การประเมินความน่าเชื่อถือของเครื่องมือวัดระดับความเจ็บปวด ภายใน 24 ชั่วโมงหลังผ่าตัดในเด็กไทยวัย 1-5 ปี

สุวรรณี สุรเศรณีวงศ์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาสุขภาพ หลักสูตรการพัฒนาสุขภาพ
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2542

ISBN 974-333-382-7

VALIDATION OF PAIN MEASUREMENTS IN THAI CHILDREN AGED 1-5 YEARS WITHIN 24 HOURS FOLLOWING OPERATION

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A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science in Health Development

Health Development Program

Faculty of Medicine

Chulalongkorn University

Academic Year 1999

ISBN 974-333-382-7

Title	:	Validation of pain measurements in Thai children aged 1-5 years within 24 hours following operation
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สุวรรณี สุรเศรณีวงศ์: การประเมินความน่าเชื่อถือของเครื่องมือวัดระดับความเจ็บปวดภายใน 24 ชั่วโมงหลังผ่าตัดในเด็กไทยวัย 1-5 ปี (VALIDATION OF PAIN MEASUREMENTS IN THAI CHILDREN AGED 1-5 YEARS WITHIN 24 HOURS FOLLOWING OPERATION) อาจารย์ที่ปรึกษา: ศ. นพ. จิตร สิทธิอมร, พ.บ. ,M.Sc.,Ph.D., อาจารย์ที่ปรึกษาร่วม: ผศ.พญ. อุบลรัตน์ สันตวัตร, พ.บ.,M.Sc.,M.B.A., 87 หน้า , ISBN 974-333-382-7

รายงานนี้เป็นการศึกษาในผู้ป่วยเด็กหลังผ่าตัดวัย 1-5 ปีเพื่อหาเครื่องมือวัดระดับความเจ็บปวดโดยการสังเกตุพฤติกรรมที่มีความจำเพาะและความไวสูง ความน่าเชื่อถือและความถูกต้อง ตลอดจนประเมินความสามารถด้านการใช้งาน การวิจัยเชิงพรรณนานี้เปรียบเทียบเครื่องมือ 3 ชนิด ได้แก่ OPS(O), TPPPS(T) และ FLACC(F) กับเครื่องมือมาตรฐาน CHEOPS(C) เครื่องมือวัดได้รับการแปลเป็นภาษาไทยรวมทั้งตรวจสอบ content validity และ reliability พฤติกรรมของผู้ป่วยจำนวน 167 รายจะถูกบันทึกในเทปวีดีทัศน์เป็น 5 ระยะ คือ ก่อนผ่าตัด ก่อนและหลังให้ยาแก้ปวดที่ห้องพักฟื้น ก่อนและหลังให้ยาแก้ปวดที่หอผู้ป่วย ผู้ให้คะแนน 4 คนซึ่งไม่เคยเห็นผู้ป่วยจะให้คะแนนจากเทปวีดีทัศน์ซึ่งได้รับการตัดต่อแบบสุ่มโดยไม่เรียงลำดับขั้นตอน ผู้ให้คะแนน 1 คนใช้ CHEOPSตลอดและอีก 3 คนใช้ 3 pain scales ที่เหลือในการให้คะแนน นอกจากนั้นยังประเมินความสามารถด้านการใช้งาน และทดสอบความพึงพอใจในการใช้งานจากพยาบาลจำนวน 30 ราย

ผลการศึกษาพบว่า Interrater reliability ดีมาก (ICC ของC=0.9164 , O = 0.9754 , T = 0.9092 และ F= 0.9265) สำหรับ Content validity พบว่า CHEOPS 7 ข้อ และ TPPPS 1 ข้อ มีค่า IC < 0.5 แต่เป็นข้อขัดแย้งเรื่องระดับคะแนนเป็นส่วนใหญ่ ส่วน Discriminant validity พบว่าทุกเครื่องมือมีคะแนนก่อนและหลังให้ยาแก้ปวดแตกต่างกันอย่างมีนัยสำคัญ ($p<0.001$) สำหรับ Predictive validity เมื่อเปรียบเทียบกับ CHEOPS cutoff point 6 ที่ห้องพักฟื้นพบว่า OPS และ FLACC ให้ความจำเพาะสูง (92.7% และ95.1% ตามลำดับ);ความไวสูง(90.7% และ 89.8% ตามลำดับ) ที่cutoff point 3 ขณะที่ TPPPS ด้อยกว่าให้ความจำเพาะเพียง 80.5% ความไว85.2% ส่วนที่หอผู้ป่วยไม่พบว่าเครื่องมือใดที่สามารถให้ความจำเพาะ และความไวได้สูงถึง 90% เลย ถ้าลดระดับ cutoff point ลงไปที่ 2 จะให้ค่าความจำเพาะและความไวที่พอรับได้ OPS ให้ความจำเพาะ 81.7% ความไว 80% และ FLACC ให้ความจำเพาะ 80.3% ความไว81.4% ส่วน TPPPS ไม่มี cutoff point ที่เหมาะสมเลย แต่ถ้าใช้ cutoff point เดิมที่ 3 พบว่าความไวของเครื่องมือต่ำเกินไป โดยOPS ให้ ความจำเพาะ 87.3% ความไว68.6% ,FLACC ความจำเพาะ 84.5% ความไว72.9% ส่วน TPPPS ให้ความจำเพาะ 88.7%ความไว 72.9% ส่วน Concurrent validity กับ CHEOPS พบว่าAgreement ที่ห้องพักฟื้น (Kappa: O = 0.792 ,T=0.619, F =0.795)และ ที่หอผู้ป่วย (Kappa: O= 0.617 , F=0.617)เป็นที่น่าพอใจ ค่า Spearman correlation อยู่ในระดับปานกลางถึงดีทั้งที่ห้องพักฟื้น (r O =0.799 , T 0.790 ,F =0.765 $p<0.001$) และที่หอผู้ป่วย (r O =0.798 ,T =0.826 , F =0.804 $p<0.001$) สำหรับ Practicality CHEOPS เสียเวลามากที่สุด (59 วินาที) TPPPS น้อยที่สุด (40.1 วินาที) และพบว่า CHEOPS เป็นที่นิยมกว่า OPS, TPPPS, FLACC การศึกษานี้พบว่าจากเครื่องมือทดสอบ 3 ชนิด OPS และ FLACC เป็นเครื่องวัดที่เหมาะสมโดยเฉพาะที่ห้องพักฟื้น แต่คุณสมบัติด้อยลงสำหรับการใช้ที่หอผู้ป่วย

ภาควิชา .....การพัฒนาสุขภาพ..... ลายมือชื่อนิสิต .....

สาขาวิชา ....การพัฒนาสุขภาพ..... ลายมือชื่ออาจารย์ที่ปรึกษา .....

ปีการศึกษา ...2542..... ลายมือชื่ออาจารย์ที่ปรึกษาร่วม .....

4175389830 : MAJOR HEALTH DEVELOPMENT
KEYWORD : POSTOPERATIVE PAIN/ MEASUREMENT/ CHILD
SUWANNEE SURASERANIVONGSE : VALIDATION OF PAIN MEASUREMENTS IN THAI CHILDREN AGED 1-5 YEARS WITHIN 24 HOURS FOLLOWING SURGERY. THESIS ADVISOR : PROF. CHITR SITTHI-AMORN, M.D.,M.Sc.,Ph.D. , THESIS CO-ADVISOR : ASSIST. PROF. UBOLRAT SANTAWAT, M.D.,M.Sc.,M.B.A., 87 pp. ISBN 974-333-382-7

This research aimed to find out the appropriate observational pain measurement with high specificity, sensitivity, reliability, validity and assess their practicality for Thai children aged 1-5 years within 24 hours following operation. This descriptive study validated the target tests: OPS (O), TPPPS(T), FLACC(F) with respect to the accepted reference tool:CHEOPS(C). All tools were translated and tested for reliability and content validity. Pain related behaviors in 167 children were videotaped in 5 periods: preoperative, before and after analgesics in recovery room, before and after analgesics in wards. Four observers, blinded to sequence of analgesics, rated the videotaped behaviors. One observer rated pain behaviors by using CHEOPS whereas the other 3 observers used target tests for rating. Satisfaction in pain scales were also evaluated in 30 nurses.

All tools had excellent interrater reliability(ICC of C=.9164, O=.9754, T=.9092, F=.9265).Concerning content validation, 7 items of CHEOPS and 1 item of TPPPS had IC less than 0.5, most of them were related to scale in ranking. All pain scales showed accepted discriminant validity from significantly different scores between before and after analgesics($p<.001$).

Predictive validity with respect to CHEOPS were tested. In recovery room, using cutoff point 3, OPS and FLACC yielded high specificity and sensitivity(OPS: specificity 92.7% sensitivity 90.7%, FLACC: specificity 95.1% sensitivity 89.8%). In wards, no tool could yield specificity and sensitivity as high as 90%. Provided cutoff point was lowered to 2, OPS and FLACC yielded the reasonable performance(OPS: specificity 81.7% sensitivity 80%, FLACC: specificity 80.3% sensitivity 81.4%). There was no suitable cutoff point for TPPPS. If previous cutoff point 3 was selected, sensitivity of all target tests were too low. OPS yielded specificity 87.3% sensitivity 68.6%, FLACC yielded specificity 84.5% sensitivity 72.9% and TPPPS yielded specificity 88.7% sensitivity 72.9%.

Concurrent validity of target tests with CHEOPS were compared. Agreement both in recovery room and wards were acceptable (Recovery room: Kappa O=.792, T=.619, F=.795 and Ward: Kappa O=.617, F=.617). Spear·man correlation of all target tests were moderate to good in recovery room(r: O=.799, T=.790, F=.765, $p<.001$) and wards(r: O=.798, T=.826, F=.804 $p<.001$). Practicality of scales were tested. Time consumed in rating CHEOPS was the most (59sec) and TPPPS was the least(40.1sec). CHEOPS was more satisfied than the target tests. This study indicated that among the three target tests, OPS and FLACC were appropriate especially in recovery room. The predictive capability of target tests were less efficient in wards.

ภาควิชา .....การพัฒนาสุขภาพ..... ลายมือชื่อนิสิต .....Suwannee Suraseranivongse.....
สาขาวิชา .....การพัฒนาสุขภาพ..... ลายมือชื่ออาจารย์ปรึกษา .....Chitr Sitthi-amorn.....
ปีการศึกษา .....2542..... ลายมือชื่ออาจารย์ที่ปรึกษาร่วม .....Ubolrat Santawat.....

ACKNOWLEDGMENT

I wish to express my deep gratitude to my advisor, Professor Chitr Sitthi-Amorn for his exceptionally wise and encourage criticism and advices , and co-advisor, Assistant Professor Ubolrat Santawat for her invaluable comments, suggestion and encouragement throughout this program. Special thanks for Associate Professor Aroon Chirawatkul for comments on part of data analysis. I also wish to thank Professor Chanika Tuchinda, the Dean of Faculty of Medicine, Siriraj Hospital, Mahidol University and Dr. Wilai Ratreesawat, the Director of Queen Sirikit National Institute of Child Health for their permission in carrying out the project. Finally, I would like to thank Dr. Anchalee Attachu, the Co-ordinator of Queen Sirikit National Institute of Child Health, the nurse staff of the Department of Surgery, Orthopedics, Otorhinolaryngology and Opthalmology in Siriraj Hospital and Queen Sirikit National Institute of Child Health for their appreciated cooperation.

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CHAPTER 1

BACKGROUND AND RATIONALE

Unrelieved postoperative pain results in psychological and pathophysiological responses. Psychological responses to severe and prolonged acute pain include fear, anxiety, depression, helplessness, sleep deprivation and regression behavior. Pathophysiological responses affect several organ systems: (1) ***respiratory system:*** muscle splinting from pain may decrease functional residual capacity and increase respiratory rate with small tidal volume which results in high oxygen consumption and contribute to hypoxemia (2) ***cardiovascular system:*** sympathetic overactivity from pain will increase heart rate, peripheral vascular resistance, blood pressure and cardiac output which result in increasing myocardial oxygen demand while intense sympathetic stimulation may produce coronary vasoconstriction and decrease myocardial blood supply (3) ***other system:*** pain may induce changes in blood coagulability and immobility of patients which may lead to venous thrombosis and pulmonary embolism. Increase sympathetic overactivity may result in gastric stasis, paralytic ileus and urinary retention[1].

Postoperative pain in children has been undertreated compared to adults[2]. The prevalence of pain on the day of surgery in children was varied up to institution. Mather and Mackie(*1983*)[3]reported that irrespective of treatment received, only 25% of the children were pain free on the day of surgery and approximated 40% experienced pain classified as moderate or severe pain. Khamrat, et al(*1998*)[4] surveyed postoperative pain

in Thai children aged from 4 years old and found that 80% reported at least 1 episode of unacceptable pain on the day of surgery. Difficulty in pain assessment frequently leads to undertreatment of pain in young children[3,5]. Children before school age usually lack of verbal and cognitive skill to describe their pain feeling or physical discomfort. Pain assessment and effective management in this population depend on the observation and expertise of the care provider.

Pain response is affected by several psychological factors such as culture differences, observational learning, cognitive appraisal, neuroticism and extroversion, attention and distraction, coping style, perceived control of events, fear and anxiety[1]. Behavioral observation pain assessment tools for toddler and preschool aged children were all developed in western countries. Therefore, these pain scales used in ethnic diversity as Thai children should be revalidated before using. In addition, the difference in categories of each behavioral pain scale may affect the practicality(table1). So this study aims to assess the appropriate behavioral observation pain measuring tools with high practicality for Thai children aged 1-5 years.

Table 1 Categories of behavior in pain assessment tools

CHEOPS	Conventional OPS	Modified OPS	TPPPS	FLACC
Facial expression			Facial pain expression	Face
Leg movement	Movement	Movement		Legs
Torso movement	Agitation	Agitation	Bodily pain expression	Activity
Cry	Cry	Cry	Vocal pain expression	Cry
Touching of the wound	Blood pressure	Posture		Consolability
Verbal report of pain	Verbal complaint and body language	Verbal complaint and body language		
Score 4-13	Score 0-10	Score 0-10	Score 0-7	Score 0-10

CHAPTER 2

LITERATURE REVIEW

2.1 Method of pain assessment in children

In general there are 3 approaches to pain measurement described as physiologic technique, behavioral observation and patient report[6].

2.1.1 Physiologic technique

In using physiologic techniques, variable changes induced by painful noxa such as increased respiratory rate, heart rate, blood pressure, palmar sweating and endocrine response are easy to measure objectively but suffer from lack of specificity. None of these variables has been proven useful in estimating pain intensity in the postoperative period.

2.1.2 Patient or self report

Patient or self report pain assessment is the best method available for both adults and children aged from 5 or 6 years who can co-operate and communicate in the process[7].

2.1.3 Behavioral Observation

In younger children who cannot rate their pain, behavioral observation has been extensively used for assessing pain intensity. Specific distress behavior: cry/communication, facial expression and body/motor movement are typically associated with pain [8-11]. However, there is ever present challenge of distinguish behavior due to other form of distress, such as hunger, thirst and anxiety. To facilitate the objective measurement of pain, clinicians and researchers have incorporated these specific distress behaviors into scales.

2.2 Behavioral observation pain assessment tools

The Children's Hospital of Eastern Ontario Pain Scale(CHEOPS)[12], the Objective Pain Scale(OPS)[13,14], the Toddler-Preschool Postoperative Pain Scale(TPPPS)[15], and the FLACC Pain Assessment Tool[16] are four such tools that have been reported in the literature.

2.2.1 CHEOPS

CHEOPS is a behavioral scale developed since 1985 by a group of pediatricians, psychologists and anesthesiologists. It was validated in children aged 1-7 years, based on observation of 6 aspects of behavior including cry, facial expression, verbal output,

movement of torso, touching of wound and movement of legs(table2). Each item was scored within a numerical interval and the total added up to arrive at a pain score. The child's responses were observed for 5 sec, followed by a 25-sec period for recording. This scale had acceptable interrater reliability with a greater than 80% agreement for all behavior categories. Validity was established by comparing the behaviors with each other, by relating CHEOPS scores to concurrent a visual analogue scale(VAS) done by nurses in the recovery room, by social validation and to changes in CHEOPS scores during administration of analgesics. A group of teachers who rated pain in films of children provided evidence of social validation. Their scores correlated with CHEOPS score obtained by a trained rater. Furthermore, CHEOPS has been validated after postoperative period in 1993 by relating to changes of pain during analgesic treatment and by correlating with self reported scales as Faces scale in patients aged 3-6.5 years (correlation=0.743, $p<0.0001$)[17]. CHEOPS will be used as "gold standard or criterion measure" behavioral pain measurement in this study due to its acceptable reliability and validity. Moreover, it has been widely used across the nations in North America, Europe and Asia[18-34]. Nevertheless, the clinical utility of CHEOPS is limited in routine practice by the inclusion of 28 separate behaviors to be evaluated across the behavior categories.

Table 2 CHEOPS

Item	Behavioral	Score	Definition
Cry	No cry	1	Child is not crying
	Moaning	2	Child is moaning or quietly vocalizing; silent cry
	Crying	2	Child is crying,but the cry is gentle or whimpering
	Scream	3	Child is in a full-lunged cry;sobbing:may be scored with complaint or without complaint
Facial	Composed	1	Neutral face expression
	Grimace	2	Score only if definite negative facial expression
	Smiling	0	Score only if definite positive facial expression
Child verbal	None	1	Child not talking
	Other complaints	1	Child complains,but not about pain;e.g., "I want to see mommy" or "I am thirsty"
	Pain complaints	2	Child complains about pain
	Both complaints	2	Child complains about pain and about other things:e.g., "It hurts; I want mommy"
	Positive	0	Child makes any positive statement or talks about other things without complaint
Torso	Neutral	1	Body (not limbs) is at rest; torso is inactive
	Shifting	2	Body is in motion in a shifting or serpentine fashion
	Tense	2	Body is arched or rigid
	Shivering	2	Body is shuddering or shaking involuntarily
	Upright	2	Child is in vertical or upright position
	Restrained	2	Body is restrained
Touch	Not touching	1	Child is not touching or grabbing at wound
	Reach	2	Child is reaching for but not touching wound
	Touch	2	Child is gently touching wound or wound area
	Grab	2	Child is grabbing vigorously at wound
	Restrained	2	Child's arm are restrained
Legs	Neutral	1	Legs may be in any position but are relaxed; includes gently swimming or serpentine-like movements
	Squirming/kicking	2	Definitive uneasy or restless movements in the legs and/or striking out with foot or feet
	Drawn up/ tense	2	Legs tensed and/or pulled up tightly to body and kept there
	Standing	2	Standing, crouching, or kneeling
	Restrained	2	Child's legs are being held down

2.2.2 OPS

Classical OPS, developed in 1988, incorporates 4 categories and requires documentation of a percentage changes in blood pressure from baseline(table1). Validity of classical OPS as measure of severe pain was established in children aged 13 to 18 years by a high correlation(0.89 to 0.98) of OPS scores with self-report using linear analogue scale[13]. The study also found that OPS scores were less valid in the presence of mild or moderate pain. In the younger children aged 8 months to 13 years, concurrent validation of classical OPS was performed with CHEOPS by using Pearson correlation. The correlation between two scales varied from 0.888 to 0.988[14]. Recently, classical OPS has been modified for parental use by excluding blood pressure measurement and adding postural observation instead, without validation reported(table3).

Table 3 Modified OPS

Criteria	observation	Score
Crying	None	0
	Consolable	1
	Not consolable	2
Movement	None	0
	Restless	1
	thrashing	2
Agitation	Asleep/calm	0
	Mild	1
	Hysterial	2
Posture	Normal	0
	Flexed	1
	Hold groin/throat	2
Verbal	Asleep/no complaint	0
	Complains/cannot localise	1
	Can localise	2
Total		*10*

2.2.3 TPPPS

TPPPS requires scoring in three general categories: vocal pain expression, facial pain expression and bodily pain expression (table4). A recent evaluation of TPPPS in children aged 1-5 years in the recovery room suggests that the scale has good reliability with estimated kappas for the pain behavior items varying from 0.53 to 0.78. There is evidence of validity and sensitivity to analgesic regimens and convergence between ratings of pain from nurses and parents. However, the validated study was restricted to patients undergoing inguinal hernia or hydrocoel repair which provided mild to moderate pain after surgery and given the disproportionate number of males. The ethnicity of the subjects was predominantly Caucasian, no Asian children were studied. Additionally, the observers were unblinded. Therefore, further studies in more painful surgery, control for analgesic factors, blind rating by observers and more ethnic diversity are recommended[15].

Table 4 TPPPS

Vocal Pain Expression:	Verbal pain complaint / Cry
	Scream
	Groan, moan, grunt
Facial Pain Expression:	Open mouth, lips pulled back at corners
	Squint, close eyes
	Furrow forehead, Brow bulge
Bodily pain expression:	Restless motor behavior /Rub or touch painful area

Score '1' if the behavior is present, score '0' if behavior is absent

2.2.4 FLACC

FLACC has been developed in 1994 and validated in 1997 for pain assessment in children aged 2 months to 7 years in the Post Anesthetic Care Unit(recovery room). The acronym FLACC(face, legs, activity, cry and consolability) was devised to facilitate recall of the categories included in the tool (table5). Construct validity of the FLACC tool was supported by the significant reduction in pain score after analgesic administration. Validity was further established by the high correlation of FLACC scores with the classical OPS(r = 0.8) and positive correlation(r = 0.41) with nurses' global pain rating scale[16]. In Thailand, pain scales are not routinely used. Decision to give analgesics are usually based on unconsolable cry after feeding (if possible), increased heart rate, increased blood pressure and long duration since last analgesics.

Table 5 FLACC

Categories	**Scoring**		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, move easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry(awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractable	Difficult to console or comfort

CHAPTER 3

CONCEPTUAL FRAMEWORK

RESEARCH QUESTION AND OBJECTIVES

3.1 Conceptual framework

3.1.1 According to the textbook of pain[1], several factors affect behaviors of pain response as illustrated in Figure 1. It might be postulated that behavioral pain observational scales developed for Western children should be re-validated in Thai children before using. In addition, pain is not constant, it varies from time to time. Pain behaviors in the recovery room or post anesthetic care unit(PACU) where there remains the residual effect of sedatives and anesthetics may not be similar to pain behaviors in the ward. So the target tests which have been validated in PACU should be re-validated in the ward.

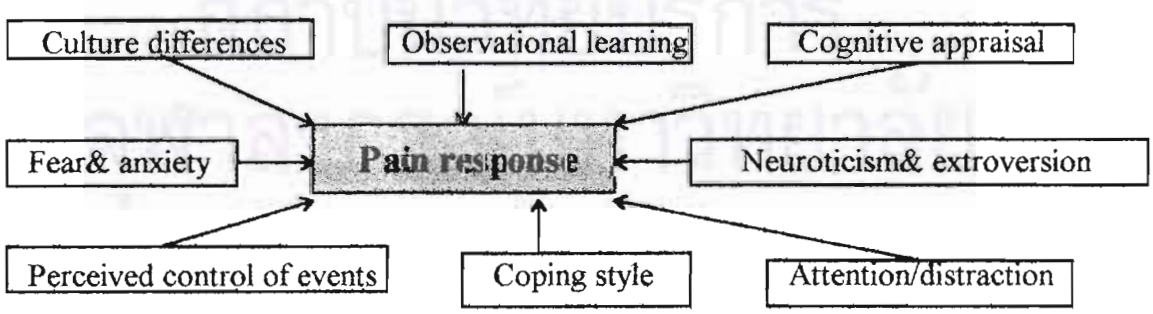


Figure 1 Factors affecting behaviors of pain response

3.1.2 There might be differences in praticality of each pain scale due to differences in categories and items (table 1).

3.2 Research questions

3.2.1. Primary research question

Among the target tests: modified OPS, TPPPS, FLACC:

(1) Which target test was most specific with respect to CHEOPS in children aged 1-5 years? The specificity of pain assessment tool was considered the most important for proper decision of effective and safe pain management.

3.2.2 Secondary research questions

(1) Which target tests had acceptable agreement (Kappa 0.8 $\pm$ 0.2) with respect to CHEOPS?

(2) Which target test was most sensitive with respect to CHEOPS in children aged 1-5 years?

(3) What were the relationship of target tests with respect to CHEOPS?

(4) What were the reliabilities of the behavioral objective pain measurement tools: modified OPS, TPPPS, FLACC and CHEOPS?

(5) Were there discriminant validities of the target tests and CHEOPS between pre- and post analgesic treatment?

(6) What were the satisfaction score of observers related to practicality of CHEOPS, modified OPS, TPPPS, FLACC?

3.3 Research objectives

The purposes of this study were to validate 3 observational pain scales: modified OPS, TPPPS, FLACC in Thai children aged 1-5 years with respect to CHEOPS and responsiveness to analgesic management within 24 hours postoperatively including both in recovery room and wards. Validation of tools with respect to CHEOPS and satisfaction score of observers due to simplicity were also determined to find out the high specificity, sensitivity, reliability, validity and high practicality for using as appropriate tools for observation pain measurement.

CHAPTER 4

RESEARCH METHODOLOGY

4.1 Research design

This was a descriptive study.

4.2 The sample

4.2.1 Target population

Thai postoperative pediatric patients aged 1-5 years who were supposed to have pain from operations such as abdominal surgery, thoracic surgery, closed heart surgery, orthopedic surgery, plastic surgery, urogenital surgery, eye and ear nose throat surgery.

4.2.2 Sample population

The patients who met eligible criteria in Siriraj Hospital and Queen Sirikit National Institute of Child Health which were the tertiary-care hospital with all kinds of surgical service for pediatric patients.

4.2.3 Eligibility criteria

4.2.3.1 Inclusion criteria

1) In-patients aged 1-5 years and either sex

2) Postoperative patients who were awaken from anesthesia

3) Parents agreed

4.2.3.2 Exclusion criteria

1) Patients with significant medical diseases who need postoperative ventilatory support including sedatives or muscle relaxants, patients with significant neurological disorders which deteriorate consciousness, sensation or muscle power.

2) Ambulatory patients

3) Intubated patients

4) Chronic pain

5) Preoperative CHEOPS > 6

4.2.4 Sample size

Sample size for specificity

Sample size calculation for diagnostic test $n = \frac{(Z_\alpha)^2 pq}{\delta^2}$

p = specificity, q = 1 - p, $\alpha = 0.05$, $Z_\alpha = 1.96$

High specificity as 90% was needed for effective and safe pain management

δ = variation of specificity = 10% = 0.1 was acceptable.

Decreased specificity from 90% to 80% or increased false positive rate from 10% to 20% was considered acceptable because harm from overdetection and overtreatment was least likely to occur due to the low prevalence of no pain[3] and safe analgesics prescription which included limited interval and maximum dose. Moreover, concerning the fear of side effects of analgesics especially narcotics, the children were routinely closed observed after the drugs given.

$$n = \frac{(1.96)^2(0.9)(0.1)}{(0.1)^2} = 34.5744$$

Prevalence of postoperative pain free= 25%[3]

Sample size for specificity = $\frac{34.5744 \times 100}{25}$ = 139 cases

4.3 Maneuvers

4.3.1 Translation of pain scales

CHEOPS, Modified OPS, TPPPS and FLACC were translated from English into Thai by 1st expert, then backtranslated from Thai into English by 2nd expert. The translated pain scales were rechecked with the original scales by 3rd expert whose English was his mother's language. Then all pain scales which were translated into Thai(Appendix 3) were corrected based on the third expert's opinion to yield the same meaning as original scales.

4.3.2 Content validation of translated pain scales

Translated pain scales: CHEOPS, Modified OPS, TPPPS, FLACC were tested for content validity by a pediatrician, a pediatric psychologist, a pediatric anesthesiologist, a pediatric surgeon, a nurse from pediatric surgical ward and a teacher from kindergarten.

4.3.3 Videotape collection of pain behaviors

1 = before surgery

2 = in recovery room when nurse called researcher that patients had pain, before analgesic administration

3 = in recovery room, 10 -30 minutes after analgesic administration

4 = in ward when nurse called researcher that patients had pain, before analgesic administration

5 = in ward, 10 -30 minutes after analgesic administration

Figure 2 Sequence of videotape collection of pain behaviors

Pain behaviors of each patient were recorded on 5 occasions as diagram in figure 2. Videotape recorder from remote area were used to record patients' behaviors to prevent patients' bias . Decision to administer pain medication in all cases would be made by nurses unassociated with the study based on routine practice using unconsolable cry, not relieved by feeding(if possible), child's complain and long duration since last analgesics.

In case that the patients had no pain in the recovery room, they would be videotaped just before they left the recovery room and recorded as the second period, no third period recorded in those cases.

Moreover, if researcher was not called when the patients stayed in wards, the patients would be assessed within 4-6 hours after last analgesic treatment (according to the duration of the last analgesics used). In case that the patients were considered to have pain, nurses would be called to decide in giving analgesics. They would be videotaped before and after analgesics in wards. If patients were not considered to have pain by nurses and researcher, their behaviors would be videotaped as the fourth period, without the fifth period in those cases.

4.3.4 Randomization of pain behaviors from videotapes

The videotaped pain behaviors, followed the sequence of diagram in figure 2, were rearranged into new sequence randomized by computer program to prevent bias about analgesic treatment.

4.3.5 Training and testing for reliability of observers

Four observers were trained how to use all pain scales from the recorded pain behaviors. Then 120 recorded pain behaviors were divided into 30 pain behaviors for each pain scale (CHEOPS, Mod. OPS, TPPPS, FLACC) to be tested for reliability. The first reliability of each pain scale was recorded. If there were defects of rating pain scores with low reliability, they would be corrected and each pain scale was retested for reliability by observing 30 behaviors for each pain scale. Any test with reliability less than 0.8 would be excluded from analysis.

4.3.6 Validation study in recovery room and wards

After training and testing reliability to acceptable level (> 0.8), the randomized videotape recorded pain behaviors were rated by 4 observers. All observers were blinded to sequence of videotape recording and analgesic treatment. There were 700 behaviors rated by each pain scale. Observer 1 rated only particular CHEOPS for all 700 behaviors independent from the other 3 observers. Whereas the target tests were rated by 3 observers as illustrated in Figure 3. Observer 2 rated behavior no. 1-233 by OPS, no. 234-467 by TPPPS, no. 468-700 by FLACC. Observer 3 rated behavior no. 1-233 by FLACC, no. 234-467 by OPS, no. 468-700 by TPPPS. Observer 4 rated behavior no. 1-233 by TPPPS, no. 234-467 by FLACC, no. 468-700 by OPS.

Figure 3 Diagram of rating pain behaviors

Number	Observer 1	Observer 2	Observer 3	Observer 4
1 - 233	CHEOPS	OPS	FLACC	TPPPPS
234 - 467	CHEOPS	TPPPS	OPS	FLACC
468 - 700	CHEOPS	FLACC	TPPPS	OPS

4.3.7 Practicality assessment

Practicality of pain scales was assessed by 30 nurses from 2 pediatric surgical wards, 1 pediatric orthopedic ward, 1 pediatric eye-ear-nose-throat ward and recovery room. After training how to use pain scales, 10 observations of pain from videotape were rated with 4 pain scales. The same 10 behaviors were repeated for each pain scale rated. Duration of rating started from the end of each behavior observation until rating finished. Then questionnaires about practicality of each pain scale including confusion in rating, easy scoring, easy interpreting, practical in routine use, expected problem in using, helping in assessment, helping in decision to treat, correlated with decision to treat were filled. Then satisfaction score were ranked as shown in Appendix 4.

4.4 Outcome measurement

4.4.1 Content validity

Content of each item of pain scale was validated and scored as 1, 0 and -1

1 = relative valid item

0 = not sure

-1 = relative irrelevant

4.4.2 Pain scores

Pain measurement were divided into 5 periods as following

1) Preoperative pain scores were defined as CHEOPS 1, OPS 1, TPPPS 1 and FLACC 1

2) Pain scores before analgesics in recovery room were defined as CHEOPS 2, OPS 2, TPPPS 2 and FLACC 2.

3) Pain scores after analgesics in recovery room were defined as CHEOPS 3, OPS 3, TPPPS 3 and FLACC 3.

In particular cases that patients were not considered to have pain, pain behaviors before leaving recovery room were recorded as CHEOPS 2, OPS 2, TPPPS 2 and FLACC 2 without pain behaviors after analgesics. Therefore, pain behaviors at period 3 in such particular cases would be omitted.

4) Pain scores before analgesics in wards were defined as CHEOPS 4, OPS 4, TPPPS 4 and FLACC 4.

5) Pain scores after analgesics in wards were defined as CHEOPS 5, OPS 5, TPPPS 5 and FLACC 5.

In some particular cases which nurses did not call researcher but she went to see the patients herself when the effect of last analgesics were expected to wear off. Those patients who were still considered "no pain" by researcher and nurses would be recorded behaviors in videotape as CHEOPS4, OPS4, TPPPS4 and FLACC4 "with no analgesics given". Then, pain behaviors at period 5 in such particular cases would be omitted.

4.4.3. Practicality assessment

Practicality of pain scales were assessed in 3 items

1) Comments in utility were scored in dichotomous scales "yes or no" concerning confusion in rating, easy scoring, easy interpreting, helping in assessment, helping in decision to treat, correlated with decision to treat, practical in routine use and expected problem in using,.

2) Duration of rating pain scales were recorded while 30 nurses rated 10 behaviors for each pain scale. Average time consumed for each pain scale used by 1 nurse was derived from summation of duration in rating 10 behaviors divided by 10. Total average time consumed for each pain scale would be yielded by summation of all time consumed from 30 nurses.

3) Satisfaction on pain scales were ranked as 1 = most satisfaction to 4 = least satisfaction.

4.5 Data processing and data analysis

4.5.1 Data processing

After the data collection forms were filled completely, the researcher assigned the code corresponding to each pain behavior according to the coding manual. Then the data was entered twice by the two independent key operators, to the computer using SPSS computer program. The two data files were then validated to check if there was any inconsistency between them. Correction was made accordingly.

4.5.2 Data analysis

Demographic data was analyzed by descriptive statistics in SPSS statistical package. Mean, median, standard deviation and proportion were applied for continuous and categorical variables respectively.

Interrater reliability of each pain scale (CHEOPS, Modified OPS, TPPPS, FLACC) was analyzed by intraclass correlation, using Reliability Analysis of SPSS Computer Program.

Content validity $IC = \frac{\Sigma R}{N}$

R = Total score of each item

Score: +1 = relative valid item, 0 = not sure, -1 = relative irrelevant

N = Number of experts

IC would be acceptable if ≥ 0.5

The results of content validity would be used for discussion and further study whereas the original scales without modification were used for pain assessment in this study.

Discriminant validity: Since pain scores were derived from ordinal scales, the interval between each score might not be the same. Therefore, Wilcoxon Rank Sum Test was used to analysed the differences, $p < 0.05$ was considered significance.

Predictive validity : By using the accepted reference test : CHEOPS score 6 documented in the literature[33,34] as the cut-off point to give analgesics or to divide low pain and high pain, sensitivity, specificity, predictive value, accuracy were calculated. ROC curve and cut-off point of the target tests (which have not been documented) in recovery room and ward were analyzed by STATA program and trading off basis.

Concurrent validity : As the minimum and maximum scores of all pain scales are not the same, the documented cut-off point of CHEOPS[33,34] score 6 and the cut-off point of target tests yielded from ROC curve and trading off sensitivity and specificity were used. The agreement between target tests and CHEOPS were analysed by kappa statistics. Additionally, since all pain scores were nonparametric data (tested by Kolmogorov Smearnov, $p < 0.05$), the correlation between target tests and CHEOPS were analysed by Spearman correlation.

The target test with acceptable agreement, correlation, specificity 90 $\pm$ 10%, sensitivity 90 $\pm$ 10% and largest area of ROC curve will be the most appropriate test with respect to CHEOPS, apart from satisfation score which will be tested later.

Comments on utility of pain scales : All items were analysed in frequency and percentage.

Duration of rating pain scores of each scale: Average time consumed for each pain scale used by 1 nurse was derived from summation of duration in rating 10 behaviors divided by 10. Total average time consumed for each pain scale would be yielded by summation of all time consumed from 30 nurses. The duration of rating pain scales were analysed by descriptive statistics.

Satisfaction ranking: The satisfaction ranking of all pain scales were analyzed by descriptive statistics.

4.6 Ethical consideration

This study did not provide any intervention to the patients, only recorded their pain behaviors. However, this proposal was sent to the ethical committee for approval and parents were informed and asked for permission and written informed consent. All data was kept confidentially. Patients and parents were completely free to refuse to participate at any time.

CHAPTER 5

RESULTS

5.1 Characteristics of the study population

A total of 169 preschool aged children underwent elective surgery at Siriraj Hospital (52.7%) and Queen Sirikit National Institute of Child Health (47.3%) during February 1999 and August 1999 were recruited to the study. Two children, 1 child from each hospital, were excluded from the study because preoperative CHEOPS were more than 6. Therefore, 167 children were included in this study. Their age ranged from 1-5.5 years old with the mean of 2.9 years old (standard deviation = 1.4) and the median of 3 years old. Most of them (58.1%) aged 3 years old or less. Most of the patients (59.4%) had no experience any surgery before. According to some wards' regulation, 38.9% of parents could not stay with their children throughout the study. The common sites of operation were maxillofacial and head-neck region (24%), groin and perineum (21%) and abdomen (20.4%) respectively. See table 6 for more detail.

Table 6 General characteristics of the study population

Characteristics	Number	Percent
1. Hospital		
Siriraj	89	52.7
Children	80	47.3
Total	**169**	**100.0**
2. Age (years) (mean ± SD = 2.9 ± 1.4)		
≤ 3	97	58.1
> 3	70	41.9
Total	**167**	**100.0**
3. Experience of previous surgery		
No	82	59.4
Yes	56	40.6
Total	**138**	**100.0**
4. Parent presence		
No	65	38.9
Yes	102	61.1
Total	**167**	**100.0**

Table 6 (continued)

Characteristics	Number	Percent
5. Site of surgery		
Maxillofacial & head-neck	40	24.0
Groin & perineum	35	21.0
Abdomen	34	20.4
Limb	22	13.2
Ear, nose, throat	17	10.2
Eye	11	6.6
Thoracic	5	3.0
Trunk (burn)	3	1.8
Total	**167**	**100.0**

5.2 Reliability of pain scales

Intraclass correlation (ICC) of 4 raters on each translated pain scale : CHEOPS (r = 0.9164), OPS (r = 0.9754), TPPPS (r = 0.9092) and FLACC (r = 0.9265) were all acceptable as the example of calculation shown.. See table 7 for more detail. Therefore, all four pain scales could be further validated.

Example of calculation ICC of CHEOPS

p = 0.0568

Mean Square between people = MSp = 17.9724

Mean Square between measure = MSm = 1.0444 (not used if $p > 0.05$)

Mean Square residual = MSE = 0.4008

m = number of observers = 4

n = number of sample = 30

$$ICC = \frac{\sigma^2 \text{ people}}{\sigma^2 \text{ people} + \sigma^2 \text{ residual} + \sigma^2 \text{ measure}}$$

σ^2 people = [MSp - MSE] / m = [17.9724 - 0.4008] / 4 = 4.3929

σ^2 measure = [MSm - MSE] / n = [1.0444 - 0.4008] / 30 = 0.0214

σ^2 residual = MSE = 0.4008

ICC = 4.3929 / [4.3929 + 0.4008] = 0.9164

Table 2 Reliability test

No.	C				No.	O				No.	T				No.	F			
	R 1	R 2	R 3	R 4		R 1	R 2	R 3	R 4		R 1	R 2	R 3	R 4		R 1	R 2	R3	R 4
1	5	5	5	5	31	0	0	0	0	61	0	0	0	0	91	0	0	0	0
2	6	6	5	6	32	1	1	1	1	62	0	0	0	0	92	0	0	0	0
3	5	5	5	5	33	1	1	1	1	63	7	6	7	6	93	8	6	6	8
4	5	5	4	5	34	0	0	0	0	64	5	3	4	6	94	7	4	3	4
5	5	5	5	5	35	0	0	0	0	65	1	2	0	3	95	3	0	1	3
6	10	10	9	9	36	0	0	0	0	66	0	0	0	0	96	4	0	1	0
7	6	5	5	6	37	10	9	9	9	67	1	0	0	0	97	0	0	0	0
8	5	5	5	5	38	0	0	0	0	68	5	4	5	6	98	10	8	9	9
9	12	13	11	13	39	4	4	5	5	69	4	2	1	1	99	0	0	0	0
10	5	6	5	5	40	0	0	0	1	70	2	2	0	1	100	10	8	10	10
11	11	10	10	11	41	0	0	0	0	71	4	2	3	3	101	7	6	8	8
12	9	10	11	10	42	0	0	0	0	72	0	0	0	0	102	4	4	5	6
13	5	5	5	5	43	0	0	0	0	73	0	0	0	1	103	0	0	0	0
14	10	8	5	6	44	0	0	0	0	74	5	6	5	6	104	7	8	7	10
15	11	10	10	10	45	0	0	0	0	75	0	0	0	0	105	0	0	0	0
16	5	5	5	5	46	0	0	0	0	76	0	0	0	0	106	0	0	0	0
17	8	7	8	8	47	1	1	0	0	77	1	0	0	0	107	3	2	2	1
18	5	5	5	5	48	3	1	1	2	78	0	0	0	0	108	0	0	0	0
19	5	5	5	5	49	0	0	0	0	79	0	0	0	1	109	0	0	0	0
20	5	6	5	5	50	0	0	0	0	80	0	0	0	1	110	3	2	1	3
21	4	4	4	4	51	0	0	0	0	81	8	8	8	7	111	0	0	0	0
22	5	6	5	5	52	0	1	0	0	82	4	5	7	6	112	1	0	1	3
23	5	5	5	5	53	0	0	0	0	83	2	3	1	2	113	0	0	0	0
24	5	7	5	5	54	0	0	0	0	84	0	0	0	0	114	7	9	10	6
25	5	7	6	5	55	0	0	0	0	85	0	0	2	2	115	0	0	0	0
26	5	5	5	5	56	0	0	0	0	86	0	0	0	0	116	9	10	10	10
27	5	5	5	5	57	0	0	0	0	87	5	6	4	8	117	2	3	5	6
28	8	6	6	6	58	0	0	0	0	88	0	0	0	1	118	0	0	0	2
29	5	5	5	6	59	1	1	1	1	89	2	3	1	1	119	3	2	2	3
30	5	5	5	4	60	5	4	6	5	90	0	0	0	0	120	5	4	4	4

C = CHEOPS **O = OPS** **T = TPPPS** **F = FLACC**

Intraclass correlation

r CHEOPS = 0.9164	r OPS = 0.9754	r TPPPS = 0.9092	r FLACC = 0.9265

5.3 Validity of pain scales

5.3.1 Content validity

CHEOPS

There were 7 unacceptable items (IC < 0.5) which were cry-none, face-composed, verbal - none, torso - upright, touch - grab wound, leg - neutral and leg-standing. The opposed opinion about scaling were cry-none, face-composed, verbal - none should have score 0, less severe than other behaviors in those items. In addition, touch - grab wound should have score 3, more severe than other behaviors in Touch-Item. However, most experts disagreed with torso - upright and leg - standing behaviors in Thai children. See table 8 for more detail.

OPS

All items were acceptable. Only one expert commented about the translated description of "thrashing and hysterical" that they should not be behaviors in this age group. See table 9 for more detail.

TPPPS

Most items were acceptable except squint eyes. See table 10 for more detail.

FLACC

All items were totally agreed. See table 11 for more detail.

Table 8 Content validation of CHEOPS

Item	Behavioral	Score	R1	R2	R3	R4	R5	R6	IC=∑R/6
Cry	No cry	1	1	-1	1	1	-1	1	0.33
	Moaning	2	1	1	1	1	-1	1	0.67
	Crying	2	1	1	1	1	1	1	1
	Scream	3	1	1	1	1	1	1	1
Facial	Composed	1	1	-1	-1	1	1	1	0.33
	Grimace	2	1	1	1	1	1	1	1
	Smiling	0	1	1	1	-1	1	1	0.67
Child verbal	None	1	1	-1	-1	1	1	-1	0
	Other complaints	1	1	-1	1	1	1	1	0.67
	Pain complaints	2	1	1	1	1	1	1	1
	Both complaints	2	0	1	1	1	1	1	0.83
	Positive	0	1	1	1	1	1	1	1
Torso	Neutral	1	1	-1	0	1	1	1	0.5
	Shifting	2	1	1	1	1	1	1	1
	Tense	2	1	0	1	1	1	1	0.83
	Shivering	2	1	1	1	1	1	1	1
	Upright	2	0	0	1	1	-1	1	0.33
	Restrained	2	1	1	1	1	1	1	1
Touch	Not touching	1	1	0	1	0	1	1	0.67
	Reach	2	1	0	1	1	1	1	0.83
	Touch	2	1	0	1	1	1	1	0.83
	Grab	2	1	0	-1	1	1	-1	0.17
	Restrained	2	1	0	-1	1	1	1	0.5
Legs	Neutral	1	1	-1	1	0	-1	1	0.17
	Squirming/kicking	2	1	1	1	1	1	1	1
	Drawn up/ tense	2	1	1	1	1	1	1	1
	Standing	2	0	0	1	1	-1	1	0
	Restrained	2	1	1	1	1	1	1	1

Table 9 Content validation of Modified OPS

Criteria	Observation	Score	R1	R2	R3	R4	R5	R6	IC=$\sum$R/6
Crying	None	0	1	1	1	1	1	1	1
	Consolable	1	1	1	1	1	1	1	1
	Not consolable	2	1	1	1	1	1	1	1
Movement	None	0	1	1	1	1	1	1	1
	Restless	1	1	1	1	1	1	1	1
	thrashing	2	0	1	1	1	1	1	0.83
Agitation	Asleep/calm	0	1	1	1	1	1	1	1
	Mild	1	1	1	1	1	1	1	1
	Hysterial	2	1	1	1	-1	0	1	0.5
Posture	Normal	0	1	1	1	1	1	1	1
	Flexed	1	1	1	1	1	1	1	1
	Hold groin/throat	2	1	1	1	1	1	1	1
Verbal	Asleep/no complaint	0	1	1	1	1	1	1	1
	Complains/cannot localise	1	1	-1	1	1	1	1	0.67
	Can localise	2	1	1	1	1	1	1	1

Table 10 Content validation of TPPPS

Criteria	Observation	R1	R2	R3	R4	R5	R6	IC=∑R/6
Vocal Pain Expression	Verbal pain complaint / Cry	1	0	1	1	1	1	0.83
	Scream	1	0	1	1	1	1	0.83
	Groan, moan, grunt	1	0	1	1	1	1	0.83
Facial Pain Expression	Open mouth, lips pulled back at corners	1	0	1	1	1	1	0.83
	Squint, close eyes	1	0	1	-1	0	1	0.33
	Furrow forehead, Brow bulge	1	0	1	1	1	1	0.83
Bodily pain expression	Restless motor behavior	1	0	1	1	1	1	0.83
	Rub or touch painful area	1	0	1	1	1	-1	0.50

Score '1' if the behavior is present, score '0' if behavior is absent

Table 11 Content validation of FLACC

Categories	Scoring	Definition	R1	R2	R3	R4	R5	R6	IC= $\Sigma R/6$
Face	0	No particular expression or smile	1	1	1	1	1	1	1
	1	Occasional grimace or frown, withdrawn, disinterested	1	1	1	1	1	1	1
	2	Frequent to constant quivering chin, clenched jaw	1	1	1	1	1	1	1
Legs	0	Normal position or relaxed	1	1	1	1	1	1	1
	1	Uneasy, restless, tense	1	1	1	1	1	1	1
	2	Kicking, or legs drawn up	1	1	1	1	1	1	1
Activity	0	Lying quietly, normal position, move easily	1	1	1	1	1	1	1
	1	Squirming, shifting back and forth, tense	1	1	1	1	1	1	1
	2	Arched, rigid or jerking	1	1	1	1	1	1	1
Cry	0	No cry (awake or asleep)	1	1	1	1	1	1	1
	1	Moans or whimpers; occasional complaint	1	1	1	1	1	1	1
	2	Crying steadily, screams or sobs, frequent complaints	1	1	1	1	1	1	1
Consolability	0	Content, relaxed	1	1	1	1	1	1	1
	1	Reassured by occasional touching, hugging or being talked to, distractable	1	1	1	1	1	1	1
	2	Difficult to console or comfort	1	1	1	1	1	1	1

5.3.2 Discriminant validity

5.3.2.1 In recovery room

All pain scales had significantly higher scores before analgesics treatment than after analgesic treatment in recovery room. See table 12 for more detail.

Table 12 Discriminant validity of pain scales before and after analgesics in recovery room

	Period 2	Period 3	p value
CHEOPS	7.70 ± 1.91*	5.19 ± 0.92 *	< 0.001
OPS	4.82 ± 3.10 *	0.48 ±1.32 *	< 0.001
TPPPS	4.28 ± 2.48 *	0.57 ± 1.43 *	< 0.001
FLACC	5.09 ± 3.35 *	0.47 ± 1.29 *	< 0.001

Value was mean ± SD

* Statistical difference, Wilcoxon Rank Sum Test

5.3.2.2 In wards

All pain scales had significantly higher scores before analgesics treatment than after analgesic treatment in wards. See table 13 for more detail.

Table 13 Discriminant validity of pain scales before and after analgesics in wards

	Period 4	Period 5	p value
CHEOPS	6.65 ± 1.84 *	4.95 ± 0.42 *	< 0.001
OPS	3.09 ± 2.92 *	0.21 ± 0.69 *	< 0.001
TPPPS	2.94 ± 2.56 *	0.36 ± 1.06 *	< 0.001
FLACC	3.06 ± 3.10 *	0.33 ± 1.00 *	< 0.001

Value was mean ± SD

* Statistical difference, Wilcoxon Rank Sum Test

5.3.3 Predictive validity

The predictive or diagnostic performance of three pain scales (OPS, TPPPS, FLACC) with respect to the accepted reference standard CHEOPS were tested in 2 periods : 1) immediate postoperative period in recovery room or postanesthetic care unit and 2) delayed postoperative period in wards within 24 hours following surgery.

According to nurses' misunderstanding in the early period of this study, researcher was often called just after children had already been given analgesics, some in recovery room and some in wards. So in such particular cases, no behaviors before analgesics could be videotaped. Both behaviors before and after analgesics in that period were recorded as missing. In recovery room, there were 18 children missing from 167 children, only 149 children were enrolled in the study. In wards, there were 26 children missing from 167 children, only 141 children were enrolled in the study.

5.3.3.1 In recovery room

OPS

Among 149 children, there were various cases categorized into severe or mild pain by using cutoff points vary from 0 to 10 corresponding to the accepted reference test: CHEOPS which cutoff point 6 was used. See table 14 for more detail. The diagnostic performance of OPS using various cutoff points and the Receiver Operative Characteristics (ROC) curve of the test were shown in table 15 and figure 4 respectively. Area under the ROC curve was 0.9796.

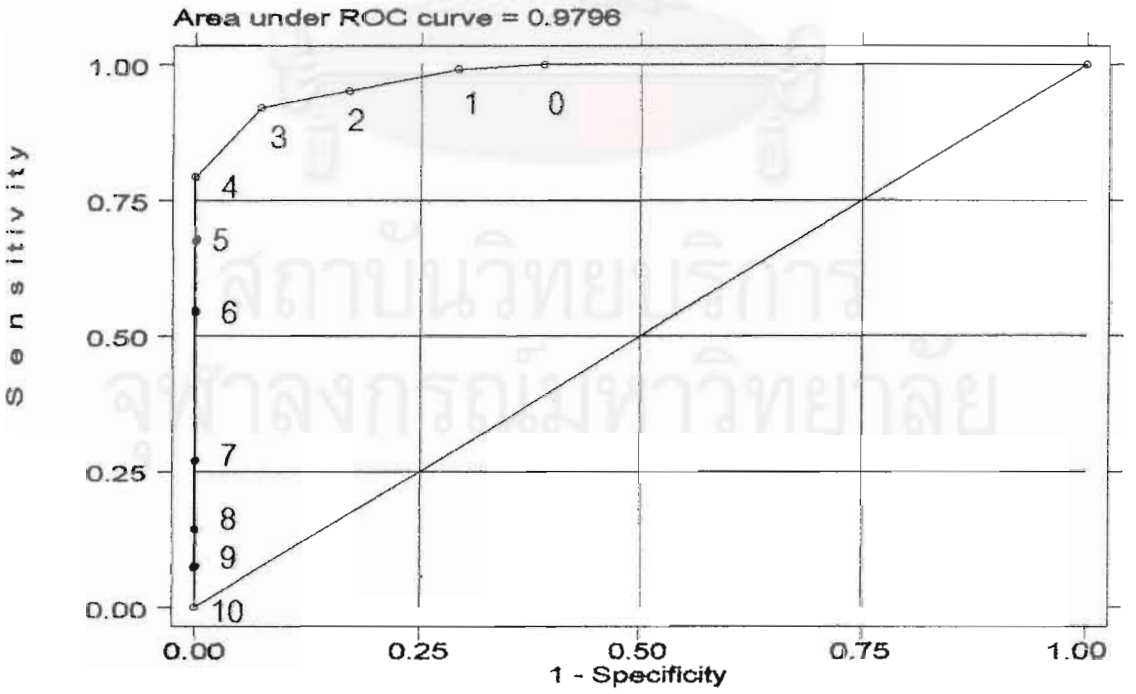
Table 14 Number of cases categorized into severe and mild pain by various OPS cutoff points in recovery room

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
OPS	0	0	25	25
	1	1	4	5
	2	5	5	10
	3	4	4	8
	4	16	3	19
	5	9	0	9
	6	17	0	17
	7	28	0	28
	8	9	0	9
	9	12	0	12
	10	7	0	7
Total		108	41	149

Table 15 Diagnostic performance of OPS in recovery room using various cutoff points

OPS cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	100(108/108)	61.0(25/41)	87.1(108/124)	100.0(25/25)	89.3(133/149)
1	99.1(107/108)	70.7(29/41)	89.9(107/119)	96.7(29/30)	91.3(136/149)
2	94.4(102/108)	82.9(34/41)	93.6(102/109)	85.0(34/40)	91.3(136/149)
3	90.7(98/108)	92.7(38/41)	97.0(98/101)	79.2(38/48)	91.3(136/149)
4	75.9(82/108)	100.0(41/41)	100.0(82/82)	61.2(41/67)	82.6(123/149)
5	67.6(73/108)	100.0(41/41)	100.0(73/73)	53.9(41/76)	76.5(114/149)
6	51.9(56/108)	100.0(41/41)	100.0(56/56)	44.1(41/93)	65.1(97/149)
7	25.9(28/108)	100.0(41/41)	100.0(28/28)	33.9(41/121)	46.3(69/149)
8	17.6(19/108)	100.0(41/41)	100.0(19/19)	31.5(41/130)	40.3(60/149)
9	6.5(7/108)	100.0(41/41)	100.0(7/7)	28.9(41/142)	32.2(48/149)
10	0(0/108)	100.0(41/41)	0(0/0)	27.5(41/149)	27.5(41/149)

Figure 4 ROC curve of OPS in recovery room



Comparing the performance of OPS between cutoff point 3 and 4, we could see that cutoff point 3 yielded high sensitivity (90.7%), high specificity (92.7%) whereas cutoff point 4 could yield 100% specificity but rather low sensitivity (75.9%). See table 16 for more detail. As postoperative pain in children were still underestimated[3,5], high sensitivity of tool was needed. However, overtreatment of pain was detrimental, so high specificty was also necessary. Therefore, cutoff point 3 should be the most suitable.

Table 16 Comparing diagnostic performance using OPS cutoff point 3 and 4 in recovery room

Cutoff point 3

		CHEOPS		Total
		severe pain (>6)	mild pain (≤6)	
OPS	severe pain (>3)	98	3	101
	mild pain (≤3)	10	38	48
Total		**108**	**41**	**149**

Cutoff point 4

		CHEOPS		Total
		severe pain (>6)	mild pain (≤6)	
OPS	severe pain (>4)	82	0	82
	mild pain (≤4)	26	41	67
Total		**108**	**41**	**149**

Table 16 (continued)

	Cutoff point 3	Cutoff point 4
Sensitivity(%)	**90.7**(98/108)	**75.9**(82/108)
Specificity(%)	**92.7**(38/41)	**100.0**(41/41)
Positive predictive value(%)	**97.0**(98/101)	**100.0**(82/82)
Negative predictive value(%)	**79.2**(38/48)	**61.2**(41/67)
Accuracy(%)	**91.3**(136/149)	**82.6**(123/149)

TPPPS

Varying cutoff points from TPPPS 0 to 8, one hundred and forty-nine children in recovery room were categorized into severe and mild pain group corresponding to cutoff point 6 of the accepted reference test : CHEOPS. See table 17 for more detail. The diagnostic performance of TPPPS using various cutoff points and the Receiver Operative Characteristics (ROC) curve of the test were illustrated in table 18 and Figure 5 respectively. Area under ROC curve was 0.9264.

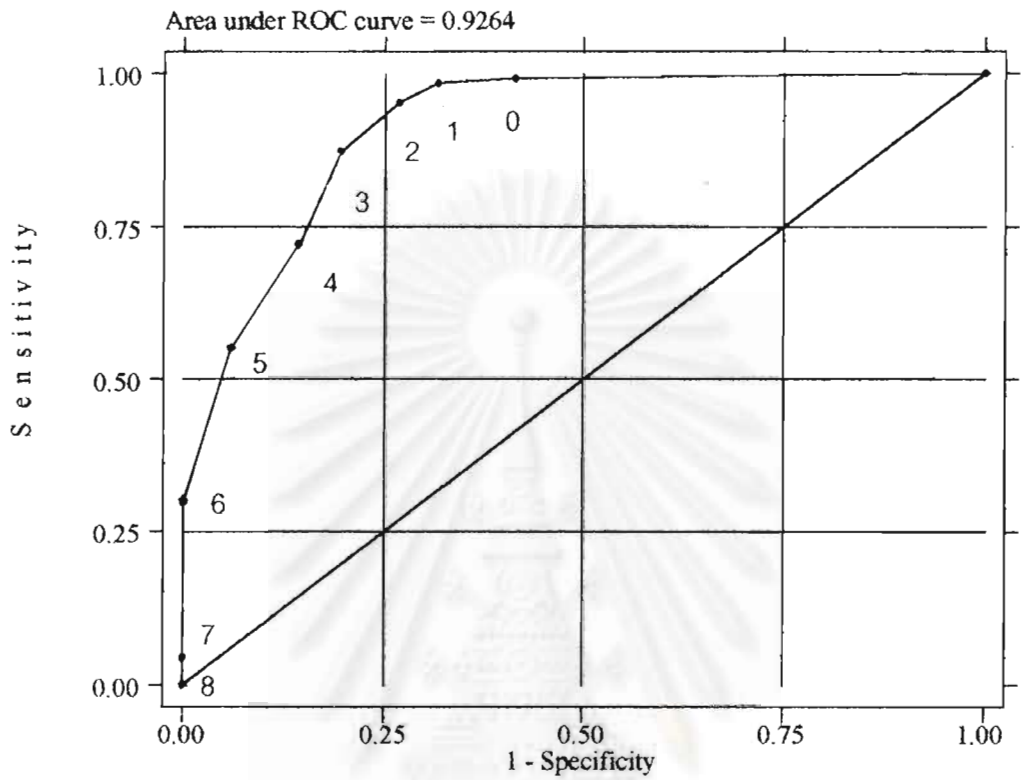
Table 17 Number of cases categorized into severe and mild pain by various TPPPS cutoff points in recovery room

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
TPPPS	0	1	24	25
	1	1	4	5
	2	4	2	6
	3	10	3	13
	4	13	2	15
	5	18	4	22
	6	30	2	32
	7	29	0	29
	8	2	0	2
Total		108	41	149

Table 18 Diagnostic performance of TPPPS in recovery room using various cutoff points

TPPPS cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	99.1(107/108)	58.5(24/41)	86.3(107/124)	96.0(24/25)	87.9(131/149)
1	98.1(106/108)	68.3(28/41)	89.1(106/119)	93.3(28/30)	89.9(134/149)
2	94.4(102/108)	73.2(30/41)	90.3(102/113)	83.3(30/36)	88.6(132/149)
3	85.2(92/108)	80.5(33/41)	92.0(92/100)	67.3(33/49)	83.9(125/149)
4	73.1(79/108)	85.4(35/41)	92.9(79/85)	54.7(35/64)	76.5(114/149)
5	56.5(61/108)	95.1(39/41)	96.8(61/63)	45.3(39/86)	67.1(100/149)
6	28.7(31/108)	100.0(41/41)	100.0(31/31)	34.7(41/118)	48.3(72/149)
7	0.2(2/108)	100.0(41/41)	100.0(2/2)	27.9(41/147)	28.9(43/149)
8	0(0/108)	100.0(41/41)	100.0(0/0)	27.5(41/149)	27.5(41/149)

Figure 5 ROC curve of TPPPS in recovery room



TPPPS could not provide both high sensitivity (≥ 90%) and high specificity (≥ 90%) at any cutoff point. However, trading off specificity and sensitivity yielded the acceptable cutoff point 3 which provided specificity (85.2%) and sensitivity(80.5%).

FLACC

Corresponding to the accepted reference test : CHEOPS, 149 children in recovery room were classified into severe and mild pain group by using various cutoff point from FLACC 0 to 10. See table 19 for more detail. The diagnostic performance of FLACC using various cutoff points and the Receiver Operative

Characteristics (ROC) curve of the test were illustrated in table 20 and figure 6 respectively. Area under ROC curve was 0.9788.

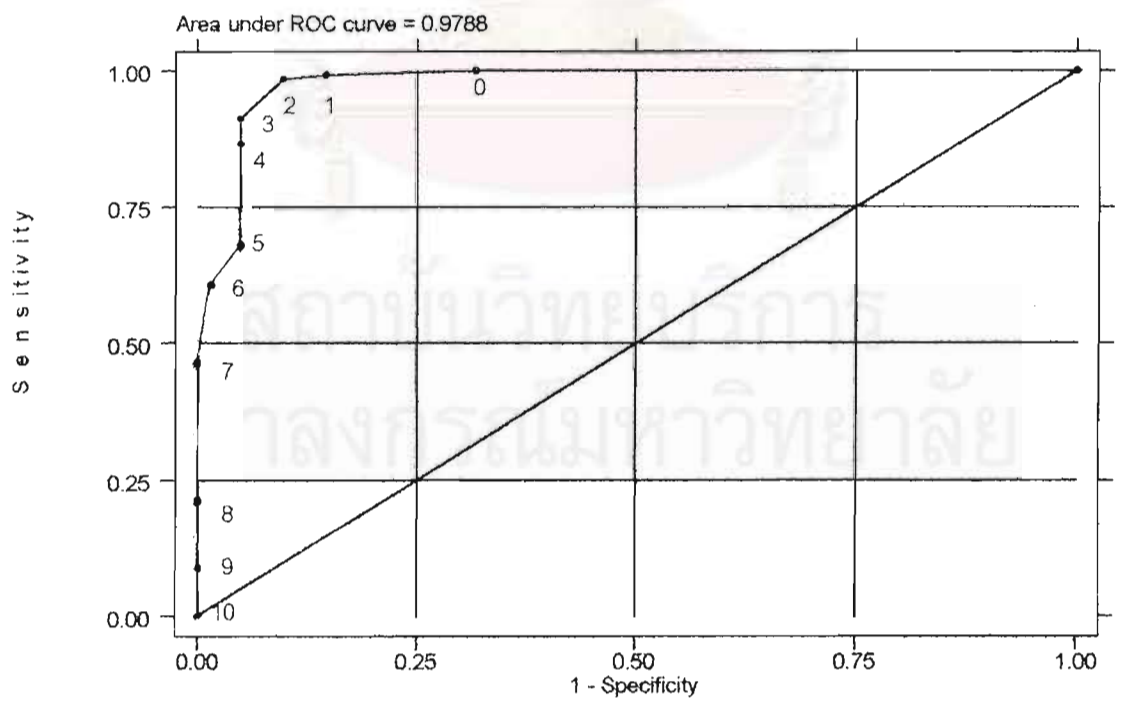
Table 19 Number of cases categorized into severe and mild pain by various FLACC cutoff points in recovery room

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
FLACC	0	0	28	28
	1	1	7	8
	2	1	2	3
	3	9	2	11
	4	6	0	6
	5	16	0	16
	6	10	1	11
	7	18	1	19
	8	23	0	23
	9	15	0	15
	10	9	0	9
Total		108	41	149

Table 20 Diagnostic performance of FLACC in recovery room using various cutoff points

FLACC cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	100(108/108)	68.3(28/41)	89.3(108/121)	100.0(28/28)	91.3(136/149)
1	99.1(107/108)	85.4(35/41)	94.7(107/113)	97.2(35/36)	95.3(142/149)
2	98.1(106/108)	90.2(37/41)	96.4(106/110)	94.9(37/39)	96.0(143/149)
3	89.8(97/108)	95.1(39/41)	98.0(97/99)	78.0(39/50)	91.3(136/149)
4	84.3(91/108)	95.1(39/41)	97.8(91/93)	69.6(39/56)	87.2(130/149)
5	69.4(75/108)	95.1(39/41)	97.4(75/77)	54.2(39/72)	76.5(114/149)
6	60.2(65/108)	97.6(40/41)	98.5(65/66)	48.2(40/83)	70.5(105/149)
7	43.5(47/108)	100.0(41/41)	100.0(47/47)	40.2(41/102)	59.1(88/149)
8	22.2(24/108)	100.0(41/41)	100.0(24/24)	32.8(41/125)	43.6(65/149)
9	8.3(9/108)	100.0(41/41)	100.0(9/9)	29.3(41/140)	33.6(50/149)
10	0(0/108)	100.0(41/41)	100.0(0/0)	27.5(41/149)	27.5(41/149)

Figure 6 ROC curve of FLACC in recovery room



Comparing cutoff point 2 and 3, both provided high sensitivity (98.1% and 89.9%), high specificity (90.2% and 95.1%), high positive predictive value (96.4% and 98.0%) and high accuracy (96.0% and 91.3%). Likelihood ratio, which equaled to sensitivity divided by (1 - specificity), was used to determine the most appropriate cutoff point. Cutoff point 3 provided more likelihood ratio(18.41) than cutoff point 2 (10.06). Therefore, cutoff point 3 was selected . See table 21 for more detail.

Table 21 Comparing diagnostic performance of FLACC in recovery room using cutoff point 2 and 3

Cutoff point 2

		CHEOPS		Total
		severe pain (>6)	mild pain (≤6)	
FLACC	severe pain (>2)	106	4	110
	mild pain (≤2)	2	37	39
Total		**108**	**41**	**149**

Cutoff point 3

		CHEOPS		Total
		severe pain (>6)	mild pain (≤6)	
FLACC	severe pain (>4)	97	2	99
	mild pain (≤4)	11	39	50
Total		**108**	**41**	**149**

Table 21 (continued)

	Cutoff point 2	**Cutoff point 3**
Sensitivity % (proportion)	**98.1**(106/108)	**89.9**(97/108)
Specificity % (proportion)	**90.2**(37/41)	**95.1**(39/41)
PPV % (proportion)	**96.4**(106/110)	**98.0**(97/99)
NPV % (proportion)	**94.9**(37/39)	**78.0**(39/56)
Accuracy % (proportion)	**96.0**(145/149)	**91.3**(136/149)
Likelihood ratio (= sensitivity/1-specificity)	**10.06**	**18.41**

5.3.3.2 In wards

OPS

One hundred and forty-one children were categorized into severe and mild pain group with respect to the accepted reference test CHEOPS by using various cutoff points. See table 22 for more detail. The diagnostic performance of OPS in wards and the Receiver Operative Characteristics (ROC) curve of the test were shown in table 23 and figure 7. Area under ROC curve was 0.9186.

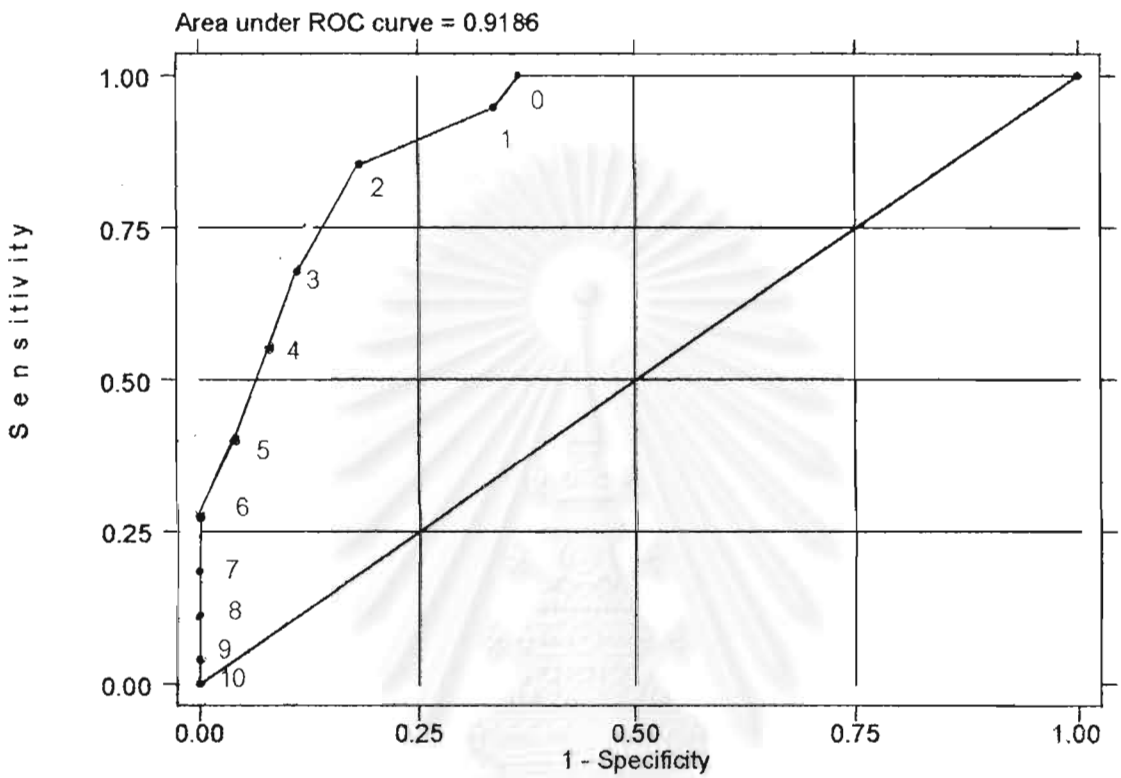
Table 22 Number of cases categorized into severe and mild pain by various OPS cutoff points in wards

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
OPS	0	0	45	45
	1	5	2	7
	2	9	11	20
	3	8	4	12
	4	7	2	9
	5	14	3	17
	6	7	0	7
	7	7	4	11
	8	5	0	5
	9	7	0	7
	10	1	0	1
Total		70	71	141

Table 23 Diagnostic performance of OPS in wards using various cutoff points

OPS cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	100.0(70/70)	63.4(45/71)	72.9(70/96)	100.0(45/45)	81.6(115/141)
1	92.9(65/70)	66.2(47/71)	73.0(65/89)	90.4(47/52)	79.4(112/141)
2	80.0(56/70)	81.7(58/71)	81.2(56/69)	80.6(58/72)	80.9(114/141)
3	68.6(48/70)	87.3(62/71)	84.2(48/57)	73.8(62/84)	78.0(110/141)
4	58.6(41/70)	90.1(64/71)	85.4(41/48)	68.8(64/93)	74.4(105/141)
5	38.6(27/70)	94.4(67/71)	87.1(27/31)	60.9(67/110)	66.6(94/141)
6	28.6(20/70)	100.0(71/71)	100.0(20/20)	59.2(67/120)	64.5(91/141)
7	18.6(13/70)	100.0(71/71)	100.0(13/13)	55.5(71/128)	59.6(84/141)
8	11.4(8/70)	100.0(71/71)	100.0(8/8)	53.4(71/133)	56.0(79/141)
9	1.4(1/70)	100.0(71/71)	100.0(1/1)	50.7(71/140)	51.1(72/141)
10	0(0/70)	100.0(71/71)	100.0(0/0)	50.4(71/141)	50.4(71/141)

Figure 7 ROC curve of OPS in wards



Cutoff point 3 and 4 provided high specificity (87.3% and 90.1%) but sensitivity were rather low (68.6% and 58.6%) and accuracy was also low (78.0% and 74.4%). Corresponding the trading off between specificity and sensitivity, cutoff point 2 yielded reasonable specificity (81.7%), sensitivity (80%) and accuracy (80.9%) which were still within 10% lower than expected value (90%).

TPPPS

Varying cutoff points from TPPPS 0 to 8, one hundred and forty-one children in wards were categorized into severe and mild pain group corresponding to cutoff point 6 of the accepted reference test : CHEOPS. See table 24 for more detail. The diagnostic performance of TPPPS in wards and the Receiver Operative Characteristics (ROC) curve of the test were illustrated in table 25 and figure 7 respectively. Area under ROC curve was 0.9399.

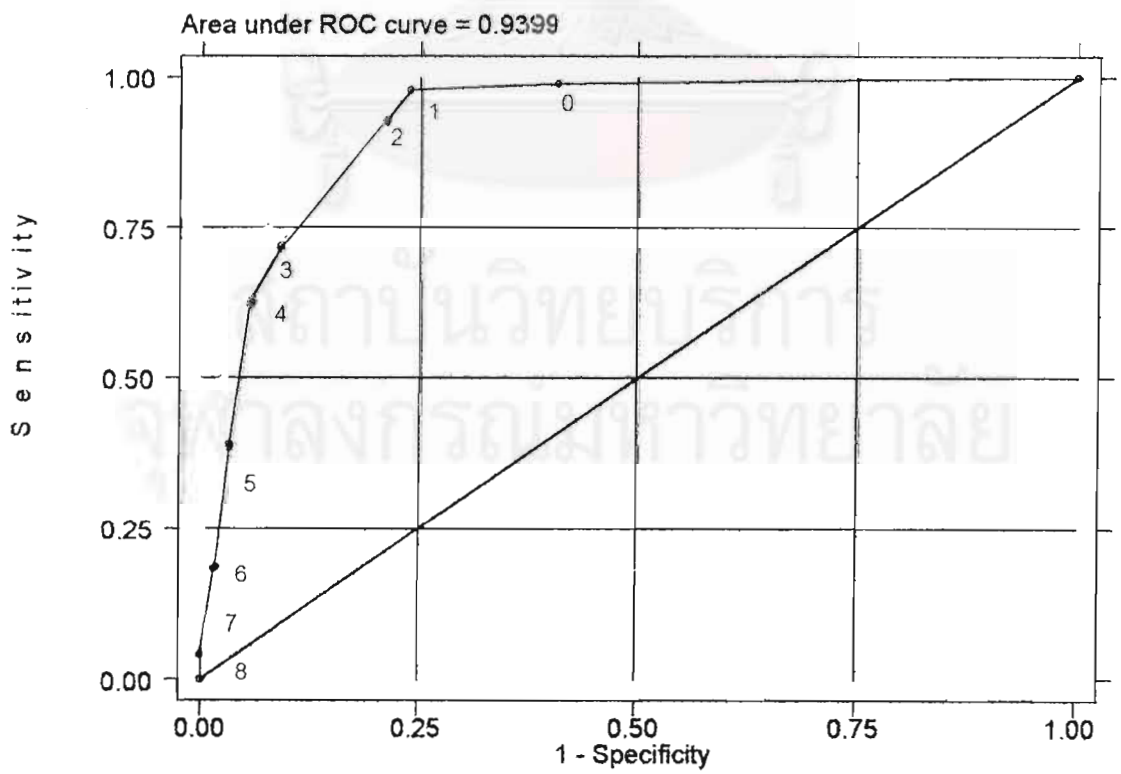
Table 24 Number of cases categorized into severe and mild pain by various TPPPS cutoff points in wards

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
TPPPS	0	1	42	43
	1	1	12	13
	2	5	2	7
	3	12	7	19
	4	7	4	11
	5	17	2	19
	6	13	1	14
	7	12	1	13
	8	2	0	2
Total		70	71	141

Table 25 Diagnostic performance of TPPPS in wards using various cutoff points

TPPPS cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	98.6(69/70)	59.2(42/71)	70.4(69/98)	97.7(42/43)	78.7(111/141)
1	97.1(68/70)	76.1(54/71)	80.0(68/85)	96.4(54/56)	86.5(122/141)
2	90.0(63/70)	78.9(56/71)	80.8(63/78)	88.9(56/63)	84.4(119/141)
3	72.9(51/70)	88.7(63/71)	86.4(51/59)	76.8(63/82)	80.9(114/141)
4	62.9(44/70)	94.4(67/71)	91.7(44/48)	72.0(67/93)	78.7(111/141)
5	38.6(27/70)	97.2(69/71)	93.1(27/29)	61.6(69/112)	68.1(96/141)
6	20.0(14/70)	98.6(70/71)	93.3(14/15)	55.6(70/126)	59.6(84/141)
7	2.9(2/70)	100.0(71/71)	100.0(2/2)	51.1(71/139)	51.8(73/141)
8	0(0/70)	100.0(71/71)	100.0(0/0)	50.4(71/141)	50.4(71/141)

Figure 8 ROC curve of TPPPS in wards



There was no appropriate cutoff point which yielded high specificity (90% ± 10%) and high sensitivity (90% ± 10%).

FLACC

Corresponding to the accepted reference test : CHEOPS, 141 children in wards were classified into severe and mild pain group by using various cutoff point from FLACC 0 to 10. See table 26 for more detail. The diagnostic performance of FLACC using various cutoff points and the Receiver Operative Characteristics (ROC) curve of the test were illustrated in table 27 and figure 9 respectively. Area under ROC curve was 0.9162.

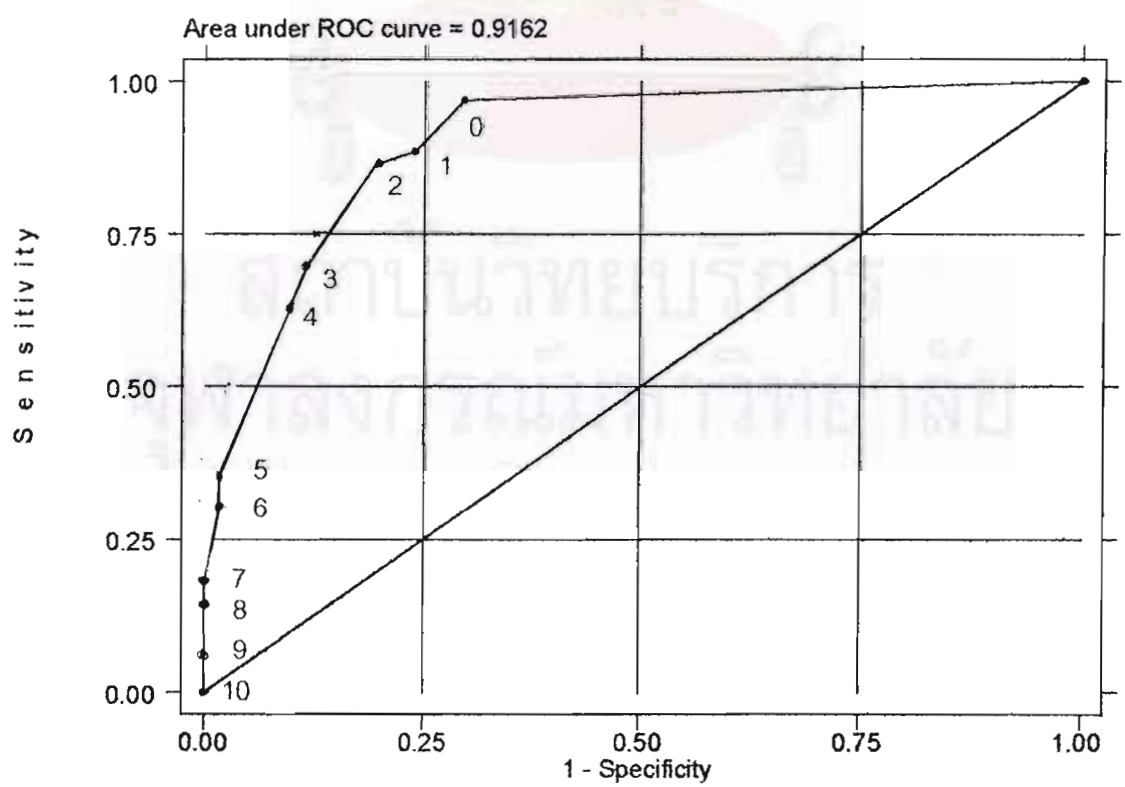
Table 26 Number of cases categorized into severe and mild pain by various FLACC cutoff points in wards

		CHEOPS		Total
		Severe pain (score > 6)	Mild pain (score ≤ 6)	
FLACC	0	3	50	53
	1	8	4	12
	2	2	3	5
	3	6	3	9
	4	5	2	7
	5	19	7	26
	6	6	0	6
	7	9	2	11
	8	1	0	1
	9	7	0	7
	10	4	0	4
Total		70	71	141

Table 27 Diagnostic performance of FLACC in wards using various cutoff points

FLACC cutoff point	Sensitivity% (proportion)	Specificity% (proportion)	PPV% (proportion)	NPV% (proportion)	Accuracy% (proportion)
0	95.7(67/70)	70.4(50/71)	76.1(67/88)	94.3(50/53)	83.0(117/141)
1	84.3(59/70)	76.6(54/71)	77.6(59/76)	83.1(54/65)	80.1(113/141)
2	81.4(57/70)	80.3(57/71)	80.3(57/71)	81.4(57/70)	81.0(114/141)
3	72.9(51/70)	84.5(60/71)	82.3(51/62)	75.9(60/79)	78.7(111/141)
4	65.7(46/70)	87.3(62/71)	83.6(46/55)	72.1(62/86)	76.6(108/141)
5	38.6(27/70)	97.2(69/71)	93.1(27/29)	61.6(69/112)	68.1(96/141)
6	30.0(21/70)	97.2(69/71)	91.3(21/23)	58.5(69/118)	63.8(90/141)
7	17.1(12/70)	100.0(71/71)	100.0(12/12)	55.0(71/129)	58.9(83/141)
8	15.7(11/70)	100.0(71/71)	100.0(11/11)	54.6(71/130)	58.2(82/141)
9	5.7(4/70)	100.0(71/71)	100.0(4/4)	51.8(71/137)	53.1(75/141)
10	0(0/70)	100.0(71/71)	100.0(0/0)	50.4(71/141)	50.4(71/141)

Figure 9 ROC curve of FLACC in wards



There was no cutoff point which provided both high specificity (≥ 90%) and sensitivity (≥ 90%). Nevertheless, cutoff point 2 provided reasonable specificity(80.3%) and sensitivity (81.4%) which were within 10% lower than expected (90%).

5.3.4 Concurrent validity

5.3.4.1 Agreement

As the scales of the accepted reference test and target tests were not similar: CHEOPS 4-13, OPS 0-10, TPPPS 0-7, FLACC 0-10, cutoff points were used to categorize each scale. Then agreement of each target test with respect to the accepted reference test was analysed by Kappa.

5.3.4.1.1 In recovery room

Since cutoff point 3 were considered appropriated for all target tests in recovery room, the agreement of OPS, TPPPS, FLACC with CHEOPS were 0.792, 0.619 and 0.795 respectively. See table 28, 29, 30 for more detail. According to the guideline for kappa interpretation[35] in table 31, all pain scales had good agreement with CHEOPS.

Table 28 Agreement between OPS and CHEOPS in recovery room

			CHE OPS		Total
			severe pain (>6)	mild pain (≤6)	
OPS	severe pain (>3)	Observed	98	3	**101**
		Expected	73.2	27.8	
	mild pain (≤3)	Observed	10	38	**48**
		Expected	34.8	13.2	
Total			**108**	**41**	**149**

$$Po = P\ observed = \frac{98+38}{149} = \frac{136}{149} = 0.9128$$

$$Pe = P\ expected = \frac{[(101*108)/149] + [(48*41)/149]}{149}$$

$$= \frac{73.2 + 13.2}{149}$$

$$= 0.5799$$

$$K = \frac{Po - Pe}{1 - Pe} = \frac{0.9128 - 0.5799}{1 - 0.5799} = 0.792$$

Table 29 Agreement between TPPPS and CHEOPS in recovery room

			CHE OPS		Total
			severe pain (>6)	mild pain (≤6)	
TPPPS	severe pain (>3)	Observed	92	8	**100**
		Expected	72.5	27.5	
	mild pain (≤3)	Observed	16	33	**49**
		Expected	35.5	13.5	
Total			**108**	**41**	**149**

K = 0.619

Table 30 Agreement between FLACC and CHEOPS in recovery room

			CHE OPS		Total
			severe pain (>6)	mild pain (≤6)	
FLACC	severe pain (>3)	Observed	97	2	**99**
		Expected	71.8	27.2	
	mild pain (≤3)	Observed	11	39	**50**
		Expected	36.2	13.8	
Total			**108**	**41**	**149**

K = 0.795

Table 31 Interpretation of Kappa[35]

Value of Kappa	Strength of agreement
< 0.20	Poor
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Good
0.81 - 1.00	Very good

5.3.4.1.2 In wards

Cutoff point 2 was considered appropriated for OPS and FLACC in wards corresponding with cutoff point 6 of CHEOPS. However, TPPPS had no suitable cutoff point which could provide both reasonable specificity and sensitivity (at least 80%). Kappa of OPS and FLACC were 0.617 and 0.617 which were good agreement. See table 32, 33 for more detail.

Table 32 Agreement between OPS (cutoff point 2)and CHEOPS in wards

			CHE OPS		Total
			severe pain (>6)	mild pain (≤6)	
OPS	severe pain (>2)	Observed	56	13	**69**
		Expected	34.3	34.7	
	mild pain (≤2)	Observed	14	58	**72**
		Expected	35.7	36.3	
Total			**70**	**71**	**141**

K = 0.617

Table 33 Agreement between FLACC (cutoff point2) and CHEOPS in wards

			CHE OPS		Total
			severe pain (>6)	mild pain (≤6)	
FLACC	severe pain (>2)	Observed	57	14	**71**
		Expected	35.2	35.8	
	mild pain (≤2)	Observed	13	57	**70**
		Expected	34.8	35.2	
Total			**70**	**71**	**141**

K = 0.617

5.3.4.2 Correlation

5.3.4.2.1 In recovery room

Among 149 chlidren, pain scores rated before analgesics by OPS, TPPPS and FLACC were all significant correlated with CHEOPS (Spearman correlation : OPS: $r = 0.799$, $p < 0.001$, TPPPS: $r = 0.790$, $p < 0.001$, FLACC: $r = 0.765$, $p < 0.001$)

5.3.4.2.2 In wards

Among 141 chlidren, pain scores rated before analgesics by OPS, TPPPS and FLACC were all significant correlated with CHEOPS (Spearman correlation : OPS: $r = 0.798$, $p < 0.001$, TPPPS: $r = 0.826$, $p < 0.001$, FLACC: $r = 0.804$, $p < 0.001$)

5.4 Practicality of pain scales

5.4.1 Characteristics of the evaluators

All evaluators of pain scales were 30 nurses who took care of the children postoperatively. They were pioneers from 4 wards (2 surgical wards, 1 orthopedics ward, 1 eye ear nose throat ward) and 1 recovery room. Their experience with

postoperative care in children ranged from 1 to 24 years with the mean 6.97 years (standard deviation 6.96 years). Most of the nurses (63.3%) had experience 1-5 years. See table 34 for more detail.

Table 34 Experience of evaluators (mean $\pm$ SD = 6.97 $\pm$ 6.96)

Experience (year)	number of nurses	Percent
1-5	19	63.3
6-10	3	10.0
11-15	3	10.0
16-20	4	13.4
21-25	1	3.3
	30	**100.0**

5.4.2 Comments on pain scales

CHEOPS was the best scale in helping pain assessment and helping decision to treat pain (100%) including easy interpreting (83.3%). However, it was the most confused scale (40%), least easy in scoring (60%). Nurses expected more problem in using CHEOPS for routine practice than any other scales (40%). Apart from CHEOPS, FLACC was considered better than OPS and TPPPS in helping pain assessment (86.7%), helping decision to treat pain (90%), correlation with decision to treat pain (90%) and practical in routine use (90%). See table 35 for more detail.

Table 35 Comments on pain scales

Comments	CHEOPS n(%)	OPS n(%)	TPPPS n(%)	FLACC n(%)	Total n(%)
Confused	12(40.0)	8(26.7)	6(20.0)	8(26.7)	30(100.0)
Easy scoring	18(60.0)	24(80.0)	24(80.0)	23(76.7)	30(100.0)
Easy interpreting	25(83.3)	22(73.3)	22(73.3)	22(73.3)	30(100.0)
Help in pain assessment	30(100.0)	25(83.3)	24(80.0)	26(86.7)	30(100.0)
Help in decision to treat	30(100.0)	25(83.3)	23(76.7)	27(90.0)	30(100.0)
Correlated with decision to treat	30(100.0)	25(83.3)	24(80.0)	27(90.0)	30(100.0)
Practical in routine use	24(80.0)	23(76.7)	24(80.0)	27(90.0)	30(100.0)
Expected problem in using	12(40.0)	9(30.0)	10(23.3)	9(30.0)	30(100.0)

5.4.3 Duration of rating pain scales

The most time consumed pain scale was CHEOPS with the mean 59.0 seconds (standard deviation 15.8 seconds). The least time consumed scale was TPPPS with the mean 40.1 seconds (standard deviation 15.3 seconds). Mean duration of rating OPS and FLACC were 44.1 seconds (standard deviation 12.7 seconds) and 45.5 seconds (standard deviation 14.2 seconds). See table 36 for more detail.

Table 36 Duration of rating pain scales

	Mean duration(sec)	SD(sec)	Number
CHEOPS	59.0	15.8	30
FLACC	45.5	14.2	30
OPS	44.1	12.7	30
TPPPS	40.1	15.3	30

5.4.4 Satisfaction score ranking

According to satisfaction assessment, CHEOPS was the most satisfied scale whereas TPPPS was the least satisfied scale. See table 37 for more detail.

Table 37 Satisfaction ranking on pain scales

Grading	CHEOPS n(%)	OPS n(%)	TPPPS n(%)	FLACC n(%)
1 = Good	14(46.7)	6(20.0)	4(13.3)	6(20.0)
2 = Moderate	5(16.7)	8(26.7)	4(13.3)	14(46.7)
3 = Fair	5(16.7)	10(33.3)	10(33.3)	6(20.0)
4 = Poor	6(20.0)	6(20.0)	12(40.0)	4(13.3)
Total	**30(100)**	**30(100)**	**30(100)**	**30(100)**

5.5 Summary

All relevant results were summarized in table 38.

Table 38 Summary of relevant results

	CHEOPS (Ref.Test)	**OPS**	**TPPPS**	**FLACC**
VALIDATION				
Reliability	0.9164	0.9754	0.9092	0.9265
Content validity				
(Items that IC <0.5) / total items	7 / 28	0 / 15	1 / 7	0 / 15
Discriminant validity in recovery room	p<.001	p<.001	p<.001	p<.001
Difference of pain score before-after analgesics				
Discriminant validity in wards	p<.001	p<.001	p<.001	p<.001
Difference of pain score before-after analgesics				
Predictive validity in recovery room				
(with respect to CHEOPS)				
Cutoff point		3	3	3
Specificity (%)		92.7	80.5	95.1
Sensitivity (%)		90.7	85.2	89.8
Area under ROC curve		0.9796	0.9264	0.9788

Table 38 (continued)

	CHEOPS (Ref.Test)	OPS	TPPPS	FLACC
Predictive validity in wards				
(with respect to CHEOPS)				
Cutoff point		2		2
Specificity (%)		81.7		80.3
Sensitivity (%)		80.0		81.4
Area under ROC curve		0.9186		0.9162
Concurrent validity in recovery room				
Agreement		0.792		0.795
Correlation		0.799		0.765
Concurrent validity in wards				
Agreement		0.617		0.617
Correlation		0.798		0.804
PRACTICALITY				
Comments on practicality				
Confused (%)	40	26.7	20	26.7
Easy scoring (%)	60	80	80	76.7
Easy interpreting (%)	83.3	73.3	73.3	73.3
Help in assessment (%)	100	83.3	80	86.7
Help in decision to treat (%)	100	83.3	76.7	90
Correlated with decision to treat (%)	100	83.3	80	90
Practical in routine use (%)	80	76.7	80	90
Expected problem in using (%)	40	30	23.3	30

Table 38 (continued)

	CHEOPS (Ref.Test)	OPS	TPPPS	FLACC
Duration of rating pain scales (seconds)				
Mean ± SD	59.0±15.8	44.1±12.7	40.1±15.3	45.5±14.2
Saisfaction score ranking (%)				
Good	46.7	20.0	13.3	20.0
Moderate	16.7	26.7	13.3	46.7
Fair	16.7	33.3	33.3	20.0
Poor	20.0	20.0	40.0	13.3

CHAPTER 6

DISCUSSION, CONCLUSION AND RECOMMENDATION

6.1 Discussion

CHEOPS, OPS, TPPPS and FLACC were initially developed and validated in western countries[12-16]. Different culture in oriental countries may affect the behavioral response of children especially older age group. Therefore, cross-validation of all translated pain scales are necessary before using. In addition, most of scales were validated only in immediate postoperative period, further evaluation in delayed postoperative period were also needed. Consequently, practicality was assessed to improve clinical utility.

All translated scales provided excellent reliability. According to content validation, all experts were totally agreed with OPS and FLACC while CHEOPS had 7 items with IC less 0.5. Five from 7 items were opposed particularly about scaling, such as no cry, composed face, no verbal response, leg in neutral position and grab in touch item . The more important disagreement in content were items torso-upright and leg-standing which were the rare behaviors in Thai children with severe pain. However, those items were alternatives in several items of severe pain characteristics in those categories. Such opposed behavior might be more common in western children.

Therefore, whether or not omitting such items for using in Thai children, it will not change the content validity of CHEOPS.

TPPPS had only one opposed item : squint which was also an alternative. The other choice in that category was accepted. Therefore, both CHEOPS and TPPPS were still considered appropriate regarding content validity.

Discriminant validity or constructing validity were tested by selecting extreme groups . Groups that should have high levels of pain (before anlgesics) were compared on the measure to groups that should have low levels of pain (after analgesics). All pain scales had similar trends. Pain scores before analgesics were significantly higher than after analgesics both in immediate and delayed postoperative period, supporting construct validity of all pain scales.

Criterion validity of the target tests : OPS, TPPPS and FLACC were assessed coresponding to the accepted reference standard. In measuring pain in children, there is no "gold standard", so that approach to criterion validity is more approximate than some tests for disease might be. In this study, CHEOPS which has been commonly used was[13-34] selected to be the accepted reference test or silver standard. The two approaches to criterion validity are related to the timing of correlation of the measures, predictive validity and concurrent validity.

To assess and strengthen the predictive validity of the measures, sensitivity and specificity analyses were evaluated. As postoperative pain might induce several pathophysiological consequences[1] and it was still underestimated in children[3,4], high sensitivity was necessary. Nevertheless, overtreatment of pain was also detrimental, therefore high specificity was also needed.

In immediate postoperative period, OPS and FLACC yielded higher specificity, sensitivity and agreement than TPPPS. All target tests had good correlation with CHEOPS. However, in delayed postoperative period, predictive capability of all target tests were lower. Using the same cutoff point 3 as in immediate postoperative period, specificity was lower but sensitivity was even worse. So cutoff point was reduced to 2, OPS and FLACC could yield lower specificity and sensitivity but still in acceptable range (90 $\pm$ 10%). TPPPS had no appropriate cutoff point. Moreover, agreement and correlation of OPS and FLACC with respect to CHEOPS were moderate to good.

Difference in predictive capability of tools over time may be due to several reasons. Firstly, severity of pain in wards was lower than immediate postoperative period, as the incidence of pain in this study, corresponding to CHEOPS more than 6, in recovery room was 72.5% and in wards was 49.6%. Secondly, the incidence of emergence delirium or agitation occurred most common in preschool-aged children. Pain, patient temperament, age and developmental maturity were all factors that could affect emergence agitation[36-38]. However, there are evidences[39,40] support that pain is the major factor that distorts the emergence from anesthetics. Reginal anesthesia and intraoperative opioid[39] or non steroidal inflammatory drugs[40] could profoundly reduce the incidence of emergence agitation. Besides, the mimic signs of emergence agitation and pain might increase the severity of behavior in immediate postoperative period especially in young children. Thirdly, in delayed postoperative period where the children were widely awake, older children, in particular, may behave in a social desirable way or may underestimate their pain to avoid unpleasant testing medication or unacceptable methods of administration (e.g. injections). Some of them may escalate

their pain report to acquire increased attention especially their parents presence. However, 38.9% of the parents did not stay with their children during the study. Without their parents, most of Thai children were normally shy and fear of stranger , trend of behaviors or pain report are likely to be underexpression.

In case that the cutoff points of OPS and FLACC were lowered in wards, whether it was still appropriate to use the same cutoff point of accepted reference test CHEOPS at 6 as decision to treat pain in both immediate and delayed recovery periods. Considering CHEOPS in detail, it consisted of several alternatives of behaviors with ordinal scales in each category. Even the underexpressed postoperative children who were quiet, composed, lying still and tense in wards would get CHEOPS score 8 (>6 = moderate to severe pain) whereas OPS would get score 2 (>2 = moderate to severe pain), TPPPS would get score 1 (no suitable cutoff point) and FLACC would get score 3 (>2 = moderate to severe pain). Therefore, it could be supported the validity of CHEOPS in term of cutoff point 6 in both periods.

Concerning practicality evaluation, inspite CHEOPS was the most confused, complicated, difficult to employ and needed considerable time to rate pain, all evaluators still totally agreed with its utility in pain assessment and correlation with decision to treat pain. The target tests were less satisfied than CHEOPS inspite of shortness and simplicity. Especially TPPPS, which was the most simple scale, was considered the least valuable in pain assessment. The reasons were due to few characteristics and nominal scales (0 or 1) which the raters commented of difficulty in decision to score.

6.2 Conclusion

OPS and FLACC were appropriate alternative tools which are simple, short, reliable, valid, specific, sensitive and practical in Thai children aged 1-5 years especially in immediate postoperative period. Cutoff point of OPS and FLACC in recovery room were 3 and in wards were 2. Specificity and sensitivity in wards of both scales were lower than in recovery room. TPPPS was inappropriate due to unacceptable specificity and sensitivity. CHEOPS was still the most satisfied scale inspite of difficulty in using.

6.3 Limitation and obstacles

Confounders as other forms of distress such as hunger, thirst, full bladder, nausea and anxiety including emergence agitation would be difficult to distinguish behavior from pain in preverbal children. To minimize this limitation, most of data collection were performed in day time when parents present, after consolating and feeding if possible and after excluding the other causes. However, there were 65 children (38.9%) whose operation finished lately in the evening so that parents were not allowed to stay with them during the study.

Children's distracting bias during videotape recording might interfere with their behavioral responses to pain. To minimize this bias, videotape was recorded from a remote area. Some parents and nurses' behaviors or consolated verbal response to children's pain including the background of recovery room and ward could not be blinded in videotape.

6.4 Recommendation

1. In immediate postoperative period, OPS and FLACC could be excellent substitute of CHEOPS. But in delayed postoperative period, CHEOPS is still invaluable in measuring aspect than other target tests. Therefore, some modification of CHEOPS for practicality should be develpoed.

2. According to the observation during this study, pain measures in wards may need some more items to increase the sensitivity including comfort, interaction with environment, self-limited movement, pain with active or passive movement, sleep disorder and emotional status. Further validation are also needed.

3. Triability of innovation for clinical practice is the major concern. To lessen the "provider burden", measures need to be short, simple, memorable, easy to employ and generalizable. Routinization by coupling pain measurement with vital signs may be a solution.

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APPENDIX 1

Consent form

I have been informed that Department of Anesthesiology, Faculty of Medicine, Siriraj Hospital, Mahidol University is conducting a study of postoperative pain measurement in children aged 1-5 years. The purpose of this study is to find out the appropriate tools with high specificity, sensitivity, reliability, validity and high practicality for using as for observation pain measurement in preschool aged children.

I, being the guardian of _____ (the patient's name), agree this patient to participate in this study, understanding that it involves:

1. Patient will receive routine analgesic treatment following surgery.

2. Behaviors of the patient will be recorded by videotaped in 5 periods as 1) before operation, 2) before - and 3) after - analgesics in recovery room , 4) before- and 5) after- analgesics in wards.

3. The videotaped pain behaviors will be rated by nurses unaware of the patients by using the accepted reference standard test and the target tests.

4. All information and videotapes will be kept confidential. No one will be identified individually in any publish reports. Only the researchers will have assess to the study.

I also have been informed that there is no intervention, so there should not be any adverse effects occur from this study.

I understand that my agreement of my patient's participation in this study is entirely voluntary and that I may withdraw my consent to participate at any time without penalty and without any way affecting the heath my patient receives.

I have an opportunity to ask questions about this study and if I have further questions about this study, I may contact the researchers in this hospital on Pager 1500-651778.

Subject' s guardian signature_____(relation:_____)

Physician' s name_____

Date of participation_____

APPENDIX 2

Pain data collecting form

Data collecting form for research topic of

Validation of pain measurements in Thai children aged 1-5 years

within 24 hours following operation

For Master Degree, Faculty of Medicine, Chulalongkorn University

****

1. Identification and demographic data

1. Study number.....[ ][ ]
2. Subject's name.....
3. Subject's address.....
4. Hospital number.....[ ][ ][ ][ ][ ]
5. Date of operation.....[ ][ ][ ][ ][ ][ ][ ]
6. Hospital.....[ ]
    1. Siriraj Hospital
    2. Queen Sirikit's National Institute of Child Health
7. Department.....[ ]
    1. Surgery
    2. Orthopedics
    3. Eye
    4. Ear Nose Throat

5. Pediatrics

2. General information

8. Birth date.....[ ][ ][ ][ ][ ][ ]

9. Age.....[ ]yr [ ]mo

10. Body weight.....kilogram [ ][ ]

11. Parental presence during study.....[ ]

1. Yes
2. No

12. Surgical experience.....[ ]

1. Yes
2. No

3. Operation and intraoperative analgesia

13. Site of surgery.....[ ]

1. Head-neck and maxillofacial
2. Eye
3. Ear, nose, throat
4. Limb
5. Chest
6. Abdomen
7. Groin and perineum
8. Trunk(superficial)

14. Duration of surgery.....hour .....minutes [ ][ ]hr[ ][ ]min

15. Intraoperative analgesia.....[ ]

1. None
2. Regional block or local infiltration
3. Narcotics
4. Others e.g. ketamine

4. Immediate postoperative period

16. Immediate postoperative analgesia

1. None
2. Fentanyl
3. Pethidine or morphine
4. Paracetamol

5. Delayed postoperative period

17. Assessment

1. Nurses call
2. Researcher visits patients according to duration of last analgesics
3. Not sure
4. Assess after analgesics given

18. Duration from last analgesics given to time of assessment ..... [ ][ ]hr[ ][ ]min

19. Postoperative analgesics.....[ ]

1. None
2. Narcotics
3. Paracetamol
4. Others

6. CHEOPS score

20. Preoperative score C1.....[ ]

21. Recovery room: before analgesics C2.....[ ]

22. Recovery room: after analgesics C3.....[ ]

24. Ward: before analgesics C4.....[ ]

25. Ward: after analgesics C5.....[ ]

7. OPS score

26. Preoperative score O1.....[ ]

27. Recovery room: before analgesics O2.....[ ]

28. Recovery room: after analgesics O3.....[ ]

29. Ward: before analgesics O4.....[ ]

30. Ward: after analgesics O5.....[ ]

8. TPPPS score

31. Preoperative score T1.....[ ]

32. Recovery room: before analgesics T2.....[ ]

33. Recovery room: after analgesics T3.....[ ]

34. Ward: before analgesics T4.....[ ]

35. Ward: after analgesics T5.....[ ]

9. FLACC score

36. Preoperative score F1.....[ ]

37. Recovery room: before analgesics F2.....[ ]

38. Recovery room: after analgesics F3.....[ ]

38. Ward: before analgesics F4.....[ ]

39. Ward: after analgesics F5.....[ ]

APPENDIX 3

Translated pain scales

CHEOPS

Item	Behavioral	Score	คำจำกัดความ
ร้องไห้	ไม่ร้อง	1	เด็กไม่ร้อง
	ครวง	2	ครวงฮือ ๆ หรือร้องไห้เงียบ ๆ
	ร้องไห้	2	กำลังร้องไห้, ร้องไห้เบา ๆ หรือครวงเบา ๆ
	หวีดร้อง	3	ร้องไห้สุดเสียง สะอึกสะอื้น อาจบ่นหรือ ไม่บ่นก็ได้
สีหน้า	เฉย ๆ	1	สีหน้าเฉย ๆ
	เบ้	2	ให้คะแนนเมื่อมีสีหน้าไปทางลบ
	ยิ้ม	0	ให้คะแนนเมื่อมีสีหน้าไปทางบวก
การส่งเสียง	ไม่มี	1	เด็กไม่พูด
	บ่นอื่น ๆ	1	เด็กบ่นอย่างอื่นเช่นหิว, หาแม่ แต่ไม่บ่นปวด
	บ่นปวด	2	เด็กบ่นว่าปวด
	บ่นปวดและอื่น ๆ	2	เด็กบ่นว่าปวดและบ่นอื่น ๆ เช่น ปวด หาแม่
	พูดทางบวก	0	ส่งเสียงร่าเริง พูดเรื่องอื่นโดยไม่บ่น
ท่าทาง(ลำตัว)	ธรรมดา	1	ลำตัว (ไม่ใช่แขนขา) อยู่ในท่าพักสบาย ๆ
	ดิ้นไปมา	2	ลำตัวส่ายหรือดิ้นไปมาเหมือนงูเลื้อย
	ตัวงอแข็ง	2	ลำตัวโค้ง หรือแข็งเกร็ง
	สั่น	2	ลำตัวสั่นหรือขนลุกโดยควบคุมไม่ได้
	ท่ายืน	2	เด็กอยู่ในท่ายืดตัวตรง หรือในแนวดิ่ง
	เกร็ง	2	ร่างกายจะปกป้อง ไม่ให้เจ็บมากขึ้น
สัมผัสแผล	ไม่สัมผัส	1	เด็กไม่แตะหรือตะปบแผล
	เอื้อมมาที่แผล	2	เด็กเอื้อมมือมาที่แผลแต่ไม่แตะแผล
	แตะแผล	2	เด็กจะแตะแผลหรือบริเวณแผลเบา ๆ
	ตะปบแผล	2	เด็กตะปบหรือตะครุบอย่างแรงที่แผล
	เกร็งแขนไม่ให้ถูกแผล	2	แขนเด็กจะเกร็งเพื่อไม่ให้ถูกแผล
ขา	ท่าสบาย	1	ขาอยู่ในท่าใดก็ได้ หย่อนสบาย ๆ รวมทั้ง ท่าขาตีน้ำเบา ๆ หรือแกว่งขาคล้ายท่างูเลื้อย
	บิดตัวไปมา/เตะ	2	ขายยับอย่างกระสับกระส่ายไม่สบายและ/ หรือ เตะเท้าไปมาข้างเดียวหรือทั้ง 2 ข้าง
	ดึงกลับ/เกร็ง	2	ขาเกร็งและ/หรือดึงขาขึ้นไปบริเวณลำตัว เกร็งไว้ในท่านั้น
	ยืน	2	ยืน, คู้ตัวจนเป็นนั่งยอง ๆ กอดเข่า, คุกเข่า
	เกร็งไม่เคลื่อนไหว	2	ขาเด็กเกร็งอยู่ในท่าใดท่าหนึ่ง

Modified OPS

Criteria	Observation	Score
ร้องไห้	ไม่ร้อง	0
	ร้องแต่ปลอบก็นิ่ง	1
	ร้องปลอบไม่นิ่ง	2
การเคลื่อนไหว	ไม่มี	0
	กระสับกระส่าย	1
	ดิ้นรนไปมาเหมือนถูกเฆี่ยน	2
ความกระวนกระวาย	หลับ/สงบ	0
	เล็กน้อย	1
	กระสับกระส่ายเหมือนเป็นโรคประสาท	2
ท่าทาง	ปกติ	0
	งอ	1
	คุดคู้งอบริเวณขาหนีบ/คอ	2
การส่งเสียง	หลับ/ไม่บ่น	0
	บ่นปวด/แต่ระบุตำแหน่งไม่ได้	1
	ระบุหรือชี้ตำแหน่งที่ปวดได้	2

TPPPS

การออกเสียงแสดงความปวด	- บ่น/ร้องไห้
	- หวีดร้อง
	- ครวญครางร้องโอย ๆ ร้องซี๊ด ๆ กรีดร้อง โหยหวน
สีหน้าแสดงความปวด	- อ้าปาก, เบะปาก
	- ตาเหล่, หลับตาแน่น
	- ขมวดคิ้วเข้าหากัน
ท่าทางแสดงความปวด	- กระสับกระส่าย
	- ถูหรือสัมผัสบริเวณที่ปวด

ให้คะแนน “1” ถ้ามีพฤติกรรมข้างต้น

ให้คะแนน “0” ถ้าไม่มีพฤติกรรมข้างต้น

FLACC Scale

Categories	Scoring	Definition
สีหน้า	0	เฉย , ไม่ยิ้ม
	1	หน้าตาเบะ หรือขมวดคิ้ว ถอยหนี ไม่สนใจสิ่งแวดล้อมเป็นบางครั้ง
	2	คางสั่น, กัดฟันแน่น เป็นบ่อย ๆ หรือตลอดเวลา
ขา	0	อยู่ในท่าปกติหรือท่าสบาย ๆ
	1	อยู่ในท่าไม่สบาย, กระสับกระส่าย, เกร็ง
	2	เตะ หรืองอขาขึ้น
การเคลื่อนไหว	0	นอนเงียบ ๆ , ท่าปกติ, เคลื่อนไหวสบาย ๆ
	1	บิดตัวไปมา, แอ่นหน้าแอ่นหลัง, เกร็ง
	2	ตัวงอ เกร็งตัวจนแข็ง หรือสั่นกระตุก
ร้องไห้	0	ไม่ร้อง (ตื่นหรือหลับก็ได้)
	1	ครางฮือ ๆ หรือครางเบา ๆ บ่นเป็นบางครั้ง
	2	ร้องไห้ตลอด หวีดร้อง สะอึกสะอื้น บ่นบ่อย ๆ
การสนองต่อการปลอบโยน	0	เชื่อฟังดี, สบาย ๆ
	1	สามารถปลอบโยนด้วยการสัมผัส โอบกอด พูดคุยด้วย เพื่อดึงดูดความสนใจเป็นระยะ ๆ
	2	ยากที่จะปลอบโยนหรือทำให้สบาย

APPENDIX 4

Practicality data collecting form

Name of observer.....Ward.....
Year of experience.....

1. Please draw the circle around Y if yes or N if no for each pain scale according to your opinion

	CHEOPS	OPS	TPPPS	FLACC
1.1 After training how to use these scales, are you confused?	Y N	Y N	Y N	Y N
1.2 Are they easy in scoring?	Y N	Y N	Y N	Y N
1.3 Are they easy in interpreting?	Y N	Y N	Y N	Y N
1.4 Are the results of pain scales correlated with your decision to treat pain?	Y N	Y N	Y N	Y N
1.5 Will these pain scales help your decision to treat pain?	Y N	Y N	Y N	Y N
1.6 Will these pain scales improve your pain assessment in children?	Y N	Y N	Y N	Y N
1.7 Can you use these pain scales in routine practice?	Y N	Y N	Y N	Y N
1.8 Do you expect any problem in using these pain scales? If yes, please specify.....	Y N	Y N	Y N	Y N .....

2. Time spent

	CHEOPS		OPS			TPPPS			FLACC		
start	finish	total	start	finish	total	start	finish	total	start	finish	total
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											

Average time spent (mean±SD) CHEOPS =..... OPS = ...
TPPPS = ... FLACC = ...

3. Which pain scale will you select for your routine practice? Please write the number of sequence in front of each pain scale. 1= first or best to 4= least or worst

.....CHEOPS .....OPS .....TPPPS .....FLACC

4. Comment.....
.....

VITAE

Suwannee Suraseranivongse was born on 18 December1955 at Pattani province, Thailand. Graduate degree of Bachelor of Medicine from Faculty of Medicine, Siriraj Hospital, Mahidol University in 1979. Graduate Thai Board of Anesthesiology in 1985. Then working as the staff of Department of Anesthesiology, Samutprakarn Hospital until 1988 and started working as the staff of Department of Anesthesiology, Siriraj Hospital, Mahidol University since then.

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