Timing for Removal of Asymptomatic Long-Term Ventilation Tube in Children

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Abstract Otitis media with effusion (OME) is the most frequent illness in children. Surgical treatment options include ventilation tube insertion, adenoidectomy or both. Opinions regarding the risks, benefits and intubation period of ventilation tube insertion vary greatly. To determine the appropriate time for when to remove asymptomatic long-term ventilation T-tubes in children. In this prospective study, we analyzed the results of 120 pediatric patients (6–12 years) (240 ears) with persistent OME; we employed the Goode T-silicone tubes. We intentionally planned to remove the tubes at different time points of the study and divided our patients randomly into four subgroups with 30 patents (60 ears in each) according to the intubation period; group I: intubation for 6 months, group II: intubation for 12 months, group III: intubation for 18 months and group IV: intubation for 24 months. The relationship between intubation period and OME recurrence, the rate of persistent tympanic membrane (TM) perforation, granulation tissue or discharge near the tympanostomy tubes, normalization of Eustachian tube function and change of hearing level was analyzed in each patient group. The χ^2 analysis showed that the rate of normalization of ET function was significantly higher when tubes were removed after 12-months of intubation ($P = 0.002$), the rate of OME recurrence was significantly higher when tubes were removed before 12-months of intubation ($P = 0.004$). The rate of otorrhea significantly increased after 12-months of intubation, development of granulation around tubes was

significantly higher after 18-months of tube insertion. The rate of appearance of permanent TM perforation significantly increased after 18-months from tube insertion ($P = 0.008$). Adenoidectomy did not significantly influence the recurrence rate of OME or the rate of persistent TM perforation after tube removal. Our present results suggest that the appropriate intubation period for healing OME in children would be at 12–18 months. Also, we can conclude that longterm ventilation tubes are recommended to avoid repeated intubation and to obtain sufficient results, although their performance is not always satisfactory; mainly because of accompanying complications.

Keywords Otitis media with effusion · Ventilation tube · T-Tubes · Eustachian tube function test

Introduction

Otitis media with effusion (OME) is the most frequent illness in infants after upper airway infections [1] and is the most common cause of hearing impairment in school-age children. Both the high incidence and the high rate of spontaneous resolution suggest that the presence of OME is a natural phenomenon, its presence at some stage in childhood being a normal finding [2]. Notwithstanding this, some children with OME may go on to develop chronic otitis media with structural changes [tympanic membrane (TM) retraction pockets, erosion of portions of the ossicular chain and cholesteatoma], language delays and behavioral problems [2]. It remains uncertain whether or not any of these findings are direct consequences of OME. The most common medical treatment options for OME include the use of decongestants, mucolytics, steroids, antihistamines and antibiotics. The effectiveness of these

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therapies has not been established. Surgical treatment options include ventilation or tympanostomy tube insertion, adenoidectomy or both. Opinions regarding the risks and benefits of tympanostomy tube insertion vary greatly [2]. The management of OME therefore remains controversial.

The use of tympanostomy tubes as a treatment for OME was first introduced by Armstrong in 1954 [3] and has become one of the most common procedures performed on children [4]. The tube insertion relieves the symptoms of the effusion such as the conducting hearing loss and episodes of acute otitis media. The procedure is not without risk; the formation of granulation tissue, tube extrusion into the middle ear space, cholesteatoma formation, external otitis media and suppurative otitis media are some of the recognized complications [5, 6]. The closure of a perforation of the TM after tube extrusion occurs by migration of the squamous epithelial layer with the fibrous and mucosal layer following behind [7]. Failure of closure of the TM and creation of a persistent perforation is a well-recognized complication following use of long-term ventilation tubes [8]. The persistence of a perforation may result in the development of chronic suppurative otitis media which ultimately may require further surgery in the form of a tympanoplasty to close the defect.

The tubes are usually displaced naturally, except for types intended for long-term stay [9]. If a tube is removed too soon, OME is likely to recur, but if it is retained too long, the chances of complications become higher [5, 6]. When a tube does not displace spontaneously, the otorhinolaryngologist faces the difficult decision for when to remove the tube with no definite consensus regarding the optimal length of the intubation period. Few studies have addressed the indication of removal of asymptomatic T-tubes. The objective of this prospective study was to determine the appropriate time for when to remove asymptomatic T-tubes. The relationship between the intubation period; the recurrence rate of OME and complications 2ry to T-tubes application were addressed. Also we tried to assess the effect of T-tubes on the change of hearing and Eustachian tube (ET) function during the period of intubation.

Materials and Methods

In this prospective study, we analyzed the results of 120 pediatric patients (6–12 years) (240 ears) between January 2010 and January 2014 at Minia University Hospital, Minia, Egypt. There were 70 (58 %) male and 50 (42 %) female patients. The tubes employed were the Goode T-silicone tubes (I.D. 1.3 mm, length 4.75 mm, 1.14 lumen) (Medtronic Xomed, Inc). We included for the study patients with bilateral OME having the following criteria:

(1) continuous conductive hearing loss with ≥ 20 dB air-bone gap (ABG), (2) resistance to conservative therapy for over 3 months, and (3) retracted and glue-colored TM with type B tympanogram. We excluded from the study 40 patients who had one or more of the following exclusion criteria: (1) patients who didn't complete their follow-up visits, (2) patients with spontaneously extruded T-tubes, (3) patients developed continuous otorrhea not responding to medical treatment and needed early removal of the tubes, and (4) patients with craniofacial abnormalities such as cleft palate or with intelligence decline.

The preoperative evaluation was based on clinical history, clinical findings and an audiologic evaluation including audiometry and tympanometry. Equipment used was Zodiac 401 (Madsen-Zodiac 401, GN. Otometrics, Denmark) middle ear analyzer. The tympanograms were classified in the standard manner according to Jerger [10]. A tympanogram with middle ear pressure peak between +50 and –200 daPa was classified as type A in children. Tympanogram with middle ear pressure peak of –200 daPa or more negative was classified as type C. A tympanogram with a flattened peak of less than 0.3 ml admittance was classified as type B. All patients underwent pre and postoperative audiological evaluation including hearing threshold at 0.5, 1, 2 and 4 kHz. We reported the air-bone gap (ABG) as the four pure-tone average for air conduction minus the same average for bone conduction determined at the same time. The mean and standard deviation of the post-operative ABG and number of decibels of closure of the gap were reported according to the recommendations of the committee on hearing and equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss [11].

We assessed the ET function while patients had OME, while the T-tubes are in place and in patients with residual TM perforation through the modified inflation-deflation test [12] which evaluates both active and passive function of the ET. After removal of the tube and healing of the TM we used the Valsalva maneuver and Toynbee maneuvers [13] to evaluate the ET function.

All patients underwent tube placement under general anesthesia. Myringotomy was made at the anterior-inferior quadrant in the eardrum, and then the middle ear effusion was aspirated and a tube inserted. At the time of tube placement, adenoidectomy was performed in 50 (42 %) patients who presented with mouth breathing and hyponasalality and were found to have hypertrophic adenoids on X-ray analysis. We intentionally planned to remove the tubes at different time-points of the study and divided our patients randomly into four subgroups with 30 patients (60 ears in each) according to the intubation period; group I: intubation for 6 months, group II: intubation for 12 months, group III: intubation for 18 months and group

Table 1 Patients characteristics

	Group I: 30 (60 ears)	Group II: 30 (60 ears)	Group III: 30 (60 ears)	Group VI: 30 (60 ears)
Gender (male:female)	16:10	18:13	20:14	16:13
Mean age at intubation (years)	8.4	7.3	8.1	7.5
Air-bone gap (dB)	20–35	22–36	25–40	22–38
Patients with Adenoidectomy	12 (40 %)	15 (50 %)	13 (43 %)	10 (33 %)

IV: intubation for 24 months. All the tube removals were done under local anesthesia on an outpatient basis with direct microscopy by means of straight pick or alligator forceps.

Patients were followed with 1-month intervals after surgery. Patients were instructed to use earplugs in bathing or swimming. Patients who developed otorrhea after surgery were treated with ofloxacin ototopical drops and if the infection could not be controlled the tube was removed. When the tube was occluded with crusts, the crusts were removed using ear drops. Granulation that formed around the tube was removed as soon as possible. The condition of tubes, condition of TM, hearing level and ET function was recorded at each visit.

After the tubes were removed, the patients were followed to 6-months; during the period of follow-up, we reported the following: the TM perforation closure, OME recurrence, the ET function and hearing level. The criterion for recurrent OME was middle ear effusion resistance to conservative therapy over 3 months after re-accumulation of middle ear fluid. The criterion for residual TM perforation was persistent TM perforation for a 6-months period after tube removal. The relationship between intubation period and OME recurrence, the rate of persistent TM perforation, granulation tissue or discharge near the tympanostomy tubes, normalization of ET function and change of hearing level was analyzed in each patient group.

The study was approved by the Institutional Review Board at El-Minia University. The study involved no deviation from existing standard therapy for these patients and no new drugs, an explanation of the research was provided to each patient's parents and an individual consent was taken.

The Statistical Package for Social Science (SPSS) (Illinois, Chicago, USA) was used for data analysis. Mean, median, and SD were used to describe quantitative data. Qualitative data were summarized using frequency and percentage. The cut-off point for each comparison was set through logistic regression for statistical significance of the analyzed results and comparisons were made by Chi square test and Fisher's exact probability test. P values less than 0.05 were considered significant.

Fig. 1 Normalization of Eustachian tube function based on intubation period (n = 240 ears), the cut-off point was set as 12 months. X-axis shows the group of patients according to period of tube removal. Y-axis shows the rate of normalization of Eustachian tube function. Data are expressed as rate (%)

Results

Patients Characteristics (Table 1)

The mean age at the time of tube insertion was (8.4 years) for group I, 7.3 years for group II, 8.1 years for group III and 7.5 years in group IV with no statistical difference between the different groups regarding the age and sex distribution. Adenoidectomy was in 50 (42 %) patients, with no statistical difference regarding the distribution of patients who had adenoidectomy throughout different groups.

Change of Eustachian Tube Function

144 (60 %) ears had significantly better ET function tests at some time-point after tube insertion. The relationship between the normalization of ET function and the intubation period is shown in Fig. 1. The χ^2 analysis showed that the rate of normalization of ET function was higher when tubes were removed after, compared to before, 12-months from the date of insertion ($P = 0.002$). Using logistic regression, the cut-off point was set at 12-months. Adenoidectomy significantly influenced the rate of ET function normalization. 40 % of ears in patients with adenoidectomy had normal ET function compared to 20 % of ears of other patients at this cut-off time point ($P = 0.02$).

Fig. 2 Recurrence of OME based on intubation period ($n = 240$ ears), the cut-off point was set as 12 months. X-axis shows the group of patients according to period of tube removal. Y-axis shows the recurrence rate of OME. Data are expressed as rate (%)

Recurrence Rate of OME

60 (25 %) ears had recurrent OME at some time-point after removal of T-tubes. The relationship between the OME recurrence rate and the intubation period is shown in Fig. 2. The χ^2 analysis showed that the rate of chronic OME recurrence was higher when tubes were removed before, compared to after, 12-months from the date of insertion ($P = 0.004$). Using logistic regression, the cut-off point was set at 12-months. There was a tendency for the recurrence rate to decrease the longer the tube stayed in its position.

Adenoidectomy did not influence the recurrence rate of OME. The recurrence of OME occurred in 10 % ears in patients with adenoidectomy and 14.5 % of ears of other patients without adenoidectomy ($P = 0.1$).

Rate of Infection According to Intubation Duration

Infection near the tube was defined as discharge (otorrhea) or granulation tissue. 80 (33 %) ears had recurrent OM infection near T-tubes at some time-point after tube insertion. All these ears included in the study were managed promptly with local antibiotic drops with no need for early tube removal. Using a logistic regression test, the cut-off point was set at 12-months (Fig. 3). The rate of otorrhea significantly increased after 12-months of intubation ($P = 0.004$). Development of granulation around tubes was significantly higher after 18-months of tube insertion. Using a logistic regression test, the cut-off point was set at 18-months ($P = 0.003$).

Rate of Permanent TM Perforation According to Intubation Duration

66 (28 %) ears had permanent TM perforation in the last follow-up visit after the removal of T-tubes. The rate of permanent TM perforation was analyzed (Fig. 4), by

Fig. 3 Persistent TM perforation based on intubation period ($n = 240$ ears), the cut-off point was set as 12 months. X-axis shows the group of patients according to period of tube removal. Y-axis shows the rate of TM perforation. Data are expressed as rate (%)

Fig. 4 Infection (otorrhea and granulation tissue) around tubes based on intubation period ($n = 240$ ears), the cut-off point was set as 12 months with a significant increase in rate of otorrhea after 12-months and the cut-off point was set as 18 months. X-axis shows the group of patients according to period of tube removal. Y-axis shows the rate of infection. Data are expressed as rate (%)

logistic regression test the cut-off point was set at 18-months. The rate of appearance of permanent TM perforation significantly increased after 18-months from tube insertion ($P = 0.008$). Adenoidectomy did not influence the rate of permanent TM perforation.

Change of Conductive Hearing Loss According to Intubation Duration

In the initial audiological evaluation before tube insertion; we observed a minimum ABG of 20 dB and maximum of 40 dB in the whole study patients. At the final evaluation of all patients; we observed a minimum ABG of 10 dB and maximum of 30 dB (mean value of 15 dB), 220 (92 %) ears had improvement in their ABG ($P = 0.009$). 50 (22 %) ears with improved hearing still had ≥ 20 dB ABG. By logistic regression test, the cut-off point for improving ABG was set at 1-month after tube insertion. None of the patients showed sensorineural hearing loss. Adenoidectomy did not influence significantly the rate of hearing improvement.

Discussion

OME is one of the most common illnesses presented in Otolaryngology practice. Adult patients account for 0.6–2.7 % of all OME patients in outpatient practice [14, 15]. Approximately 80 % of children before school age experience chronic OME at least once [16]. Although chronic OME in children is a disease with the characteristic of spontaneous resolution, hearing impairment in childhood can have serious implications for an individual's social and intellectual development [17]. Insertion of a ventilation tube is the most common surgical procedure for treating OME in children resistant to conservative therapy. However, the indications for tube insertion should be strict, and unnecessary surgery should be avoided because accompanying complications sometimes occur during and after the tube placement [18]. Placed tubes are extruded by epithelial migration. However, a tube retained for a long time that fails to extrude naturally can cause infection, peritubal TM atrophy and permanent TM perforation [19]. Guidelines for placement of tympanostomy and intentional removal for problematic situations are relatively clear [20], but opinions on the appropriate duration of intubation vary [21–23] with no clear guidelines exist for the optimal time to remove asymptomatic tubes that do not cause any of the complications. Our prospective study was intended to provide a guideline based on clinical data for deciding when to remove the T-tubes. In this study, we classified our patients according to duration of intubation (from 6 to 24 months).

In our study it was clear that there was a significantly higher recurrence of OME when the tubes removed before 12-months of intubation, this can be explained by the possibility of insufficient mucosal recovery, loss of mucus glands, and pneumatization of the mastoid. Yaman et al. [24] studied 91 patients to determine the relationship between intubation period and OME recurrence rate and found recurrence rates of 36.5 % for intubations shorter than 6 months, 17.74 % for intubation of 6–12 months, and 9.1 % for intubation longer than 12 months. Iwaki et al. [25] reported that the recurrence rate drops after 12 months of intubation and OME is less likely to recur with longer durations.

The usefulness of adenoidectomy in controlling OME is quite a controversial subject. The dispute concerning the value of adenoidectomy as a therapeutic measure in OME has led to a number of studies. In some of these, there is no definitive proof of the usefulness of adenoidectomy in treating OME [26–29], whereas other investigators reported that the procedure was highly effective [30–34]. Nichols et al. [35] reported that patients with history of adenoidectomy had a higher incidence of TM perforation

after the tube extrusion, and they explained that by the possibility that patients who need adenoidectomy may have inherently worse ET function or middle ear disease, leading to a poor outcome after tube removal. In our study, Adenoidectomy did not influence the recurrence rate of OME nor the rate of persistent TM perforation after tube removal; however further investigation is necessary to clarify the relationship between the incidence of OME and nasopharyngeal infection.

If T-tubes are retained too long, infections may occur such as otorrhea and granulation tissue [36]. Otorrhea is a common complication that appears after intubation and is caused by immunization of the tympanostomy tube itself. The source of infection is the external auditory canal and is affected by many factors [37]. The causes of granulation tissue are a foreign body reaction to trapped squamous epithelium [38] or increased oxygen density in the middle ear [13]. In our study the otorrhea significantly increased after 12-months and granulation tissue formation after 18-months of intubation. Van Herrbeek [39] reported that otorrhea appeared in 53 % of patients and granulation tissue appeared in 6 % of patients with an average intubation period of 31.5 months. However, Moon et al. [40] reported that infection rate significantly increased after 18 months.

In our study the rate of permanent TM perforation significantly increased after 18-months from tube insertion which is shorter than the reported duration in the previous studies. Nichols et al. [35] reported a 40 % rate of TM perforation when intubation duration was longer than 36 months and a perforation rate of more than 19 % when intubation duration was shorter than 36 months. El Bitar [41] reported that the chance of permanent TM perforation increased if the inserted tube was retained more than 4-years and perforation is more likely in cases of intentional removal (14.3 %) than in cases of natural displacement (4.0 %). Permanent TM perforation is related to long intubation period created by a reverse growth of the outer surface epithelium towards the under-surface of the eardrum [42]. The reason for the difference in our study may be due to intentional removal that was performed too aggressively, or error caused by delayed intentional removal performed in other studies.

ET dysfunction has been considered the most important factor for the timing of the ventilation tube removal. However, it was reported that there was no relation between tubal function during the treatment with a ventilation tube and the healing of OME [43]. Furthermore, tubal function did not improve during the intubation period [44, 45] suggesting that the appropriate time for removal of the tube cannot be determined by the ET function test. In our study, patients had significantly better ET function during

the intubation period and the rate of normalization of ET function was higher when tubes were removed after, compared to before, 12-months from the date of insertion with a significant effect of adenoidectomy. This tubal function improvement in our study can be explained by the natural anatomic changes during growth and a maturity process of the neuro-muscular reflex system during the period of intubation and not due to the idea of intubation itself [46].

In our study, patients had significantly better hearing results compared to their pre-tube hearing levels with no significant additional results of adenoidectomy. However, some patients who had better hearing still had mild conductive hearing loss even after complete absence of middle ear effusion, healing of TM and restoration of normal ET function. In a multicenter otitis media study group [47], patients with ventilation tubes had partially alleviated conductive impairment, and they concluded that children with a functioning ventilation tube cannot be considered to have 'normal' hearing once the tube has extruded and ears that no longer have OME still have a small conductive hearing impairment but this improves with time. In the randomized controlled trials [2] that studied the effect of grommet insertion alone, the mean hearing levels improved by around 9 dB after the first 6 months, and 6 dB after 12 months, the additional effect of the adenoidectomy on hearing levels was improvement by 3–4 dB at 6-months and about 1–2 dB at 12-months, however, ears treated with ventilation tubes had an additional risk for tympanosclerosis of 0.33 1–5 years later which could explain the persistence of some degree of conductive hearing loss after well-functioning ventilation tubes.

A successful ventilation tube is one that requires the fewest intubations until spontaneous middle ear ventilation occurs [6]. In our study OME recurrence significantly increased when T-tubes were removed before 12-months of intubation. Intubation periods longer than 18-months showed significantly higher rates of infection and rates of permanent TM perforation.

Conclusion

Our present results suggest that the appropriate intubation period for healing OME in children would be at 12–18 months. Also, we can conclude that long-term ventilation tubes are recommended to avoid repeated intubation and to obtain sufficient results, although their performance is not always satisfactory; mainly because of accompanying complications.

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