Outcome of patients with cleft lip and cleft palate operated at Mahosoth, Mitthaphab and Setthathirath Hospitals in Lao People's Democratic Republic

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Background: *Cleft lip and cleft palate or both are the most common orofacial congenital malformations found among live births. The causes of which are not clear but have a trend that includes 2 etiological factors, genetic and environmental. The incidence rate of cleft lip and palate is similar in every country worldwide and it stands at approximately 1-2/1000 newborn. For instance, it is 1.09/1,000 in India, South Korea and Thailand. Estimate, in Lao PDR could be 0.02/1,000 newborn. Cleft lip and cleft palate and craniofacial anomalies are congenital defects with numerous sequels in dental, speech, hearing, body-image and psychosocial realms. Cleft lip and palate operation is still limited in many parts of Lao PDR.*

Objective: *To study the outcome of patients with cleft lip and cleft palate, particularly the Nasolabial appearance and quality of life, who were operated in Lao People's Democratic Republic.*
Material and Method: *The present study was reviewed and approved by the Ethics for Human Research, Khon Kaen University in Thailand and National Ethics Committee for Health Research in Lao PDR. This was a cross-sectional study of 50 persons who were chosen as samples and were divided into two age groups, group A, which included subjects between 5 and 15 years of age (31 persons) and group B composed of those above 15 years (19 persons). Data collection was done by means of a questionnaire and the latter was divided into three main headings: demographic characteristics, quality of life and Nasolabial appearance. The list of patients with cleft lip and palate was obtained from the 3 Hospitals in Vientiane, the capital, and then entered directly as samples. Demographic data and quality of life were analyzed by means of percentage, frequency, mean and standard deviation with the help of SPSS version 13. Similarly, Inter-rater reliability using Kappa statistics was done for the evaluation of Nasolabial appearance*
Results: *The inter-rater reliability for Nasolabial appearance was 0.2044 or 20.44% (P-value <0.0001). Average score in each dimension of Nasolabial appearance (nasal form, nasal symmetry, vermillion border Nasolabial profile) are scored 3.15, 3.16, 3.36 and 3.06 respectively. This placed it on fair level (3.18 point). The quality of life: group (A) and (B) were whose have the quality of life on fair to good level for mentalities and satisfaction on fair level that is comparable.*
Conclusion: *The result of the research revealed that the rating of reliability of inter-rater was rather low. However, each dimension of quality of life of both groups was at fair level.*

Keywords: *Cleft lip and cleft palate, Lao PDR, Nasolabial appearance, Quality of life*

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Cleft lip and cleft palate or both are the most common orofacial congenital malformations found among live birth the causes of which are not clear but have a trend that includes 2 etiological factors, genetic and environmental[1].The incidence rate of cleft lip and palate is similar in every country worldwide and it stands at approximately 1-2/1000 newborn. For instance, it is 1.09/1,000 in India, South Korea, and Thailand[2-4] respectively. For Lao PDR does not research the incidence rate of CLP; an estimate can be based on the incidence in neighboring countries that possible rate of CLP in Lao PDR could be 0.02/1,000[5]. Cleft lip and cleft palate and other craniofacial anomalies are

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congenital defects that affect other parts of the body as well, such as dental health, speech, hearing, and body-image. In addition to these, psychosocial realms encompassing parents' feeling and budget of treatment are also of great concern.

People's Democratic Republic of Lao (Lao PDR) has a population of about 6,168,000[6]. A majority of the population lives in rural and remote areas. A study shows that 87% of the families with a family member treated for cleft lip and palate had an income of less than 124$/month[7]. The Lao government or the Ministry of Health has now made an attempt to cooperate with various sectors, organizations and foundations that have contributed towards the alleviation of cleft lip and cleft palate in the country. At present, surgical treatment is limited and depends highly on experts and budgets from a foreign country. Most of the surgeries are performed in central Hospitals, for instance, Mahosoth Hospital. Evaluation of such surgeries lacks clarity and continuity.

Surgical treatment of patients with cleft lip and palate begins at an early age and brings about a positive effect on their quality of life. The parents or families with a cleft lip and palate child face physical and mental harassment. They develop the feeling to look after their offspring with cleft lip and palate more than others which affects their relationship within the family. There has been no study in the past about the Nasolabial appearance and quality of life after cleft lip and palate surgery. A study on the outcome of patients with Cleft lip and cleft palate could be of importance in counseling for future surgeries.

The aim of the present study was to examine the outcome of patients, with cleft lip and cleft palate, particularly the Nasolabial appearance and quality of life, who were operated in Lao People's Democratic Republic.

Material and Method

This was a cross-sectional study in which the sample size was not calculated but samples were chosen according to the standards of The Eurocleft project[8] respectively which selected 35 - 40 samples at least; but researchers will choose 50 persons. The samples were divided into two age groups, group A composed of subjects between 5 and 15 years of age (31 persons) and group B with those above 15 years (19 persons). Data collection was done by means of a questionnaire and the latter was divided into three main headings: demographic characteristics, quality of life and Nasolabial appearance. The list of patients with cleft lip and palate was obtained from the 3 Hospitals in the capital, Vientiane, and then enrolled directly as samples. The researchers obtained informed consent from subjects and then each one was interviewed at his/her home and a photo of their appearance was taken as part of the present study. The entire process took about 45-60 minutes to complete.

Quality of life was evaluated under 3 dimensions[9]: socio-economic (8 questions), Mentality (4 questions) and satisfaction (5 questions) by using a rating scale (1-5 point). 1 point meant very good, 2 points meant good, 3 meant fair, 4 meant poor and 5 meant very poor. The method of scoring for Nasolabial appearance consisted of 5 committees such as surgeon, orthodontist, nurse, speech pathologist and lay person who could see patients' photos from 2 views, frontal and profile and scored the Nasolabial appearance (1-5points): Nasal form, Nasal symmetry, vermillion border and Nasolabial profile[10] shown on Fig 1, 2, 3 and 4. Demographic data and quality of life were analyzed by means of percentage, frequency, mean and standard deviation with the help of SPSS version13. Similarly, strength of agreement of Inter-rater reliability was perfect (0.81-1.00)[11]; using weighted Kappa statistics was done for the evaluation of Nasolabial appearance. Figure shown the method of scoring for Nasolabial appearance (1-5points): Nasal form, Nasal symmetry, vermillion border and Nasolabial profile.

Results

Demographic data (group A: 5-15 years)

Of the 31 subjects 19 (61.3 %) were males. About 11 of them (35.5%) had completed their first surgery and above 3/4th (24, 77.4%) of the total surgeries were performed by foreign surgeons. Average age of the subjects was between 5 and 10 years and there were a total of 18 (58.1%) cases that fell under the same age group. A total of 10 (32.3%) subjects had bilateral cleft lip and palate with unilateral cleft lip and palate (left side). Among the caregivers who were with the subjects, 10 (32.3%) were housekeepers and 8 (25.8%) were in agriculture. Of the total subjects, 12 (38.7%) had finished primary school. 18 (58.1%) of them hailed from a family with an income of around 62 - 124 $/ month. The mostly, to accessed to the information of operation by tale 23(74.2%) cases—(this sentence is totally incomprehensible). Details in Table 1.

Group B (above 15 years)

Of the 19 subjects 11 (57.9%) were females. Nearly 3/4th of the subjects (14, 73.7%) had already

gotten their secondary operation and almost all the surgeries (18, 94.7%) were performed by foreign surgeons. The average age of the subjects was 15-30 years and 17 (89.5%) of the total fell in this age group. 6 (31.6%) subjects had unilateral cleft lip and palate (left side), while 5 (26.3%) had cleft lips (left side). The occupations of the subjects were in agriculture including the laborers and students equaling 5 (26.3%). Six (31.6%) of them had only completed their primary schooling, 5 (26.3%) of them had undergone secondary schooling and another 5 (26.3%) had finished high school. The income level varied between the groups with about 10 (52.6%) patients having an income of less than 62$/month, 8 (42.1%) of about 62 - 124 $/month, and 1 (5.3%) of in the category of 125 - 375$/month. Generally, to access to the information of operation by tale 9 (47.3%) cases as well television 9 (47.3%) (totally incomprehensible.) See details in Table 1.

Quality of life data

Socio-economic

Group A: transportation expenditure was the responsibility of the project for 21 (67.7%) participants. The expenditure for transportation by project was 11$/time; the average personal expense for 25 (80.6%) was 101$/time when admitted to hospital. Patients lost income was about 49$/time. Groups B: the project was responsible for transportation expenses of which 18 (94.7%) participants availed themselves. On an average about 16 (84.2%) participants said that they spent $70 each time they were admitted to the hospital and each time led to a loss of 38$ in their income. Most of the patients did not express any problems related to expenditures, or working harder than normal during the surgery period.

Mentalities

Group A: the mentality of the subjects remained mostly between fair and good levels. For instance, 21 (67.7%) ranked self-confidence at a good level and 15 (48.4%) subjects placed their adaptation to work in society at a fair level. Also, 15 (48.4%) of them had a good level of impression towards their appearance after the operation.

Group B: the mentality of the subjects mostly remained on a fair to good level with14 (73.7%) expressing fair and 5 (26.3%) expressing a good level of self-confidence. When asked how they had adapted back into society quite a number of subjects (15, 78.7%) ranked it at a fair level. When being asked if they were impressed with their appearances after surgery, 12 persons (63.2%) said their appearance made a fair impression, while 4 (21.1%) said it made a good one.

Satisfaction

Group A: Satisfaction on their appearance was ranked as good by 13 (41.9%) subjects. More than half of them (19, 61.3%) shared that their satisfaction level towards their health was good and there were about15 (48.4%) expressed poor level of anxiousness toward their illness. More than half of the subjects (18, 58.1%) thought their level of behavioral problems was poor.

Group B: of the subjects above 15 years of age, more than half of the subjects (12, 63.4%) allowed that their satisfaction level for their appearance was only fair. There wasn't much difference among the

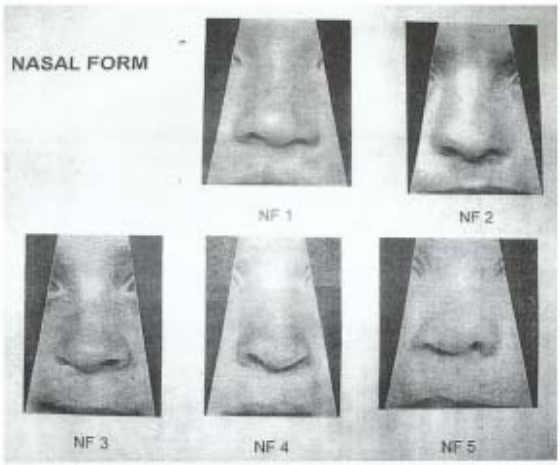

Fig. 1 Nasal form

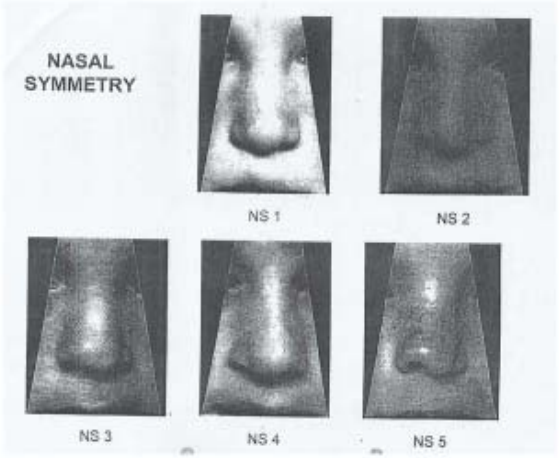

Fig. 2 Nasal symmetry

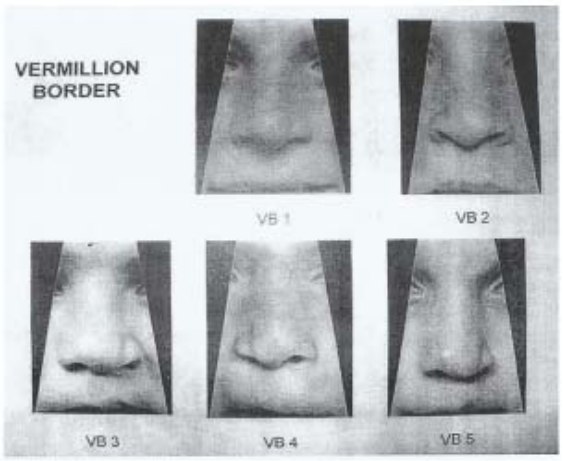

Fig. 3 Vermillion border

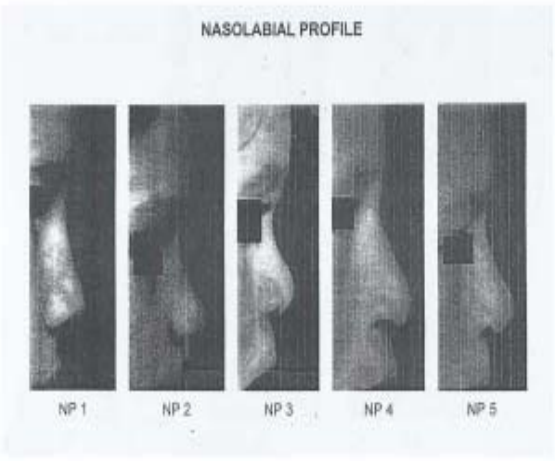

Fig.4 Nasolabial profile

number of people who scaled their level of satisfaction related to health as fair and good with 9 subjects (47.4%) stating fair and 8 (42.1%) stating good. In addition, on being asked about anxiety regarding their illness, 6 (31.6%) of them expressed not to have any while 8 (42.2%) ranked it at the fair level. Furthermore, 8 (42.1%) said they did not have any behavioral problem.

Nasolabial Appearance

Analysis of photos of patients with cleft lip and palate, particularly the Nasolabial appearance after surgery, was carried out between 2010 and 2012. A total of 50 subjects (24 females and 26 males) were scored by a committee of 5 members who hailed from different backgrounds namely, surgeon, orthodontist, nurse, speech pathologist and lay personnel. They gave a scored subjects between 1 and 5 points, with 1- very good, 2 - good, 3 - fair, 4 - poor and 5 - very poor. Average scores ranged for good (1-2.5), fair (2.6-3.5) and very poor (3.6-5)[11]. The scores were based on the appearance of the nasal form, nasal symmetry, Vermillion border and Nasolabial profile, (after had the score to make association Interrater by weighted kappa's statistic using Stata version 10—totally incomprehensible text).

Data analysis showed that the average score in each dimension that the 5-member committee ranged from good to fair level regarding nasal form, nasal symmetry, vermillion border and Nasolabial profile getting a score of 3.15, 3.16, 3.36 and 3.06, respectively. Total mean score was 3.18 (Table3).

Strength of agreement for rating of Inter-rater scored at 0.2044 or agreement = 20.44% p-value<0.0001 –unclear and confusing text, impossible to sort out and render a comprehensible text.

Discussion

Nasolabial appearance shown at the fair level (mean= 3.18) similarly corresponded to Ana Mercado *et al (*2011)[12] as compared to the Nasolabial Aesthetics from 4 centers that found average scores of the centers between 2.80 - 2.98, except where another center was at 3.02 and where the Pieter J.P.M *et al* (2007)[13] study compared 6 centers and found that 3 centers are at between 2.8 - 2.9 scores and 3 other centers are 3.0 - 3.4 showed the evaluation of treatment outcome to be at the fair to poor levels which stems from many reasons such as patients' severity, patients' pre-surgery, technique and experience of surgeons. However, the facial image is important and relates to high expectation of everybody, especially for patients in the Lao PDR who lack opportunity to access surgery on timely way and pre-surgical orthodontics treatment which would affect surgical outcome in this research. Quality of life showed that most patients and caregivers which were at fair level corresponded to Niramol Patjanasoontorn *et al* (2012)[14], which studied Quality of life outcome with CLP patients and found that most subjects had a satisfactory outcome. Due to the fact that Lao and northeastern Thai subjects are similar in culture, socio-economic, mentality and life style, in general, there is little difference in quality of life for the two peoples.

Conclusion

The present study is cross-sectional composed of 50 subjects and divided into 2 age groups:

Table1. General information for group A (5-15 years of age, N=31) and group B (above 15 years of age N=19)

Data	group A (5-15 years of age, N=31)		group B (above 15 years of age)	
Demographics	numbers	percentage	numbers	percentage
Gender				
Female	12	38.7	11	7.9
Male	19	61.3	8	42.1
Age				
5 – 10 years	18	58.1		
11– 15 years	13	41.9		
>15 – 30 years			17	89.5
31– 45 years			1	5.3
>45 years			1	5.3
Operation				
First operation	11	35.5	5	26.3
Secondary operation	20	64.5	14	73.7
Lao surgeon	7	22.6	1	5.3
Project surgeon	24	77.4	18	94.7
Type of deformities				
BCLP	10	32.3	3	15.8
UCLP(Lt)	10	32.3	6	31.6
UCLP(Rt)	1	3.2	1	5.3
BCL	1	3.2	0	0
CL(Lt)	6	19.4	5	26.3
BCL(Rt)	3	9.7	4	21.1
Relative heredity situation				
Parents or relative with cleft lip and palate	13	41.9	6	31.6
No heredity	18	58.1	13	68.4
Marital status				
Single	31	100.0	14	73.7
Married	0	0	4	21.1
Divorced	0	0	1	5.3
Relationship with patients				
Father	11	35.5	2	10.5
Mother	15	48.4	1	5.3
Grandfather	2	6.5	1	5.3
Grandmother	3	9.7	1	5.3
Other	0	0	0	0
No	0	0	14	73.7
Occupation				
Officer	4	12.9	1	5.3
Agriculture	8	25.8	5	26.3
Housekeeper	10	32.3	2	10.5
Private business	3	9.7	1	5.3
Laborer	6	19.4	5	26.3
Student	0	0	5	26.3
Literacy level				
Primary school	12	38.7	6	31.6
Secondary school	9	29.0	5	26.3
High school	6	19.4	5	26.3
More than high school	4	12.9	3	15.3

Table 1. Cont.

Data	group A (5-15 years of age, N=31)		group B (above 15 years of age)	
Income				
<62$/month	7	22.6	10	52.6
62 – 124 $/month	18	58.1	8	42.1
125 – 375$/month	2	6.5	1	5.3
>375$/month	4	12.9	0	0
Expense for operation				
Project	31	100.0	19	100.0
Accessibility of information for operation				
Radio		1	3.2	1 5.3
Television	7	22.6	9	47.3
By tale	23	74.2	9	47.3
Other	0	0	0	0

Table 2.1. Socio–economic data shown on average loss of income, number of days in the hospital and number of people/time for group A (5-15 years of age, N=31) and group B (above 15 years of age N=19)

Data	Group A (N=31) Average	Group B(N=19) Average
How much of your income do you lose when you are admitted at the hospital?	49 $/time	38$/time
How many days do you remain at the hospital?	4 days	4 days
How many people come to look after you at the hospital after your operation?	2 people	2 people
Average personal expense on transportation	11$/time	11$/time
Average expense on transportation provided by the project	12$/time	70$/time
Average expenditure of patients when admitted at the hospital on their own	101$/time	74$/time
Average expenditure of patients when admitted at the hospital via the project	31$/time	47/time

Data	Group A (5-15 years)		Group B (above 15 years)	
	No	Yes	No	Yes
Do you have expendable problem in many operation s for your child/	26 (83.9)	5 (16.1)	18 (94.7)	1 (5.3)
Do you work harder to spend for operation of your child/ by yourself?	27 (87.1)	4 (12.9)	19 (100.0)	
Do you have more than debt when your child gets illness/ yourself?	26 (83.9)	5 (16.1)	18 (94.7)	1 (5.3)

Table 2.2. Mentalities data shown on Mean and Standard deviation for group A (5-15 years of age, N=31) and group B (above 15 years of age N=19)

Data	Group A		Group B	
	Mean	SD	Mean	SD
Your self confidence	3.93	0.57	3.26	0.45
You adapted to the society	3.58	0.62	3.10	0.45
You adapt to work in the society	3.48	0.62	3.10	0.56
Your impression towards your appearance after operation	3.80	0.87	3.21	0.71

Table 2.3. Satisfaction data shown on Mean and Standard deviation for group A (5-15 years of age, N=31) and group B (above 15 years of age N=19)

Data	Group A		Group B	
	Mean	SD	Mean	SD
You satisfied about your appearance	3.74	1.03	3.21	0.71
You satisfied with your health	3.64	0.60	3.63	0.68
You worried about your health +	2.29	0.73	1.89	0.80
You are anxious about your illness +	2.16	0.77	2.10	0.87
You have the level of behavioral problems +	1.90	0.65	2.05	1.07

Table 3. Nasolabial appearance shown on mean and standard deviation in each dimension from the committee of 5 members

Data	Mean	SD
Nasal form	3.15	0.67
Nasal symmetry	3.16	0.65
Vermillion Border	3.36	0.50
Nasolabial Profile	3.06	0.59
Total mean score of 4 nasolabial appearances	3.18	

group (A) was 5-15 years (male = 19 cases) and group (B) was above 15 years (female = 11 years.) Results of this study found that Inter-rater reliability score was at a rather low level such as 0.2044 or 20.44% P-value <0.0001. Mean score of each committee was rated by the Nasolabial appearance (nasal form, nasal symmetry, vermillion border Nasolabial profile) was 3.15, 3.16, 3.36 and 3.06, respectively. Total mean score is 3.18 on fair levels. Quality of life showed both groups have on average fair to good levels of mentality and satisfaction.

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Potential conflicts of interest

None.

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ผลลัพธ์ของผู้ป่วยปากแหว่งเพดานโหว่ที่ได้รับการผ่าตัดที่โรงพยาบาล มะโหสด มิตพาบ และ เชดถาทิราดใน สาธารณรัฐ ประชาธิปไตยประชาชนลาว

นาลิน พันทะวง, สุธีรา ประดับวงษ์, วริสรา ลุวีระ, เกิดมี ขันสุลิวงศ์, บวรศิลป์ เชาวน์ชื่น

ภูมิหลัง: *โรคปากแหว่ง เพดานโหว่เป็นความพิการมาแต่กำเนิดที่พบมากที่สุดในผู้ป่วยที่มีความพิการของศีรษะและใบหน้าซึ่งพบเห็นได้ระหว่างการฃลอดบุตร สาเหตุของโรคยังไม่ทราบแน่นอน แต่ส่วนมากพบ 2 ปัจจัย คือ กรรมพันธุ์ และ สิ่งแวดล้อม ซึ่งแต่ละประเทศที่มีอัตราการเกิดที่เหมือนกันประมาณ 1-2 ราย/1,000 ในเด็กแรกเกิด เช่น ประเทศอินเดีย เกาหลีใต้ ไทย และ สปป.ลาว ประมาณการ 0.02 ราย/1,000 ในเด็กแรกเกิด นอกจากนั้น โรคปากแหว่งเพดานโหว่และฃวามผิดปกติยังมีผลกระทบตามมาภายหลังมากมาย เช่น ผลกระทบต่อฟัน การพูด การได้ยิน ภาพลักษณ์ และ จิตใจ ซึ่งใน สปป. ลาว การผ่าตัดยังมีข้อจำกัดโดยเฉพาะผู้ป่วยที่อยู่ต่างจังหวัด*

วัตถุประสงค์: *เพื่อศึกษาผลลัพธ์ของผู้ป่วยปากแหว่ง เพดานโหว่ โดยเฉพาะที่บริเวณริมฝีปากจมูก และคุณภาพชีวิตที่ได้รับหลังการผ่าตัดใน สปป. ลาว*

วัสดุและวิธีการ: *ในการศึกษาครั้งนี้ได้รับพิจารณาและอนุญาตจากคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยขอนแก่น และฃณะกรรมการจริยธรรม แห่ง ส ป ป.ลาว, การศึกษาเป็นแบบตัดขวางมีกลุ่มตัวอย่าง 50 ราย แบ่งเป็นสองกลุ่ม คือกลุ่ม ก ประกอบด้วย 31 ราย อายุแต่ 5-15 ปี กลุ่ม ข อายุมากกว่า 15 ปี มี 19 ราย วิธีการเก็บข้อมูลมี 3 ข้อ คือ ข้อมูลด้านประชากรศาสตร์ ด้านฃุณภาพชีวิต และข้อมูลบริเวณริมฝีปากจมูก รายชื่อกลุ่มตัวอย่างครั้งแรกได้จาก 3 โรงพยาบาลในนครหลวงเวียงจันทน์ จากนั้นเข้าไปสัมภาษณ์ถึงกลุ่มตัวอย่างโดยตรงที่บ้าน ข้อมูลด้านประชากรศาสตร์ ด้านคุณภาพชีวิต วิเคราะห์เป็นค่าเฉลี่ย ร้อยละ ความถี่ ส่วนเบี่ยงเบนมาตรฐานโดยใช้โปรแกรม SPSS เวอร์ชั่น 13.0 และคะแนนความน่าเชื่อถือของกรรมการใช้สถิติ Kappa's statistics ในการประเมินบริเวณริมฝีปากและจมูก*

ผลการศึกษา: *คะแนนความน่าเชื่อถือในบริเวณจมูกริมฝีปากอยู่ในระดับ 0.2044 หรือร้อยละ 20 (P-value <0.0001) คะแนนรวมแต่ละมิติของบริเวณจมูกริมฝีปากเท่ากับ 3.15, 3.16, 3.36 และ 3.06 ตามลำดับ คะแนนรวมทั้งหมด เท่ากับ 3.18 คุณภาพชีวิต กลุ่ม ก เป็นเพศชาย 19 (61.3) ราย มีคุณภาพชีวิตในระดับปานกลางในด้านจิตใจ และความพึงพอใจ กลุ่ม ข เป็นเพศหญิง 11 (57.9) ราย มีคุณภาพชีวิตในระดับปานกลางเหมือนกลับกลุ่ม ก*

สรุป *: ผลลัพธ์ของการวิจัยในครั้งนี้แสดงให้เห็นว่า คะแนนความน่าเชื่อถือระหว่างคณะกรรมการผู้ทำการประเมินอยู่ในระดับค่อนข้างต่ำ อย่างไรก็ตามคุณภาพชีวิต 2 กลุ่มตัวอย่างอยู่ในระดับปานกลาง*