

Influence of the Frequency of Speech Therapy on the Velopharyngeal Gap in Cleft Lip and Palate Patients After Primary Palatoplasty

Supitchaya Jaruvattanadilok¹, Chayada Kasirawat¹, Wasana Ko-iam¹, Nuntigar Sonsuwan³ and Krit Khwanngern^{1,2}

¹Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand; ²Princess Sirindhorn IT Foundation Craniofacial Center, Chiang Mai University, Chiang Mai, Thailand; ³Department of Otolaryngology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

Correspondence:

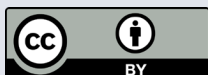
Krit Khwanngern, MD,
Department of Surgery, Faculty of
Medicine, Chiang Mai University
110 Intawaroros Road, Sripoom
Sub-district, Muang District,
Chiang Mai 50200, Thailand.
E-mail: kkhwanngern.research@gmail.com

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ABSTRACT

OBJECTIVE The craniofacial conditions of cleft lip and cleft palate (CLP) have been found to be common worldwide, especially in Asia and Thailand. Nevertheless, there are few studies of the association between the frequency of speech therapy and the impact on the velopharyngeal (VP) gap and speech outcome. This study aimed to evaluate the association between the frequency of speech therapy and the VP gap after primary palatoplasty.

METHODS This retrospective cohort study collected data on 95 patients with CLP or isolated cleft palate who underwent primary palatoplasty at Maharaj Nakorn Chiang Mai Hospital between 2006 and 2018. Log risk regression analysis was carried out to identify the effect of frequency of speech therapy in reducing the VP gap including relative risk (RR) and 95% confidence interval (95%CI).

RESULTS From univariable analysis, influence of speech therapy frequency on the presence of a VP gap showed a crude RR = 0.70 (95%CI = 0.49-0.98). Additionally, the frequency of speech therapy in the multivariable analysis showed an adjusted RR = 0.74, 95%CI = 0.46-1.19. The associated anomalies and syndromes showed a statistically significant correlation with a VP gap (adjusted RR = 1.60, 95%CI = 1.12-2.28).

CONCLUSION Patients who receive speech therapy 5-10 times or more showed a decrease in the incidence of a VP gap of at least 26%; however, this did not reach statistical significance. Nevertheless, it is recommended that speech therapy with cleft lip and cleft palate patients should be continued for at least 5 to 10 sessions.

KEYWORDS frequency of speech therapy, velopharyngeal gap, primary palatoplasty, cleft lip and cleft palate, isolated cleft palate

INTRODUCTION

Cleft lip and cleft palate (CLP) are deformities of the lips and palate that develop during pregnancy (1). CLP is recognized as a common craniofacial disease worldwide (1:700), especially in Asia

and Thailand. According to the 2012 Thai population database, the incidence of CLP in Thailand is 1 to 1.5 per 1,000 live births, which equates to about 800 to 1,200 newborns per year. The incidence of CLP in Chiang Mai has been recorded as

having an incidence of 3.9 per 1,000 live births (2).

CLP is related to facial functions including hearing, swallowing and feeding as well as problems of malocclusion. CLP has also been found to have an effect on physical health (e.g. infection, oral and dental health) and the psychological health of both the individual and family. In addition to facial function and overall patient and family health, poor speech outcome and speech development have been found to be the most common problems in CLP patients (3). More than half of CLP patients need speech therapy (Figure 1). Speech therapy is a critical therapeutic modality for reducing velopharyngeal gap and achieving good speech outcomes in cases of cleft palate. It constitutes the first-line intervention in patients presenting with a velopharyngeal gap or unsatisfactory speech outcome.

For the purpose of optimizing speech outcome of patients, both speech therapy and surgery are essential (4). With regard to surgery, palatoplasty, the primary surgical correction for cleft palate, is usually performed at between 9 to 12 months of age to ameliorate cleft palate deformities (5). This early intervention can help normalizing speech and language as well as reducing hearing and psychological problems (6). Outcomes after palatoplasty are commonly assessed by nasal emission, nasal tone of voice, articulatory defects and nasal resonance. However, these measurements of speech outcomes are operator-dependent, indicating a degree of subjectivity in the assessment of speech outcomes.

A numerical measurement, post-operative velopharyngeal gap (VP gap) which is the length

between soft palate and posterior pharynx (Figure 2A and 2B), would be useful in order to evaluate the speech outcome more precisely. Previous studies have found that the speech outcome and VP gap are significantly associated (7-9). In this study, the VP gap was investigated as a reflection of speech outcome and used as an outcome variable in this study.

With regard to factors that are related to VP gap and speech outcomes, studies have shown factors that have an impact on the VP gap and speech outcome include age at primary palatoplasty, type of cleft and associated syndromes (10-12). However, previous studies have been very limited with regard to demonstrating any association between frequency of speech therapy and VP gap. Relationships between Speech outcome and clear-cut points of frequency of speech therapy for CLP patients have not yet been clarified (12). This study was conducted to investigate the association between the frequency of speech therapy and the VP gap and to improve protocol regarding the frequency of speech therapy in order to minimize VP gap in CLP patients after primary palatoplasty (13).

METHODS

Study design

This is a retrospective cohort study. The inclusion criteria included CLP or isolated cleft palate patients who underwent primary palatoplasty from 2006 to 2018 at Princess Sirindhorn IT Foundation Craniofacial Center, Chiang Mai University. Only patients who had a successful initial nasendoscopy were included in the study. Patients

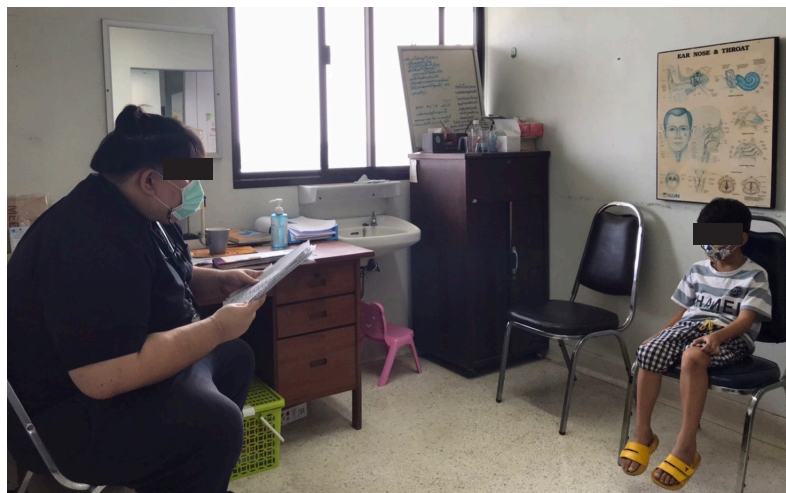


Figure 1. Post operative speech therapy

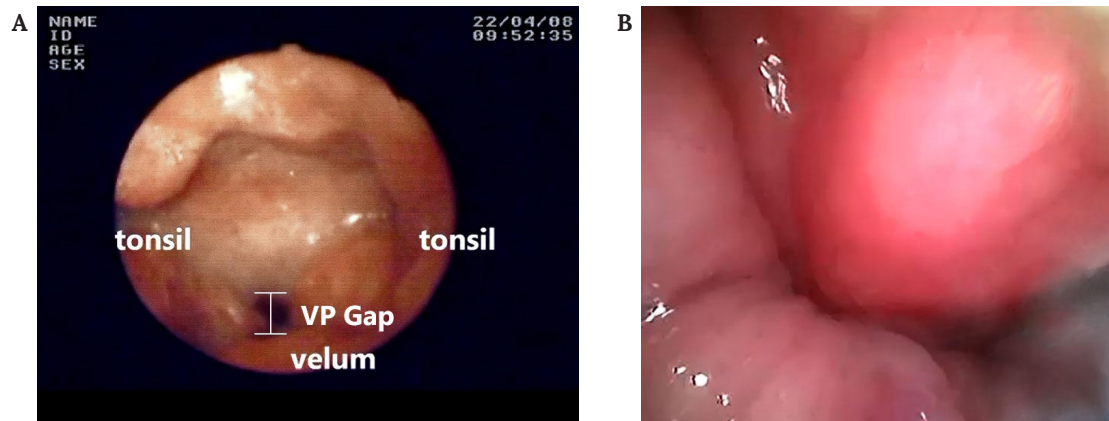


Figure 2. (A) Presence of VP gap in cleft lip and cleft palate patient, (B) not presence of VP gap in cleft lip and cleft palate patient

with incomplete data were excluded. The surgical procedures were performed by a single plastic surgeon with extensive experience in palatoplasty. The surgeon consistently performed the Bardach two-flap palatoplasty technique as the operative method. Following this center's protocol, nasendoscopic evaluations are performed at age 5 years and above.

Ethical considerations

The present study has been approved by the Research Ethics Committee of the Faculty of Medicine, Chiang Mai University, certificate of ethical approval number 486/2021.

Data collection

Data was collected from the medical records of Maharaj Nakorn Chiang Mai Hospital including both the Digicard program and data from the Princess Sirindhorn IT Foundation Craniofacial Center, Chiang Mai University. All data was recorded on Microsoft Excel spreadsheets.

Sample size calculation

Based on a pilot review of 30 cases from the database of Princess Sirindhorn IT Foundation Craniofacial Center, Chiang Mai University, the required sample size needed to address the main research question, i.e., the frequency of speech therapy in both groups (with and without VP gap), was calculated as follows:

- Estimated sample size for a two-sample means test
- Satterthwaite's t test assuming unequal variance

- $H_0: M_2 = M_1$ versus $H_a: M_2 \neq M_1$
- Study parameters
 - o $\alpha = 0.05$, power = 0.80, delta = 8.72
 - o $M_1 = 5.69$ (Mean frequency of speech therapy in the gap group)
 - o $M_2 = 14.41$ (mean frequency of speech therapy in the no gap group)
 - o $SD_1 = 5.73$ (SD of the frequency of speech therapy in the gap group)
 - o $SD_2 = 15.85$ (SD of the frequency of speech therapy in the no gap group)
 - o $N_1/N_2 = 1.00$
- Estimated sample sizes:
 - o $N = 62$ (Total sample size)
 - o $N_1 = 31$ (patients in the no gap group)
 - o $N_2 = 31$ (patients in the gap group)
- The investigator recruited a sample of 62 cases

Statistical analysis

The categorical data is shown as frequency and percentage. Fisher's exact test was used for comparison between groups. Continuous data is shown as mean and standard deviation (normal distributions) or median and interquartile range (non-normal distributions), and were compared using Student's t-test or Wilcoxon's rank-sum test, respectively. Log risk regression (univariable and multivariable analysis) was performed to identify the effect of frequency of speech therapy on reducing the velopharyngeal gap, and also to adjust for potential confounders. A p -value < 0.05 was considered statistically significant. STATA version 16.0 was used for data analysis.

RESULTS

A total of 95 patients who received palatoplasty at Maharaj Nakorn Chiang Mai Hospital between 2006 and 2018 were recruited into this study. Of those patients, 56 patients (58.95%) presented with a VP gap after the first successful nasendoscopy for post primary palatoplasty and 39 patients (41.05%) did not present with a VP gap. The gender balance of patients was 52 males and 43 females. The age at primary palatoplasty, cleft type, gender and distance from speech therapy center to patients' address between patients who presented with VP gap and those who did not present with VP gap were not statistically significantly different. However, there was a statistically significant difference in the presence of associated anomalies between the two groups. The presence of a VP gap in patients with and without associated anomalies was 100% and 58.95%, respectively ($p = 0.039$). The number of patients who first started speech therapy before 2019 (80.00%) and those who started therapy in or after 2019 (20%) was also statistically significant ($p = 0.038$). (Table 1).

Among patients who received their first speech therapy before 2019, 94.03%, 70.59% and 9.09% had a frequency of speech therapy of < 5 times, 5-10 times and > 10 times, respectively. Of patients who had their first therapy in 2019 or later, the frequency of speech therapy was < 5 times (5.97%), 5-10 times (29.41%) and > 10 times

(90.91%), respectively. The difference between the date of the first speech therapy and the frequency of speech therapy between patients who underwent their first speech therapy before 2019 and those who had their first therapy in 2019 or later was significant ($p < 0.001$) (Table 2). Two postoperative factors were evaluated: the type of surgery and the frequency of speech therapy, the independent factors in this study. The patients who underwent palatoplasty and cheilo-palatoplasty developed a VP gap, however the outcome was not statistically significant. The frequency of speech therapy was divided into three groups: < 5 times, 5-10 times and > 10 times. In the group of patients who received speech therapy < 5 times, the frequency of a VP gap was 65.67%. In the group which received speech therapy 5-10 times, 52.94% presented with a VP gap. Among the patients who had more than 10 sessions of speech therapy, only 27.27% had a VP gap ($p = 0.054$) (Table 3).

Univariable analysis found that factors associated with the presence of a VP gap included the frequency of speech therapy, type of cleft palate and the time of first speech therapy. Frequency of speech therapy (crude RR = 0.70, 95%CI = 0.49-0.98, $p = 0.040$) and of associated anomalies (crude RR = 1.80, 95%CI = 1.49-2.16, $p < 0.001$) significantly affected the manifestation of the VP gap.

Table 1. Baseline characteristics of the study population

Characteristics	Patients with VP gap (n = 56)	Patients without VP gap (n = 39)	p-value
Age at primary palatoplasty (year), median (IQR)	1.20 (0.99-1.74)	1.20 (0.98-1.43)	0.586
Gender, n (%)			1.000
Male	31 (59.62)	21 (40.38)	
Female	25 (58.14)	18 (41.86)	
Cleft type, n (%)			0.312
Isolated cleft palate (including soft palate)	14 (73.68)	5 (26.32)	
Unilateral CLP	28 (52.83)	25 (47.17)	
Bilateral CLP	14 (60.87)	9 (39.13)	
Associated anomalies or syndromes, n (%)			0.039
Yes	7 (100.00)	0 (0.00)	
No	49 (58.95)	39 (41.05)	
Distance from speech therapy center (km), median (IQR)	109 (34.4-177)	86 (47.2-136)	0.292
The time of speech therapy, n (%)			0.038
Before 2019	49 (64.47)	27 (35.53)	
Since 2019	7 (36.84)	12 (63.16)	

IQR, interquartile range; VP gap, velopharyngeal gap; CLP, cleft lip and cleft palate

The time of first speech therapy was associated with the gap presentation as a crude RR = 0.57, 95%CI = 0.31-1.06, but the association was not statistically significant ($p = 0.075$). All the prognostic factors were adjusted in the multivariable analysis between the VP gap and non-VP gap groups. Greater frequency of speech therapy was

associated with a slightly reduced the presence of a VP gap with the relative risk being 0.74, 95% CI = 0.46-1.19, but these findings were again not statistically significant ($p = 0.557$) (Table 4).

DISCUSSION

The main focus of this study was independent factors, including the frequency of speech therapy, and how that frequency affected the VP gap among the patient groups. It was found that the greater the frequency of speech therapy, the lower the percentage of patients who presented with a VP gap, as shown in Table 3. Among patients who received speech therapy fewer than five times, 34.33% did not develop a VP gap, whereas 72.73% of those who received more than ten sessions did not present with a VP gap. Univariable analysis

Table 2. Association between period of first speech therapy and frequency of speech therapy

Frequency of speech therapy	The time of first speech therapy, n (%)		p-value
	Before 2019	Since 2019	
< 5 times	63 (94.03)	4 (5.97)	< 0.001
5-10 times	12 (70.59)	5 (29.41)	
> 10 times	1 (9.09)	10 (90.91)	

Table 3. Postoperative factors

Characteristics	Patients with VP gap (n = 56)	Patients without VP gap (n = 39)	p-value
Type of surgery, n (%)			0.137
Palatoplasty	37 (66.07)	19 (33.93)	
Cheilopalatoplasty	19 (48.72)	20 (51.28)	
Frequency of speech therapy, median (IQR)	2 (1-4)	4 (1-9)	0.054
< 5 times, n (%)	44 (65.67)	23 (34.33)	
5-10 times, n (%)	9 (52.94)	8 (47.06)	
> 10 times, n (%)	3 (27.27)	8 (72.73)	

IQR, interquartile range; VP gap, velopharyngeal gap

Table 4. Association between frequency of speech therapy among patients with and without velopharyngeal gap and adjusted prognostic factors

Prognostic factors	Univariable analysis			Multivariable analysis		
	Crude RR	95%CI	p-value	Adjusted RR	95%CI	p-value
Frequency of speech therapy	0.70	0.49-0.98	0.040	0.74	0.46-1.19	0.557
< 5 times						
5-10 times						
> 10 times						
Age at palatoplasty	1.04	0.98-1.10	0.204	1.02	0.96-1.10	0.476
Gender	1.03	0.73-1.44	0.885	1.27	0.67-2.40	0.462
Type of cleft palate						
Isolated cleft palate (including soft palate)	1.00			1.00		
	(reference)			(reference)		
Unilateral CLP	0.72	0.83-1.36	0.309	0.86	0.39-1.89	0.701
Bilateral CLP	0.83	0.39-1.73	0.613	1.09	0.42-2.81	0.858
Type of surgery	1.36	0.93-1.97	0.111	1.22	0.80-1.85	0.355
Distance from speech therapy center	1.00	0.99-1.00	0.297	1.00	1.00-1.01	0.257
Associated anomalies and syndromes	1.80	1.49-2.16	< 0.001	1.60	1.12-2.28	0.009
The time of first speech therapy since 2019	0.57	0.31-1.06	0.075	0.72	0.35-1.50	0.385

CLP, cleft lip and cleft palate

found the frequency of speech therapy was significantly associated with the VP gap ($p = 0.040$). Adding emphasis to this point, the RR values from the univariable and multivariable analyses were nearly identical (crude RR = 0.70; adjusted RR = 0.74).

The factors that significantly impacted the presence of a VP gap were associated anomalies which is consistent with the findings of a study by Tache, et al. and Sie, et al. (10, 11). The associated anomalies and syndrome included the Pierre Robin sequence, VACTERL syndrome, and congenital cardiac valve defects. According to a study by Kocaaslan, et al, the Pierre Robin sequence is associated with more significant velopharyngeal insufficiency compared to patients without this sequence (14).

Furthermore, the timing of first speech therapy showed a statistically significant correlation with the VP gap. This factor was included because of the establishment of the Princess Sirindhorn IT Foundation Craniofacial Center at Chiang Mai University in 2019. That center provided an increased number of speech therapy sessions. The frequency of speech therapy was significantly increased after the center was inaugurated ($p < 0.001$) (Table 2). Although the adjusted RR in the multivariable analysis indicated that a higher frequency of speech therapy decreased the likelihood of a VP gap, this relationship did not reach statistical significance (Table 4).

The frequency of speech therapy in our center was considered to be an important factor as the proportion of patients who had received therapy sessions since 2019 remained low (20.00% of all patients). Thus the number of patients who had speech therapy more than 10 times much lower than the other groups (< 5 times and 5-10 times). Future studies should include more samples with over 10 therapy sessions. A multi-center collaboration could potentially enhance the evaluation of the significance of the association between frequency of speech therapy and the presence of a VP gap. Additionally, if the patients had undergone nasendoscopy before speech therapy, the reduction in the length of the VP gap could have been evaluated more definitively, allowing a clearer determination of the true effect of speech therapy.

CONCLUSIONS

Patients who received speech therapy either 5-10 times or more than 10 times showed at least a 26.00% reduction in the presence of a VP gap, although this did not reach statistical significance. However, it is recommended that speech therapy be provided at current levels in clinical practice for patients with cleft lip and cleft palate.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

S.J.: investigation, data curation, formal analysis, writing — original draft preparation, writing — review & editing; C.K.: investigation, writing — original draft preparation; W.K.: methodology, formal analysis, validation, writing — review & editing; N.S.: conceptualization, methodology, writing — review & editing; K.K.: conceptualization, methodology, resources, writing — review & editing, supervision, project administration

All authors have read and agreed to the published version of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

INSTITUTIONAL REVIEW BOARD STATEMENT

The present study has been approved by the Research Ethics Committee of the Faculty of Medicine, Chiang Mai University, bearing the certificate of ethical approval number 486/2021.

INFORMED CONSENT STATEMENT

Informed consent was not obtained from all participants, as the study was conducted retrospectively.

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