Development of a Clinical Pain Scale for Preterm Neonates

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Abstract: This instrument developmental research developed a pain scale for preterm neonates and to examine its psychometric properties. A developmental neurobiological approach was used to guide construction of the scale. Seven pain indicators were initially identified by the synthesis of data from a concept analysis, clinical observations, and expert interview; and were then reviewed for content validity by a panel of six experts. After the review, the respiratory support indicator was eliminated. Six indicators remained with two scoring formats for two age groups (< 32 weeks and ≥ 32 weeks to 36 weeks and 6 days)

During psychometric testing, 53 blood collecting occasions from 19 preterm neonates in two neonatal intensice care units in Thailand were examined by two observers using the 6-indicator Clinical Pain Scale for Preterm Neonates scale and the Premature Infant Pain Profile-Revised scale. Prior to reliability analysis, length of the unit stay and previous pain exposure indicators were deleted because of low inter-item and item-total correlations. Cronbach's alpha coefficient of the 4-indicator scale was 0.94 and the intraclass correlation coefficients ranged from 0.91 to 1.00. Construct validity was tested by comparing median pain scores of three phases. The results revealed that the median pain score of the puncture phase was significantly higher than those of baseline and recovery phases. Convergence examination showed a positive correlation between pain scores measured by the new scale and the Premature Infant Pain Profile-Revised Scale. Clinical utility evaluation of the new scale revealed satisfactory results. Thus, the Clinical Pain Scale for Preterm Neonates scale proved to be valid, reliable, and clinically applicable for procedural pain assessment in preterm neonates in neonatal intensive care unit.

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Introduction

Preterm neonates are exposed to early and repeated procedural pain as a result of numerous diagnostic, monitoring, and therapeutic procedures which are essential for their survival in intensive care management. A systematic review of 18 observation studies reported that the average numbers of painful procedures per neonate per day ranged from 7.5 to 17.5.[1] The lower the gestational age of preterm

neonates, the more invasive the procedures required to ensure their survival.[2]

Soon after birth, preterm neonates have almost all the anatomical requirements for nociception which is the detection and transmission of pain signals from the site of the stimulus to the brain. This involves the unique nociceptive pathways which exist during developmental transition including a greater density of receptor fields per area of skin, a slow conduction speed of C-fibers, and immature descending inhibition.[3,4] The painful procedural experiences during the first postnatal days and weeks, which are abnormal nociceptive input experiences, lead to alterations in pain signal processing and also alter the hardwiring of the neuronal organization of the brain.[5] It is crucial for the improvement of the situation in the clinical setting to reduce pain exposures, encourage accurate pain assessment, and promote pain relieving interventions for this vulnerable patient population.

To date, there are 13 uni-dimensional and multi-dimensional pain assessment scales available for preterm neonates. However, no gold standard scale for clinical practice exists.[3,6] In addition, examination of those scales identified three limitations. First, a lack of developmentally important behaviors of preterm neonates causes issues of difficulty in recognizing pain responses by preterm neonates. Although term and preterm infants have similar patterns of pain response in general, the responses of preterm infants may be less noticeable or completely absent. For example, Neonatal Facial Coding System [NFCS][7] scale was developed from observations a vigorous magnitude of pain behavior of full-term neonates. Evidence showed that only 4 out of 10 facial expressions (brow bulge, eye squeeze, nasolabial furrow, and vertical mouth stretch) of NFCS were sensitive indicators of pain in preterm neonates.[8,9] The uniqueness of the pertinent nociceptive pathways from currently evidence should be considered in the measurement.[3,10]

Second, failure to include factors affecting the intensity of the pain reactions in previous scales causes consistent under-estimation of pain in preterm neonates. Anand[6] insisted that prematurity, sleep states, and previous painful procedure exposures affected specific responses to pain in preterm neonates. One systematic review found that most studies reported a statistically significant effect of gestational age on behavioral response to pain with greater behavioral response as gestational age increased.[11] An empirical study also concluded that number of painful procedure exposures predicted dampened facial expressions.[5] Interestingly, the length of a neonatal intensive care (NICU) stay and the mode of respiratory support influenced the number of painful procedures and pain reactivity of preterm neonates.[1,11] This can be explained by the idea that the exposure to repetitive pain may cause excessive N-methyl-D-aspartate (NMDA)/ excitatory amino acid activation leading to initiate excitotoxic cell death and alter pain pathways.[12] The importance of measuring pain multi-dimensionally including factors associated with pain responses has been suggested.[13] Thus, previous pain exposures and the impact of other factors need to be explored.

Third, complicated methods of score calculation and the inclusion of many pain indicators in one dimension or many score levels in each indicator, of existing pain scales result in little use at the bedside which has an impact on clinical issues.[14] The need for additional clarification on how to use the measures and calculate the total pain score was reported by nurses who used the Premature Infant Pain Profile-Revised (PIPP-R) scale. The uni-dimension scale of PACEFI has 20 behavioral indicators.[15] The facial tension indicator of COMFORTneo has 6 scoring levels making a definite judgment difficult.[16] Complex scoring makes the instrument unfeasible for implementation at the bedside, and limits the ability of nurses to work with real-time instruments to improve pain management. Since the NICU environment is busy, pain measures with fewer indicators that are more user-friendly, are preferred.

Major issues concerning existing pain assessment scales leave room for improvement. Several literature reviews and expert opinions also have suggested that a new pain scale for preterm neonates be developed.[6,17] A well-developed, clinically applicable scale will enhance the ability of the health care provider to detect pain in preterm neonates in critical periods at the bedside and will enable the providers to administer effective pain management. Therefore, a new pain assessment scale for preterm neonates in the NICU aligned to the developmental maturity of those infants and the factors affecting their pain responses is urgently needed. The purpose of this study was to develop a clinical pain assessment scale for preterm neonates in the NICU and to examine its psychometric properties and clinical utility.

Conceptual framework

A developmental neurobiological approach was used to guide construction of an assessment scale for preterm neonates in NICU. The pain pathway from the site of injury to behavioral and physiological consequences is explained, and the pain reactivity of preterm neonates is described in a quantitative manner.[3] The anatomical and functional requirements for nociceptive pathways are established by 24 weeks' gestational age and develop continuously through their postnatal age.[18] Invasion of the skin by a needle is a common occurrence in the treatment of neonates. Immediately after a needle invades the skin, the noxious stimulus is converted to electrical activity and transmitted into peripheral receptors, dorsal root ganglion in the spinal, thalamus, and cortical through the thickly myelinated A-delta fibers and unmyelinated C-fibers. Myelination of ascending pathways is completed by 37 weeks of gestation. The velocity of transmission is influenced by the size of the nerve fiber and the presence of myelin, therefore the lack of myelination contributes to a low speed of CNS processing and latency of pain response in preterm neonates. The perception of pain occurs when an action potential reaches the thalamus and cortex. Facial expression, arousal, and increased heart rate are reflexes mediated at the level of spinal cord through the supraspinal area.[10,19,20] These behavioral and physiological responses of preterm neonates could be utilized as pain indicators of the scale.

The perception and meaning of pain in preterm neonates are complex and not determined by structural and functional maturation alone, but they are influenced by multiple factors. Gestational age impacts on the ability to modify facial expression and the transition of the sleep-wake state.[11,21] The length of NICU stay and the mode of respiratory support influence previous pain exposures and pain reactivity of preterm neonates.[1,11] The younger neonates who require respiratory support in NICU and encounter previous pain exposures have a less robust response to painful stimuli. The repetitive pain causes excessive NMDA/excitatory amino acid activation resulting in the achievement of pain thresholds and stimulation of the associated responses.[12] Therefore, these factors affecting pain reactivity need to be considered and included in the pain scale for preterm neonates.

Method

Study design

An instrument developmental research design was used to develop the Clinical Pain Scale for Preterm Neonates (CPSPN) scale in NICU. The scale development process consisted of 3 phases: phase one, the initial scale construction[22]; phase two, psychometric testing; and phase three, clinical utility evaluation.

Setting and samples

The study was carried out at 2 NICUs in a university hospital in northern Thailand. In phase one (step 2), 8 preterm neonates were purposively recruited for clinical observation based on the following inclusion criteria: 1) being hospitalized in the NICU; 2) having gestational age at birth ≥ 24 weeks to 36

weeks and 6 days; 3) being scheduled to receive a painful procedure within a 24- hour period, and 4) having permission granted by their parent(s) or legal guardian(s) to participate in this study indicated by their written informed consent. They were observed in 15 painful occasions which provided enough information based on prior exploratory studies.[23,24] All infants needed respiratory support and their gestational age at birth ranged from 27 to 29 weeks and 4 days and their mean postnatal age on the study day was 17.20 days (SD = 5.66).

In phase two, for testing the difference between mean pain scores of three phases of painful procedures, eta-squared was used to estimate the required number of events. In this study, a medium effect (eta-squared 0.06) was chosen.[25] Assuming an α of 0.05 and power of 0.80, a sample of 53 events per group was required. Data from 53 occasions that clinically required blood collection were obtained from 19 preterm neonates (11 males and 8 females). All neonates were recruited based on the same inclusion criteria used in phase one. Their gestational age at birth ranged from 24 weeks to 36 weeks and 1 day and the mean postnatal age on the study day was 12.06 days (SD = 14.53). Thirty three sets of data were obtained from 11 preterm neonates with a gestational age ≥ 32 weeks to 36 weeks and 6 days and 20 sets of data were obtained from 8 preterm neonates with a gestational age <32 weeks. All preterm neonates needed respiratory support. The average number of previous pain exposures after birth was 20.27 (SD = 29.30, range 1 to 137).

Ethical considerations

This study was approved by the Research Ethics Review Committee of the Faculty of Nursing and the Faculty of Medicine, Chiang Mai University, number FULL-012-2558. Prior to data collection, the parents or legal guardians of any preterm neonates who met the stated criteria were asked to allow their infants to participate in the study. The primary investigator (PI) explained the purpose of the study and the research procedures, including benefits and risks and expected time needed for the study, to parents of preterm neonates. Following this, parents were given written informed consent forms and time to read all the information with understanding before signing. During the painful procedures, the usual care of pain management was continued. A minimum standardized protocol for comforting strategies such as positioning support, swaddling and providing some regulatory support to infants was still employed for all infants. All parents or legal guardians of preterm neonates were informed that they had the right to withdraw from the study at any time without prejudice or negative effect.

Instruments. For psychometric testing, the PIPP-R scale[26], a commonly used scale, was used to examine convergence validity of the newly developed scale. It comprises 3 facial actions, 2 physiological indicators, and 2 contextual items (gestational age and behavioral state). The scoring technique includes 4 steps: (1) observing an infant at rest for 15 seconds to record the highest heart rate, lowest oxygen saturation, and behavioral state; (2) observing an infant for 30 seconds after the procedure to record changes in the highest heart rate, lowest oxygen saturation, and duration of each facial action; (3) scoring for contextual items if scores of facial actions and physiological indicators were more than zero; and (4) calculating total score by adding sores of all 7 items. Its construct validity had been initially tested in extremely low gestational age infants.[26] data from 2 randomized cross-over studies were utilized to: (1 The inter-rater reliability coefficient of the scale in the previous study was 0.92[27] and in this study was 1.00.

For clinical utility evaluation, the Clinical Utility Questionnaire (CUQ) developed by the research team based on 4 dimensions (appropriateness, accessibility, practicability, and acceptability) of the Multi-dimensional Model of Clinical Utility by Smart[28] was used. Blueprint of the questionnaire was established to specific scope

of dimensions and emphasis of the nurse opinions' measure. It was composed of 17 questions in those 4 dimensions and each question was rated on a four-point Likert's scale ranging from 1 (poor) to 4 (very good). An additional open-ended question was utilized for comments and suggestions.

Data collection and data analysis.

Step 1 Analyzing pain concept in preterm neonates. Since the concept of pain in preterm neonates was not clearly understood, published articles describing pain in preterm neonates were reviewed and analyzed to clarify it and to identify its indicators. In this study, pain in preterm neonates was defined as an acute unpleasant sensory and emotional experience associated with actual or potential tissue damage caused by medical or nursing procedures that invade the preterm neonate's body integrity, causing skin injury or mucosal injury. The measurement of procedural pain in preterm neonates has to be detected from behavioral indicators, physiological indicators, and factors affecting pain reactivity. At the end of this step, both pain indicators and specific factors affecting pain reactivity were drafted for the structured observation checklist in step 2.

Step 2 Generating a list of pain indicators by clinical observations. Since pain in preterm neonates can be measured by observation only, pain indicators must be generated from real painful situations. On a day shift of the observation day and after routine clustered nursing care was completed, an infant was immediately prepared. Then, a timer started for a washout period, a 10-minute-period which an infant received no handling to ensure that any previous conditions affecting pain reactivity were eliminated (or assumed to be eliminated). The nurse educator and the PI simultaneously, but independently, observed preterm neonates using the draft of the structured observation checklist for baseline (30 second intervals of a 10-minute observation), puncture (30 second interval until needle removal), and recovery phases (30 second intervals of a 10-minute observation). Video recording ran continuously from the end of the washout period to the end of recovery and was played for review in cases of discrepancy between the two observers. The frequency of occurrence of each pain indicator (heart rate, facial expression, and sleep-wake state) during each phase were calculated and used for generating a list of pain indicators.

Step 3 Determining the format for measurement by clinical expert interview. Five clinical experts including a neonatologist, a registered nurse (RN) with a bachelor degree, and three RNs with master degree, were individually interviewed by the PI following the interview guide to determine the format of the pain assessment scale. Interview contents included the applicability of each indicator, clarity of the indicator descriptions, appropriateness of response levels and scoring of each indicator, and other comments and suggestions. After receiving their permission, note-taking and audio-recording were done during the interviews. The face-to-face interviews were conducted during working-time on a working-day in a conference room and lasted approximately 60 minutes. The interview contents were transcribed and content analyzed. Then, the indicators of the scale were revised and scoring of each indicator was identified.

Step 4 Having the initial scale reviewed by content experts. The first version of 7-indicator CPSPN scale was examined for content validity and appropriateness of scoring format. The panel consisted of 6 content experts including two nursing educators, two advanced practice nurses (APN) in pediatric nursing, a neonatologist, and a neurologist. The I-CVI was calculated to indicate content validity of each indicator. The indicator with an I-CVI less than 0.80 was discarded from the scale. An S-CVI of at least 0.90 was regarded as acceptable.[29] For appropriateness of the scale format, the experts' rating of each item as well as additional comments and suggestion were summarized. All indicators except previous pain exposures had a possible score of 0, 1 or 2. The number of previous pain exposures of >20 is rated zero and those of

0-19 are rated one point. The length of NICU stay indicator is rated zero (> 14 days), one point (8-14 days), or two points (0-7 days). This scoring format is used for the 2 age groups included in the study. The total score was calculated by adding all scores obtained from all indicators.

Outcomes of step 1 to 4 were summarized in **Table 1.**

Table 1 The development process of the CPSPN scale

Development process	Sample and instrument	Outcomes
Phase one: construction of the initial scale		
Step 1		
Analyzing pain concept in preterm neonates	Sample: none Instrument: none	3 dimensions (behavioral, physiological, and factors affecting pain reactivity)
Step 2		
Generating a list of pain indicators by clinical observations	Sample: 15 occasions (8 preterm infants) Instrument: structured observation checklist	10 indicators (4 types of facial expression, sleep-wake state, heart rate changes, gestational age, respiratory support, length of NICU stay, previous pain exposures)
Step 3		
Determining the format for measurement by clinical expert interview	Sample: none Instrument: interview guide	7 indicators of 2 age groups (upper facial expression, lower facial expression, sleep-wake state, heart rate changes, respiratory support, length of NICU stay, previous pain exposures)
Step 4		
Having the initial scale reviewed by content experts	Sample: none Instrument: indicator evaluation form	6 indicators of 2 age groups (upper and lower facial expressions, sleep-wake state, an increased heart rate, length of NICU stay, previous pain exposures)
Phase two : psychometric testing		
Implementing the CPSPN scale with target group for validity and reliability testing	Sample: 53 occasions (19 preterm neonates) Instrument: CPSPN scale and PIPP-R scale	4 indicators of infants with GA at birth < 32 and ≥ 32 to 36 weeks and 6 days (upper and lower facial expressions, sleep-wake state, an increased heart rate)

Step 5 Psychometric testing. Data was collected through clinical observations using the 6-indicator CPSPN scale and the PIPP-R scale. On a morning shift and after routine clustered nursing care was completed, the RN and the PI simultaneously, but independently, observed and rated the pain score of a preterm neonate during each occasion of clinically required blood collection. Within the observation of

the painful event, the PIPP-R scale and the CPSPN scale were used concurrently to measure pain during baseline, puncture, and recovery phases. The PIPP-R scale was scored and recorded based on its instruction, while the CPSPN scale was also scored and recorded at 30, 60, and 60 seconds, respectively. The same process was repeated on all 53 occasions.

Reliability analysis. Reliability of the CPSPN scale was examined in 3 steps: (1) internal consistency, (2) item analysis, and (3) inter-rater reliability. Internal consistency was calculated using Cronbach's alpha coefficient and a result of 0.70 or above was considered as acceptable.[30] Item analysis was performed by computing the corrected item-total correlation and inter-item correlation for indicators of the CPSPN scale. The correlation coefficient equal to or higher than 0.30 was regarded as satisfactory.[31] These two analyses used a total of 159 pain score ratings by the PI using the CPSPN scale. For inter-rater reliability, an intra-class correlation coefficient (ICC) was calculated using total pain scores measured by two observers with the CPSPN scale. A value of ICC above 0.80 was considered as excellent reliability.[30]

Construct validity. Construct validity was ascertained using two approaches, hypothesis testing and convergence examination. The hypothesis was formulated postulating that the total pain scores during the puncture phase (painful event) would differ from those during baseline and recovery phases (non- painful event). ANOVA was planned to use for determining the difference of total pain scores across three phases. However, the assumption of normality and homogeneity of variance have not been met for the given samples, thus, the Kruskal-Wallis test was used instead. Convergence evidence was analyzed by determining how closely the CPSPN scale measured the same construct as the PIPP-R scale. It was planned to use Pearson's correlation coefficient but the assumption of normality was not met, therefore Spearman's rank correlation was used instead.

Step 6 Clinical utility evaluation. Thirty NICU RNs were trained to use the CPSPN scale with video case scenarios. Then, each of these nurses used the CPSPN scale to measure pain from 5 occasions of procedures in preterm neonates and completed the CUQ. Quantitative data were analyzed using descriptive statistics. Qualitative data from an open-ended question were content analyzed.

Results

The initial CPSPN scale composed of 6 indicators including 3 behavioral indicators (upper facial expression, lower facial expression, and sleep-wake state), 1 physiological indicator (an increased heart rate), and 2 factors affecting pain reactivity (length of NICU stay and previous pain exposures). Gestational age was considered as a factor influencing behavioral indicators instead of another indicator. Thus, it was divided into two age groups for which two scoring formats were determined (see **Table 2**). Respiratory support indicator was also excluded due to low I-CVI (< 0.80). The S-CVI of the initial scale was 0.92.

Psychometric Properties of the CPSPN scale

Reliability analysis.

Internal consistency and item analysis. Cronbach's alpha coefficient of the 6-indicator CPSPN scale was 0.78. The item analysis of 6 indicators showed that the item-total correlation and the inter-item correlation coefficients of all indicators, except length of NICU stay and previous pain exposures, were greater than 0.30. Therefore, length of NICU stay and previous pain exposures with low correlation values were eliminated from the scale. The final pain scale with 4 indicators (see **Table 2**) had Cronbach's alpha coefficient of 0.94.

Table 2 Final version of the CPSPN scale

Indicators	Findings	Score
Upper facial expression		
GA< 32 weeks	Relaxed	0
	Brow bulge	1
	Brow bulge and eye squeeze	2
GA ≥ 32–36 weeks and 6 days	Relaxed	0
	Brow bulge and eye squeeze once	1
	Brow bulge and eye squeeze > once	2
Lower facial expression		
GA< 32 weeks	Relaxed	0
	Nasolabial furrow	1
	Nasolabial furrow and open mouth slightly	2
GA ≥ 32–36 weeks and 6 days	Relaxed	0
	Nasolabial furrow and open mouth slightly	1
	Nasolabial furrow and open mouth widely	2
Sleep–wake state[#]		
GA< 32 weeks	No change	0
	Waking and no cry	1
	Waking and cry	2
GA ≥ 32–36 weeks and 6 days	No change	0
	Movement and tense body	1
	Cry	2
An increased heart rate (HR)[*]	< 5 beats/min from baseline	0
	≥ 5–9 beats/min from baseline	1
	≥ 10 beats/min from baseline	2

Notes GA = gestational age at birth

[#]State change in relation to the baseline pattern (quiet sleep, active sleep, & waking)

*An increased HR in relation to baseline HR ..... beats/minute (baseline phase = 30 seconds before puncture) and puncture HR ..... beats/minute (puncture phase = 60 seconds after needle insertion)

Inter-rater reliability. Intra-class correlation coefficients of two independent raters on total scores of the 4-indicator CPSPN scale obtained before, during, and after procedures were 0.95, 0.91, and 1.00, respectively.

Construct validity.

Evidence from hypothesis testing. The mean scores of baseline, puncture, and recovery phases were 0.37, 6.57, and 2.49, respectively. *Kruskal-Wallis* testing indicated that the median pain scores among three phases were significantly different (Chi-Square = 95.95, p = 0.000). This finding indicated that at least one pair of median scores was significantly different. The post-hoc analysis using Mann-Whitney tests indicated that the median score of the puncture phase was significantly different from the baseline and recovery phases (p = 0.000).

Evidence from convergence examination. There were positive relationships between the pain scores which were assessed by the CPSPN scale and the PIPP-R scale in the baseline phase (r_s = 0.375, p = 0.006), puncture phase (r_s = 0.789, p = 0.000), and recovery phase (r_s = 0.878, p = 0.000).

For clinical utility evaluation, mean scores on appropriateness, accessibility, practicability, and acceptability dimensions were 3.66, 3.93, 3.66, and 3.83, respectively. The majority of nurses achieved a rating of "very good" for every item apart from two. Those items were related to requirement for training (the practicability dimension) and not being certain about parent / guardian satisfaction (acceptability dimension).

Discussion

The CPSPN scale is a newly developed instrument for measuring acute procedural pain in preterm neonates. It is composed of 4 indicators, 3 behavioral and 1 physiological indicator. The 3 behavioral indicators include upper facial expression, lower facial expression, and sleep-wake state. The separation of facial expression into two indicators differs from several existing scales. Some existing scales (such as NIPS[32]) use the whole face as one indicator leading to ambiguous and subjective determination. While other scales (such as COMFORTneo[16]) included both the whole face and each facial expression resulting in complexity. Inclusion of only two facial expressions makes the new pain scale easier for observation at the bedside.

Regarding the scoring of the 3 behavioral indicators, two scoring formats are proposed for two age groups of neonates, < 32 weeks and³ 32 to 36 weeks and 6 days, due to the fact that more mature infants display more vigorous facial expressions and a more organized sleep-wake state.[33,34] For the sleep-wake state indicator, a 3-scoring level is used instead of the 4- or 5-scoring levels used in the existing scales making the new scale easier to use.

For the heart rate indicator, a clear term of "an increased heart rate" rather than "heart rate change" is used because it is specific and more understandable. The 3-scoring level of an increased heart rate including < 5, ≥ 5-9, and ≥ 10 beats/minute that is set based on observation finding and previous studies is suitable for clinical use and easy to apply.[9,35] During the baseline phase, the heart rate changed within a narrow range, 1.27 to 5.82, with a median variation of 2.60. A heart rate change >5 beats/minute was found on only 1 out of 15 occasions from the observation step of this study and is consistent with previous study.[35] Scoring this indicator requires evaluations comparing behavioral changes and heart rate at 30 seconds of the baseline phase and that at 60 seconds after the puncture phase because preterm neonates usually have a delayed response.[36,37] prospective, open-label, single-arm, observational study. Routine capillary or peripheral blood takes were filmed. The model consisting of a baseline, a preparatory, an interventional and a return-to-baseline phase was filmed. After a pilot evaluation, experienced medical and nursing neonatal intensive care unit (NICU

Two factors affecting pain reactivity, length of NICU stay and previous pain exposures, were unexpectedly excluded from the scale because of unacceptable statistical values. There is a need for reexamination in a further study because previous studies indicated that the cumulative previous number of painful procedures and length of NICU stay were reportedly significant in relating to pain reactivity.[1,20]

The CPSPN scale was tested for psychometric properties including internal consistency, inter-rater reliability, and construct validity. The overall Cronbach's alpha coefficient of the CPSPN scale was greater than 0.90 which is acceptable for a new scale. It indicated internal consistency implying that indictors measure the same thing and the same construct. The values of ICCs on total scores were also higher than 0.90 indicating that the new scale had acceptable inter-rater reliability.[38]

The CPSPN scale had good construct validity supported by two pieces of evidence from hypotheses testing and convergence examination. The results of hypothesis testing demonstrated the score differences between pain and non-pain events as expected. A positive and high degree of correlation across three phases of painful procedures between the new pain scale and the PIPP-R scale signifies convergent evidence of the new scale. This is in line with the idea that convergence of different measures of the same trait should correlate highly with other one.[39]

Clinical utility of the new pain scale was evaluated based on the users' judgment on its appropriateness, accessibility, practicability, and acceptability. The results revealed this and the scale was well accepted and was in fact preferred by NICU nurses, apart from the issue related to training. On the negative question, "a user can use a scale without training", most nurses disagreed with it and indicated that they needed to be trained before using a scale. In this study a 1-hour training session was provided for all nurses for demonstrating scoring. Video examples were used for practicing especially in the skills of facial expression observation, and testing. After training, they had no questions during the actual assessment of pain. It could be concluded that a 1-hour training session is adequate for enhancing nurses' understanding in regard to use of the new scale but maybe extra support after the session could be given to improve confidence.

Limitations and recommendations

First, the scale was developed and tested with acute procedural pain only. It would be inappropriate for use with post-operative pain or chronic pain and needs for testing for other types of procedural pain that can cause prolonged pain such as IV insertion. Second, inclusion of behavioral indicators limits use of the scale in paralyzed infants who cannot perform behavioral responses. Third, two scoring levels of previous pain exposure indicators may limit variation of the scores. Fourth, repeated several pain events that occurred in the same infants may lead to less variation in samples. Finally, fixed scores of length of NICU stay and previous pain exposure indicators across three phases of painful procedures resulted in deletion of these indicators. Therefore, future research is needed to reexamine these two indicators and should estimate sample size using number of infants rather than number of occasions. In addition, only data obtained from puncture phases of procedures should be used for item analysis.

Conclusion and implication for nursing practice.

The 4-indicator CPSPN scale for use in NICU is a multi-dimensional measure consisting of indicators involving upper facial expression, lower facial expression, the sleep-wake state, and an increased in heart rate (see **Table 2**). The scale has two scoring formats for two age groups (< 32 weeks and ≥ 32 to 36 weeks and 6 days). The CPSPN scale is accurate and timely for use by nurses and other health care providers in the clinical setting. Based on this preliminary study, the scale is appropriate for routine assessment in the NICU, especially during a heel stick procedure in early gestational age preterm neonates because it provides behavioral indicators corresponding with different levels of maturity, a small number of indicators, and clear instructions for observation enabling the capture of their delayed pain responses. However, further study is needed with a larger sample size and the same painful procedures for establishing cut-off scores of the two age ranges. Nurses can use this scale to assess pain in preterm neonates and to differentiate between the preterm neonate's pain reactivity to other clinically relevant characteristics or non-pain events. Therefore, they can detect and manage the procedural pain in the vulnerably preterm neonates appropriately.

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การพัฒนาแบบวัดความปวดทางคลินิกสำหรับทารกเกิดก่อนกำหนด

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บทคัดย่อ: การวิจัยนี้มีวัตถุประสงค์เพื่อพัฒนาและตรวจสอบคุณสมบัติการวัดของ แบบวัดความปวดสำหรับทารกเกิดก่อนกำหนด โดยใช้แนวคิดพัฒนาการทางประสาทและชีววิทยาเป็นแนวทางในการสร้างในขั้นตอนแรกตัวบ่งชี้ความปวดเจ็ดรายการถูกกำหนดจากการสังเคราะห์ข้อมูลจากการวิเคราะห์มโนทัศน์ การสังเกตในคลินิก และการสัมภาษณ์ผู้เชี่ยวชาญ จากนั้นนำไปตรวจสอบโดยผู้เชี่ยวชาญด้านเนื้อหา จำนวน 6 คน หลังการตรวจสอบได้ตัดตัวบ่งชี้การดูแลทางเดินหายใจออกคงเหลือตัวบ่งชี้ความปวดหกรายการ กำหนดรูปแบบการให้คะแนนเป็นสองรูปแบบสำหรับสองช่วงอายุ คือ <32 สัปดาห์และ ≥32 สัปดาห์ถึง 36 สัปดาห์และ 6 วัน

การตรวจสอบคุณสมบัติการวัดใช้วิธีการประเมินความปวดของทารกเกิดก่อนกำหนดจำนวน 19 คน ขณะได้รับการเจาะเลือดจำนวน 53 ครั้งในหอผู้ป่วยหนักทารกแรกเกิด 2 แห่งในประเทศไทย โดยผู้สังเกตสองคนใช้แบบวัดความปวดสำหรับทารกเกิดก่อนกำหนดที่มีตัวบ่งชี้ความปวดหกรายการที่สร้างขึ้นและแบบวัด Premature Infant Pain Profile-Revised ผลการวิเคราะห์ตัวบ่งชี้ก่อนการประเมินความเที่ยง พบว่าตัวบ่งชี้ระยะเวลาที่รับการรักษาในหอผู้ป่วยหนักทารกแรกเกิด และตัวบ่งชี้ประสบการณ์การได้รับความปวดถูกคัดออกเพราะมีค่าความสัมพันธ์ระหว่างแต่ละตัวบ่งชี้และค่าความสัมพันธ์ระหว่างตัวบ่งชี้กับคะแนนรวมอยู่ในระดับต่ำ แบบวัดที่มีตัวบ่งชี้ความปวดสี่รายการมีค่าสัมประสิทธิ์แอลฟ่าของครอนบาคเท่ากับ 0.94 และค่าสัมประสิทธิ์ความสัมพันธ์ภายในกลุ่มอยู่ ระหว่าง 0.91 ถึง 1.00 การตรวจสอบความตรงเชิงโครงสร้างโดยการเปรียบเทียบคะแนนความปวดในสามระยะของการทำหัตถการพบว่า ค่ามัธยฐานของคะแนนความปวดในขณะทำหัตถการสูงกว่าระยะก่อนและหลังการทำหัตถการอย่างมีนัยสำคัญทางสถิติ การตรวจสอบความตรงเชิงลู่เข้าพบความสัมพันธ์เชิงบวกระหว่างคะแนนความปวดที่ได้จากแบบวัดใหม่กับ Premature Infant Pain Profile Revised scale การประเมินอรรถประโยชน์ทางคลินิกของแบบวัดใหม่พบว่าได้ผลระดับดี สรุปได้ว่าแบบวัดความปวดสำหรับทารกเกิดก่อนกำหนดนี้มีความตรง ความเที่ยง และเหมาะสมในการนำไปใช้ทางคลินิกเพื่อประเมินความปวดที่เกิดจากการทำหัตถการในทารกเกิดก่อนกำหนดในหอผู้ป่วยหนักทารกแรกเกิด

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คำสำคัญ: อรรถประโยชน์ทางคลินิก หอผู้ป่วยหนักทารกแรกเกิด ทารกเกิดก่อนกำหนด ความปวดที่เกิดจากการทำหัตถการ การตรวจสอบคุณสมบัติการวัด การพัฒนาแบบวัด

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