

# Audiologic Outcomes after Myringotomy with Pressure Equalizing Tube Insertion in Cleft Palate Children with Otitis Media with Effusion

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**Objectives:** To examine: 1) the audiology outcomes in cleft palate patients with otitis media with effusion (OME) after myringotomy with pressure equalizing tube (PE tube), 2) the extrusion time of the PE tubes, and 3) the recurrence of the disease.

**Material and Method:** Study population were patients with cleft palate who received treatment in a multidisciplinary program "Smart Smile & Speech Project" at Srinagarind Hospital from January 1, 2006 to December 31, 2009. Retrospective chart review was conducted to identify patients with OME who had received treatment by myringotomy with PE tube at least one year or more before the time of study. Thirty-six patients (69 ears) were enrolled in the study. The patient's parents or caregiver(s) were contacted by telephone call or mail for a patient's follow-up of hearing evaluation. The audiology outcomes before and after myringotomy with PE tube were compared.

**Results:** The results of the hearing, comparing before and after myringotomy with PE tube at least 1 year, were found improvement in 11 ears (16%). The hearing did not improve in 58 ears (84%) all due to extrusion of the PE tube prior to the time of study (69/69, 100%). Recurrence of the disease was observed in 30 patients (84%). Persistent tympanic membrane perforation with chronic otorrhea was found in 7 ears (10%).

**Conclusion:** After at least 1 year of myringotomy with PE tube, the audiology outcomes in the patients of cleft palate with OME did not improve and additionally a high recurrence rate was observed.

**Keywords:** Otitis media with effusion, Secretory otitis media, Tympanostomy tube insertions, Myringotomy, Cleft palate, Audiometry, Audiology

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Cleft palate is a common congenital anomaly. The incidence in the United States was 1 in 700 births<sup>(1)</sup>, and in Thailand the incidence in Srinagarind Hospital was reported at 1.1 in 1,000 births<sup>(2)</sup>. A common problem found in this group of patients is otitis media with effusion (OME). This condition is due to abnormality of the tensor veli palatini muscle resulting in dysfunction of eustachian tube and conductive hearing loss, in which these may affect the development of speech and language. The incidence of OME in cleft palate children has been reported at 92-97%<sup>(3)</sup>. The current recommendation for OME in this group of children who are at risk for delayed speech and language is to do a myringotomy and insertion of a pressure-equalizing (PE) tube. The surgery is recommended because the occurrence of OME in cleft

palate patients is at a younger age, longer duration and more repetitive than normal children<sup>(4,5)</sup>. Srinagarind hospital has participated in the "Smart smile and speech project" which is a collaboration of the Ministry of Health, Thai Red Cross Society and National Health Security Office of Thailand. All cleft palate patients in this project would undergo surgery to correct the deformities and restore speech function. A hearing test will be performed prior to cleft palate surgery, and if OME is found, myringotomy and insertion of a PE tube will be performed at the same time as cleft palate surgery. The results of treatment in the previous studies were controversial, with better speech and hearing in the myringotomy with PE tube insertion groups compared to the controls, but no differences were found in some studies<sup>(6)</sup>. This present study focused at the treatments in the "Smart smile and speech project" and information from the study will help to improve the quality of care in cleft palate with OME patients. The objectives were therefore to evaluate the audiology outcomes of the patients after myringotomy with PE tube insertion, the

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**Table 1.** Reasons for exclusion of the cleft palate patients

Exclusion criteria	No. (%)
Hearing test was not performed before myringotomy	60 (46.9)
Hearing test was performed but incomplete data	24 (18.6)
Hearing test was performed but myringotomy with PE tube was not performed	28 (21.9)
Having other congenital anomalies	5 (3.9)
Having autism or global delayed development or Down's syndrome	4 (3.1)
Tympanometry has no OME	7 (5.5)
Total	128

extrusion rates and recurrence of OME.

### Material and Method

A retrospective cohort study was conducted with patients in the "Smart smile and speech project" in Srinagarind Hospital from June 1, 2006 to December 31, 2009 who had received myringotomy with PE tube insertion for at least one year. All patients used the same type of tube with different appropriately selected lengths, i.e., a polyethylene tube with one sided flange produced by the operative unit of Srinagarind Hospital. None of the cases were given commercial tubes due to reimbursement restrictions. The caregivers of the patients were contacted by telephone calls or mails to bring the patient back for an ear and audiology examination. Exclusion criteria were patients with other congenital anomalies or those with incomplete data. The patients were evaluated by otoscopic examination, tympanometry and audiometry both before and after myringotomy with PE tube insertion. The audiometry comprised of visual reinforced audiometry or conditioned play audiometry of conventional audiometry which depended on the age of the patient. The definition of improvement in hearing was that the audiology results was within normal limits or had no air-bone gap; whilst worsened hearing meant the audiologic results was abnormal limits or having an air-bone gap or a physical examination revealed OME. The criteria of hearing in children were; 10-15 dB was normal hearing; 16-25 dB was slight hearing loss; 26-40 dB was mild hearing loss; 41-55 dB was moderate hearing loss; 71-90 dB was severe hearing loss; and more than 91 dB was profound hearing loss<sup>(7)</sup>. The duration until tube extrusion, recurrence rate and complications of myringotomy and PE tube insertion were also recorded.

### Results

There were 183 patients registered in the "Smart smile and speech project" in Srinagarind

Hospital during June 1, 2006 to December 31, 2009. Fifty-five patients were included whilst 128 patients had to be excluded due to reasons in Table 1.

There were 55 eligible patients, all of which were contacted by telephone call. Those, who did not respond via phone calls, were sent an invitation to participate in the study through mails. In all, 32 patients agreed to come back for audiology testing. Twenty-nine patients had audiology testing, two of which were uncooperative thus were unable to test and one withdrew from the study (Fig. 1). Thirty-six patients (69 affected ears) had complete data, accounting for 17 males and 19 females. Average age was 4 years and 9 months (range 2 years and 8 months to 12 years and 5 months). Five subjects had cleft palate, cleft palate and unilateral cleft lip and seven had cleft palate and bilateral cleft lip. All participants had received palatoplasty and cleft lip repair.

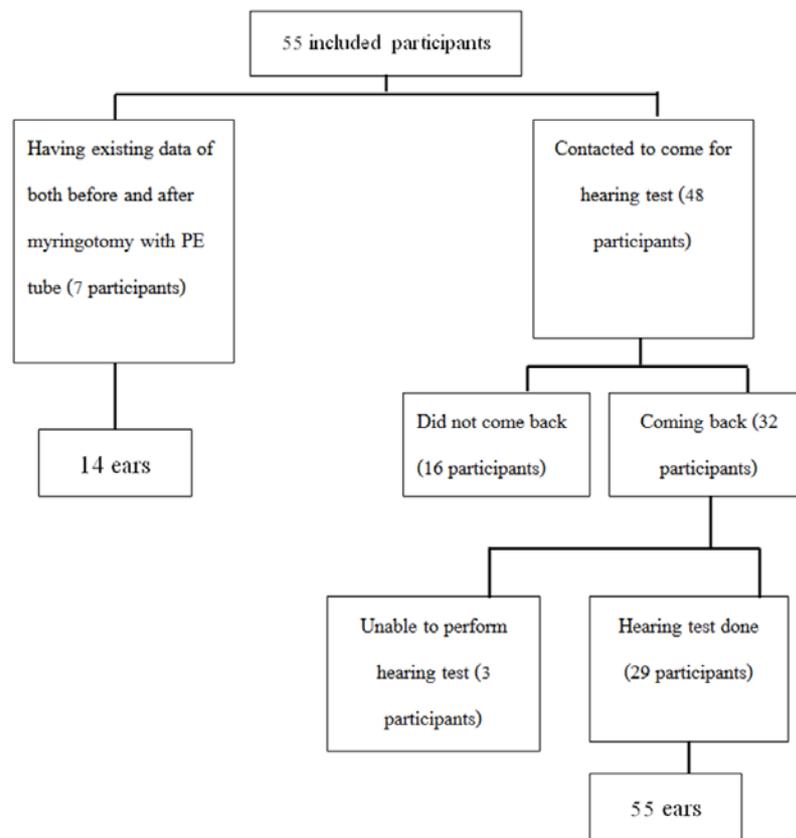
Most of the subjects (48 affected ears, 70%) had moderate hearing loss prior to myringotomy with PE tube, 48 affected ears (Table 2).

The average time gap between the pre and post myringotomy with PE tube was 2 years and 4 months. The shortest duration was 1 year and 1 month and the longest duration was 5 years and 9 months.

The audiology outcomes improved in 11 ears (16%) and did not improve in 58 ears (84%). The most common type of tympanometry was type B which was found before myringotomy with PE tube in 65 ears and after surgery 58 ears (Table 3).

There were 58 ears (84%) that hearing did not improve. In this group when compared before and after surgery, the hearing level changed to better hearing level in 21 ears (36%), worsened hearing level in 4 ears (7%) and unchanged in 33 ears (57%) as shown in Table 4.

There were post-operative complications in 9 ears (13%) with the most common was tympanic membrane perforation with chronic otorrhea (7 ears,



**Fig. 1** Flow of included participants.

**Table 2.** Hearing loss prior to myringotomy with PE tube

Hearing level	Ears (n)	%
Normal hearing loss	0	0
Slight hearing loss	2	3
Mild hearing loss	14	20
Moderate hearing loss	48	70
Moderately severe hearing loss	3	4
Severe hearing loss	2	3
Profound hearing loss	0	0
Total	69	100

10%), followed by tympanosclerosis (2 ears, 3%). We were unable to determine the time of PE tube extrusion due to insufficient data from the patients records. However upon otoscopic examination after undergoing myringotomy with PE tube for at least one year, we found that 61 ears (88%) did not have any remaining PE tubes and 8 ears (12%) had dislodged PE tubes. Thirty patients (84%) had persisting OME after PE tube extrusion, in which 2 patients (7%) underwent a second

operation and still had persisting OME.

### Discussion

Otitis media with effusion (OME) is a common problem in cleft palate patients, resulting in conductive hearing loss which may affect speech and language development. Management of OME is still controversial. Myringotomy with insertion of pressure equalizing tubes has been recommended in order to improve hearing thresholds and to achieve speech and language milestones in this at risk population. In this present study, we found that hearing was improved in only 16% and did not in 84%. These results differed from Hubbard et al and Liu et al which showed an improvement in hearing<sup>(5)</sup>.

The possible explanation for unimproved audiologic outcomes at post-surgery was the obstructed or dislodged of the tube which were found in the majority of the case in this present study. In the patients with cleft palate, the abnormality of the tensor veli palatini muscles was found, resulting in eustachian dysfunction and thus persistence of otitis media with

**Table 3.** Tympanometry before and after myringotomy with PE tube

	Tympanometry type			Total
	A	B	C	
Before myringotomy with PE tube	0	65	4	69
After myringotomy with PE tube	9	58	2	69

**Table 4.** Hearing levels before and after myringotomy with PE tube in the group that hearing did not improve

	Hearing level before myringotomy with PE tube	Hearing level after myringotomy with PE tube	No. of ears (%)
Better	Moderate hearing loss	Slight hearing loss	1 (2)
	Moderate hearing loss	Mild hearing loss	15 (26)
	Moderately severe hearing loss	Mild hearing loss	1 (2)
	Moderately severe hearing loss	Moderate hearing loss	2 (3)
	Severe hearing loss	Moderate hearing loss	2 (3)
Worsened	Mild hearing loss	Moderate hearing loss	4 (7)
Unchanged	Moderate hearing loss	Moderate hearing loss	33 (57)
Total			58 (100)

effusion after absence of the ventilation tube.

Robson et al<sup>(8)</sup> and Valtonen et al<sup>(9)</sup> found no significant differences between the groups that did or did not have myringotomy with PE tube. In the aspect of hearing and speech development of the patients undergoing this procedure, results are still controversial. A systematic review conducted by Ponduri et al<sup>(6)</sup> with 18 reviewed studies showed that most studies had small sample sizes and some studies showed benefits whilst the others did not. Furthermore the cases had complications from the procedure.

The complication rate in this study was 13%, tympanic perforation with chronic otorrhea (10%) was the most common complication. One study had a complication rate of 47% whilst other studies had a perforation rate from 9-16%<sup>(8-12)</sup>.

Although the authors were unable to determine the time of PE dislodgement, it was found at one year that 84% (30/36) of the patients had recurrent OME and only two cases (7%) had done a repeated procedure (because the caregivers did not agree with the repeated surgery). Comparing with the study by Tanpaopong et al<sup>(11)</sup>, their PE tubes remained 307.2±204.7 days with the longest duration was 760 days, and the repeated procedure rate by Sheahan et al<sup>(13)</sup> was 38%. Due to the high recurrent rate found in the present study, we suggest to consider the type of the PE tube, in which a longer sustainability should be

selected.

The limitation of this present study was that not all cases in the “Smart Smile & Speech Project” could be included in the study. A majority of the cases did not receive preoperative hearing tests (33%, 60 of 183 patients), and there were also those who had a hearing test but did not undergo myringotomy. This might have been because of the constrained audiology services. Despite the efforts of the multidisciplinary team; with the burden of governmental services, the hospital was unable to provide a one stop service. The different clinics that a patient and the caregivers have to visit for all necessary assessments, e.g. surgery, ear nose and throat, dental and speech pathology, does become a burden for the caregiver when they have to come to the hospital for several visits, especially for low socioeconomic families. However we assessed the patient’s long term post-operative results of the pressure equalizing tube insertion.

This information can be used as baseline data to improve health care for cleft palate patients who are at risk of having hearing, speech and language and learning problems. Further studies to create a care plan for patients in the context of a developing country should be conducted.

## Conclusion

The hearing levels of the cleft palate patients

who had myringotomy with PE tube after at least one year did not improve and there was a high recurrence rate. The risk of complications such as chronic otorrhea and tympanic membrane perforation and possible repeated surgery should be considered and advised to the caregivers.

#### **What is already known on this topic?**

Cleft palate children with OME are at risk for delayed speech and language development due to hearing loss. However, the improvement of speech and hearing after the procedure was reported to be better in some studies and some showed no improvement.

#### **What this study adds?**

This study showed that at one year after myringotomy with pressure equalizing tube the hearing levels in cleft palate patients did not improve and there was a high recurrence rate of OME. These results should be considered in the planning of care for cleft palate patients.

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#### **Potential conflicts of interest**

None.

#### **References**

1. Vanderas AP. Incidence of cleft lip, cleft palate, and cleft lip and palate among races: a review. *Cleft Palate J* 1987; 24: 216-25.
2. Ratanasiri T. The birth incidence of cleft lip and palate at Srinagarind Hospital, 1990-1999. *Srinagarind Med J* 2001; 16: 3-7.
3. Grant HR, Quiney RE, Mercer DM, Lodge S. Cleft palate and glue ear. *Arch Dis Child* 1988; 63: 176-9.
4. Schonweiler R, Schonweiler B, Schmelzeisen R. Hearing capacity and speech production in 417 children with facial cleft abnormalities. *HNO* 1994; 42: 691-6.
5. 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.
6. Ponduri S, Bradley R, Ellis PE, Brookes ST, Sandy JR, Ness AR. The management of otitis media with early routine insertion of grommets in children with cleft palate-a systematic review. *Cleft Palate Craniofac J* 2009; 46: 30-8.
7. Clark JG. Uses and abuses of hearing loss classification. *ASHA* 1981; 23: 493-500.
8. Robson AK, Blanshard JD, Jones K, Albery EH, Smith IM, Maw AR. A conservative approach to the management of otitis media with effusion in cleft palate children. *J Laryngol Otol* 1992; 106: 788-92.
9. 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.
10. Szabo C, Langevin K, Schoem S, Mabry K. Treatment of persistent middle ear effusion in cleft palate patients. *Int J Pediatr Otorhinolaryngol* 2010; 74: 874-7.
11. Tanpowpong K, Saisukul I, Kittimanont H, Rattanasiri S. Outcome of myringotomy with ventilation tube for otitis media with effusion in Thai children: Ramathibodi experiences. *J Med Assoc Thai* 2007; 90: 1866-71.
12. Kwan WM, Abdullah VJ, Liu K, van Hasselt CA, Tong MC. Otitis media with effusion and hearing loss in Chinese children with cleft lip and palate. *Cleft Palate Craniofac J* 2011; 48: 684-9.
13. 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.

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ผลลัพธ์เกี่ยวกับการไต่ถามหลังการผ่าตัดเจาะแก้วหูและใส่ท่อปรับความดันในเด็กเพดานโหว่ที่มีภาวะหูชั้นกลางอักเสบชนิดมีน้ำขัง

สุวรรณธ เลาศิริวิงศ์, วรพล กรมขุนทด, ชีรพร รัตนาเอนกชัย, พนิดา ธนาวิรัตนานิจ

วัตถุประสงค์: เพื่อศึกษาถึง 1) ผลของการไต่ถามในเด็กปากแหว่งเพดานโหว่ที่มีภาวะหูชั้นกลางอักเสบชนิดมีน้ำขัง หลังการเจาะแก้วหูพร้อมใส่ท่อปรับความดัน 2) เพื่อศึกษาถึงระยะเวลาที่ท่อปรับความดันหลุด 3) การกลับเป็นซ้ำของโรค

วัสดุและวิธีการ: ทำการศึกษาในผู้ป่วยเด็กปากแหว่งเพดานโหว่ที่มีภาวะหูชั้นกลางอักเสบชนิดมีน้ำขังที่เข้าร่วมโครงการ “ยิ้มสวย เสียงใส” ในโรงพยาบาลศรีนครินทร์ ตั้งแต่วันที่ 1 มิถุนายน พ.ศ. 2549 ถึง 31 ธันวาคม พ.ศ. 2552 นำข้อมูลเวชระเบียนผู้ป่วยมาทบทวนและค้นหาวินิจฉัยรายใดที่ได้รับการรักษาโดยการรับการเจาะแก้วหูพร้อมใส่ท่อปรับความดันไปแล้วอย่างน้อย 1 ปี ผู้ป่วยที่เข้าเกณฑ์การศึกษา 36 คน (หู 69 ข้าง) จากนั้นทำการส่งจดหมายหรือโทรศัพท์ถึงผู้ปกครองให้พาผู้ป่วยกลับมาตรวจหู และส่งตรวจการไต่ถามเปรียบเทียบผลการตรวจก่อนและหลัง ทำการเจาะแก้วหูพร้อมใส่ท่อปรับความดัน

ผลการศึกษา: ผลการตรวจการไต่ถามเปรียบเทียบก่อนและหลังทำการเจาะแก้วหูพร้อมใส่ท่อปรับความดันไปแล้วอย่างน้อย 1 ปี พบว่ามีการไต่ถามดีขึ้น มีจำนวน 11 ข้าง (ร้อยละ 16) ส่วนการไต่ถามไม่ดีขึ้น 58 ข้าง (ร้อยละ 84) เนื่องจากจำนวนหูทั้งหมด 69 ข้าง มีท่อปรับความดันหลุดไปแล้วหรือไม่อยู่ในตำแหน่งที่จะทำหน้าที่ระบายของเหลวในหูชั้นกลางได้ ในวันที่กลับมาตรวจการไต่ถามหลังการเจาะแก้วหูพร้อมใส่ท่อปรับความดัน การกลับเป็นซ้ำของโรค 30 คน (ร้อยละ 84) ภาวะแทรกซ้อนที่พบคือ แก้วหูทะลุและมีน้ำจากหูชั้นกลางเรื้อรัง 7 ข้าง (ร้อยละ 10)

สรุป: ผลลัพธ์ของการไต่ถามในผู้ป่วยปากแหว่งเพดานโหว่ที่มีหูชั้นกลางอักเสบชนิดมีน้ำขังหลังการเจาะแก้วหูพร้อมใส่ท่อปรับความดันแล้วอย่างน้อย 1 ปี ส่วนใหญ่ผลการไต่ถามไม่ดีขึ้นและมีอัตราการกลับเป็นซ้ำของโรคที่สูง

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