
แพทยสมาคมแห่งประเทศไทย
ในพระบรมราชูปถัมภ์
Medical Association of Thailand
Under His Majesty the King's Patronage

Original Article

Extended Medium-term Middle Ear Ventilation Tube for Otitis Media with Effusion: A Randomized Controlled Trial

Patorn Piromchai MD, MSc, PhD, FRCOT, FICS[1], Ekkarit Somdee MD[1], Pattaramon Wijakkanalan MD, FRCOT[1], Supaporn Srirompotong MD, FRCOT[1]

[1] Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

Background: Otitis media with effusion is a frequent problem encountered in patients with craniofacial anomalies (i.e., cleft lip/palate). Tympanostomy with ventilation tube insertion is the treatment of choice in cases with effusion greater than 3 months or evidence of delayed speech and language development. In such cases, the middle ear ventilation tube needs to remain in the middle ear until the Eustachian tube has gained normal function. In the current study, we designed a new ventilation tube that would remain in the middle ear longer than the standard tube.

Objective: Our aim was to assess the retention duration, ventilation, and audiological function when using the new middle ear ventilation tube for otitis media with effusion.

Materials and Methods: Patients with otitis media with effusion who need a middle ear ventilation tube were recruited. In the control group, the standard ventilation tube was used while in the experimental group the new ventilation tube was used. The retention duration, types of tympanogram, hearing level, and complications data were collected.

Results: Fourteen males and six females between 29 to 60 years of age were enrolled in the present study. The respective average retention time of the ventilation tube in experimental and control group was 7 months and 4.6 months ($p = 0.052$). During follow-up, 9/10 tubes (90%) in the experimental group were functional vs. 6/10 in the control group (60%). The mean A-B gaps before tube insertion and at the last follow-up were better in the experimental group ($p = 0.062$).

Conclusions: The new extended medium-term middle ear ventilation tube can be used to treat otitis media with effusion in patients needing a longer retention period.

Keywords: Ventilation tube, Tympanostomy tube, Otitis media, Otitis media with effusion, Cleft palate

J Med Assoc Thai 2018; 101 (Suppl. 5): S47-S51
Full text. e-Journal: http://www.jmatonline.com

Language development begins early in life, but otitis media with effusion can delay speech and language development in children. Fluids, either serous or mucous, in the middle ear space can obstruct sound entering the ear.

Otitis media with effusion is commonly found in cleft palate patients[1]. The peak incidence of ear problems in cleft palate patients is between 2 and 6 years of age, and ear problems and below normal hearing can persist for many years. In nearly one-quarter of 12-year-old and older patients reported having some degree of hearing loss[2].

Watchful waiting is the usual recommendation for otitis media with effusion without a hearing problem. If the effusion has persisted more than 3 months, or there is documented deterioration of hearing, tympanostomy with middle ear ventilation tube insertion may be used.

As the disease nature of otitis media with effusion persists throughout the early life, some

Correspondence to:
Srirompotong S, Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand.
Phone: +66-85-0078922
Email: ssrirompotong@gmail.com

How to cite this article: Piromchai P, Somdee E, Wijakkanalan P, Srirompotong S. Extended medium-term middle ear ventilation tube for otitis media with effusion: a randomized controlled trial. J Med Assoc Thai 2018;101;Suppl. 5: S47-S51.

practitioners advocate the use of a long-term ventilation tube that can be held in place for more than one year. The reported hearing results were favorable and comparable to normal children, and the residual tympanic membrane perforation rate was also not significantly different from normal children[3,4].

At our institute, the grommet tube is usually inserted in cleft palate patients. We have, however, found that the tube frequently no longer functions after 6 months, and the Eustachian tube has not yet regained its function. As a consequence, the patient will need to undergo a myringotomy with re-insertion of a ventilation tube.

To prevent the problem of a re-insertion, we wanted to design a new grommet that would increase retention time. We knew that the new middle ear ventilation tube should survive in the middle ear longer than conventional ventilation tube. The current study assessed retention time, ventilation, and audiological function when using the new extended medium-term middle ear ventilation tube vs. the standard ventilation tube for otitis media with effusion.

Materials and Methods

New ventilation tube design

As the grommet-shaped ventilation tube is already familiar to the surgeon, the new ventilation tube was also based on the grommet shape. We modified the proportion of the grommet ventilation tube and increased the flange for longer retention. The size and proportion of the new extended medium-term ventilation tube was 1) tube total length 2.5 mm; 2) inner and outer flange diameter 2.5 mm; and 3) inner lumen diameter 1.14 mm.

After creation of each ventilation tube, the tube was quality controlled by the author under a microscope (Figure 1). The tubes were then sterilized with an ethylene flame before packaging.

Population

We included patients between 20 and 60 years presenting with persistent otitis media with effusion longer than 3 months. The study was conducted at the Otorhinolaryngology Department, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, between October 30, 2015 and March 31, 2017.

We excluded patients with (a) a history of tympanic membrane surgery, (b) no documentation of fluid in the middle ear after tympanostomy, (c) auditory canal stenosis, (d) Eustachian tube dysfunction, and/or (e) failure to performed tympanostomy.

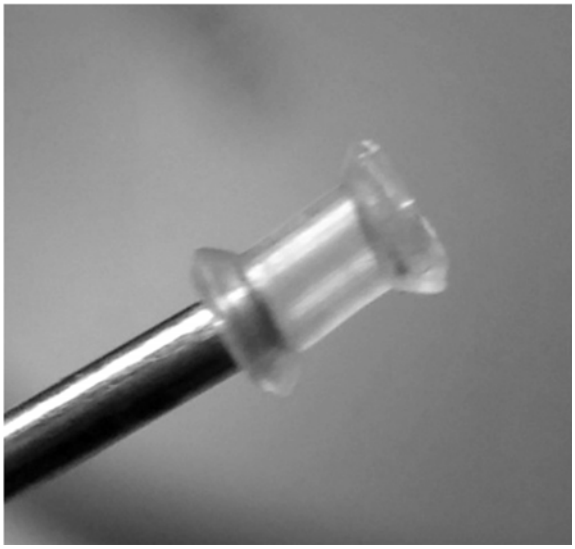

Figure 1. Microscopic view of the extended medium-term ventilation tube.

Ethical consideration

The research protocol was reviewed and approved by the Khon Kaen University Ethics Committee for Human Research (HE581301). Patients eligible for investigation were approached by the research assistant. The patients were given a detailed explanation about the research procedures and possible impacts of the study. Patients who agreed to participate gave written informed consent.

Randomization and procedures

The patients were then randomly allocated to receive the new extended medium-term ventilation tube or the standard ventilation tube. We selected the Donaldson ventilation tube as the standard ventilation tube because it is commonly used in our hospital.

The randomisation list was computer-generated by a statistician based on the block randomisation method and sealed in opaque, sequentially numbered envelopes.

All medical personnel in the operating room were not apprised of the patient group allocations. The patients were given local anesthesia before performing the operation. After the tympanostomy, the nurse opened the allocation envelope. The Donaldson tube or the new extended medium-term tube was inserted through the tympanic membrane according to the respective allocation received.

The position of the ventilation tube and

bleeding were checked. The patients were given ofloxacin ototopical antibiotics for one week.

Follow-up

The patients were followed-up 2 weeks after the operation and every 2 months for 1 year or until the ventilation tube was dislodged. Audiography and tympanography were performed at every 2-month visit.

Statistical analysis

Statistical analyses were performed using the SPSS version 20.0. Data were described as either means for the continuous variables or frequencies and percentages for the categorical variables. Significant differences between groups were determined using the Student t-test or the Mann-Whitney U test for continuous variables. The Chi-square test or the Fisher-exact test was used to determine whether there was a significant difference between the expected frequencies and the observed frequencies. For all tests, $p<0.05$ was considered statistically significant.

Results

There were 20 patients enrolled in the study. Ten patients received the new ventilation tube; while the balance received the standard tube.

There were 14 males and 6 females and age ranged between 29 and 60 years (average 48.5). The procedure duration, the hearing level, and affected ear were not statistically different between groups (Table 1).

The respective mean retention time of the new extended medium-term ventilation tube vs. the standard ventilation tube was 7 months vs. 4.6 months. There was no significant difference in mean survival time ($p = 0.052$). There was no significant difference in the level of hearing after the operation between groups ($p = 0.062$). There were no major complications (i.e., ventilation dislodge into the middle ear, ear infections, or sensorineural hearing loss) (Table 2).

Discussion

There were subgroups of otitis media with effusion that required longer retention time of ventilation tubes; namely, cleft palate, a congenital defect of the middle ear, and Eustachian tube dysfunction. In these two subgroups, the medium- or long-term middle ear ventilation tubes were usually used.

Based on the data in our hospital, the

Table 1. Demographic data

	New extended medium-term ventilation tube	Standard ventilation tube	*p*-value
Sex			
Male (%)	7	7	
Female (%)	3	3	
Age (mean)	49	48	0.93
Affect side			
Left ear	4	7	0.37
Right ear	6	3	
Procedure duration (min)	6.6	7.6	0.20
A-B gap of hearing level (dB)	23.3	20.9	0.38

Table 2. Retention time and hearing level

	New extended medium-term ventilation tube	Standard ventilation tube	*p*-value
Tube retention (months)	7	4.6	0.052[a]
Tube patency (months)	9	6	0.3[a]
A-B gap of hearing level (dB)	17.7	9.6	0.062[a]

[a] = Mann-Whitney U test

commercial medium-term ventilation tubes (i.e., the Armstrong, Paparella, and Donaldson) have retention times under 6 months. The long-term ventilation tube (i.e., the T-tube) was infrequently used for fear of permanent tympanic membrane perforation.

We thus proposed a new grommet design that should last longer in the middle ear. The principals of the design were to shorten the total length of the ventilation tube so as to decrease the torque and to increase its flexibility[5]. The inner flange should be greater than 2.5 mm in order to increase retention time. There was no clear benefit of the outer flange. However, it might help to prevent the tube from dislodging into the middle ear[6]. The inner diameter of the ventilation tube should be larger to improve ventilation.

We found that the standard Donaldson ventilation tube can survive for 4.6 months; while Gordts et al documented that the Donaldson ventilation tube can survive longer (11.3 months). This discrepancy might be due to differences in mucosal and epithelial function between adult and pediatric patients.

Our new extended medium-term ventilation tube can survive for 7 months which is comparable to the results of a systematic review by Hellstrom et al in which survival of an extended medium-term ventilation tube was between 8 and 24 months[7].

The polyethylene tube that we used to make this extended medium-term ventilation tube was inexpensive and easy to find. This design and material can be modified by hand as needed.

The current study was limited to adults, so the results might not be generalized to children even though the new grommet was designed for young children with otitis media with effusion and craniofacial anomaly. It was after discussion with the institutional ethical committee that we agreed to trial in adults first. The positive results suggest that we might conduct the trial in children.

Conclusion

The new extended medium-term middle ear ventilation tube can be used to treat otitis media in adult patients with effusion that needs longer retention.

What is already known on this topic?

Otitis media with effusion is commonly found in craniofacial anomaly patients.

Otitis media with effusion can cause hearing loss and delayed speech development.

Middle ear ventilation tube can drain the secretion from the middle ear.

What this study adds?

The new extended medium-term middle ear ventilation tube can be used to treat otitis media with effusion that needs longer retention.

Acknowledgements

The authors thank (a) the patients for their participation in the trial; (b) the staff at Srinagarind Hospital for their assistance; (c) the Center of Cleft Lip-Cleft Palate and Craniofacial Deformities, Khon Kaen University under Tawanchai Royal Grant Project for its support; and, (d) Mr. Bryan Roderick Hamman for assistance with the English-language presentation of the manuscript.

Financial support

This work was internally supported by the Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand.

Potential conflicts of interest

The authors declare no conflicts of interest.

References

1. Paradise JL, Bluestone CD, Felder H. The universality of otitis media in 50 infants with cleft palate. Pediatrics 1969;44:35-42.
2. Sheahan P, Miller I, Sheahan JN, Earley MJ, Blayney AW. Incidence and outcome of middle ear disease in cleft lip and/or cleft palate. Int J Pediatr Otorhinolaryngol 2003;67:785-93.
3. Valtonen H, Dietz A, Qvarnberg Y. Long-term clinical, audiologic, and radiologic outcomes in palate cleft children treated with early tympanostomy for otitis media with effusion: a controlled prospective study. Laryngoscope 2005;115:1512-6.
4. Gordts F, Clement PA, Derde MP. Lens tube vs Donaldson tube: results of a prospective study comparing a new with a conventional ventilation tube. Clin Otolaryngol Allied Sci 1993;18:410-4.
5. Vard JP, Kelly DJ, Blayney AW, Prendergast PJ. The influence of ventilation tube design on the magnitude of stress imposed at the implant/tympanic membrane interface. Med Eng Phys 2008;30:154-63.
6. Gui Q, Wang Z, Chen P. Retaining time of tympanic ventilation tube and aural complications. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi

2009;23:1027-9.
7. Hellstrom S, Groth A, Jorgensen F, Pettersson A, Ryding M, Uhlen I, et al. Ventilation tube treatment: a systematic review of the literature. Otolaryngol Head Neck Surg 2011;145:383-95.

ท่อปรับความดันในหูชั้นกลางระยะปานกลางถึงยาวสำหรับโรคหูน้ำหนวกชนิดมีน้ำคั่งในหูชั้นกลาง: การวิจัยแบบสุ่มที่มีกลุ่มควบคุม

ภาธร ภิรมย์ไชย, เอกฤทธิ์ สมดี, ภัทรมน วิจักขณาลัญฉ์, สุภาภรณ์ ศรีร่มโพธิ์ทอง

ภูมิหลัง: หูน้ำหนวกชนิดมีน้ำคั่งในหูชั้นกลางพบได้บ่อยในผู้ป่วยที่มีความผิดปกติของศีรษะและใบหน้า เช่น ผู้ป่วยปากแหว่ง เพดานโหว่ การเจาะแก้วหู และใส่ท่อปรับความดันเป็นการรักษาที่แนะนำในรายที่มีน้ำคั่งในหูมากกว่า 3 เดือนหรือมีพัฒนาการทางด้านการพูดและภาษาช้า ผู้ป่วยกลุ่มนี้ท่อปรับความดันควรจะอยู่ในหูชั้นกลางจนกว่าการทำงานของท่อยูสเตเชียนจะกลับมาเป็นปกติ ผู้นิพนธ์ได้ออกแบบท่อปรับความดันชนิดใหม่ โดยหวังว่าจะสามารถคงอยู่ในหูชั้นกลางได้ยาวนานกว่าท่อมาตรฐาน

วัตถุประสงค์: เพื่อประเมินการคงอยู่ความสามารถในการปรับความดันและการได้ยินของท่อปรับความดันในหูชั้นกลางระยะปานกลางถึงยาวชนิดใหม่สำหรับโรคหูน้ำหนวกชนิดมีน้ำคั่งในหูชั้นกลาง

วัสดุและวิธีการ: ผู้ป่วยโรคหูน้ำหนวกชนิดมีน้ำคั่งในหูชั้นกลางที่จำเป็นต้องได้รับการใส่ท่อปรับความดันในหูชั้นกลางจะได้รับการชักชวนเข้าร่วมการวิจัยในกลุ่มควบคุม ผู้ป่วยจะได้รับท่อปรับความดันมาตรฐาน ส่วนกลุ่มทดลองจะได้รับท่อปรับความดันชนิดใหม่ ผู้นิพนธ์บันทึกข้อมูลการคงอยู่ของท่อความสามารถในการปรับความดัน การได้ยินและผลข้างเคียงเพื่อเปรียบเทียบระหว่างสองกลุ่ม

ผลการศึกษา: ผู้ป่วยชาย 15 คนและหญิง 5 คน อายุระหว่าง 29 ถึง 60 ปีเข้าร่วมการศึกษานี้ อัตราการคงอยู่ของท่อปรับความดันชนิดใหม่เฉลี่ย 7 เดือน ส่วนท่อปรับความดันมาตรฐานมีอัตราการคงอยู่เฉลี่ย 4.6 เดือน (p = 0.052) เมื่อตรวจการทำงานของท่อพบว่า 9/10 คน ในกลุ่ม ท่อปรับความดันชนิดใหม่ยังปรับความดันได้ดี ส่วนในกลุ่มควบคุมมีเพียง 6/10 คนที่ยังปรับความดันได้ การได้ยินเปรียบเทียบก่อนใส่ท่อระบายและหลัง ใส่ท่อระบายดีขึ้นในกลุ่มใส่ท่อปรับความดันชนิดใหม่ (p = 0.062)

สรุป: ท่อปรับความดันชนิดใหม่สามารถใช้รักษาโรคหูน้ำหนวกชนิดมีน้ำคั่งในหูชั้นกลางที่ต้องการท่อปรับความดันที่คงอยู่ได้นาน