Original Article

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Long Term Study of Otitis Media with Effusion after Palatoplasty and Myringotomy with Ventilation Tube Insertion

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Abstract:

Objective: To identify the incidence of recurrent otitis media in cleft palate patients after palatoplasty and myringotomy with ventilation tube (VT) insertion in addition to identifying risk factors of recurrent otitis media with effusion (OME).

Material and Methods: This retrospective cohort study was conducted from; January 2002 – December 2014. A total of 120 non- syndromic cleft palate patients were included and analyzed for risk factors contributing to recurrent otitis media with effusion.

Results: In total, 77.5% of the VT slipped off at 10 months after their initial operation. The incidence of recurrent OME was 54.2% at 7 months after VT slipped off. Significant risk factors that were associated to recurrent OME included: complete cleft palate, two-stage palatoplasty and VT slip-off (p-value<0.05).

Conclusion: The incidence of recurrence OME was 54.2%, and risk factors for recurrence OME are VT slipped off, complete cleft palate and two-stage palatoplasty.

Keywords: cleft palate, otitis media with effusion, palatoplasty

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Introduction

The worldwide incidence of cleft lip/cleft palate approximately ranges from 0.1 to 2 per 1,000 live births[1], and the incidence in Thailand is 1.10 to 2.49/1,000 live births[2–4]. Hence, cleft lip/cleft palate is a major public health concern in Thailand.

More than 96% of cleft palate patients have been diagnosed with otitis media with effusion (OME)[4], because a cleft palate (CP) effects the function of the Eustachian tube, due to an abnormal position of the levator veli palatini muscle and tensor veli palatini muscle. This can impair the hearing function of patients[5–11], as chronic obstruction of drainage leads to otitis media with effusion. In the long term, OME can result in hearing loss[12].

Previous studies demonstrated that gender is one of the risk factors for OME after palatoplasty and myringotomy with ventilation tube insertion. Males have more chance to get recurrence OME than females. In addition, complete cleft palate and tympanogram type B also play a role in OME after an operation[13]. However, the incidence and the clinical risk factors for OME after palatoplasty and myringotomy with VT have not yet been identified.

According to a prior research, studying long-term VT in OME patients, otorrhea occurred after 24% of all tube insertions, and recurring otorrhea occurred in 29%. After the tube was extruded or removed, a persistent perforation appeared in 19% of cases[14]. Muscle function should return in 1-2 years in cleft palate patients having undergone a palatoplasty with myringotomy and VT insertion[7,15,16]. Therefore, short-term VT can be chosen due to the decreased rate of complications related to silicone tubes.

The aim of this study was to identify the rate of OME in CP patient after palatoplasty and myringotomy with ventilation tube insertion. In addition to identification of clinical risk factors associated with OME after palatoplasty and myringotomy with a VT insertion.

Material and Methods

After approval by Siriraj Institutional Review Board (SIRB), a retrospective cohort study was conducted from chart reviews of cleft palate patients undergoing palatoplasty with myringotomy and VT insertion in Siriraj Hospital; from January 2002 to December 2014, by using the ICD10 number for cleft palate (Q351-Q359) and the ICD 9 number for palatoplasty (2762).

According to this study, all non-syndromic cleft palate patients; including the OME patients, underwent ear examination before the operation. Then a palatoplasty was operated on by the plastic surgeons. Subsequently, the myringotomy and VT were inserted by the otolaryngology surgeons as indicated. In this study, a short-term silicone tubes were used, whilst waiting for muscle function in addition to reducing any complications related to silicone tubes.

After the operation, patients were followed up at the outpatient department at 1 week, 1 month and then every 3 months until the VTs were removed or slipped off. Afterwards, the clinical risks probably effected to OME after palatoplasty and myringotomy with VT insertion, were recorded.

In this study, there were 312 non-syndromic cleft palate patients included to this study. Nonetheless, only 120 patients were enrolled into this study, due to loss to follow-up and incomplete data.

All values are expressed as mean±S.D. or a number (%) and statistical analyses were performed by SPSS for Mac version 21, releasing 21.0.0.0. We applied a T test for continuous data and used a Pearson chi-square test to identify associated risk factors contributing to OME after palatoplasty and myringotomy with VT insertion. The cut off for statistically significant was defined with a p-value <0.05.

Results

In total, 120 non-syndromic cleft palate patients were enrolled into this study; the male to female ratio was 68:52. Most of the patients were term for gestational age, with normal birth weight at 90.8%, and complete unilateral cleft palates was 47.5%. There were no submucous cleft palate in this study. All associated anomalies found in this study were Pierre Robin Sequence (Table 1).

The mean age for patients receiving a palatoplasty was 16 months, while for myringotomy with VT insertion was approximately 17 months of age. Simultaneous operations and single stage palatoplasty operations consisted of 84.2% and 95%, respectively.

Most of the operations were performed as two flap palatoplasty with intravelar veloplasty 86.7%, and myringotomy with Siriraj VT insertion 95% (Table 2). The effusion consisted of various types of fluid being found; however, normal cultures were shown as no growth of bacteria. Moreover, most of the patients received antibiotics postoperatively at 99.2% for 7 days.

After following up, 77.5% of patients were found to have the tube being slipped off at 10 months after their initial operation (Table 2).

The incidence of OME after a palatoplasty and a myringotomy with a VT insertion in this study was 54.2% (95% confidence interval: 45.3%-62.8%) at 7 months after VT slip off. From this, 49.2 % of this group required repeat a myringotomy with a VT tube insertion; repeated operations were usually performed at 22 months after VT slip-off.

In the VT slipped off group, who did not had OME occurring after an operation, the timing of VT slip off was 12±6 months.

Table 1 Demographic data

Factors	N=120	%	Mean±S.D.
Gender			
Male	68	56.7	
Female	52	43.3	
Age (years)			5.8±2.8
GA			
Preterm (GA<37 week)	11	9.2	
Term (GA>37 week)	109	90.8	
Birth weight (gram)			2,884.3±523.3
Associated anomaly			
No associated anomaly	108	90.8	
Associated anomaly	12	9.2	
Type of cleft			
UCLP	57	47.5	
BCLP	23	19.2	
Isolated CP	40	33.3	
Type of cleft palate			
Complete CP	79	65.8	
Incomplete CP	29	24.2	
Cleft soft palate	12	10.0	

GA=gestational age, UCLP=unilateral complete cleft palate, BCLP=unilateral complete cleft palate, CP=cleft palate

Table 2 Details of operative procedures used in this study

Variable	N=120	%	Mean±S.D.
Age at the time of operation (months)			
Palatoplasty			16.0±11.7
Myringotomy with VT			17.4±21.0
Palatoplasty/myringotomy			
Simultaneous	101	84.2	
Non-simultaneous	19	15.8	
Method of operation for palatoplasty			
1 stage	114	95.0	
2 stages	6	5.0	
Hard palate repair			
None	14	11.7	
2 flap palatoplasty	98	81.7	
V-Y push back	6	5.0	
Von langenbeck	2	1.7	
Soft palate repair			
Furlow	16	13.3	
IVV	104	86.7	
Type of VT			
Siriraj tube	114	95.0	
Commercial tube	6	5.0	
Discharge			
None	3	2.5	
Glue	34	28.3	
Serous	28	23.3	
Mucous	9	2.0	
Pus	2	1.7	
Not identify	43	35.8	
Discharge culture			
Positive	46	38.3	
Negative	64	53.3	
Not sent	10	8.3	
Antibiotic postoperative			
Yes	119	99.2	
No	1	0.8	
VT slip off			
Yes	93	77.5	
No	24	20.0	
Not identify	3	2.5	
Time to VT slip off (months)			10.0±5.1
Operation time of palatoplasty (hour)			1.8±0.9

VT=ventilation tube, IVV=intravelar veloplasty

The most common complication after palatoplasty in this study was oronasal fistula that usually occurred at the incisive foramen. The second most common complication was dehiscence; which was found in 6 cases, and detected 1 week after operation. This problem was corrected with re-suture under general anesthesia, and after follow up cases in this group were found to have developed ONF for 50% of cases, mean follow up time in this study was 3.67±2.8 years (Table 3).

From statistical analysis, for identifying clinical risk factors associated to OME after operation, it was found that complete cleft palate, 2 stage palatoplasty and VT tube slip off were significant risk factors of recurrent OME (p-value<0.05) (Table 4).

Table 3 Operative outcomes including complications

Variable	N=120	%	Mean±S.D.
OME after operation			
Yes	65	54.2	
No	55	45.8	
Time to OME occurred (month)			7.0±7.0
Repeated VT insertion			
Yes	32	26.7	
No	88	73.3	
Time to repeat VT (month)			22.6±9.3
Complication			
Dehiscence	6	5.0	
Hematoma	0	0	
Infection	0	0	
ONF	18	15.0	
ONF type			
1	0	0	
2	1	0.8	
3	7	5.8	
4	1	0.8	
5	12	57.1	
Follow up time (year)			3.7±2.8

VT=ventilation tube, IVV=intravelar veloplasty, ONF=oronasal fistula, OME=otitis media with effusion

Table 4 Risk factors for otitis media with effusion after palatoplasty and myringotomy with ventilation tube insertion

Risk factors	OME after operation		
	Yes N (%)	No N (%)	p-value
Sex			
Male	37 (54.4)	31 (45.6)	0.951
Female	28 (53.8)	24 (46.2)	
GA			
Term	61 (56.0)	48 (44.0)	0.214
Preterm	4 (36.4)	7 (63.6)	
Associated anomaly			
No associated anomaly	60 (55.6)	48 (44.4)	0.185
Associated anomaly	4 (36.4)	7 (63.6)	
Type of cleft			
ULCP	33 (57.9)	24 (42.1)	0.056
BLCP	16 (69.9)	7 (31.1)	
Isolated CP	16 (40.0)	23 (60.0)	
Type of cleft palate			
Complete CP	50 (63.3)	29 (36.7)	0.019
Incomplete CP	10 (34.5)	19 (65.5)	
Cleft soft palate	5 (41.7)	7 (58.3)	
Palatoplasty + myringotomy			
Simultaneous	51 (50.5)	50 (49.5)	0.063
Non-simultaneous	14 (73.7)	5 (26.3)	

Table 4 (continued)

Risk factors	OME after operation		
	Yes N (%)	No N (%)	p-value
Method of operation			
1 stage	59 (51.8)	55 (48.2)	0.031
2 stages	6 (100.0)	0 (0.0)	
Hard palate repair			
None	7 (50.0)	7 (50.0)	0.979
2 flap palatoplasty	54 (55.1)	44 (44.9)	
V-Y push back	3 (50.0)	3 (50.0)	
Von langenbeck	1 (50.0)	1 (50.0)	
Soft palate repair			
Furlow	7 (43.8)	9 (56.3)	0.369
Intravelar veloplasty	58 (55.8)	46 (44.2)	
Type of VT			
Siriraj tube	62 (54.9)	51 (45.1)	1.000
Commercial tube	3 (50.0)	3 (50.0)	
Discharge			
None	1 (50.0)	1 (50.0)	0.924
Glue	17 (51.5)	16 (48.5)	
Serous	18 (56.3)	14 (43.8)	
Mucous	4 (44.4)	5 (55.6)	
Pus	1 (100.0)	0 (0.0)	
Not identify	24 (55.8)	19 (44.2)	
Discharge culture			
Negative	24 (52.2)	22 (47.8)	0.897
Positive	35 (54.7)	29 (45.3)	
Not sent	6 (60.0)	4 (40.0)	
Antibiotic postoperative			
No	0 (0.0)	1 (100.0)	0.275
Yes	65 (54.6)	54 (45.4)	
VT slip off			
No	0 (0.0)	24 (100.0)	<0.001
Yes	63 (67.7)	30 (32.3)	
Not identify	2 (66.7)	1 (33.3)	
Complication of palatoplasty			
None	54 (56.3)	42 (43.8)	0.511
Dehiscence	2 (33.3)	4 (66.7)	
ONF	9 (50.0)	9 (50.0)	

OME=otitis media with effusion, CP=cleft palate GA=gestational age, BLCP=bilateral cleft lip cleft palate, ULCP=unilateral cleft lip cleft palate, VT=ventilation tube, ONF=oronasal fistula

Discussion

Cleft palate is a common disorder in Thailand, as it has increased by 51% as of 1998[2,4]. Typically, more than 96% of cleft palate patients have been diagnosed with the OME. This is because cleft palate effects the function of the eustachian tube, due to the abnormal position of the levator and tensor palatini muscles, which can affect the hearing function of patients[5–11]; wherein, chronic obstruction of drainage leads to OME. Additionally, in long term, OME may cause hearing loss[12]. Therefore, myringotomy, with the insertion of the VT, has been used as a preference treatment that will help cleft palate patients with OME[7,9,15,17,18].

One study has demonstrated that gender type is one of the risk factors for OME after palatoplasty as well as a myringotomy with a VT insertion. For example, a male has more chance to get OME again than a female. In addition, complete cleft palate and tympanogram type B also play a role in OME after palatoplasty and myringotomy with VT insertion[13].

In this study, the incidence of OME after palatoplasty and myringotomy with VT insertion was 54.2%. Usually, this happens around 7 months after VT slipped off, which was initially managed by conservative treatment. It appeared that 49.2% of the cases, who had VT slipped off requires reoperation.

After analyzing the VT slipped off group, who did not have OME occurring after operation, it was found that the timing of VT slipped off was 12±6 months. From this data it is recommend that reinsertion of a VT be considered, if VT slipped off before 12 months; due to patients having a high chance of OME recurrence, and whilst waiting for recovery of muscle function.

From univariate analysis, by pearson chi-square test, the risks factors contributing to OME after a palatoplasty and a myringotomy with a VT insertion were: complete cleft palate, two-stage palatoplasty and VT slipped off. However, multivariate analysis could not be applied, due to errors in the statistical analyses. Therefore, the most significant factor contributing to OME after operation was VT slipped off.

VT slipped off is the main cause of OME after palatoplasty and myringotomy with VT insertion. After palatoplasty, muscles generally require time to recover their functions; upwards of approximately 1–2 years[7,15,16.] However, the VT slipped off at around 10 months after the initial operation. The chance to aquire OME after operation from the VT slipped off before recovery of muscle function in this study was 67.7%.

Limitations of this study were that this was a retrospective study that may have had many confounding factors. Additionally, it was difficult to achieve complete data for analysis, as more than half of the patients in this study were excluded from this study.

Conclusion

Incidence of OME after palatoplasty and myringotomy with VT insertion is 54.2% in non-syndromic cleft palate. This usually occurs at 7 months after VT slipped off. Factors contributing to OME are VT slipped off and repeated VT insertion being considered if VT slipped off before 1 year.

Conflict of interest

The authors declare no conflicts of interest in this study

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