Preliminary Report

Outcome of Myringotomy with Ventilation Tube for Otitis Media with Effusion in Thai Children: Ramathibodi Experiences

Kunchitthape Tanpowpong MD*, Intuorn Saisukul MD*,
Hataikorn Kittimanont MSc**, Sasivimol Rattanasiri PhD***

** Department of Otolaryngology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University*
*** Department of Nursing, Faculty of Medicine, Ramathibodi Hospital, Mahidol University*
**** Clinical of Epidemiology Unit, Faculty of Medicine, Ramathibodi Hospital, Mahidol University*

Objective: *Study the otologic and audiologic outcome when using a ventilation tube (VT) for the treatment of otitis media with effusion (OME) in Thai children.*
Material and Method: *The medical records of twenty-three pediatric patients,17 male and 6 female, aged 4 to 11 (mean age of 6.8 years), with the diagnosis of OME who attended the Department of Otolaryngology, Faculty of Medicine Ramathibodi Hospital, between January 2001 and December 2006 were reviewed. Seventeen (73.9%) patients had associated diseases, 26% with allergic rhinitis (AR), 21.7% with obstructive sleep apnea from chronic hypertrophic tonsillitis and adenoid hypertrophy (OSA), and 26% with cleft palate (CP). The audiometric with tympanometric assessment were done pre- and post-operative with mean of 47.3 and 294.2 days respectively. All children were treated with myringotomy and insertion of VT. Oto-microscopic examinations for tympanic membrane pathologic abnormalities were confirmed. Post operative otorrhea cases were identified. The extrusion rates of VT were also recorded after the insertion.*
Results: *Twenty-three patients were enrolled in the present study. Mean air-bone gap was 18.24 (SD = 13.04) and 10.83 (SD = 8.26) before and after the operation respectively, and the difference was statistically significant (p = 0.0013). This could be interpreted that myringotomy with insertion VT could improve hearing by decreasing the air-bone gap dB. Having assessed the effect of associated diseases (i.e., AR, OSA, and CP) on differences of air-bone gap between before and after operation, the authors found that having AR, OSA, and CP did not statistically affect the results of the operation. However, the mean differences of air-bone gap between before and after operation were quite different for AR versus non-AR (-11.58 vs. -5.78), and OSA versus the non-OSA group (-12.10 vs. -5.95). This might have the effects of the two factors but with this small sample size and thus low power could not detect the effect. Tympanometric pattern was mainly type B in the pre-operative (79.3%) and post operative (62.5%) period after tympanic membrane closure in both ears. Mucoid fluid in the middle ear cavity of both ears was detected during the operation in all patients. Post operative otorrhoea occurred in 16.7%.The mean of extrusion rate of VT was 307.2 $\pm$ 204.7 days with maximum of 760 days. The mean duration of OME before surgery was 384.1 days.*
Conclusion: *The effects of conventional VT in Thai children with OME could improve statistical significant hearing by decreasing the air-bone gap. The associated diseases (i.e., AR, OSA, and CP) did not statistically affect the results of the operation.*

Keywords: *Otitis media with effusion, Myringotomy, Ventilation tube*

J Med Assoc Thai 2007; 90 (9): 1866-71
Full text. e-Journal: *http://www.medassocthai.org/journal*

Correspondence to : Tanpowpong K, Department of Otolaryngology, Faculty of Medicine Ramathibodi Hospital, Mahidol University, 270 Rama VI Rd, Ratchathevi, Bangkok 10400, Thailand. Phone: 0-2201-1051, Fax: 0-2354-7233, E-mail: raktp @mahidol.ac.th

Otitis media with effusion (OME) is defined as middle ear effusion without signs or symptoms of an acute infection. OME may occur as a primary disorder or as a sequalae to acute otitis media. OME or 'glue ear' and is very common in children, especially between the age of one and three years with a prevalence of 10% to 30% and a cumulative incidence of 80% at the age of four years[1]. Oto-microscopy seems to have the potential to become the standard for diagnosis of OME and for validation of pneumatic otoscopy in children. Type B tympanograms were accepted as positive results for ears with effusion. However, when otoscopic, oto-microscopic findings and tympanogram of the suspected ear show poor correlation, myringotomy can be used to confirm the presence of OME, as the diagnostic modality. The functional effect of OME is a conductive hearing level of about 25 to 30 dB associated with fluid in the middle ear[2]. 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[3]. Some children with OME may go on to chronic otitis media with structural changes (tympanic membrane retraction pockets, erosion of portions of the ossicular chain and cholesteatoma), language delays, and behavioral problems. It remains uncertain whether any of these findings are direct consequences of OME[4]. Surgical treatment options include grommet (ventilation or tympanostomy tube, VT) insertion, adenoidectomy or both. Opinions regarding the risks and benefits of grommet insertion vary greatly. The insertion of VT is one of the most common surgical procedures performed in children. These children are under significant oxidative stress. Insertion of a ventilation tube and adenoidectomy significantly decreased the oxidative stress in these patients, but could not normalize it completely[5]. In the present report, the effects of conventional ventilation tubes in Thai children with OME were studied.

Material and Method

The complete medical records of pediatric patients with a diagnosis of OME who attended at Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, between January 2001 and December 2006 were reviewed. The diagnosis of OME was made on the basis of the clinical criteria at the Department of Otolaryngology and confirmed by audiometry and tympanometry at the Audiology Service. The present study was reviewed and received approval from the Institutional Ethics Review Committee. It included 23 children (17 male and 6 female) whose ages ranged from 4 years through 11 years with a mean age of 6.8 years. The residential area of the children in Bangkok and the suburbs (Nonthaburi, Samutprakarn, Pathumthani, and Chachoensao) was 62.5%, and that in other provinces was 37.5%. Seventeen (73.9%) patients had associated diseases: six (26%) had cleft palate (CP), five (21.7%) had obstructive sleep apnea (OSA) from chronic hypertrophic tonsillitis and adenoid hypertrophy, and six (26%) had allergic rhinitis (AR). There were no children with gastroesophageal reflux and Down's syndrome. The mean duration of OME before surgery was 384.1 days.

All children from whom informed consents were obtained were treated with myringotomy and insertion of VT. The operations were performed under general anesthesia. The ear canals were cleaned with tincture of merthiolate. Myringotomy was done at the infero-anterior quadrant of the tympanic membranes by using surgical oto-microscope, and VT was inserted. The VT was made from sterilized medical grade polyethylene tubes that were easily available and cost-effective. The middle ear fluid was aspirated and assessed for quality and type. Adenoidectomy and/or tonsillectomy were done in children with signs and symptoms of OSA. Mean duration for admission was 2 days.

All patients were followed up and oto-microscopic examinations for tympanic membrane pathologic abnormalities were recorded at each visit. Pure-tone average audiometric thresholds with tympanometric assessment were done once for comparison with preoperative status. The audiometric with tympanometric assessment were done pre- and post operative with mean of 47.3 and 294.2 days respectively. Post operative otorrhea cases were identified. The extrusion rates of the VT were recorded after insertion.

Statistical analysis

Mean $\pm$ SD (or median and range where appropriated) and frequency (%) were used to describe continuous and categorical data, respectively. Two-factor ANOVA with repeated measures on both factors, which were time (before and after operation) and ear sides (left and right), were used to compare the difference of air-bone gap between before and after operation. Regression analysis was applied to assess the effects of associated diseases (i.e., AR, OSA, and CP) on differences of air-bone gap between before and after operation. All analyses were performed using STATA version 9.20. p-value less than 0.05 were statically significant.

Results

Twenty-three patients were enrolled in the present study. Air-bone gap between before and after operation were described and compared using repeated measurement ANOVA, Table 1. Mean air-bone gap was 18.24 (SD = 13.04) and 10.83 (SD = 8.26) for before and after operation, respectively, and the difference was statistically significant (p = 0.0013). This could be interpreted that myringotomy with insertion VT could improve hearing by decreasing the air-bone gap dB.

The authors further questioned whether associated diseases (i.e., AR, OSA, and CP) affected improving hearing (i.e., decreased air-bone gap) after operation. These factors were separately fitted in the regression model and found that having AR, OSA, and CP or not did not statistically affect the results of the operation, as described in Table 2. However, the mean differences of air-bone gap between before and after operation were quite different for AR versus non-AR (-11.58 vs. -5.78), and OSA versus non-OSA group (-12.10 vs. -5.95). This might have the effects of the two factors but with this small sample size and thus low power could not detect the effect.

Oto-microscopic findings during the operation showed mucoid fluid in the middle ear cavity of both ears of all patients (23). Hearing evaluation by audiometry before and after VT insertion showed hearing loss of three worst heard frequencies between 250 and 4000 Hz. Tympanometric pattern was mainly type B in pre-operative (79.3%) and post operative (62.5%) period after tympanic membrane closure in both ears (Table 3).

Post operative otorrhoea (discharge) was the most common complication with a reported incidence in four cases (17.4%). Only one of those cases developed persistent discharge, and the other three cases had ear discharge after operation with a mean of 73.7 days. No serious otologic complications were found in the present study. There were no anesthetic and operative complications. The mean $\pm$ SD of actual extrusion rate of VT for all, AR, non-AR, OSA, non-OSA, CP, and non-CP patients was 307.2 $\pm$ 204.7, 279.7 $\pm$ 195.4, 316.4 $\pm$ 212.4, 339.8 $\pm$ 195.9, 298.6 $\pm$ 211.3, 129.8 $\pm$ 70.2, and 366.3 $\pm$ 201.1 days respectively, with a maximum of 760 days.

Table 1. Comparison of air-bone gap between before and after operation (n = 23)

Condition	Air - bone gap*		p-value
	Before	After	
All	18.24 (13.04)	10.83 (8.26)	0.0013
AR	19.83 (10.58)	8.25 (9.10)	0.0140
Non-AR	17.68 (13.91)	11.74 (7.89)	0.0274
OSA	19.70 (12.08)	7.60 (8.07)	0.0463
Non-OSA	17.83 (13.43)	11.72 (8.20)	0.0151
CP	22.92 (10.69)	15.33 (9.18)	0.0655
Non -CP	16.59 (13.53)	9.24 (7.42)	0.0105

* mean $\pm$ (standard deviation) of pure-tone average audiometric thresholds in dB

Table 2. Mean difference between before and after operation of air-bone gap and associated p-values of regression analysis (n = 23)

Condition	Mean difference (95%CI)	p-value*
AR		
Yes	-11.58 (-20.00, -3.17)	0.600
No	-5.78 (-10.73, -0.82)	
OSA		
Yes	-12.10 (-24.56, 0.36)	0.600
No	-5.95 (-10.52, -1.38)	
CP		
Yes	-7.58 (-16.26, 1.10)	0.219
No	-7.11 (-12.26, -1.96)	

* adjusting for side of ears and status of operation

Table 3. Types of pre-operative (Pre-op) and post-operative (Post-op) tympanograms after tympanic membrane closure in both ears (n = 23)

Tympanogram types	Rt		Lt	
	Pre-op	Post-op	Pre-op	Post-op
A	1	0	4	4
B	19	19	17	16
C	3	4	2	3

Discussion

The myringotomy with insertion VT could improve hearing by decreasing the air-bone gap dB in Thai Children with OME. A strong recommendation for clinicians is to use pneumatic otoscopy as the primary diagnostic method to distinguish OME from acute otitis media (AOM). Tympanometry and/or reflectance spectroscopy are also promising when used for the diagnosis of OME [6]. If OME persists for 8 to 12 weeks,

bilateral myringotomy and VT placement with short-term tubes will improve hearing and help resolve OME after AOM in children less than 2 years of age[7]. To prevent later developmental impairments, myringotomy with the insertion of the VT has often been undertaken in young children who have persistent OME. If delayed insertion of the VT in children with persistent effusion who are younger than three years of age does not result in improved developmental outcomes at three or four years of age, prompt insertion of the VT will not improve developmental outcomes at six years of age[8-10]. Ventilation tubes might be used in young children that grow up in an environment with a high infection load (for example, children attending day-care), or in older children with a hearing level of 25 dB HL or greater in both ears persisting for at least 12 weeks[11].

Young children treated with the VT due to persistent OME have a higher risk of developing otorrhoea because of the tubes, and they have a higher risk of needing treatment with antibiotics. There is a variety of causes of otorrhea in children. The most important factor in reaching the proper diagnosis and providing relief of the problem is aural toilet. Once adequate cleaning has been performed, the diagnosis is usually clearer, and treatment with oto-topicals is significantly more effective. Clinicians considering antibiotic treatment need to balance any potential benefit against the risks of side effects and antibiotic resistance[12]. Intra-operative saline irrigation of the middle ear provides an effective, easy, and cheap treatment in preventing postoperative purulent otorrhea[13]. The elevated hearing thresholds and tympanic membrane pathologic abnormalities were more common in the VT subjects 6 to 10 years after insertion. In healthy children who have persistent OME during their first 3 years of life, to myringotomy with the insertion of the VT results in far more tympanic membrane abnormalities at age 5 than does selective management in which most children do not receive the procedure. However, hearing levels at age 6 do not differ[14]. The prognosis of children with cleft palate treated with early tympanostomy is favorable and does not differ from children without a cleft palate[15].

Combined pneumococcal conjugate and polysaccharide vaccination does not prevent the recurrence of OME among children 2 to 8 years of age previously known to have persistent OME. Receipt of PncCRM vaccine in infancy is associated with a reduction in VT placement from 2 to 4-5 years of age [16]. Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present or significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. When a child becomes a surgical candidate, the VT insertion is the preferred initial procedure[17,18].

Conclusion

The difference of mean air-bone gap before and after operations in Thai children with OME was statistical significant. This could be interpreted that myringotomy with insertion VT could improve hearing by decreasing the air-bone gap dB.

The associated diseases (i.e., AR, OSA, and CP) did not statistically affect the results of the operation. Tympanometric pattern was mainly type B in pre-operative and post operative period after tympanic membrane closure in both ears. Post operative otorrhoea (discharge) was the most common complication. The actual extrusion rate of VT was presented.

References

1. Rosenfeld RM, Culpepper L, Doyle KJ, Grundfast KM, Hoberman A, Kenna MA, et al. Clinical practice guideline: otitis media with effusion. Otolaryngol Head Neck Surg 2004; 130(5 Suppl): S95-118.
2. Straetemans M, van Heerbeek N, Schilder AG, Feuth T, Rijkers GT, Zielhuis GA. Eustachian tube function before recurrence of otitis media with effusion. Arch Otolaryngol Head Neck Surg 2005; 131: 118-23.
3. Lous J, Burton MJ, Felding JU, Ovesen T, Rovers MM, Williamson I. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. Cochrane Database Syst Rev 2005; 1: CD001801.
4. Witsell DL, Stewart MG, Monsell EM, Hadley JA, Terrell JE, Yueh B, at al. The Cooperative Outcomes Group for ENT: a multicenter prospective cohort study on the outcomes of tympanostomy tubes for children with otitis media. Otolaryngol Head Neck Surg 2005; 132: 180-8.
5. Hammaren-Malmi S, Saxen H, Tarkkanen J, Mattila PS. Adenoidectomy does not significantly reduce the incidence of otitis media in conjunction with the insertion of tympanostomy tubes in children who are younger than 4 years: a randomized trial. Pediatrics 2005; 116: 185-9.
6. Sundberg M, Peebo M, Oberg PA, Lundquist PG, Stromberg T. Diffuse reflectance spectroscopy of the human tympanic membrane in otitis media.

Physiol Meas 2004; 25: 1473-83.
7. American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. Pediatrics 2004; 113: 1412-29.
8. Paradise JL, Campbell TF, Dollaghan CA, Feldman HM, Bernard BS, Colborn DK, et al. Developmental outcomes after early or delayed insertion of tympanostomy tubes. N Engl J Med 2005; 353: 576-86.
9. Paradise JL, Dollaghan CA, Campbell TF, Feldman HM, Bernard BS, Colborn DK, et al. Otitis media and tympanostomy tube insertion during the first three years of life: developmental outcomes at the age of four years. Pediatrics 2003; 112: 265-77.
10. Paradise JL, Feldman HM, Campbell TF, Dollaghan CA, Colborn DK, Bernard BS, et al. Early versus delayed insertion of tympanostomy tubes for persistent otitis media: developmental outcomes at the age of three years in relation to prerandomization illness patterns and hearing levels. Pediatr Infect Dis J 2003; 22: 309-14.
11. Rovers MM, Black N, Browning GG, Maw R, Zielhuis GA, Haggard MP. Grommets in otitis media with effusion: an individual patient data meta-analysis. Arch Dis Child 2005; 90: 480-5.
12. Ford-Jones EL, Friedberg J, McGeer A, Simpson K, Croxford R, Willey B, et al. Microbiologic findings and risk factors for antimicrobial resistance at myringotomy for tympanostomy tube placement - a prospective study of 601 children in Toronto. Int J Pediatr Otorhinolaryngol 2002; 66: 227-42.
13. Kocaturk S, Yardimci S, Yildirim A, Incesulu A. Preventive therapy for postoperative purulent otorrhea after ventilation tube insertion. Am J Otolaryngol 2005; 26: 123-7.
14. Johnston LC, Feldman HM, Paradise JL, Bernard BS, Colborn DK, Casselbrant ML, et al. Tympanic membrane abnormalities and hearing levels at the ages of 5 and 6 years in relation to persistent otitis media and tympanostomy tube insertion in the first 3 years of life: a prospective study incorporating a randomized clinical trial. Pediatrics 2004; 114: e58-e67.
15. 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.
16. van Heerbeek N, Straetemans M, Wiertsema SP, Ingels KJ, Rijkers GT, Schilder AG, et al. Effect of combined pneumococcal conjugate and polysaccharide vaccination on recurrent otitis media with effusion. Pediatrics 2006; 117: 603-8.
17. Hartman M, Rovers MM, Ingels K, Zielhuis GA, Severens JL, van der Wilt GJ. Economic evaluation of ventilation tubes in otitis media with effusion. Arch Otolaryngol Head Neck Surg 2001; 127: 1471-6.
18. Medical Research Council Multicentre Otitis Media Study Group. Surgery for persistent otitis media with effusion: generalizability of results from the UK trial (TARGET). Trial of Alternative Regimens in Glue Ear Treatment. Clin Otolaryngol Allied Sci 2001; 26: 417-24.

ผลของการเจาะแก้วหูและใส่ท่อระบายเพื่อรักษาโรคหูชั้นกลางอักเสบ ชนิดที่มีของเหลวขังอยู่ในเด็กไทย: ประสบการณ์จากคณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

ครรชิตเทพ ตั้นเผ่าพงษ์, อินทุอร สายสกุล, หทัยกร กิตติมานนท์, ศศิวิมล รัตนสิริ

วัตถุประสงค์: *ผลกระทบต่อหูและการรับฟังเสียงภายหลังการเจาะแก้วหูและใส่ท่อระบายเพื่อรักษาโรคหูชั้นกลางอักเสบชนิดที่มีของเหลวขังอยู่ในเด็กไทย*

วัสดุและวิธีการ: *เป็นการศึกษาทบทวนเวชระเบียนผู้ป่วยเด็กโรคหูชั้นกลางอักเสบชนิดที่มีของเหลวขังอยู่ 23 ราย ชาย 17 ราย หญิง 6 ราย อายุ 4-11 ปี เฉลี่ย 6.8 ปี ณ ภาควิชาโสต ศอ นาสิกวิทยา คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล ระหว่างมกราคม พ.ศ. 2544 ถึงธันวาคม พ.ศ. 2549 ผู้ป่วยมีโรคอื่นร่วมร้อยละ 70.8 โรคภูมิแพ้ช่องจมูกร้อยละ 25 ภาวะหยุดหายใจขณะนอนหลับเนื่องจากต่อมทอนซิล / อดีนอยด์โตร้อยละ 20.8 และเพดานโหว่ร้อยละ 25 เด็กมีอาการของโรคหูชั้นกลางอักเสบชนิดที่มีของเหลวขังอยู่ก่อนทำการผ่าตัดเป็นระยะเวลาเฉลี่ย 384.1 วัน ทุกรายได้รับการเจาะแก้วหูและใส่ท่อระบาย ตรวจความดันหูชั้นกลางด้วย tympanometer ตรวจการได้ยินด้วย audiometer ทั้งก่อนและหลังผ่าตัดเป็นระยะเวลาเฉลี่ย 47.3 วันและ 294.2 วันตามลำดับ ส่องตรวจหูด้วยกล้องจุลทรรศน์ขณะผ่าตัด บันทึกจำนวนผู้ป่วยที่มีของเหลวไหลจากหูชั้นกลางและบันทึกอัตราการหลุดออกของท่อระบายหลังผ่าตัด*

ผลการศึกษา: *จากจำนวนผู้ป่วย 23 ราย พบว่าผลต่างของค่าเฉลี่ย $\pm$ ค่าเบี่ยงเบนมาตรฐาน ของการได้ยินเสียงผ่านอากาศและกระดูกก่อนและหลังผ่าตัดเท่ากับ 18.24 $\pm$13.04 และ 10.83 $\pm$ 8.26 ซึ่งมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.0013$) แสดงว่าการเจาะแก้วหูและใส่ท่อระบายทำให้การได้ยินดีขึ้น ผู้ป่วยซึ่งมีโรคอื่น ๆ ร่วมด้วย ได้แก่ โรคภูมิแพ้ช่องจมูก ภาวะหยุดหายใจขณะนอนหลับเนื่องจากต่อมทอนซิล / อดีนอยด์โต และภาวะเพดานโหว่ พบว่าไม่มีผลต่อการผ่าตัดอย่างมีนัยสำคัญทางสถิติ อย่างไรก็ตามผลการศึกษาพบว่าค่าเฉลี่ยของการได้ยินเสียงผ่านอากาศและกระดูกก่อนและหลังผ่าตัดในกลุ่มผู้ป่วยโรคภูมิแพ้ช่องจมูกและไม่เป็นโรคนี้เท่ากับ -11.58 และ -5.78 และกลุ่มภาวะหยุดหายใจขณะนอนหลับเนื่องจากต่อมทอนซิล / อดีนอยด์โตและไม่มีภาวะนี้เท่ากับ -12.10 และ -5.95 ตามลำดับ แต่เนื่องจากขนาดตัวอย่างมีจำนวนน้อยจึงไม่สามารถพบความแตกต่างอย่างมีนัยสำคัญทางสถิติได้ ส่วนผลการตรวจความดันหูชั้นกลางเป็นชนิดบี ก่อนผ่าตัดร้อยละ 79.3 และหลังผ่าตัดร้อยละ 62.5 ในหูทั้งสองข้าง ตรวจพบของเหลวชนิดมูกจากหูชั้นกลางในผู้ป่วยทุกรายและพบของเหลวไหลจากหูชั้นกลางหลังผ่าตัดร้อยละ 16.7 ระยะเวลาเฉลี่ยของการหลุดออกของท่อระบายเท่ากับ 307.2 $\pm$ 204.7 วันและนานที่สุด 760 วันหลังผ่าตัด*

สรุป: *การเจาะแก้วหูและใส่ท่อระบายเพื่อรักษาโรคหูชั้นกลางอักเสบชนิดที่มีของเหลวขังอยู่ในเด็กไทย ทำให้การได้ยินดีขึ้นอย่างมีนัยสำคัญทางสถิติ ส่วนผู้ป่วยซึ่งมีโรคอื่น ๆ ร่วมด้วย ได้แก่ โรคภูมิแพ้ช่องจมูก ภาวะหยุดหายใจขณะนอนหลับ เนื่องจากต่อมทอนซิล / อดีนอยด์โต และภาวะเพดานโหว่ ไม่มีผลต่อการผ่าตัดอย่างมีนัยสำคัญทางสถิติ*