

Time for Eustachian Tube Function Recovery in Children with Cleft Palate after the 2-Flap Palatoplasty with Intravelarveloplasty

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Objective: Evaluate the clinical outcomes regarding the time needed for Eustachian tube recovery and evaluate associated factors for the recovery in children with cleft palate undergoing primary 2-flap palatoplasty with intravelarveloplasty at Srinagarind Hospital.

Material and Method: This was a retrospective descriptive study of 82 consecutive non-syndromic cleft palate patients with/without cleft lip, who underwent primary palatoplasty at Srinagarind Hospital between January 2007 and December 2010. Demographic data were collected including sex, cleft type, age of palatoplasty, operating surgeon, type of tympanogram, oronasal fistula, ventilation tube insertion, age of ventilation tube insertion, and number of ventilation tube insertion.

Results: Forty-five boys and 37 girls were included in the study for a total sample of 82 patients. The majority of cleft types was Veau IIIb (37.8%), followed by Veau IV (21.95%), Veau IIIa (20.73%), Veau I (9.76%), and Veau II (9.76%). Mean age of palatoplasty was 11.4 months (range, 9-23). There were three plastic surgeons and plastic surgery residents. The average time for Eustachian tube recovery was 37.5 months. Oronasal fistula was 15.9%. Ventilation tube insertion was 58.5% (one time: 40.2%, two and three times: 18.3%). Average age of ventilation tube insertion was 16 months (range, 9-64). There was no statistically significant difference in sex, age of palatoplasty, operating surgeon, ventilation tube insertion, or number of ventilation tube insertions in Eustachian tube recovery, but there was a statistically significant difference in cleft type, oronasal fistula, and mean age for ventilation tube insertion in Eustachian tube recovery.

Conclusion: The median recovery time for Eustachian tube function after primary 2-flap palatoplasty with intravelarveloplasty at Srinagarind Hospital was 37.5 months. Eustachian tube recovery was associated with severity of cleft types, oronasal fistula formation, and age of ventilation tube insertion.

Keywords: Two flaps palatoplasty, Intravelarveloplasty, Eustachian tube dysfunction, Otitis media with effusion, Cleft palate, Oronasal fistula

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Cleft lip and cleft palate represent the most common congenital anomalies^(1,2), 1.51 in 1,000 in Thailand⁽³⁾. The goals of palatoplasty are complete and intact closure of the palate resulting avoidance of palatal fistula, restoration of the velopharyngeal sphincter for development of normal speech, good maxillary growth and Eustachian tube function, improvement of the otitis media with effusion (OME), and normal hearing^(4,5). Patients with cleft palate have loose insertion of the tensor veli palatini muscle with the palate with

consequent decreased tension in opening the Eustachian tube⁽⁶⁾ resulting in Eustachian tube dysfunction and OME. Patients with OME have conductive hearing loss^(7,8), abnormal and delayed speech, delayed language, and learning and psychosocial development problems^(9,10).

The Eustachian tube is an important organ that is predicted to improve after palatoplasty. The literature remains ambiguous about the recovery time to Eustachian tube function in children after cleft palate repair. Two flap palatoplasty with intravelarveloplasty is commonly used in cleft palate repair with the hypothesis that intravelarveloplasty can rearrange the palate muscles such that Eustachian tube function can be improved. However, some studies have reported that palatoplasty did not improve Eustachian tube

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function. Srinagarind Hospital, Khon Kaen principally performs 2-flap palatoplasty with intravelarveloplasty. Therefore, it can report retrospectively on the recovery time to Eustachian tube function in children with cleft palate after this procedure.

Objective

To study recovery time to Eustachian tube function in children with cleft palate after 2-flap palatoplasty with intravelarveloplasty.

Material and Method

Setting

Srinagarind Hospital, Khon Kaen University.

Population

Medical records between 2007 and 2010 of patients who underwent primary palatoplasty.

Study design

Retrospective, descriptive study.

Statistics

Survival analysis of the data was done to determine recovery time to Eustachian tube function plus a Cox regression analysis for associated factors.

Ethic consideration

The study design was reviewed and approved by the Committee for Human Research, Khon Kaen University (HE581250).

Demographic data

Demographic data included sex, age of palatoplasty, type of cleft palate (Veau classification), operating surgeons, pre/post-operative tympanogram, ventilation tube (VT) insertion, age of VT insertion, number of VT insertion and oronasal fistula (ONF) were obtained from medical records.

Oronasal fistula

Oronasal fistula was defined as a patency between the oral and nasal cavities caused by failure of healing or a breakdown in the primary surgical repair of the palate. Intentionally unrepaired lingual-alveolar and labial-alveolar fistulas were not included in the condition.

Eustachian tube function assessment

Tympanometry

Type A = normal Eustachian tube function

Type B, C = abnormal Eustachian tube function

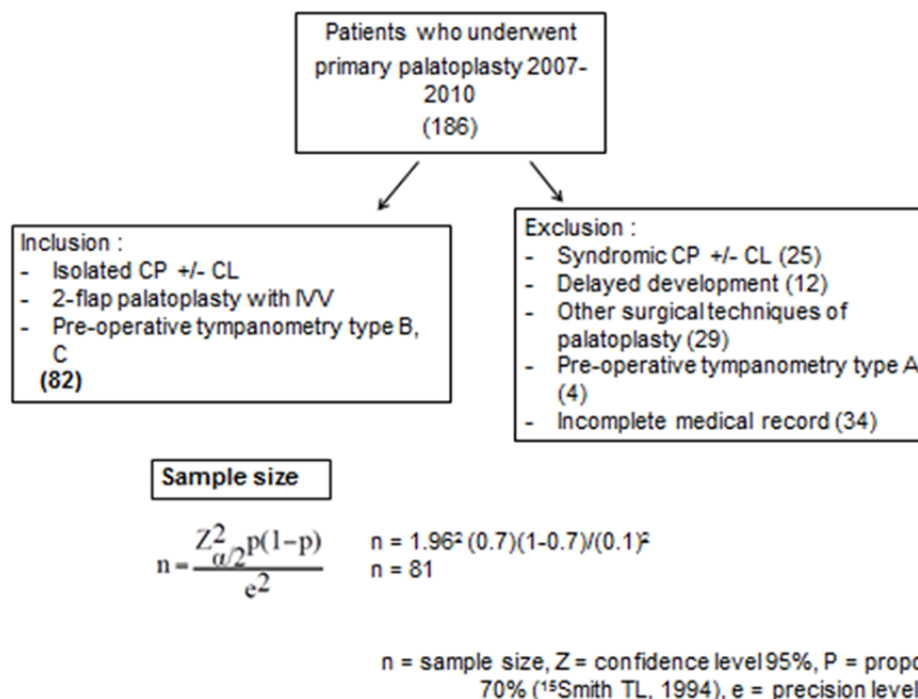


Fig. 1 Sample size calculation, including inclusion and exclusion criteria.

We included the patients with abnormal preoperative tympanogram (Type B, C) and followed-up until they had their first post-operative tympanogram type A; meaning that their Eustachian tubes had recovered.

Results

Demographic characteristics of the patients

Over half of males (53.3%) experienced

Eustachian tube recovery vs. 48.7% of females. A respective 75%, 25%, 47%, 48% and 61% of patients with Veau type I, II, IIIa, IIIb, and IV experienced Eustachian tube recovery. Mean age at surgery in the recovered group was 11.5 months (SD 1.99). The first surgeons had a post-operative recovery rate of 52.9%, the second 44.5%, the third 50%, and the fourth 45.7%. Half of patients (52.2%) who did not have ONF experienced Eustachian tube recovery while 38.5% with

Table 1. Treatment protocol

Age	Management
0-3 months	Presurgical orthopedics Otoscope examination (BOA/Tym)
3-4 months	Primary cleft lip repair Otoscope examination and treatment (BOA/Tym)
4-9 months	Otoscope examination and treatment (BOA/VRA/Tym)
9-12 months	Primary palatoplasty Myringotomy + VT if indicated
1-4 years	Annual otoscopic examination (VRA/Tym/audiometry) Speech therapy Fistula closure
4-6 years	Secondary cleft lip nose correction VPI surgery Annual otoscopic examination (VRA/Tym/audiometry) Speech assessment and speech therapy Dental evaluation, orthodontic treatment
6-9 years	Secondary cleft lip nose correction VPI surgery Annual otoscopic examination (audiometry) Speech therapy Orthodontic management

From: Center of Cleft Lip-Cleft Palate and Craniofacial Deformities, Khon Kaen University in Association with the Tawanchai Project, Tawanchai Cleft Center

Table 2. Veau classification system

Veau I	Cleft soft palate
Veau II	Hard and soft cleft palate
Veau III	Soft and hard palates and unilateral cleft of the primary palate
Veau IV	Soft and hard palates and bilateral clefts of the primary palate

John. Plastic Reconstructive Surgery. 2008⁽⁴⁾

Table 3. Demographic and clinical characteristics of patients with cleft palate with/without cleft lip who underwent primary palatoplasty

Cleft types (Veau classification)	
Veau I (soft palate)	8 (9.8%)
Veau II (soft and hard palate)	8 (9.8%)
Veau IIIa (Soft and hard palate and Rt. unilateral pre-palatal cleft)	17 (20.7%)
Veau IIIb (Soft and hard palate and Lt. unilateral pre-palatal cleft)	31 (37.8%)
Veau IV (Soft and hard palate and bilateral pre-palatal cleft)	18 (22.0%)
Operating surgeon	
Surgeon 1	34 (41.5%)
Surgeon 2	9 (11.0%)
Surgeon 3	4 (6.1%)
Surgeon 4	35 (42.7%)
No ONF	69 (84.3%)
ONF	13 (15.9%)
Veau I	0 (0%)
Veau II	2 (15.4%)
Veau IIIa	2 (15.4%)
Veau IIIb	4 (30.8%)
Veau IV	5 (38.5%)
VT insertion	48 (58.5%)
1 time	33 (40.2%)
2 and 3 times	15 (18.3%)
Average age of VT insertion (range), months	16 (9-64)
Preoperative tympanogram	
Type B	75 (91.5%)
Type C	7 (8.5%)
Eustachian tube function	
Recovery	42 (51.2%)
Tympanogram type C→A	6 (88.7%)
Tympanogram type B→A	36 (5%)
Not recovered	40 (48.8%)
Average recovery of Eustachian tube	37.5 months
Hearing status	
Normal hearing	45 (54.9%)
Conductive hearing loss	35 (42.7%)
Sensorineural hearing loss	2 (2.4%)

VT = ventilation tube, ONF = oronasal fistula

Table 4. Number and percentage of recovery rate by each factors

	Not recovered (%)	Recovered (%)	Total (%)
Sex			
Male	21 (46.7)	24 (53.3)	45 (54.9)
Female	19 (51.4)	18 (48.7)	37 (45.1)
Type of CP			
Veau I	2 (25.0)	6 (75.0)	8 (9.8)
Veau II	6 (75.0)	2 (25.0)	8 (9.8)
Veau IIIa	9 (52.9)	8 (47.1)	17 (20.7)
Veau IIIb	16 (51.6)	15 (48.4)	31 (37.8)
Veau IV	7 (38.9)	11 (61.1)	18 (22.0)
Mean age at surgery (SD) (month)	11.38 (2.9)	11.50 (2.0)	11.44 (2.5)
Operating surgeon			
Surgeon 1	16 (47.1)	18 (53.0)	34 (41.5)
Surgeon 2	5 (55.6)	4 (44.5)	9 (11.0)
Surgeon 3	2 (50.0)	2 (50.0)	4 (6.1)
Surgeon 4	19 (54.3)	16 (45.7)	35 (42.7)
ONF			
No ONF	33 (47.8)	36 (52.2)	69 (84.2)
ONF	8 (61.5)	5 (38.5)	13 (15.9)
Mean age at VT insertion (months)	19.33 (14.1)	13.38 (4.0)	16.04 (10.2)
Number of VT insertion			
1 time	17 (51.5)	16 (48.5)	33 (40.2)
2 and 3 times	5 (33.3)	10 (66.7)	15 (17.8)
VT insertion			
No	18 (52.9)	16 (47.1)	34 (41.5)
Yes	22 (45.8)	26 (54.2)	48 (58.5)

Table 5. Sensitivity analysis for crude hazard ratio and 95% confidence interval

Factors	Crude hazard ratio (95% CI)	<i>p</i> -value
Females vs. males	0.91 (0.49, 1.70)	0.768
Mean age at palatoplasty (months)	1.08 (0.95, 1.22)	0.251
Operating surgeons	0.96 (0.52, 1.61)	0.698
VT insertion	0.78 (0.35, 1.76)	0.436
Number of VT insertion		0.064
1 time	0.77 (0.41, 1.47)	
2 and 3 times	0.95 (0.46, 1.95)	

ONF did. Mean age at VT insertion in the recovered group was 13.38 months. Nearly half (48.5%) of patients who underwent VT insertion once experienced Eustachian tube recovery while 66.6% of those who underwent the procedure two or three times experienced recovery.

The difference between Eustachian tube recovery between males and females was not statistically significant albeit female recovery was nominally lower (p -value = 0.768). When palatoplasty

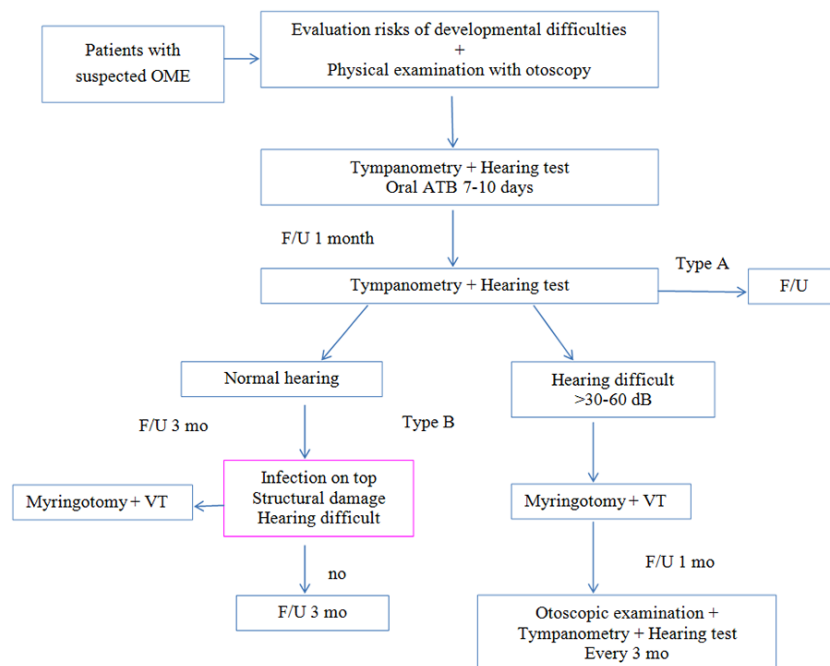
was performed in children over 11.5 months, Eustachian recovery trended to increase but again not a statistically significant finding (p -value = 0.251). There was no statistically significant difference among operating surgeons in Eustachian recovery (p -value = 0.698). The patients receiving ventilation tube insertions trended to decrease the recovery rate but not significantly (p -value = 0.436). The number of ventilation tube insertions had no statistically significant impact on recovery (p -value = 0.064).

Table 6. Adjusted hazard ratio and 95% confidence interval for mean recovery time

Factor	Adjusted hazard ratio (95%CI)	p-value
Veau classification		0.018
Veau II	<0.001 (NA)	
Veau IIIa	0.04 (0.003, 0.43)	
Veau IIIb	0.14 (0.01, 1.40)	
Veau IV	0.15 (0.01, 1.65)	
ONF	0.21 (0.10, 0.57)	0.012
Mean age at VT insertion	0.77 (0.65, 0.91)	0.003

Table 7. Literature reporting fistula rate of two-flap palatoplasty

Study	Institution	Fistula rate
Muhammad Aslam (2015)	Department of Plastic Surgery, Services Hospital, Lahore, Pakistan	5.6%
Murthy (2009)	George Washington University Medical Center	2.4%
Salyer (2006)	Singapore General Hospital	10%



From: clinical practice guidelines on management of pediatric OME at Srinagarind Hospital

Fig. 2 Clinical practice guidelines for management of pediatric otitis media with effusion at Srinagarind Hospital.

The type of cleft palate had a statistically significant effect on Eustachian tube recovery (p -value = 0.018). Veau I had the best recovery result followed

by Veau IV, Veau IIIb, Veau IIIa and Veau II, respectively. The patients who had ONF had a significantly decreased Eustachian tube recovery rate (p -value =

0.012). Mean age at VT insertion (13.4 months) had a significant effect on Eustachian tube recovery rate (p -value = 0.003): if inserted at an older age, Eustachian tube recovery rate trended to decrease.

Discussion

The goals of palatoplasty include (a) complete and intact closure of the palate resulting avoidance of palatal fistula, (b) restoration of the velopharyngeal sphincter for development of normal speech, (c) good maxillary growth and Eustachian tube function, (d) improvement of otitis media with effusion (OME), and (e) normal hearing^(4,5). Some studies have reported on the rate of Eustachian tube recovery after palatoplasty. Smith (1994) reported a retrospective study on 81 cleft

palate (CP) patients; followed-up for between 1 and 17.3 (average 6) year: Eustachian tube recovery was 70% over an average 6 years (range, 1.0-10.3)⁽¹¹⁾. Koudounakis (2012) also reported a retrospective study in 257 CP patients; followed-up for between 1 and 12 years (average 50 months), in whom Eustachian tube recovery was 45% within 2 to 8 months⁽¹²⁾. Chin-Lung Kuo et al (2013) completed a literature review (for the period 1948 to 2012) and found that follow-up after palatoplasty was between 6 and 7 years: the recurrent OME rate was 90%⁽¹³⁾. Robinson (1992) performed a prospective study in 150 CP patients, followed-up after palatoplasty for four years. They reported that the OME rate slightly decreased from 92% to 70%⁽¹⁴⁾.

The current study found the median recovery time to Eustachian tube function at Srinagarind Hospital, a single center, regularly performing two-flap palatoplasty with intravelarveloplasty (IVV)-was 37.5 months. Eustachian tube function was improved through rearrangement and tightening of the IVV (tensor velipalatini muscle). Our outcome is difficult to compare with other studies due to different study designs, outcome measures, surgical techniques, and treatment protocols. Notwithstanding, the authors found 2-flap palatoplasty with IVV trended to improve recovery time to Eustachian tube function.

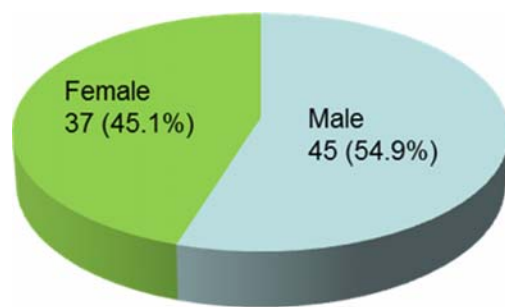


Fig. 3 Sex distribution.

Number of patients (persons)

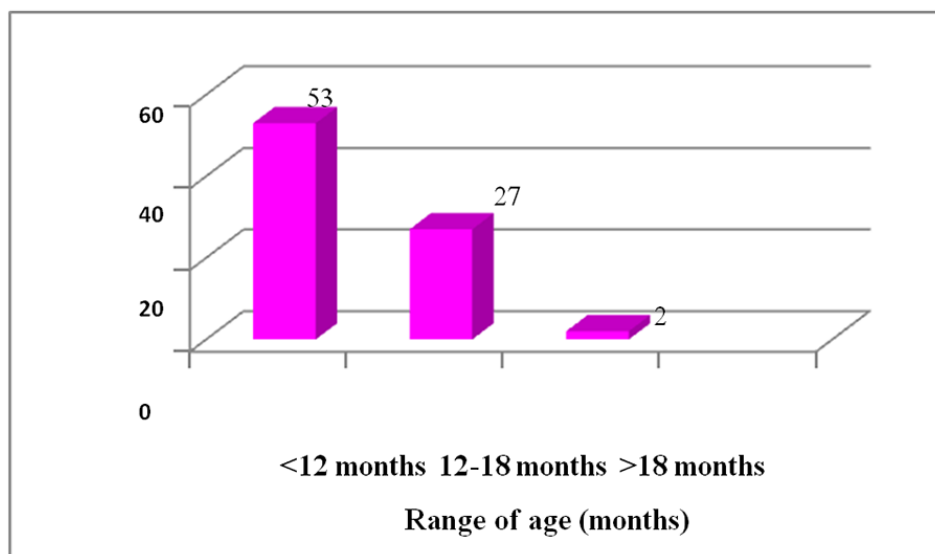


Fig. 4 Age at palatoplasty.

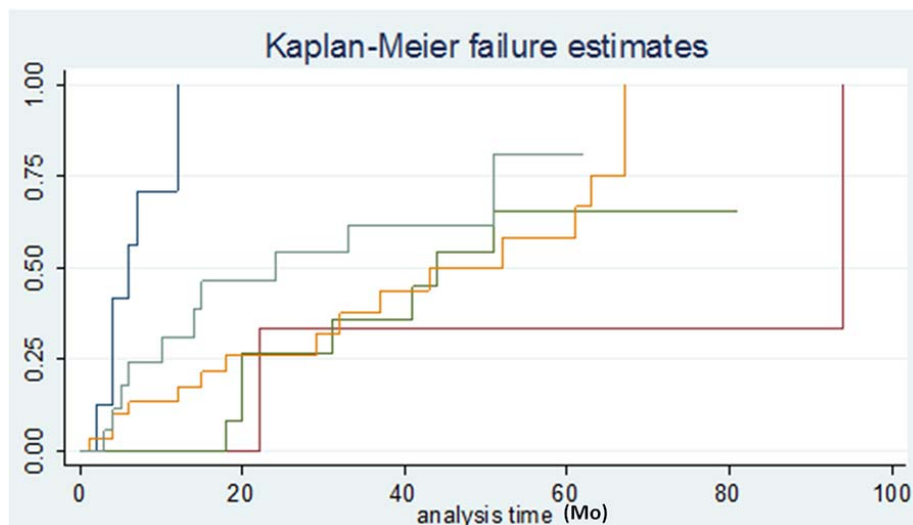


Fig. 5 Kaplan-Meier survival analysis of recovery length of Eustachian tube according to type of cleft

The rank of the most common types of CP in the present study was Veau III, IV, I, and II. This finding is similar to previous studies. The type of CP had a statistical significant effect on Eustachian tube recovery ($p = 0.018$); Veau I had earlier recovery than Veau IV and III because extension of the cleft defect was an important determinant of Eustachian tube recovery, different from Robinson et al⁽¹⁴⁾ and Zingade & Sanji⁽¹⁵⁾. The authors found the rate of ONF was 15.85%, which was in range of rate of ONF from previous studies (3-45%, Yun SP, 2008)⁽¹⁶⁾. There is sparse literature on the fistula rate following two-flap palatoplasty.

The respective ONF rate for Veau type III, IV, II, and I in the current study was 46.15%, 38.46%, 15.38%, and 0%. This is comparable to Hosseinabad et al⁽¹⁷⁾ who reported an ONF rate of 23.7%, a fistula rate for Veau type IV and III of 40.9% and 16.9%, respectively. The current study had a fistula rate of 15.85%, which is higher than reported by others. Since the majority of our patients (80.5%) had a severe cleft extension (Veau III & IV), it might have affected the higher fistula rate. Anderson et al (2008) reported that the ONF rate was higher in patients with a greater severity of CP (i.e., Veau III & IV) because of a higher tension⁽¹⁸⁾. To our knowledge, there is no previous data on the association of ONF and Eustachian tube recovery, but if ONF persisted, food reflux into the nasopharynx and irritated the nasal cavity resulting in Eustachian tube opening-obstruction followed by Eustachian tube dysfunction⁽⁶⁾. We found that patients with ONF had a significantly lower Eustachian tube recovery rate ($p =$

0.012).

Ventilation tube (VT) insertion was another associated factor with Eustachian tube recovery. Robinson et al (1992) reported that the pre-operative OME rate was 92% 4 years after palatoplasty, while the post-operative OME rate was 70%. They suggested early routine unilateral VT insertion for improving hearing function⁽¹⁴⁾. Koudounakis et al (2012) reported a Eustachian tube recovery rate of 45% within two to eight months after palatoplasty without VT insertion⁽¹²⁾.

Meanwhile we found patients who underwent ventilation tube insertion had decreased Eustachian tube recovery albeit not statistically significant ($p = 0.436$). Carroll et al (2013) reported a retrospective study on 69 CP patients, for whom the age of VT insertion was four to six months and that this had no effect on improvement of hearing⁽¹⁹⁾.

We found that average age of VT insertion of 13.4 months was a statistically significant factor in Eustachian tube recovery (p -value = 0.003). Ventilation tube insertion was not performed in all patients, because of wanting to avoid the complication of myringotomy; myringosclerosis, tympanic membrane (TM) atrophy, permanent TM perforation, atelectasis, and cholesteatoma⁽²⁰⁾. The patients with OME should undergo myringotomy with VT insertion when there is (a) difficulty hearing (b) structural damage or (c) infection on top. If patients needed a myringotomy with VT insertion, early VT insertion should be performed in order to increase the chances of Eustachian tube recovery.

The current study is important because (a) it

was done at a large single center, where 2-flap palatoplasty with intravelarveloplasty are performed regularly and (b) it is the first report about recovery time to Eustachian tube function after primary 2-flap palatoplasty with intravelarveloplasty, including the associated factors.

The primary limitations of the study were due to its retrospective nature.

Conclusion

The median length of recovery time for the Eustachian tube to function in cleft palate patients who underwent primary 2-flap palatoplasty with intravelarveloplasty at Srinagarind Hospital during our previous management protocol was 37.5 months. Eustachian tube recovery was associated with severity of cleft types, oronasal fistula formation, and age of ventilation tube insertion.

What is already known on this topic?

Patients with cleft palate often have Eustachian tube dysfunction. The Eustachian tube is an important organ that is predicted to improve after palatoplasty, but previous literature was equivocal about the recovery of Eustachian tube function in children after primary 2-flap palatoplasty with intravelarveloplasty.

What this study adds?

Eustachian tube of cleft palate patients after undergoing primary 2-flap palatoplasty with intravelarveloplasty will recover in 37.5 months. If patients have a more severe type of cleft or oronasal fistula or delayed ventilation tube insertion, Eustachian tube recovery might be delayed.

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Potential conflicts of interest

None.

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ระยะเวลาฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนของเด็กเพดานโหว่หลังได้รับการผ่าตัดเพดานโหว่ด้วยวิธีการผ่าตัดเสริมสร้างเพดานโหว่แบบสองแผ่นเนื้อร่วมกับการตกแต่งกล้ามเนื้อภายในเพดานอ่อน

จิตติมา นาสมตริก, บวรศิลป์ เชวณชื่น, พลากร สุรกุลประภา, ธีรพร รัตนอนเนกชัย, พนิดา ธนาวิรัตนานิจ

วัตถุประสงค์: เพื่อศึกษาระยะเวลาฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนของเด็กเพดานโหว่และปัจจัยที่มีผลต่อการฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนหลังได้รับการผ่าตัดเพดานโหว่ด้วยวิธีการผ่าตัดเสริมสร้างเพดานโหว่แบบสองแผ่นเนื้อ ร่วมกับการตกแต่งกล้ามเนื้อภายในเพดานอ่อน

วัสดุและวิธีการ: การศึกษาแบบพรรณนาในกลุ่มตัวอย่างผู้ป่วยเด็กเพดานโหว่ที่ไม่มีโรคร่วมจำนวน 82 คน ที่มารับการผ่าตัดเพดานโหว่เป็นครั้งแรกที่โรงพยาบาลศรีนครินทร์ตั้งแต่ พ.ศ. 2550 ถึง 2553 โดยรวบรวมข้อมูลเรื่องเพศ, ชนิดของเพดานโหว่, อายุที่ผ่าตัดเพดานโหว่, ศัลยกรรมที่ผ่าตัด, ผลการตรวจ tympanogram, การเกิดรูรั่วระหว่างช่องปากและโพรงจมูก, การใส่ท่อปรับความดัน, อายุและจำนวนครั้งที่ใส่ท่อปรับความดัน

ผลการศึกษา: มีเพศชาย 45 คน เพศหญิง 37 คน ส่วนใหญ่เป็นเพดานโหว่ชนิดสมบูรณ์ข้างเดียว อายุเฉลี่ยที่ผ่าตัดเพดานโหว่ 11.44 เดือน (9-23 เดือน), ศัลยกรรมที่ผ่าตัดเป็นศัลยกรรมตกแต่งและแพทย์ประจำบ้านศัลยศาสตร์ตกแต่ง, ระยะเวลาฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนคือ 37.5 เดือน, อัตราการเกิดการเกิดรูรั่วระหว่างช่องปากและโพรงจมูก 15.85%, มีการใส่ท่อปรับความดัน 58.54% (1 ครั้ง: 40.24%, 2 และ 3 ครั้ง: 18.30%), อายุเฉลี่ยที่ใส่ท่อปรับความดันคือ 16 เดือน (9-64 เดือน), เพศ, อายุที่ผ่าตัดเพดานโหว่, ศัลยกรรมที่ผ่าตัด, การใส่ท่อปรับความดัน และจำนวนครั้งที่ใส่ท่อปรับความดัน ไม่มีนัยสำคัญทางสถิติต่อการฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียน แต่ปัจจัยที่มีนัยสำคัญทางสถิติต่อการฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนได้แก่ ชนิดของเพดานโหว่, การเกิดรูรั่วระหว่างช่องปากและโพรงจมูกและอายุที่ใส่ท่อปรับความดันเป็นครั้งแรก

สรุป: ระยะเวลาฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนหลังได้รับการผ่าตัดเพดานโหว่ด้วยวิธีการผ่าตัดเสริมสร้างเพดานโหว่แบบสองแผ่นเนื้อ ร่วมกับการตกแต่งกล้ามเนื้อภายในเพดานอ่อน คือ 37.5 เดือนปัจจัยที่มีผลต่อการฟื้นคืนสู่การทำงานปกติของท่อยูสเตเชียนได้แก่ ชนิดของเพดานโหว่, การเกิดรูรั่วระหว่างช่องปากและโพรงจมูกและอายุที่ใส่ท่อปรับความดันเป็นครั้งแรก
