

## Effects of Innovated Preparation Program for Caregivers of Pediatric Patients Undergoing Palatoplasty

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**Objective:** To study the effects of an innovated preparation program for caregivers on their anxiety, understanding of how to care, and ability to conduct pain assessment and pain management for children after palatoplasty.

**Materials and Methods:** This research was a quasi-experimental study of 2-groups pre-posttest design. The sample group comprised of 40 cases, including pediatric patients with cleft palate who were currently in the preparation stage prior to surgery, as well as their caregivers. They were divided into an experimental group and a control group with 20 subjects each. The research procedure for the experimental group was based on the implementation of an innovated preparation program for the caregivers of the cleft palate children undergoing palatoplasty in combination with care as conventional method. Meanwhile, the control group received care as without the preparation program.

**Results:** The caregivers of the experimental group showed decreased anxiety with lower average anxiety score than those of the control group ( $p$ -value  $<0.05$ ). In addition, the caregivers in the experimental group had more understanding of how to take care of the postoperative children, and they were able to perform pain assessment and management for the children significantly better ( $p$ -value  $<0.05$ ) than those of the control group.

**Conclusion:** The innovated preparation program for caregivers of cleft palate children can reduce anxiety and increase understanding of how to take care of children after palatoplasty.

**Keyword:** Cleft lip and palate [CLP], Palatoplasty, Caregivers

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Worldwide, the incidence of cleft lip and palate was 1.1 persons per 1,000 live births<sup>(1)</sup>. In Thailand, more than 2,000 newborns had all types of cleft<sup>(2)</sup>, and in northeast of Thailand, approximately 2.49 of every 1,000 live births had cleft lip and cleft<sup>(3)</sup>.

Pediatric patients with all types of cleft, undergone surgery, 65 percent of them had cleft lip with cleft palate<sup>(1)</sup>. The treatment procedure for cleft lip and palate [CLP] is divided into two stages of surgery. The first stage is to correct cleft lip (Cheiloplasty) for

children ages 3 to 6 months, and the second stage is to correct cleft palate (Palatoplasty) for children ages 10 to 18 months<sup>(2)</sup>.

Palatoplasty has more complicated surgical procedures and need more special child care than cheiloplasty for example, hunger from food and drink abstention before surgery, pain from the surgery wound, difficulty with eating because of mouth wounds, postoperative fevers, etc. The operation performed on these children contributes to anxiety in their caregivers<sup>(4)</sup>.

One previous study found that caregivers of children with cleft lip and palate, undergo surgery had high anxiety and need help. However, the results of information giving strategies regarding caring after surgery was not significantly reduced caregivers'

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anxiety due to one time teaching before receiving surgery, no appropriate training for pain management and lack of skill training for post-operative care<sup>(5)</sup>. In addition, several studies regarding pre-operative intervention programs found that caregivers' experience on visiting operation room, knowing steps of caring for their children before and after surgery could reduce caregivers' anxiety significantly. Teaching and training for caregivers should be more than one time and occur 2 to 7 days before surgery<sup>(6)</sup>.

Effective care of children undergoing palatoplasty requires developing the caregivers' potential in order to take care of the children more effectively post-surgery. The caregivers have to prepare the children before undergoing palatoplasty. This requires the children to refrain from breastfeeding or bottle-feeding for some time prior to the surgery. Preparation must continue to take place until the caregiver gains enough confidence to care for the child properly. The present researchers, therefore, developed a new preparation program for the caregivers of children with cleft palate who are undergoing palatoplasty. Nurses also play an important role in supporting caregivers' potential for caring for the children.

This research study aimed to investigate effects of the aforementioned innovated preparation program for caregivers on their anxiety levels, their understanding of how to care for the children, and their pain assessment and management post-operation, where children have undergone corrective cleft palate surgery.

## Materials and Methods

### Sample size calculation

The sample size was calculated in order to compare the mean between two independent populations with the confidence level 95% and test's power at 80%. These values were derived from Sangkhamal's study (2002)<sup>(7)</sup>, which investigated the effects of a preparation program prior to surgery on caregivers' anxiety when caring for pediatric patients ages one month to 6 years undergoing an open heart operation. It was found that the difference in means of anxiety levels between the experimental and control groups was 9.40, with a standard deviation of 11.67; the sample size was calculated using the following formula:

$$n/\text{group} = \frac{(Z_{\alpha} + Z_{\beta})^2 2\sigma_d^2}{(\mu_1 - \mu_2)^2}$$

Where: n = number of samples,

$Z_{\alpha}$  = is valued at  $\alpha = .05$ , which is equal to 1.645

$Z_{\beta}$  = is valued at  $\beta = .20$ , which is equal to 0.84  
 $(\mu_1 - \mu_2)$  = the difference in means of anxiety levels between the experimental and control groups after the experiment = 9.40

$\sigma_d^2$  = covariance of anxiety score =  $(11.67)^2 = 136.19$

Therefore, this study consisted of 40 participants divided into experimental and control groups with 20 participants each.

### Participants

Inclusion criteria for pediatric patients: Diagnosis of cleft lip and palate [CLP] and currently in the preparation phase prior to get palatoplasty; ages 10 to 18 months; no complications from previous corrective cleft lip surgery; no underlying diseases or other illnesses or disabilities.

Inclusion criteria for caregivers: Primary caregivers who were parents or authorized persons that had been granted the right to take care of the affected child during pre-operation, operation, and post-operation; ages 18 to 60 years; good Thai language communication skills, including speaking, listening, reading, and writing.

Criteria for participants' withdrawal from the study included if complications arose during the surgery, such as active bleeding, a split surgical wound requiring a second operation in the same day, or in cases of requiring ICU monitoring.

### Experimental methods

This research was a quasi-experimental study of 2-groups pre-posttest design. The study employed a conceptual framework combining self-regulation theory<sup>(8)</sup> and the Symptom Management Model<sup>(9)</sup>. The sample group comprised 40 cases, including pediatric patients with cleft lip and palate who undergo palatoplasty were currently in the preparation stage prior to surgery, as well as their caregivers. They were divided into a study group and a control group with 20 subjects each. The research procedure for the study group was based on the implementation of an innovated preparation program for the caregivers of the cleft lip and palate children undergoing palatoplasty in combination with care as conventional method. Meanwhile, the control group received conventional care as without the innovated preparation program.

## **Study protocol**

### **Research tools**

1) The researcher constructed and developed research tools which were approved by 5 experts. The following research tools were improved before use:

1.1) Flip pictures with descriptions for teaching to the caregivers how to prepare the children for palatoplasty and a leaflet with descriptions about child care for the caregivers.

1.2) A VDO entitled “When You Have to Undergo Palatoplasty”.

1.3) Pain assessment form with FLACC pain scales.

2) The researcher tested the validity of the data collection tools, which were approved by experts and subsequently piloted for reliability on 20 of caregivers of cleft palate children who were undergoing palatoplasty. The quality of research tools were as follows:

2.1) Trait anxiety assessment form was adapted from the State-Trait Anxiety Inventory (STAI Form), constructed by Spielberger<sup>(10)</sup> in a part of general information form (Cronbach’s Alpha Coefficient: 0.87).

2.2) State anxiety assessment form, was adapted from the State-Trait Anxiety Inventory (STAI Form), constructed by Spielberger<sup>(10)</sup> (Cronbach’s Alpha Coefficient: 0.84).

2.3) Assessment of understanding form, on caring for children undergoing surgery (CVI:0.82, Cronbach’s Alpha Coefficient: 0.78).

2.4) Knowledge assessment form, on caring for children undergoing corrective cleft palate surgery- data collected by phone (CVI: 0.82, KR-20: 0.78).

2.5) Assessment of understanding form, on pain assessment of postoperative children (CVI: 0.87, Cronbach’s Alpha Coefficient: 0.83).

### **Data collecting procedure**

After the research project had been approved by the Khon Kaen University Ethics Committees for human research (HE591386) and the researcher was granted permission by the Srinagarind Hospital Director and Nursing Director to collect data.

Data collection: the research activities were initiated and the researcher collected data from the 20 participants in the control group, followed by the 20 participants in the study group, as follows.

1) Planning and anticipating surgery phase: The researchers explained the details of the project. If the eligible participants were willing to participate in the study, the researchers asked for consent from the

caregivers. After that, the researchers examined the date of surgery prescribed by the physician, and then proceeded to collect data prior to the experiment, using the relevant data collection tools. In the study group, the researchers proceeded to teach and demonstrate methods for caring for pediatric patients using the constructed teaching tools. After that, the researchers confirmed the date of surgery with the participants and asked permission to conduct follow-up assessments by phone on their knowledge of preparing pediatric children for surgery, informing them of the number of calls to expect (Three follow-up). As the details of the program were as follows:

Step 1: The caregivers were provided with information regarding what to do to prepare the children for the surgery. Instruction was conducted using flip pictures, lectures, and demonstrations of fever management, including proper posture for enhancing comfort and for eating during the postoperative period. The caregivers also learned how to use a pain assessment form with FLACC pain scales, a type of pain assessment tool. In addition, they were provided with an instructional leaflet reviewing ways to care for children undergoing corrective cleft palate surgery before discharge (45 minutes long).

Step 2: Three follow-up assessments on the knowledge of the caregivers regarding preparation for surgery.

First follow-up: Having received Phase 1 of the program one month prior, the caregivers were assessed through a phone call and using an assessment form for caring of children undergoing corrective cleft palate surgery. If the caregiver did not pass 80 percent of the knowledge criteria, they were required to redo the program (15 minutes long).

Second follow-up: One month prior to the appointment for surgery, the caregivers were reassessed using the same assessment form. If the caregiver did not pass 80 percent of the knowledge criteria, they were required to redo the program. At this point, the nurse also confirmed the first day for refraining from breastfeeding or bottle-feeding (20 minutes long).

Third follow-up: 14 days prior to the appointment for surgery, the nurse called to remind the caregiver of the activity’s starting day and to emphasize the importance of the activity and of keeping records in the provided leaflet (15 to 20 minutes long).

2) Surgery phase: The caregivers and children were supervised according to the usual surgical procedures of the ward. The researchers met with the participants on the evening of the day the children

were admitted in order to inquire about issues related to staying in the hospital, to listen to comments and to collect data post-experiment using the relevant data collection tools. Only study group, the caregivers was monitored about caring for the children and their record keeping using the pain assessment by the research form on the day of surgery (Day 0) and postoperative day (Day 1).

3) Preparation for discharge phase: In discharge day (Day 2), after the nurse in the ward had provided routine suggestions. In study group, the researcher collected the pain assessment form used to record the pain of the children during the post-operation period until discharge and reviewed the methods for caring for the pediatric patients, as well as provided an opportunity for the caregivers to raise any inquiries. But in control group, the researchers met with the caregivers to re-teach, re-demonstrate and practice ways to take care of pediatric patients.

#### **Statistical analysis**

1) General information derived from the caregivers and the pediatric patients was analyzed using frequency, percent, mean, and mean scores of trait anxiety in the caregivers.

2) The mean scores of state anxiety, understanding on caring for children undergoing palatoplasty and understanding on pain assessment and management for postoperative children from the pre-experiment and post-experiment periods were compared using a paired t-test and the mean scores from the control and experimental groups were compared using an independent t-test.

#### **Results**

##### ***Personal information and general medical treatment of the participants (the caregivers and the pediatric patients) and the mean scores comparison between the study and control groups of trait anxiety in the caregivers***

Seventy five percent of the 40 caregivers were the mothers of the children undergoing palatoplasty, 17.5 percent were the affected children's grandmothers, and 7.5 percent were their fathers. Furthermore, general information derived from the caregivers between the study and control groups were analyzed by Chi-square; found these participants were a homogeneous group. The trait anxiety scores of the caregivers in the control and experimental groups fell between 20 and 35, indicating minor levels of anxiety<sup>(1)</sup>. Both groups showed the same characteristics of anxiety (Table 1).

Concerning the children undergoing corrective cleft palate surgery, it was found that the average age of the children was 13.5 months old and there were 21 males and 19 females. 62.5 percent of the affected children were firstborns. It was found that a number of the patients had one or more siblings who had also been diagnosed with cleft lip and/or cleft palate. None of the affected children had another surgery in their medical history aside from corrective cleft lip surgery. 23 percent had been diagnosed with the complete unilateral type of cleft lip and palate.

##### ***Comparison of pretest and posttest mean scores between study and control groups of state anxiety, understanding on taking care of children and understanding regarding pain assessment and management for children undergoing palatoplasty***

The pretest mean scores of anxiety, understanding on taking care of children and understanding regarding pain assessment and management for children of the caregivers of the children undergoing palatoplasty in the study and control groups were compared subsequent to a statistically not significant difference was found at the level of 0.05.

The posttest mean scores of anxiety, understanding on taking care of children and understanding regarding pain assessment and management for children of the caregivers who had taken part in the preparation program was significantly different at the level of 0.05 from the mean score of those who had not attended the program (Table 2).

##### ***Comparison of pretest-posttest mean scores in study group and control group of state anxiety, understanding on taking care of children and understanding regarding pain assessment and management for children undergoing palatoplasty***

Study group, pretest-posttest mean scores of state anxiety, understanding on taking care of children and understanding regarding pain assessment and management for children were compared subsequent to a statistically significant difference was found at the level of 0.05.

Control group, pretest-posttest mean scores of state anxiety and understanding regarding pain assessment and management for children were compared subsequent to a statistically significant difference was found at the level of 0.05. But pretest-posttest mean scores of understanding on taking care of children was found not significant different at the level of 0.05 (Table 3).

**Table 1.** Personal information and general medical treatment of the participants (the caregivers)

Characteristics	Study group (n = 20)		Control group (n = 20)	
	n	%	n	%
Relationship				
Father	1	5.0	2	10.0
Mother	15	75.0	15	75.0
Grandfather/Grandmother	4	20.0	3	15.0
Age (years)				
18 to 25	5	25.0	6	30.0
26 to 35	9	45.0	9	45.0
36 to 45	2	10.0	3	15.0
46 to 55	3	15.0	2	10.0
More than 55	1	5.0	0	0.0
Age (Mean, SD)	$\bar{x} = 33.05, SD = 11.49$		$\bar{x} = 31.15, SD = 9.35$	
Sex				
Male	1	5.0	2	10.0
Female	19	95.0	18	90.0
Education level				
Primary school	5	25.0	4	20.0
Secondary school	2	10.0	5	25.0
Diploma	0	0.0	1	5.0
High Vocational	4	20.0	5	25.0
Bachelor's degree	8	40.0	5	25.0
Master's degree	1	5.0	0	0.0
Occupational				
Government/State enterprises/Private employee	9	45.0	7	35.0
Agriculture	4	20.0	8	40.0
Contractors	2	10.0	2	10.0
Retail/Business	3	15.0	2	10.0
Others	2	10.0	1	5.0
Income (bath/month, mean)	$\bar{x} = 42,050, SD = 25,075.62$		$\bar{x} = 40,650, SD = 25016.36$	
Number of family members				
2 to 4	17	85	12	60.0
More than 5	3	15	8	40.0
Number of family members (Mean, SD)	$\bar{x} = 3.85, SD = 0.81$		$\bar{x} = 4.25, SD = 0.97$	
Experience in caring for children or family members when having pain from surgery				
Yes	14	70.0	12	60.0
No	6	30.0	8	40.0
Trait anxiety of the caregivers	$\bar{x} = 34.95, SD = 4.45$		$\bar{x} = 32.60, SD = 3.50$	

### **Comparison of pain assessment and management for postoperative children**

Results from utilizing the pain assessment and management form revealed that 100 percent of the caregivers in the experimental group assessed the children's pain every four hours and recorded a pain score and pain management activities of the caregivers on the pain record form. In contrast, the caregivers in the control group did not assess or manage the children's pain in any way.

### **Discussion**

The present study shows statistical significant difference of state anxiety, understanding on taking care of children and pain management for children undergoing palatoplasty between study and control groups. In the study group, there were statistical significant difference between pretest-posttest mean scores of state anxiety, understanding on taking care of children and pain management for children undergoing palatoplasty. These findings are similar to

**Table 2.** Comparison of mean scores of state anxiety, understanding on taking care of children and regarding pain assessment and management for children undergoing corrective cleft palate surgery between study group and control groups

Variables	Pre-test				Post-test			
	Study group (n = 20) x̄ (SD)	Control group (n = 20) x̄ (SD)	t	p-value	Study group (n = 20) x̄ (SD)	Control group (n = 20) x̄ (SD)	t	p-value
State anxiety	52.05 (2.64)	51.05 (3.03)	-1.11	0.27	34.10 (4.48)	48.55 (2.89)	12.11	0.00*
Understanding on taking care of children	78.00 (2.33)	78.65 (2.62)	0.83	0.41	84.85 (2.11)	79.85 (1.79)	-0.89	0.00*
Understanding regarding pain assessment and management for children	66.05 (2.42)	67.50 (2.98)	1.69	0.09	83.55 (1.82)	69.60 (2.30)	-21.25	0.00*

p-value <0.05

**Table 3.** Comparison of mean scores of state anxiety, understanding on taking care of children and regarding pain assessment and management for children undergoing corrective cleft palate surgery between study group and control groups

Variables	Study group (n = 20)				Control group (n = 20)			
	Pretest scores x̄ (SD)	Posttest scores x̄ (SD)	t	p-value	Pretest scores x̄ (SD)	Posttest scores x̄ (SD)	t	p-value
State anxiety	52.05 (2.64)	34.10 (4.48)	14.06	0.00*	51.05 (3.03)	48.55 (2.89)	2.44	0.02*
Understanding on taking care of children	78.00 (2.33)	84.85 (2.11)	-10.28	0.00*	78.65 (2.62)	79.85 (1.79)	-2.03	0.06
Understanding regarding pain assessment and management for children	66.05 (2.42)	83.55 (1.82)	-24.18	0.00*	67.50 (2.98)	69.60 (2.30)	-2.29	0.03*

p-value <0.05

Saivaree and Chuchat's research study<sup>(11)</sup> as studied in 20 mothers who received information on an information program on the anxiety levels of mothers of children undergoing open heart surgery compared with 20 of mothers who received routine care. This study found a significant difference in mothers' anxiety levels.

Regarding the preparation phase, the caregivers' readiness was an important factor, but the short preparation phase could cause ineffective care of the children due to caregivers experiencing an information overload. One study argued that providing information for caregivers at certain proper periods of time prior to the date of surgery should be required. The current study spent 2 to 7 days providing

information to the caregivers, as according to the pre-operation program<sup>(6)</sup>. This resulted in effectively decreasing anxiety levels in the caregivers, while increasing their knowledge and understanding, as well as their level of participation in taking care of their postoperative children. However, the researchers argue that the proper range of time for providing information to the caregivers depends on the type of surgery and the postoperative guidance for said type of surgery. Guidance of caring for children undergoing corrective cleft palate surgery involved requiring behavioral adaptation from the children, as they had to adapt to being fed milk with a spoon or glass for 2 weeks<sup>(12)</sup> due to restrictions on milk consumption after surgery. Most of the time, the surgeon had set the date of operation 1



to 3 months in advance. Therefore, the researchers were able to plan a preparation program to be executed over a 1 to 3 month range of time. A reminder call to review knowledge with the caregivers must be conducted every month until the surgery date. This program provided an opportunity for caregivers to ask any questions concerning their care for the children at home prior to the surgery. During surgery, the researchers were able to prepare caregivers for providing care to the children. Understanding how to care for children undergoing corrective cleft palate surgery and having a proper attitude toward pain assessment and management for postoperative children can contribute to effective child care<sup>(13)</sup>. The program also supported children to manage different symptoms properly<sup>(14)</sup>. Finally, when caregivers had developed their potential for caring for the children, the children would be comfortable, without signs of suffering from surgical wounds.

### Conclusion

The innovated preparation program discussed in this study, tailored for caregivers of children undergoing corrective cleft palate surgery, can reduce anxiety and increase understanding of how to take care of children after palatoplasty, as well as how to assess and manage pain for postoperative children.

### What is already known on this topic?

The main treatment of cleft lip and/or cleft palate is surgery, which causes adverse symptoms to pediatric patients with cleft, which contributes to anxiety for caregivers. Therefore, caregivers should be prepared in a number of ways before the surgery. Methods to better prepare caregivers can help them plan strategies for child care ahead of time and help them prepare to take care of the child undergoing surgery.

### What this study adds?

This study presents methods to better prepare caregivers that could help them plan strategies for child care. The results from this study would be useful for future management of caregivers and pediatric patients who undergo surgery.

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### Potential conflicts of interest

The authors declare no conflicts of interest.

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## ผลของนวัตกรรมการเตรียมความพร้อมสำหรับผู้ดูแลของเด็กปากแหว่งเพดานโหว่ที่เข้ารับการผ่าตัดแก้ไขเพดานโหว่

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**วัตถุประสงค์:** ศึกษาผลของนวัตกรรมการเตรียมความพร้อมสำหรับผู้ดูแลที่มีความวิตกกังวล ความเข้าใจในการปฏิบัติตัวเพื่อดูแลเด็ก การประเมินความปวด และการจัดการความปวด แก่เด็กหลังผ่าตัดแก้ไขเพดานโหว่

**วัสดุและวิธีการ:** การศึกษานี้เป็นการวิจัยกึ่งทดลองชนิด 2 กลุ่มวัดผลก่อนและหลังการทดลอง กลุ่มตัวอย่างคือ เด็กปากแหว่งร่วมกับเพดานโหว่ที่อยู่ในช่วงเตรียมเข้ารับการผ่าตัดแก้ไขเพดานโหว่และผู้ดูแล จำนวน 40 คน ในระยะการเตรียมที่จะเข้ารับการผ่าตัดแก้ไขเพดานโหว่ แบ่งเป็นกลุ่มควบคุมและกลุ่มทดลองกลุ่มละ 20 คน ดำเนินการวิจัยสำหรับกลุ่มทดลอง คือ นวัตกรรมการเตรียมความพร้อมสำหรับผู้ดูแลของเด็กที่เข้ารับการผ่าตัดแก้ไขเพดานโหว่ร่วมกับการดูแลตามระบบปกติ ส่วนกลุ่มควบคุมได้รับการดูแลตามระบบปกติเท่านั้น

**ผลการศึกษา:** ผู้ดูแลกลุ่มทดลองมีความวิตกกังวลลดลงและต่ำกว่ากลุ่มควบคุม มีความเข้าใจในวิธีการปฏิบัติตัวเพื่อดูแลเด็ก รวมทั้งการประเมินความปวดและการจัดการความปวด แก่เด็กหลังผ่าตัดแก้ไขเพดานโหว่เพิ่มขึ้นและสูงกว่ากลุ่มควบคุม อย่างมีนัยสำคัญทางสถิติที่ระดับ 0.05

**สรุป:** นวัตกรรมการเตรียมความพร้อมสำหรับผู้ดูแลของเด็กที่เข้ารับการผ่าตัดแก้ไขเพดานโหว่ ช่วยลดความวิตกกังวลและทำให้ผู้ดูแลเกิดความเข้าใจการดูแลเด็ก เมื่อเข้ารับการผ่าตัดแก้ไขเพดานโหว่มากขึ้น

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