trial of Alternative Regimens for Glue Ear Treatment) analysed the effects of adenoidectomy on children undergoing ventilation tube insertion.[9] They showed that between three and six months' follow up, adenoidectomy did not add benefit to the hearing threshold provided by the ventilation tubes. The benefit (of magnitude 4.2 dB HL) was observed between one and two years following grommet insertion, where adenoidectomy had a positive effect on hearing once the ventilation tubes fell out. In our study similarly at one, three and six months, we found no difference in hearing or otorrhoea incidence in children who had previously undergone or were currently undergoing adenoidectomy, compared to those who had not undergone adenoidectomy.

Clinical implications

At present, specialist follow up of children with ventilation tubes, with the objective of identifying whether the ventilation tube is functioning and/or impacting on hearing, is not routine. Indeed, it is common practice in the UK and South

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Africa for children to be referred back to primary care, where the ability to carry out tympanometry and audiometry is not available.

The American Academy of Otolaryngology – Head and Neck Surgery has published 'Clinical practice guidelines: Tympanostomy tubes in children', but does not have a section advising on when and why follow-up visits are relevant. The only statement identified is in a sample Education Sheet for the parents, which states 'Routine follow-up with your doctor every 4 to 6 months is important to make sure your child's tubes are in place or to check for any possible problems'.[10] An earlier 2002 guideline[11] does suggest follow up 'usually performed within the first month', but is not referred to in subsequent articles.

Knowledge is lacking as to how to maintain the patency of ventilation tubes. A Cochrane systematic review to identify randomised, controlled trials that address this question is at the protocol stage (Verkerk *et al*., 2015).[12] An earlier review (Hellström *et al*., 2011)[6] could find no quality evidence for any method of prophylaxis against obstruction, but did not investigate methods of unblocking tubes. Topical instillation of hydrogen peroxide with or without micro-suction is common practice, but there is no evidence to support its efficacy. Blocked tubes can spontaneously clear, as was shown in this study. There are no studies investigating whether certain tubes are more inclined to obstruction or extrusion than others. Tube material, lumen diameter and length might play a role. Our tube non-function and extrusion rates (for Reuter bobbin tubes) were 21 per cent and 13 per cent (total of 34 per cent) at six months, whereas the Trial of Alternative Regimens for Glue Ear Treatment combined rate (for Shephard tubes) at the same time interval was 45 per cent.[3]

- The frequency of ventilation tube non-function is not well established; this study found a high frequency of non-function in the first six months post-operatively
- Non-functional ventilation tubes frequently regain function spontaneously
- Otoscopy underdiagnoses blocked ventilation tubes
- Hearing in ears with non-functioning tubes is worse than in functioning tubes, especially if infection is the cause
- The air–bone gap does not completely disappear after grommet insertion for otitis media with effusion, even in ears with patent tubes

Our results suggest the following: (1) the air–bone gap does not completely disappear after grommet insertion for OME, even in ears with functioning ventilation tubes; and (2) ears with non-functioning tubes have poorer hearing than those with functioning tubes. However, the difference of 3.5 dB (16 dB in ears with non-functioning but dry tubes, *vs* 12.5 dB in ears with functioning tubes) at six months is unlikely to be clinically significant. The hearing usually is still better than 20 dB HL and therefore does not warrant further intervention, unless this is due to otorrhoea or the recurrence of OME in both ears.

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Competing interests. None declared

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