

Improvement of caregivers' life quality after children with cleft lip cleft palate undergoing surgical correction : The Thai Red Cross project.

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Boonplia U, Siriwan P, Snidvongs K. Improvement of caregivers' life quality after children with cleft lip cleft palate undergoing surgical correction: The Thai Red Cross project. Chula Med J 2017 Sep – Oct;61(5): 577 - 87

- Background** : *Cleft lip and cleft palate (CL/P) are among the most common congenital malformations of the face. These facial deformities significantly impact the mother, children, society and economy of the country. Studies have shown that surgical correction can improve the patient's appearance and functionality such as feeding and speech. However, there are limited information pertaining to the quality of life (QOL) of the caregivers after their children have received corrective surgery for cleft deformities and the use of mobile surgical units to reach the hard-to-reach population.*
- Objectives** : *To assess the quality of life (QOL) of the caregivers whose children received corrective surgery for CL/P offered through 'The repair of cleft lip and cleft palate and other deformities project of the Thai Red Cross Society utilizing the mobile unit technique.*
- Methods** : *Forty-four caregivers of children who received corrective surgery for CL/P were recruited from 23 – 26 May 2016, and 27 - 30 June 2016. As for the children, post –operative examinations were administered on week 2. As for the caregivers, the WHOQOL-BREF-THAI Questionnaire was administered at day 0 and month 3 after to assess their QOL.*

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- Results** : *A significant improvement was detected in all dimensions of the QOL: Overall quality of life and general health (80.9 ± 8.3 pre-surgery; 98.5 ± 7.5 post-surgery; $P < 0.001$), physical health ($P < 0.001$), psychology ($P < 0.001$), social relationships ($P < 0.001$), and the environment ($P < 0.001$).*
- Conclusion** : *Surgical correction for CL/P in the children significantly improves the QOL of the caregivers but this is not enough to eradicate the cause of the condition. Additional techniques are needed in conjunction with the corrective surgery such as education and mobile healthcare units which, when used together, can reduce the prevalence and incidence of CL/P.*
- Keywords** : *Caregiver, cleft palate, cleft lip, quality of life, mobile surgical repair of cleft lip cleft palate and other deformities.*

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Received for publication. March 8, 2017.

อุษา บุญเปลี่ยน, พิชิต ศิริวรรณ, กรเกียรติ์ สนิทวงศ์. การพัฒนาคุณภาพชีวิตของผู้ปกครอง
หลังจากผู้ป่วยปากแหว่งเพดานโหว่ ได้รับการผ่าตัดโครงการศัลยกรรมตกแต่งแก้ไขปากแหว่ง
เพดานโหว่และความพิการอื่นของสภาวิชาชีพ. จุฬาลงกรณ์เวชสาร 2560 ก.ย. - ต.ค.;
61(5): 577 - 87

เหตุผลการทำวิจัย : ภาวะปากแหว่งเพดานโหว่ เป็นความพิการแต่กำเนิดที่พบบ่อยที่สุดของ
ใบหน้า ปัญหาที่สำคัญของภาวะปากแหว่ง เพดานโหว่ คือ ทำให้เด็กดูคนม
ลำบาก มีปัญหาการกลืน การสำลักนม การอักเสบของหูชั้นกลาง
ซึ่งทำให้หูหนวกหรือหูตึงได้ นอกจากนี้ยังมีปัญหาการได้ยิน การออกเสียง
ไม่ชัด มีปัญหาการสบฟัน และยังมีปัญหาด้านรูปลักษณ์มีผลกระทบต่อ
ผู้ปกครองที่ดูแลเด็กมีความกังวลในการเลี้ยงดู รวมทั้งมีปัญหาลังคมและ
เศรษฐกิจของประเทศอย่างมาก อย่างไรก็ตามไม่มีการศึกษาคุณภาพชีวิต
ของผู้ปกครองหลังจากที่บุตรหลานของตนได้รับการผ่าตัดแก้ไขการผ่าตัด
แก้ไขปากแหว่งเพดานโหว่จากหน่วยผ่าตัดเคลื่อนที่ของสภาวิชาชีพ

วัตถุประสงค์ : เพื่อประเมินคุณภาพชีวิตของผู้ปกครองเด็กที่ได้รับการผ่าตัดแก้ไข ปากแหว่ง
เพดานโหว่จากหน่วยแพทย์เคลื่อนที่ โครงการศัลยกรรมตกแต่งแก้ไข
ปากแหว่งเพดานโหว่ และความพิการอื่นของสภาวิชาชีพ

วิธีการทำวิจัย : ผู้ปกครองเด็กที่ได้รับการผ่าตัดแก้ไขปากแหว่งเพดานโหว่จำนวน 44 ราย
ได้รับคัดเลือกตั้งแต่วันที่ 23 - 26 พฤษภาคม พ.ศ. 2559 และวันที่ 27 - 30
มิถุนายน พ.ศ. 2559 เด็กได้รับการตรวจติดตามผลการผ่าตัดในสัปดาห์ที่ 2
การเก็บรวบรวมข้อมูลใช้แบบสอบถามข้อมูลพื้นฐานของผู้ปกครอง และ
แบบสอบถามคุณภาพชีวิต WHOQOL-BREF-THAI ก่อนผ่าตัดและ 3 เดือน
เพื่อประเมินคุณภาพชีวิตของผู้ปกครอง

ผลการศึกษา : พบว่าคุณภาพชีวิตโดยรวมดีขึ้น (ก่อนผ่าตัด 80.9 ± 8.3 , 98.5 ± 7.5
หลังผ่าตัด, $P < 0.001$), ด้านสุขภาพกาย ($P < 0.001$), ด้านจิตใจ ($P < 0.001$),
ความสัมพันธ์ทางสังคม ($P < 0.001$) และด้านสิ่งแวดล้อม ($P < 0.001$)

สรุป : การผ่าตัดแก้ไขปากแหว่งเพดานโหว่ในเด็กทำให้คุณภาพชีวิตของ
ผู้ปกครองดีขึ้นอย่างมีนัยสำคัญ นอกจากนี้ที่สำคัญคือการให้ความรู้
การป้องกันความพิการแต่กำเนิดเพื่อลดอุบัติการณ์ของ ภาวะปากแหว่ง
เพดานโหว่รวมถึงความพิการแต่กำเนิดอื่น

คำสำคัญ : ผู้ปกครอง, ปากแหว่ง, เพดานโหว่, คุณภาพชีวิต, หน่วยผ่าตัดเคลื่อนที่
โครงการศัลยกรรมตกแต่งแก้ไขปากแหว่งเพดานโหว่และความพิการอื่น.

Cleft lip and cleft palate (CL/P) are the most common craniofacial congenital malformations.⁽¹⁻²⁾ The prevalence of oral cleft in Thais is around 1.1 - 2.4 per 1,000 live births.⁽³⁻⁴⁾ The causes of the deformities are still unclear but it has been hypothesized that both internal and external factors such as hereditary and/or the environment may be responsible for such deformities. The most common problems encountered are usually of women of reproductive age that become unintentionally pregnant, regardless of marital status, and medications that contribute to the development of these facial deformities such as dilantin, corticosteroid or other types of toxic chemicals⁽⁵⁾ to relieve the feeling of sickness. On the other hand, other women may continue to smoke and consume alcohol with or without the knowledge of its consequences to the unborn.⁽⁶⁻¹²⁾

Another factor that has been shown to significantly contribute to the deformities in infants is malnutrition, especially inadequate intake of folic acid. The World Health Organization (WHO) has recognized this and recommended that all women of reproductive age take 0.4 mg of folic acid daily, regardless of their pregnancy status.⁽¹³⁾ Folic acid is a vitamin B9 that has been shown to be safe when taken continuously at any dose at any gestational age. It is even recommended that the women with infants with thalassemia should take 5 mg of folic acid for long periods of time or life-long. However, folic acid must be taken at least 8 weeks before the woman is pregnant to ensure the prevention of CL/P and other facial deformities. Therefore, many women who have undergone family planning will not encounter such a problem because such information will already be

made available for them beforehand. It has been shown that taking folic acid for 8 weeks before pregnancy can prevent 1 out of 3 infants from developing CL/P.⁽¹²⁾

CL/P can negatively affect the mother, children, society and economy of the country.⁽⁴⁾ For instance, this condition can harm infants during breast feeding due to choking and problems in swallowing which usually results in the development of inflammation in the middle ear and can cause the infant to be deaf or partially deaf.⁽¹⁵⁻¹⁶⁾ To correct the deformities, children need to undergo multiple surgeries⁽¹⁷⁾ which can contribute to financial loss because the caregiver have to take time off from work to take care of their children.⁽¹⁸⁻¹⁹⁾ In addition, children with a chronic condition or disability may contribute to a more stressful familial situation.⁽²⁰⁾ Aside from that, some mothers are ashamed of their children's deformities that they refuse to take their children out for any social meeting or encountering which can contribute to the children's emotional and psychological problems attributed to having CL/P. As the children grow older, this can cause them to have problems in pronouncing words, and inability to clearly communicate with others. As a result of this, these children will have low self-esteem, encounter stigma/discrimination/bullying by other children in school or neighborhood, and will require long-term care by their caregivers.⁽¹⁶⁻²¹⁾ We believe that it can dramatically affect the caregivers' quality of life

As for those who have infants with CL/P, corrective plastic surgeries are available. In Thailand, through the national healthcare scheme, corrective plastic surgeries are offered freely to all infants. But the problem is that the caregivers lack money to pay

for transportation and living cost during the time they are attending their child at the hospital and their inability to work during such time. Hence, they have no access to the services provided by the government. As a result, many caregivers opt not to have the corrective surgeries for their children. In order to solve this problem, the Thai Red Cross Society has developed a surgical mobile unit, known as the Repair of Cleft Lip Cleft Palate and Other Deformities Project since 1998 to provide corrective surgeries 6 times per year. This Unit actively seeks for children with CL/P by using healthcare volunteers. Notifications from the public healthcare staff at the local hospitals and community clinics also help the Unit accomplish its goals. Once a case is detected and notified to the Unit, to get corrective surgery for free with financial support to cover up for the transportation costs and to improve quality of life of the caregivers. And in the recent years the Unit provides information about prevention of the deformity by take 0.4 mg of folic acid daily to the caregivers as the World Health Organization (WHO) has recommended.

In addition, this study is aimed to assess the knowledge regarding the prevention of the congenital malformations of caregivers of the children with CL/P who have been scheduled for corrective surgery and to assess the quality of life (QOL) of the caregivers whose children have received corrective plastic surgery. The results from this study should provide more informative data regarding how the country should proceed to reduce the prevalence and incidence of CL/P and other congenital malformations.

Materials and Method

This is a prospective study. General

demographic data were collected through the first part of the questionnaire. The World Health Organization (WHO)'s short Thai version (WHOQOL- BLEF- THAI)⁽²²⁾ was used to acquire pre- and 3-month post-corrective surgery from the caregivers. Physicians, healthcare volunteers or public healthcare staff at the local hospitals and community clinics participated in the study referred the targeted study population to the authors. Caregivers were fathers, mothers, or anyone who took care of the children with CL/P. When the caregivers were interested in acquiring corrective surgery for their children, these cases were referred to the authors for the study. Non-Thai, pregnant women and caregivers with any psychological problem were excluded from the study.

Two hundred children with CL/P and other deformity were evaluated by plastic surgeons at the mobile unit. The study was performed in two provinces, Surin and Chaiyaphum. Caregivers of children with CL/P were recruited at the Surin Hospital from 23 – 26 May 2016, and at the Chaiyaphum Hospital from 27 – 30 June 2016. Forty- four children were recruited for surgery through the Thai Red Cross Society's project.

The World Health Organization (WHO)'s short Thai version (WHOQOL- BLEF- THAI developed by the World Health Organization (WHO) for quality of life was 100 instruments. The instrument reliability study was based on Cronbach's alpha coefficient of 0.8406 content validity 0.6515

This study has been approved by the Institutional Review Board (IRB), Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. Written informed consent was obtained from all caregivers prior to the screening process. The study was

conducted according to the Declaration of Helsinki and Good Clinical Practice (GCP).

Statistical analysis

The frequency, percentage, standard deviation and range were used to describe the knowledge for prevention and the characteristics of the caregivers of the children who were scheduled for surgery to correct for CL/P. Paired *t*-test was used to compare pre- and post-surgery of the caregivers' QOL.

Results

A total of forty-four caregivers participated in this study. Characteristics of the study population are shown in Table 1. 84.1% of female caretakers were between the ages 31 and 45 years. 45.5% of the

caregivers were mothers of the children. 56.8% of the caregivers had 6th grade level of education. 43.2% of the caregivers had < 6,000 baht income per month. 56.8% of the caretakers were married. 86.4 % of the caregivers had 2 children. 50% of the children had underwent operation to correct for the cleft lip. 55.4% of the children had corrective surgery for cleft palate. 38.65% of the children had corrective surgery for both cleft lip and cleft palate. Prevention Knowledge of the Caregivers are shown in Table 2. 4.5% of the caregivers had knowledge how to prevent deformities in children. At baseline, 88.6% of the caregivers did not know how to prevent deformities. At baseline, 93.2% of the caregivers did not know that folic acid prevents congenital deformities whereas only 6.8% of the caregivers knew of the information.

Table 1. Characteristics of the caregivers of children who were scheduled to receive corrective plastic surgery for cleft lip, cleft palate and other facial deformities.

Variables	Caregivers (N = 44)	Percentage (%)
Sex		
Male	7	15.9
Female	37	84.1
Age		
<18 years	2	4.5
18-30 years	13	29.5
31- 45 years	20	45.5
>45 years	9	20.5
Relationship to children with cleft lip, cleft palate and other facial deformities		
Father	8	18.2
Mother	25	56.8
Relative	11	25.0
Educational level		
≤ High school	39	88.6
≥ Bachelors	5	11.4

Table 1. (Con) Characteristics of the caregivers of children who were scheduled to receive corrective plastic surgery for cleft lip, cleft palate and other facial deformities.

Variables	Caregivers (N = 44)	Percentage (%)
Income		
≤ 6,000 baht per month	25	56.8
≥ 6,000 baht per month	19	43.2
Marital Status		
Married	38	86.4
Divorced/Separated	2	4.5
Single	4	9.1
Number of children		
1 child	11	25.0
2 children	22	50.0
3 children	9	20.5
> 3 children	2	4.5
Any disability since infancy		
Yes	16	36.4
No	28	63.6
Type of surgery		
Cleft lip	24	55.8
Cleft palate	17	39.5
Cleft lip, cleft palate	2	4.7

Table 2. Prevention knowledge of the caregivers.

		Pre		Post	
		Frequency	%	Frequency	%
Knowledge of prevention congenital malformation	Don't know	39	88.6	9	20.5
	Know	5	11.4	35	79.5
Folic acid can prevent congenital malformation	yes	3	6.8	35	79.5
	no	41	93.2	9	20.1

QOL of the caregivers

Before the children had the corrective surgery for CL/P and other facial deformities, the caregivers had poor QOL and mental health which was consistent with another study.⁽⁵⁾ The overall QOL and general health of the caregivers, after their children had surgery such as cheiloplasty and palatoplasty, at 3 months improve from moderate to good quality of life that are shown in Table 3. There was a significant improvement seen in the QOL of the caregivers after their children had had the corrective surgeries ($P < 0.001$). When all 4 dimensions of the QOL were analyzed individually for the caregivers at month 3, significant improvements were seen for the physical health, psychology, social relationships and the environment ($P < 0.001$).

Conditions of the children pre- and post-corrective surgery

Before the corrective surgery, the children with CL/P had problems during breast feeding. The cleft palate made the children difficult to suck the milk from the breast. After corrective surgery, all in all, the results were good. There were no infections of the

wounds which healed properly. The children's function improved dramatically after corrective surgery.

Knowledge pre- and post-dissemination of information

At baseline, 88.6% of the caregivers did not know that there were some kinds of vitamin that could prevent the deformities. After providing education to the caregivers, only 20.5% of the caregivers still did not know that there were items that could prevent CL/P and other deformities. It is possible that these 20.5% of the caregivers were not the parent of the child and therefore were not paying attention to the information given. Also, there were 20.5% of the caretakers that were older than 45 years who may have some difficulties retaining information.

At baseline, 6.8% of the caregivers knew about folic acid whereas 93.2% did not. After the education about folic acid was provided to the caregivers, this increased to 79.5% even though some (20.5%) still did not know that folic acid could prevent CL/P. The reason for this may be due to disregard for the child and/or problems with short-term memory.

Table 3. Overall results of the WHOQOL-BREF of the Thai caregivers.

Dimension	Pre (day 0)	S.D	Post (month 3)	S.D	t-score	P-value
Overall QOL	80.9	8.3	98.4	7.5	-12.0	<0.001
Physical health	22.2	2.4	26.7	2.0	-11.2	<0.001
Psychology	19.5	2.6	24.3	2.6	-8.8	<0.001
Social & relationships	10.0	1.6	11.3	1.6	-4.1	<0.001
Environment	23.0	3.3	28.3	2.7	-10.4	<0.001

Discussion

From this study, the authors found out that the corrective surgery could improve the QOL of the caregivers in all dimensions. Not only that, but the post-surgical outcomes of the children also improved. None of the children had any opportunistic infections post-surgery. There were no infection of the wound. There were no longer problems with sucking the milk from the breast, swallowing and choking. In addition, the children no longer had any problems with speech impediment, became more confident in themselves and were no longer bullied in schools. Unit provided transportation and living costs to the caregivers which ensured that all caregivers have no stress about living cost during the time they tended their child at the hospital

Furthermore, the authors discovered that the knowledge of the caregivers were abysmal but significantly improved after the team provided them with the right kind of information to prevent the development of CL/P and congenital malformation. Hence, the authors highly recommend a scaled-up campaign for the use of folic acid through the educational system and various social media outlets as well as making it a legal requirement that all food products must contain certain amount of folic acid. It is crucial to provide information about folic acid to women of reproducing age, regardless whether they are married or not. Preventative measures are important in reducing the prevalence and incidence of CL/P. Aside from that, caregivers that became aware of the use of folic acid became more confident in having another child. Because of this, the authors cannot emphasize enough the importance of establishing a folic acid campaign to increase the

knowledge of women of all ages in order to prevent the development of CL/P and other congenital malformation. It is essential to fix the problem at its root before the situation exacerbates otherwise the prevalence of CL/P will never go down. Prevention is more cost-effective than only providing corrective surgery.

There are some limitations to the study. First, the short Thai questionnaire from the WHO to assess the QOL, WHOQOL- BLEF- THAI, has not been used or validated in the elderly, especially those above 60 years old. It is possible that some questions may be misconstrued to mean something else. For example, the authors noticed that many had difficulties addressing their satisfaction of their sexual activity. It is possible that the elderly are not comfortable in answering such a personal, direct question. If there were any problems in reading or understanding the questionnaires, the team would orally question the participants, going through each item-by-item in laymen terms. Last, the follow-up period was only 3 months. It is possible that the caregivers could have forgotten the information given to them after a long lapse of time has passed.

Conclusion

The results from this study show the quality of life of the caregivers significantly improve after their children have had corrective surgery by the repair of cleft lip cleft palate and other deformity project. And the importance of providing education to the caregivers, particularly women of reproducing age regardless of marital status. This should be done in conjunction with many organization at national level, including policy-makers. Reducing the prevalence

and incidence of CL/P is doable and feasible if there are campaigns for the consumption of folic acid, and addition of folic acid in the right amount in all food products as seen in other developed countries.

Acknowledgements

The authors would like to offer especial thank to Dr. Nucharee Supat for her statistical analysis of the raw data. We acknowledge the following organizations for their contributions to the Repair of Cleft Lip Cleft Palate and Other Deformities Project, Relief and Community Health Bureau, The Royal Thai Red Cross Society, and the Ministry of Public Health. The authors would also like to thank all volunteer doctors and nurses who worked at Surin and Chaiyapoom Hospitals, and the plastic surgeons who worked for the mobile surgery unit, namely: Dr. Witoon Wisuthseriwong, Dr. Seni Kupgan, Dr. Pornthep Pungrasmi, Dr. Pasu Promniyom, Dr. Suttisun Jankajorn, Dr. Watchara Burapholkul, Dr. Weerachai Weerapakorn, Dr. Tanapron Termwattanaphakdee, Dr. Kamolwan Panichapong, Dr. Jitrawee Maneewong, Dr. Pathama Panyawong, and Dr. Kasama Nilprapha; orthopedics surgeon Dr. Pravit Kitidumrongsook, Dr. Nattawut Sastravaha and Dr. Pobe Luangjarmekorn; and anesthesiologists: Dr. Chaiyapruk Kusumaphanyo, Dr. Thitiya Ngammesri, Dr. Oraluxana Rodanant, Dr. Anantachote Vimuktanandana, Dr. Pornarun Charoenraj and Dr. Ratchanu Anutinmanee; pediatrician: Dr. Vorasuk Shotelersuk; and, Nurse Ms. Supanee Somwangprasert. In addition, we would like to thank the Thai Red Cross Nurses and all of the residents of King Chulalongkorn Memorial Hospital who helped us with this study. Moreover, we would like to thank the staffs at Surin Hospital and

Chaiyaphum Hospital for their kind contributions and Dr. Niti Jumpajiam and Mrs. Piyacha San-Glar for their cooperation.

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