A Comparison of Pain Scales in Patients with Disorders of Consciousness Following Craniotomy

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Objective: *Evaluate the validity, reliability, and practicality of pain assessment tools in patients with disorders of consciousness who underwent craniotomy.*
Material and Method: *This prospective observational study cross-validated three pain scales, FLACC (Face, Legs, Activity, Cry, Consolability), rFLACC (Revised FLACC), and NCS (Nociception Coma Scale), based on validity, reliability, and practicality. After translation, the three pain scales were tested for concurrent validity, construct validity, and interrater reliability in patients who experienced disorders of consciousness within 24 hours following craniotomy. Opinions regarding practicality were elicited via questionnaire from nurses who have used and are familiar with these pain scales.*
Results: *Fifty-eight patients were enrolled in the present study. Concurrent validity was supported by positive correlations among all scales, which ranged from r = 0.638 to r = 0.978. All scales yielded fair to moderate agreement (K = 0.380-0.626) with routine clinical decision to treat postoperative pain. Concurrent validity was much improved in the assessment of intubated patients. Construct validity was demonstrated by high scores (3-5) in higher pain situations before analgesic was given and low pain scores (0) in pain-free situations after analgesic was given. All scales had good interrater reliability (intraclass correlation = 0.7506-0.8810).*
Conclusion: *All pain scales were found to be valid and reliable, especially in intubated patients. In terms of practicality, NCS was found to be the most acceptable by practitioners.*

Keywords: *Craniotomy, Pain, Postoperative, Pain scales, Validity*

J Med Assoc Thai 2015; 98 (7): 684-92
Full text. e-Journal: *http://www.jmatonline.com*

Post-craniotomy pain has been demonstrated to be moderate to severe in nature[1-4]. Appropriate pain assessment and adequate pain relief are extremely important in reducing restlessness, high blood pressure, shivering, and vomiting, any or all of which may increase intracranial pressure and subsequently lead to intracranial hemorrhage[3]. Although the recognition of analgesic need following craniotomy has been increasing, evidence of suitable pain management protocols in this group of patients is still lacking[5]. As a result, the prevalence of inadequate pain relief has remained high in the range of about 60 to 70%[1,4].

Postoperative patients with disorders of consciousness are not able to communicate or appropriately report their pain. There is currently no specific pain scale that is validated for assessment of pain in patients with disorders of consciousness following craniotomy. Several pain scales validated in other patient populations who were unable to communicate have been used for this purpose. Examples of these scales include Faces, Legs, Activity, Cry, Consolability pain assessment tool (FLACC)[6,7], Nociception Coma Scale (NCS)[8], Neonatal Infant Pain Scale (NIPS)[9], Pain Assessment in Advanced Dementia Scale (PAINAD)[10], and Checklist of Non-Verbal Pain Indicator (CNPI)[11].

FLACC was validated for pain assessment in small children[6] and critically ill patients, including two cases in which the patient underwent intracranial surgery[7] (Appendix 1). FLACC has become popular for pain assessment in neurosurgical patients. There is a revised version of FLACC (rFLACC), which includes added detail that improves reliability and validity in children with cognitive impairment[12,13] (Appendix 2).

NCS was introduced for pain assessment in 48 post-comatose patients from acute care, neurology, neurorehabilitation, and nursing home center

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environments (Appendix 3). The authors validated NCS, as compared with NIPS, FLACC, PAINAD, and CNPI. They found that NCS showed high correlations with other validated assessment tools. NCS and CNPI demonstrated higher levels of effectiveness than other pain assessment tools in vegetative state patients, as compared to patients that were minimally conscious. In a comparison of the two, NCS was found to be more sensitive than CNPI in measuring pain[9].

The objective of the present study was to test the validity (concurrent and construct validity), reliability, and practicality of FLACC, rFLACC, and NCS in post-craniotomy patients who experienced disorders of consciousness and who were unable to communicate or accurately and effectively report their pain within 24 hours following surgery.

Material and Method

Language translated FLACC, rFLACC, and NCS were cross-validated to test validity (concurrent validity and construct validity), reliability, and practicality. The comparison of these same three criteria was also performed among the three pain assessment scales.

This prospective observational study was approved by the Siriraj Institutional Review Board (SiRB) (Ref: 461/2554EC2) and registered in the ClinicalTrials.gov website (NCT01547663). After obtaining written informed consent from the relatives of patients who were admitted to the Siriraj neurosurgical intensive care unit, the study was conducted in four phases.

Phase 1: Translation

First, a bilingual (English-Thai) physician translated the three pain scales from English into Thai. A second translator who was not involved in the translation phase then translated the Thai version back into English. Finally, a third translator, whose mother tongue is English, rechecked the back translated scales with the original scales. The third translator made final determinations regarding corrections to ensure accurate translation of the original English language scales.

Phase 2: Testing of concurrent validity, construct validity, and interrater reliability in post-craniotomy pain

Adult patients, aged 18 years or more, who were admitted to the neurosurgical intensive care unit with a post-craniotomy Glasgow coma score (GCS) of less than 15 were enrolled in the present study. Exclusion criteria included patients who received sedation or neuromuscular blocking drugs three days prior and patients with documented history of brain injury, delayed development, psychiatric illness, and inability to move extremities from fracture or paralysis. Patients who were diagnosed with thalamic hemorrhage were also excluded due to an inability to express feelings.

Patient demographic data, operation details, and analgesic prescribed were all recorded. All nurses in this unit were trained in how to score pain using FLACC, rFLACC, and NCS. Ten patient behaviors demonstrated during painful procedures (e.g., suctioning, blood sampling) were shown on videotape to train nurses until the intraclass correlation reached 0.8 or more. Three nurses assessed each patient every 1 or 2 hours until 24 hours postoperation or until patients were able to rate their severity of pain. During each assessment, two nurses independently evaluated the same patient using three pain scales. The third nurse assessed patients and made routine clinical decisions to treat pain based on increased blood pressure of more than 20% from baseline plus at least one pain related behavior, such as facial grimace, crying, vocal complaints (both verbal and nonverbal), restlessness, arching, rigidity, or jerking. Other etiologies of increased blood pressure, such as full bladder or increased intracranial pressure, were ruled out before analgesic was given.

Concurrent validity: Correlations were tested between FLACC, rFLACC, and NCS at the same time point for all patients.

Construct validity: The ability of each pain scale to differentiate high pain scores before analgesic was given and low pain scores after analgesic was given.

By using the average high scores of FLACC, rFLACC, and NCS before analgesic was given to determine the cut-off point, the agreement kappa (k) between the three pain scales assessed by the first and second nurses and the routine clinical decisions by the third nurse were tested.

Interrater reliability: Consistencies in scoring from each of the pain scales as evaluated by the first and second nurse were identified by interrater reliability.

Phase 3: Practicality of measures and testing content validity

Practicality of measures: Questionnaires asking for opinion when using the three pain scales

were sent to nurses who had used these scales in a neurosurgical intensive care unit. All three pain assessment scales were ranked from "0 = least" to "10 = most" in terms of simplicity of use, time consumed, feasibility in routine clinical use, ability to differentiate pain severity, assistance in decision to give analgesic, and overall satisfaction with the scales.

Testing content validity: Language translated FLACC, rFLACC, and NCS were assessed in terms of content by eight experts who were senior nurses with at least 5-years experience in a neurosurgical intensive care unit. Content assessment scoring was coded, as follows: 1 = agree, 0 = no idea, -1 = disagree.

Statistical data analysis

The sample size calculation was based on an estimated correlation of 0.5, alpha of 0.01, and power of 0.9. Using the StatsToDo statistics website, the sample size was estimated to be 48. With the addition of dropout rate of 20%, the minimum sample size was increased to 58 cases.

Patient demographic data were described as mean (SD), median (range), and percentage. Correlations among FLACC, rFLACC, and NCS were analyzed using Spearman's rank correlation coefficient. Interrater reliability was analyzed by intraclass correlation using a two-way random effect model. An intraclass correlation of 0.8 or more was considered acceptable.

Differences in pain scores before and after analgesic given (used to determine construct validity) were compared using the Wilcoxon matched-pairs signed-rank test. Agreement of all pain scales from the independent evaluations of the first and second nurse at the cut-off points (corresponding to high pain before analgesic given) with the third nurse's routine decisions to treat pain were analyzed using Cohen's kappa statistic (k). Values of k were interpreted, as follows: ≤2 poor agreement, 0.21 to 0.4 fair agreement, 0.41 to 0.6 moderate agreement, 0.61 to 0.8 good agreement, and 0.81 to 1.0 very good agreement[14]. The practicality of the three pain scales was analyzed using descriptive statistics. Content validity, in terms of behavioral items and scoring items, was analyzed by summation of scores divided by number of experts. If the results were ≥0.5, content validity for those items was accepted. SPSS for Windows v.11.5 (SPSS, Chicago, IL, USA) was used for all analyses.

Results

Fifty-eight neurosurgical patients who underwent craniotomy were enrolled in the present study. There were 26 males (44.8%) with a mean age of 58.03 years (SD 12.86 years, range 24-88 years) and median GCS of 11 (range 3-14). Fourteen patients (24.1%) had GCS less than or equal to 8 and 44 patients (75.9%) had GCS greater than 8. Diagnoses were tumor (n = 44), aneurysm (n = 10), and other (n = 4). Seven hundred sixty observations were performed. Thirty-two percent of patients were intubated and ventilated following operation. Twenty-five patients (43%) were able to ultimately provide their own assessment of pain.

Concurrent validity was evaluated in terms of correlation between pain scales in all patients (Table 1). The correlation between FLACC and rFLACC was excellent (r>0.9), whereas the correlations between NCS and FLACC or rFLACC were good (0.702-0.711). All correlations between pain scales for nurse A and B were much higher for intubated patients than for non-intubated patients. Interrater reliability between nurse A and B for all pain scales was good (FLACC = 0.8810, rFLACC = 0.8786, and NCS = 0.7506).

Construct validity was determined in all patients who underwent craniotomy. Median pain scores before analgesic was given were higher than after analgesic was given (Table 2).

The cut-off points derived from median scores of FLACC, rFLACC, and NCS before analgesic was given were 3, 3, and 4, respectively. Kappa agreements between the third nurse's clinical decision to treat pain and the three pain scales were fair to moderate (Table 3).

Regarding practicality, NCS was rated superior to FLACC and rFLACC for all criteria (Table 4). The content of FLACC, rFLACC, and NCS was accepted by all nurses, except the 'visual response' identifier in NCS.

Discussion

The present study demonstrated good concurrent validity among FLACC, rFLACC, and NCS, especially in intubated patients. All pain assessment scales showed construct validity, good interrater reliability, and fair to moderate agreement with routine clinical decisions to treat pain. Based on comments and opinions elicited from nurses, NCS was the most practical scale. The categories of all pain scales were accepted by nurses, except for the 'visual response' component of NCS.

Table 1. Spearman's rank correlation among FLACC, rFLACC, and NCS in patients following craniotomy, all *p*-value were less than 0.001

	Nurse A			Nurse B		
	FLACC	rFLACC	NCS	FLACC	rFLACC	NCS
All patients (760 observations)						
FLACC	1			1		
rFLACC	0.939	1		0.956	1	
NCS	0.704	0.711	1	0.703	0.702	1
Intubated patients (249 observations)						
FLACC	1			1		
rFLACC	0.950	1		0.978	1	
NCS	0.795	0.769	1	0.847	0.837	1
Non-intubated patients (511 observations)						
FLACC	1			1		
rFLACC	0.933	1		0.944	1	
NCS	0.662	0.687	1	0.638	0.642	1

FLACC = face, legs, activity, cry, consolability; rFLACC = revised FLACC; NCS = nociception coma scale

Table 2. Construct validity of pain scores from nurse A and B before and after giving analgesic, Wilcoxon matched-pair signed-rank test; all *p*-value were less than 0.001

Pain scales	Observer	Pain scores, median (IQR)	
		Before analgesic given	After analgesic given
FLACC	A	3 (1, 5)	0 (0, 1)
	B	3 (1, 5)	0 (0, 1)
rFLACC	A	3 (1, 5.25)	0 (0, 1)
	B	3 (1, 5)	0 (0, 1)
NCS	A	5 (2.75, 6.25)	0 (0, 2)
	B	4 (2, 6)	0 (0, 3)

Table 3. Agreement between clinical decision to treat postoperative pain and FLACC, rFLACC, and NCS in all patients, intubated patients, and non-intubated patients

Patients	Pain scales	Cut-off point	Kappa with clinical decision to treat pain (Nurse 3)	
			Nurse 1	Nurse 2
All patients	FLACC	3	0.456	0.505
	rFLACC	3	0.480	0.506
	NCS	4	0.5	0.465
Intubated patients	FLACC	3	0.513	0.552
	rFLACC	3	0.519	0.558
	NCS	4	0.626	0.5
Non-intubated patients	FLACC	3	0.434	0.487
	rFLACC	3	0.465	0.485
	NCS	4	0.444	0.380

FLACC was originally validated for acute pain assessment in small children[6], whereas rFLACC was revised and validated for children with cognitive impairment[12,13]. The rFLACC was highly correlated with FLACC because they assessed similar behaviors, except that rFLACC contained more detail in each assessment component. The NCS contained some different assessment behaviors and was validated in severely brain injured patients recovering from coma[8]. Nevertheless, the correlation between NCS and both

Table 4. Practicality aspect as evaluated by 26 nurses with mean experience of 11.19 years (SD 5.86, range 1-20 years); rating score: 0 (least likely) to 10 (most likely); presented as mean (SD)

Items of practicality	FLACC	rFLACC	NCS
Simple to use	4.62 (2.32)	4.58 (2.30)	6.12 (2.53)
Time wasting	6.88 (1.86)	7.04 (2.11)	5.38 (1.88)
Difficulty in assessing	6.50 (1.66)	6.54 (1.88)	5.04 (1.73)
Assisting in decision to give analgesic	4.62 (2.12)	4.69 (2.17)	5.38 (2.84)
Appropriate for routine practice	4.65 (1.76)	4.58 (1.75)	5.35 (2.64)
Able to differentiate pain severity	4.73 (1.99)	4.65 (1.92)	5.31 (2.48)
Global rating	5.20 (1.79)	5.20 (1.77)	6.01 (1.98)

Table 5. Content validity: item correlation (IC) = sum of rating scores/number of raters; IC should be ≥0.5

Description	FLACC	rFLACC	NCS
Facial response	0.63	0.88	0.75
Leg	0.63	0.88	-
Activity/motor response	0.63	1.0	0.63
Cry	0.5	0.88	-
Consolability	0.63	0.63	-
Verbal response	-	-	0.5
Visual response	-	-	0

FLACC and rFLACC were also positive. Common behaviors between NCS with other pain scales included facial response, motor response (FLACC & rFLACC: Leg & Activity), and verbal response (FLACC & rFLACC: Cry). Different behaviors were "consolability" from FLACC and rFLACC and "visual response" from NCS. The correlation between NCS and the other pain scales in intubated patients was much better. The reason may be that most of the intubated neurosurgical patients were non-communicative and usually had more severe disorders of consciousness. Discordance of assessment between different categories of each scale, such as consolability and visual response, may be minimal. In addition, there was no verbal response in intubated patients. Consequently, rest behaviors to be assessed were only "facial response" and "motor response", which are recommended for patients who cannot communicate their pain[15,16].

Cut-off points for the three pain scales were identified from average high pain scores before analgesic was given for purposes of implementing all pain scales in clinical practice for post-craniotomy patients. FLACC has a cut-off point of 3, similar to the study in small children[17], which meant that the FLACC score in patients with pain was 3 or higher. The cut-off points of rFLACC and NCS were not reported in previous studies. Our results demonstrate a cut-off point of 3 for rFLACC and 4 for NCS; scores that are appropriate to and consistent with their content. We also found better agreement among all pain scales in intubated patients with routine clinical decisions to treat pain, which indicated that they were appropriate to be generally applied in post-craniotomy patients with severe disorders of consciousness.

Construct validity of all pain scales was proved from higher pain behavior scores before analgesic was given and lower scores in pain-free or lower pain behaviors after analgesic was given. Good interrater reliability demonstrated that the scales yielded reproducible and consistent findings across assessors.

Concerning practicality, NCS was the most acceptable pain scale in all items, most notably for its simplicity, being less time-consuming, and its ability to differentiate pain severity. Based on pain assessment tool content reviewed and evaluated by 8 senior nurses from the neurosurgical intensive care unit, all agreed with all categories from FLACC, rFLACC, and NCS, except for the 'visual response' component of NCS. This behavior was originally validated in severely brain-injured patients who did not receive any neuromuscular blocking drugs or sedation within 24 hours of enrollment and who had preserved the sleep-wake cycle, which was indicated by the presence of an eye opening period[8]. However, this visual response was not relevant in the 24-hour postoperative period following craniotomy, because the retention of anesthetics combined with some degree of brain injury usually induced drowsiness and eyelid closure. As a result, this category was likely rated as "0 = none".

There were some limitations in the present study. First, patients who were enrolled in the present study that met the criteria of post-craniotomy and

Glasgow coma score of less than 15 may have had different degrees of consciousness disorder relating to brain injury. Most of the patients (68%) were not intubated. Some of these patients may have experienced only minimal consciousness impairment and, as such, may have been able to verbally communicate their pain. As a result, their pain behaviors may have been discordant with their feelings, similar to the result of using self-report pain scales, compared with pain behaviors in children aged 3 to 7 years[18]. However, all pain scales demonstrated higher levels of validity and reliability in intubated patients, the group that most accurately characterized severe consciousness disorder. Second, brain abnormality may induce some behaviors, such as abnormal movement of extremities and verbal responses, which may interfere with observable pain behaviors.

In conclusion, FLACC, rFLACC, and NCS were found to be valid and reliable for assessing pain in patients with disorders of consciousness within 24 hours following craniotomy, most notably in intubated patients. The NCS was rated to be the most practical assessment tool for busy routine clinical practice.

What is already known on this topic?

Post-craniotomy pain has been demonstrated to be moderate to severe in nature and the prevalence of inadequate pain relief remains high in the range of about 60 to 70%. Appropriate pain assessment and adequate pain relief are extremely important in reducing restlessness, high blood pressure, shivering, and vomiting, any or all of which may increase intracranial pressure and subsequently lead to intracranial hemorrhage.

Postoperative patients with disorders of consciousness are not able to communicate or appropriately report or describe their pain. To date, there is no specific pain scale that has been validated for the assessment of pain in patients with disorders of consciousness following craniotomy.

What this study adds?

This study cross-validated three pain scales, including Faces, Legs, Activity, Cry, Consolability pain assessment tool (FLACC), revised FLACC (rFLACC), and Nociception Coma Scale (NCS). These pain scales were validated in populations who were unable to communicate. The FLACC was validated for pain assessment in small children and critically ill patients, including two cases in which the patient underwent intracranial surgery. The revised version of FLACC (rFLACC) includes detail that improves reliability and validity in children with cognitive impairment. The NCS was introduced for pain assessment in 48 post-comatose patients from acute care, neurology, neurorehabilitation, and nursing home center environments.

The authors found that FLACC, rFLACC, and NCS were valid and reliable for assessing pain in patients with disorders of consciousness within 24 hours following craniotomy, especially in intubated patients. NCS was rated as being the most practical assessment in a busy routine clinical practice.

Acknowledgements

The authors wish to thank the Siriraj Research Development Fund for financial support, Dr. Chulaluk Komoltri for her invaluable suggestions in statistical analysis, and Ms. Nichapat Sooksri for her kind assistance.

Funding

This study was funded by a grant from the Siriraj Research Development Fund (grant number R015432063).

Potential conflicts of interest

None.

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Appendix 1. Face, Legs, Activity, Cry, Consolability (FLACC) Scale

Categories	Score		
	0	1	2
Face	No particular expression or smile	Occasional grimace, frown, withdrawn or disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless or tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, or tense	Arched, rigidity or jerking
Cry	No cry	Moans, whimpers, or 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

Appendix 2. Revised FLACC

Categories	Scoring		
	0	1	2
F Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested ***Appears sad or worried***	Frequent to constant frown, clenched jaw, quivering chin ***Distressedlooking face: expression of fright or panic***
L Legs	Normal position or relaxed	Uneasy, restless, tense ***Occasional tremors***	Kicking or legs drawn up ***Marked increase in spasticity, constant tremors, or jerking***
A Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense ***Mildly agitated (e.g., head back and forth, aggression); shallow, splinting respirations, intermittent sighs***	Arched, rigid, or jerking ***Severe agitation, head banging, shivering (not rigors); breath-holding, gasping or sharp intake of breath; severe splinting***
C Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint ***Occasional verbal outburst or grunt***	Crying steadily, screams or sobs, frequent complaints ***Repeated outbursts, constant grunting***
C Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractable	Difficult to console or comfort ***Pushing away caregiver, resisting care or comfort measures***

Appendix 3. Nociception Coma Scale (NCS)

Categories	Score			
	0	1	2	3
Motor response	None/flaccid	Abnormal posturing	Flexion withdrawal	Localization to noxious stimulation
Verbal response	None	Groaning	Vocalisation	Verbalisation (intelligible)
Visual response	None	Startle	Eye movements	Fixation
Facial expression	None	Oral reflex movement/ startle response	Grimace	Cry

การเปรียบเทียบมาตรวัดความปวดในผู้ป่วยที่มีความรู้สึกตัวไม่ปกติหลังผ่าตัดสมอง

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วัตถุประสงค์: การศึกษานี้ต้องการประเมิน ความเที่ยงตรงและความสะดวกในการใช้งานของเครื่องมือประเมินความปวดในผู้ป่วยที่มีความรู้สึกตัวไม่ปกติหลังผ่าตัดสมอง

วัสดุและวิธีการ: เป็นการศึกษาแบบสังเกตการณ์ไปข้างหน้า โดยแปลเครื่องมือวัดระดับความปวด 3 ชนิด เป็นภาษาไทย ได้แก่ FLACC (Faces, Legs, Activity, Cry, Consolability), rFLACC (Revised FLACC) และ NCS (Nociceptive Coma Scale) แล้วตรวจสอบความตรงด้วย concurrent validity และ construct validity ตรวจสอบความเที่ยงด้วย interrater reliability ในผู้ป่วยที่มีความรู้สึกตัวไม่ปกติ ภายใน 24 ชั่วโมง หลังการผ่าตัดสมอง และตรวจสอบการใช้งานง่ายโดยใช้แบบสอบถามพยาบาลที่เคยใช้เครื่องมือดังกล่าว

ผลการศึกษา: ทำการศึกษาในผู้ป่วย 58 ราย พบว่าเครื่องมือวัดระดับความปวดทั้ง 3 ชนิด มี concurrent validity คือมี positive correlation ระหว่างกัน (ค่า r อยู่ระหว่าง 0.638 ถึง 0.978) เครื่องมือทั้ง 3 ชนิด มี fair to moderate agreement กับการตัดสินใจให้ยาแก้ปวดโดยการประเมินอาการและอาการแสดงทางคลินิกที่ใช้อยู่เป็นประจำ (kappa = 0.380-0.626) สำหรับค่า concurrent validity พบสูงขึ้นในการประเมินผู้ป่วยที่ใส่ท่อช่วยหายใจ การทดสอบ construct validity พบว่า คะแนนความปวดในช่วงที่มีความปวดมาก ก่อนได้รับยาแก้ปวด (3-5) มีค่าสูงกว่าคะแนนความปวดในช่วงที่มีความปวดน้อย หลังได้รับยาแก้ปวด (0) เครื่องมือทุกชนิดมีความเที่ยงระหว่างผู้วัด หรือ ค่า interrater reliability อยู่ในเกณฑ์ดี (intraclass correlation = 0.756-0.8810)

สรุป: เครื่องมือวัดระดับความปวดทั้ง 3 ชนิด มีความเที่ยงตรง โดยเฉพาะในกลุ่มผู้ป่วยที่ใส่ท่อช่วยหายใจ ด้านการใช้งาน NCS เป็นที่ยอมรับในกลุ่มพยาบาลผู้ใช้ว่าใช้งานง่ายที่สุด