JOGNN CLINICAL RESEARCH

A Reliable Pain Assessment Tool for Clinical Assessment in the Neonatal Intensive Care Unit

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Objective: The aim of this study was to validate a clinician-friendly pain assessment tool for all groups of critically ill infants cared for in the specific neonatal intensive care units (NICUs) studied.

Design: A prospective study was undertaken to test the Pain Assessment Tool (PAT). Interrater reliability of the PAT score was assessed by two nurses who simultaneously determined an infant's PAT score. The PAT was validated against the CRIES score—crying, requires increased oxygen administration, increased vital signs, expression, sleeplessness—and the mother's assessment of her infant's discomfort using the Visual Analogue Scale (VAS).

Setting: The NICUs at two children's hospitals.

Patients: Participants were 144 preterm and term infants. Infants on a ventilator and those who had undergone surgery were included.

Results: The interrater reliability of the PAT was .85 with a mean difference of 0.17 (standard deviation: 1.73). There was a strong correlation between the PAT and CRIES scores ($r = 0.76$) and a moderate correlation (.38) between the PAT score and the VAS scores of the infant's mother. The correlation coefficient between the PAT score and CRIES score was significant for all groups ($p < .01$).

Conclusions: The PAT score was shown in this study to be a valid, reliable, and clinician-friendly pain assessment measurement tool for all infants nursed in the NICU. *JOGNN, 34,* 80-86; 2005. DOI: 10.1177/0884217504272810

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Pain in the newborn and young infant is a source of stress for the infant, family, and care providers. A major part of this stress arises because of the difficulty in interpreting the signs of pain, particularly in infants of early gestation (Anand & Hickey, 1987). Pain is often poorly managed because of inadequate clinical assessment. As a result, it has been recommended that the assessment of pain be documented every 4 to 6 hours as part of the development of evidenced-based guidelines for the management of neonatal pain (Anand & The International Evidence-Based Group for Neonatal Pain, 2001). Inconsistencies often occur among clinicians in their management of neonatal pain (Johnston, Collinge, Henderson, & Anand, 1997; Kahn et al., 1998). These inconsistencies may result from differences in the assessment of the infant's signs of pain. Therefore, effective management of newborn pain cannot be achieved without simple-to-use, standardized, and routine pain assessment for all patients in the neonatal intensive care unit (NICU) (Franck, Greenberg, & Stevens, 2000). A valid and reliable pain assessment tool is needed.

Existing instruments or tools developed to measure pain in infants can be broadly categorized as those that use behavioral cues only (Evans, Vogelpohl, Bourguignon, & Morcott, 1997; Lawrence et al., 1993) and those that use both behavioral and physiological cues (Hodgkinson, Bear, Thorn, & Van Blaricum, 1994; Krechel & Bildner, 1995; Sparshott, 1996; Stevens, Johnston, Petryshen, & Taddio, 1996). Many of the previously published tools have been described for use as research tools for specific interventions, and their practicability for clinical practice is uncertain. The

measure of both behavioral and physiological reactivity to pain has been recommended, as some preterm infants have shown opposite reactions to each domain (Morison, Grunau, Oberlander, & Whitfield, 2001). The Pain Assessment Tool (PAT) (Hodgkinson et al., 1994) incorporates both behavioral and physiological cues and includes a score based on the attending nurse's judgment of the infant's pain. Thus, individual responses can be captured, as well as assessment by the nurse who has been caring for the infant over time.

The large range of available tools, many of which have not been adequately tested for validity, reliability, and generalizability, leaves many clinicians in doubt as to which tools are most appropriate. Various pain scales have been compared for their usefulness in describing response changes for specific procedures (Blauer & Gerstmann, 1998). However, there have been no reports on the usefulness of pain scales in the routine assessment of infants in the NICU. This lack of an appropriate and useful tool has resulted in inconsistencies in the assessment and management of neonatal pain (Franck, 2002). There has been a widespread increase in the use of opioids in the NICU; to help prevent withdrawal occurring from unnecessary use of opioids, some authors have recommended the use of regular assessments of behavioral and physiological parameters using a pain assessment scale (Suresh & Anand, 2001). However, Grunau, Holsti, Whitfield, and Ling (2000) warn that the practicality of some tools used in research may not be clinically useful.

The aim of this study was to test a pain assessment measurement tool for reliability, validity, ease of use, and applicability for all infants who are cared for in the specific NICUs evaluated. We chose to test the PAT because it had already been in clinical use for a number of years and was familiar to the majority of nurses working in the NICUs at both institutions. It was anticipated that by identifying a tool that was validated and reliable, clinical nurses would consistently use the tool, making assessment and appropriate management of newborn pain a routine part of care in the NICU.

Hypotheses

The researchers proposed the following hypotheses:

1. The PAT score will be reliable between raters.
2. The PAT score will be a valid measure of pain when compared with the CRIES score—crying, requires increased oxygen administration, increased vital signs, expression, sleeplessness—and the mother's rating of infant discomfort.
3. The PAT score will be reliable and valid in infants who have had surgery and those who have not, both term and preterm infants, and in infants who have been on a ventilator and those who have not.

Methods

The researchers designed a prospective study in which the infants were assessed by three nurses at the commencement of their overall assessment of the infant. The infant was not undergoing any particular procedure or intervention at the time of assessment but was receiving the standard practices of intensive care.

> The Pain Assessment Tool is a reliable tool for use by clinical nurses.

Setting

This study was undertaken in the NICUs of two children's hospitals in Australia. The NICUs are similar in function and admit infants referred from other institutions throughout the two most populous states of Australia. Each unit has 20 intensive care beds and admits an average of 550 infants each year. Both term and preterm infants are referred for neonatal surgery, mechanical ventilation, and genetic conditions, as well as diagnostic procedures for medical and cardiac conditions.

Participants

A total of 144 infants made up the study sample. Of these, 65 (45%) were preterm, compared with 79 (55%) term (≥37 weeks of gestation) infants. Forty-eight (33%) received ventilation (17 term, 31 preterm), and 84 (58%) had undergone neonatal surgery (46 term, 38 preterm). Those who underwent surgery or who received ventilation were not excluded. The mean gestational age was 36.1 weeks (standard deviation [*SD*] 4.40), and the mean birth weight was 2,612 g (*SD* 1,010 g). Postnatal age at assessment was a median of 22 days (range 0-182 days), and the median days postsurgery was 8 (range 0-96 days).

Instruments

The PAT, developed by Hodgkinson et al. in 1994, was selected for testing because it measures both behavioral and physiological parameters, as well as the bedside nurse's perception of the infant's pain (Table 1). The tool was developed for use in term infants following neonatal surgery. The tool has 10 parameters that are scored on a scale of 0 to 2, the minimum and maximum scores being 0 and 20. Scores greater than 5 indicate that comfort measures such as tactile soothing, use of pacifier, and repositioning should be instituted, and scores greater than

TABLE 1
Pain Assessment Tool

Parameters	*0*	*1*	*2*
Posture/tone		Extended Digits widespread Shoulders raised off bed	Flexed and/or tense Fists clenched Trunk guarding Limbs drawn to midline Head and shoulders resist posturing
Cry	No		Yes When disturbed Doesn't settle after handling Loud Whimpering Whining
Sleep pattern	Relaxed		Agitated or withdrawn Wakes with startle Easily woken Restless Squirming No clear sleep/wake pattern Eye aversion "shut out"
Expression		Frown Shallow furrows Eyes lightly closed	Grimace Deep furrows Eyes tightly closed Pupils dilated
Color	Pink, well perfused		Pale/dusky/flushed Palmar sweating
Respirations		Tachypnea At rest	Apnea At rest or with handling
Heart rate		Tachycardia At rest	Fluctuating Spontaneous or at rest
Oxygen saturation	Normal		Desaturation with or without handling
Blood pressure	Normal		Hypo-/hypertension at rest
Nurse's perception	No pain perceived by me		I think the baby is in pain

Note. Infants are assessed and scores obtained every 2 to 4 hours. An infant with a score >5 requires comfort measures; >10 requires analgesia dose adjustment.

Reprinted with permission of the *Australian Journal of Advanced Nursing*. Hodgkinson, K., Bear, M., Thorn, J., & Van Blaricum, S. (1994). Measuring pain in neonates: Evaluating an instrument and developing a common language. *AJAN, 12*(1), 17-22.

10 require adjustment of the analgesia dose. The PAT score is used routinely in one NICU in this study to measure the level of pain and discomfort of infants.

The CRIES tool (Krechel & Bildner, 1995) was used to validate the PAT tool. The minimum and maximum scores for the CRIES are 0 and 10, respectively. The CRIES tool was chosen because, like the PAT score, it includes both behavioral and physiological scores. It was developed for use in term postoperative infants. The interrater reliability was greater than .72, and its validity when tested against another pain score, the Objective Pain Scale, was .73 (Spearman correlation). Some find the CRIES tool more difficult to use, as it requires the calculation of a percentage change from the infant's baseline physiological measures and relies on the use of continuous bedside monitoring.

We chose to use a Visual Analogue Scale (VAS) to gauge the mother's perception of her infant's pain and discomfort. The VAS is a fixed, 10-point scale in which the assessor rates the infant's pain on a scale that ranges from "no pain" to "severe pain." The assessor is blinded to the actual score of his or her rating. The VAS is used in assessing the pain of sick, hospitalized children.

Data collectors were recruited from among experienced neonatal nurses with a minimum of 8 years of neonatal nursing experience in either nursery. All were familiar with the use of the PAT in clinical practice.

Twelve clinical nurses collected data throughout the study. Interrater reliability of the PAT score was assessed by two nurses simultaneously determining an infant's PAT score. To measure validity, a third observer assessed the infants' CRIES scores. For consistency, a single experienced observer was used in each hospital for scoring the CRIES, as this tool was unfamiliar to the clinical nurses who served as data collectors. This observer familiarized herself with the CRIES tool before the study began.

> The Pain Assessment Tool is recommended for scoring of pain in all groups in the neonatal intensive care unit.

The mother's perception of her infant's pain or discomfort was collected using the VAS (Miller, 1996). The VAS score was obtained only if the mother was present when data were being collected from her baby. The mother was asked to rate her baby's discomfort using a 10-point VAS at the same time as the study nurses assessed the other pain scores.

Data collection was piloted with a convenience group of 19 infants before data to be entered in the final analysis were collected. This method ensured consistency in the use of the various pain tools. The convenience-group data were not included in the study results.

Procedures

The study was approved by the Institutional Ethics Committees of both institutions.

All infants in the two NICUs were eligible for inclusion unless they were receiving muscle relaxants for ventilation. Infants who met the eligibility criteria (N = 144) were randomly allocated to the study on a given study day (usually 1 day per week) determined by the availability of the clinical research nurses. Each infant was only studied once. Parental consent was obtained for all the eligible study participants on the study day. The participation rate was 93.2% for all the families approached for consent (n=155). The names of all eligible infants on the designated study day were placed on separate cards, shuffled, and put into a large opaque envelope. Alternate cards were then removed by a nurse not involved in the study. The infant named on the card was then included in the study.

Data were collected from a minimum of 60 infants to enable the validity and interrater reliability (Peat, Mellis, Williams, & Xuan, 2001) for each of the specific groups: surgery/no surgery, preterm/term, and on a ventilator/not on a ventilator. The ratios of surgical to nonsurgical and term to preterm infants in the NICU were approximately 1:1. The aim was to collect data from at least 120 infants to detect a difference and avoid a type II error. The final sample included 144 infants to ensure the study reached the target number for analysis.

Data Analysis

Reliability

To measure the interrater reliability of the PAT score, the mean score between the two raters measuring the same infant was recorded. Measurement error and intraclass correlation coefficients were calculated using the two replicate measures on each infant. A Bland and Altman plot (Bland & Altman, 1996) of the mean versus the difference between raters and the correlation coefficient were also calculated to check for any systematic bias in the PAT scale over a range of values.

Validity

To test for validity of the PAT score, the correlation coefficient between the PAT score and the CRIES scores and between the PAT score and the mother's score of discomfort (VAS) were calculated. As two values of the PAT score were obtained, the mean of these two scores was used in tests of validity.

Group-Specific Reliability and Validity

To calculate the reliability of results for each subgroup (surgical/nonsurgical, term/preterm, and on a ventilator/not on a ventilator), Levene's test was used to test for a significant difference in the variance of the difference between groups. The intraclass correlation coefficients and measurement error were also calculated for each group.

Group-specific validity was analyzed by calculating the correlation coefficient between the PAT score and the CRIES scores and the mother's score of discomfort for each group.

Results

Tests for correlation between postnatal age and the PAT score and between the number of days since surgery and the PAT score were not significant. There was no significant difference between those babies who had undergone cardio/thoracic surgery compared with those who had abdominal surgery, nor between those who did and did not receive narcotics. Therefore, the results include all surgical data as a single group.

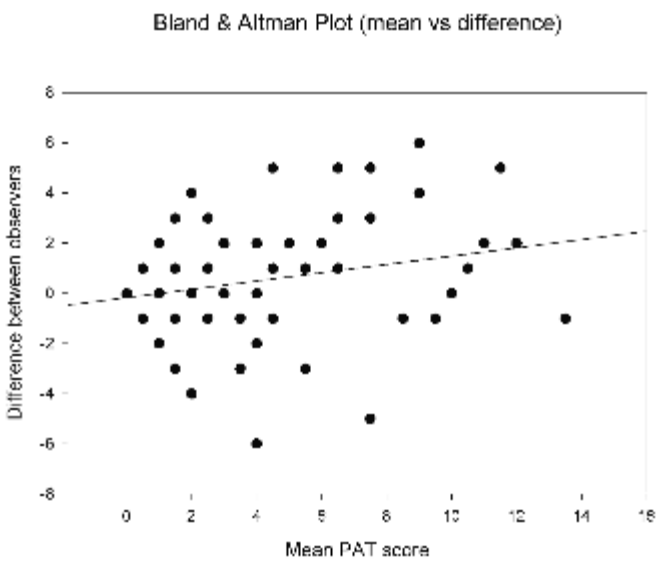

FIGURE 1
Mean versus differences between Pain Assessment Tool (PAT) assessors.

Reliability

Using intraclass correlation, the reliability between pain assessors using the PAT was .85. The mean difference was 0.17 on the scale of 1 to 10 (*SD* 1.73), showing good interrater reliability. As the standard error of measurement (Sw) was 1.22, the repeatability of the PAT score was 3.38 (Bland & Altman, 1996). Therefore, clinically, when one is comparing the score on two occasions, if the difference is greater than or equal to 4 units, one could be more than 95% confident that this was a true difference.

There was a small significant correlation when the mean score was plotted against the mean difference in a Bland and Altman plot (Spearman rho = .17; $p < .05$). This finding indicates that the reliability of the PAT score was slightly decreased at higher PAT score values (Figure 1).

Validity

There was a strong correlation between the PAT and CRIES scores (0.76) when measured by the clinical research nurses. A moderate correlation was found between the PAT score and the VAS scale used by the infant's mother 0.38) (Table 2).

Comparing Repeatability and Validity Between Groups

There was no significant difference when Levene's test was used to test for equal variances between groups, that is, surgical versus nonsurgical, term versus preterm, and on a ventilator versus not on a ventilator. The measurement error (Sw) when calculated for each group was similar: surgical = 1.29 and nonsurgical = 1.09; term = 1.16 and preterm = 1.29; on a ventilator = 1.18 and not on a ventilator = 1.24.

TABLE 2
Correlation With Other Measures of Pain

	PAT (Pearson's r)	*CRIES (Pearson's r)*
CRIES (n = 144)	0.76 $p < .001$	—
VAS/Mother's perception of pain (n = 58)	0.38 $p < .01$	0.47 $p < .001$

Note. CRIES = crying, requires increased oxygen administration, increased vital signs, expression, sleeplessness; PAT = Pain Assessment Tool; VAS = Visual Analogue Scale.

Discussion

The subjectivity of pain assessment gives rise to difficulties in evaluating infants of differing gestations and behaviors in the NICU. The authors believe a single, practical, and easy-to-use tool is required to ensure consistency in the assessment and subsequent management of infants' pain. This study shows the PAT is a reliable and valid tool for use by clinicians. It is easy to use and may be incorporated into the routines of assessment of continuous and procedural pain in newborn infants during clinical care.

Lang Porter, Wolf, Gold, Lotsoff, and Miller (1997) found that clinicians believe the management of infant pain is below optimal. The varied population of infants cared for in the NICU has also made it difficult to provide consistent clinical practice guidelines for the management of pain in sick newborns. An assessment tool that ensures consistency in the assessment of pain in all groups of infants potentially results in more regular assessments and therefore increases the implementation of appropriate comfort measures and pharmacological management of pain. A valid and reliable pain assessment tool such as the PAT may help in eliminating some of the barriers to effective pain management.

Despite the considerable number of instruments or tools developed to measure pain in the newborn, few have been tested for validity and reliability. Franck (2002) reported more than 20 published assessment tools for newborn pain; however, none has emerged as the gold standard. The Premature Infant Pain Profile has been validated in the clinical area for the assessment of procedural pain in preterm and term infants. Good construct validity and excellent inter- and intrarater reliability were established (Ballantyne, Stevens, McAllister, Dionne, &

Jack, 1999; Stevens et al., 1996). The Premature Infant Pain Profile, unlike other scoring systems, takes into account the gestational age and behavioral state of the infant at baseline. However, the use of this tool is limited to interventions and associated acute procedural pain, and it has not been tested for continuous pain or for the assessment of analgesia use.

In regard to the remaining pain assessment tools, only the CRIES and Neonatal Infant Pain Scale appear to have been validated, and both of these have been validated against other pain scores. The Neonatal Infant Pain Scale score was validated against a nurse's assessment (Lawrence et al., 1993), though clinical utility of the tool has not been established. The developers of the CRIES score (Krechel & Bildner, 1995) also demonstrated discriminant validity in that the administration of analgesia decreased the CRIES score. However, we found this tool was not particularly easy to use, as calculations from baseline were required for two of the physiological parameters that required the infant to be observed in a quiet state before assessment using the CRIES tool.

When the Pain Assessment Tool was tested for validity against the CRIES score, all results were significant.

Another concern with this range of pain assessment tools is their lack of generalizability across different populations of infants. We chose to test the PAT in our current population of neonates, which included preterm infants as well as those who had not received ventilation and had not had surgery. Other tools were developed specifically for use in low-birth-weight infants, such as the TPR, as a clinical distress scale for newborns receiving ventilation (Sparshott, 1996) or for acute procedural pain (Premature Infant Pain Profile [Stevens et al., 1996], Neonatal Infant Pain Scale [Lawrence et al., 1993]). In addition, numerous other tools have been developed, but none of these differentiate the responses of neonates on the basis of developmental levels, nor do any of the studies incorporate both surgical and nonsurgical groups. Both the PAT and CRIES systems were designed for use in postoperative term infants.

In this study, the PAT score is shown to be both reliable and valid in various groups of infants; therefore, this tool can be used with confidence in the NICU. The correlation between the number of days since surgery and the PAT score was negative and significant, a finding to be expected as the postoperative pain decreases or is adequately managed with analgesia. The reliability of the PAT score was slightly decreased at higher values, an issue that needs further exploration in the clinical setting. In addition, this study has shown what difference in scores on the PAT scale constitutes a clinically meaningful difference. This finding is particularly useful when nurses are changing shifts and handing over supervision of their allocated infants and for conveying information on the infant's response to analgesia for the management of pain.

Limitations of the Study

The limitations of this study could be related to the testing of validity against another pain score. We cannot be sure that the tools used for validation are themselves truly measuring newborn pain. The investigators acknowledge this limitation and, if further validation is required, would consider using other physiological indicators of newborn pain, such as endocrine stress responses. Another limitation is that the study population did not include extremely low-birth-weight infants, and further exploration of the use of the tool in this group is warranted.

Recommendations for Future Research

As the PAT score has been found to be reliable and valid, future research may be able to identify what aspects of the PAT score represent discomfort other than pain by using the comfort interventions of Als et al. (1994), and behavioral observations may be recorded as part of a developmental care strategy (Cheng & Chapman, 1997; Grunau et al., 2000). The infant's behavioral state and environmental factors at the time of the assessment could also be factors to measure to determine their influence on the infants' pain scores (Grunau et al., 2000; Morison et al., 2001). Regular documentation of the PAT score can also be used to provide evidence of the management and treatment of pain in all groups of neonates (Franck, 2002; Suresh & Anand, 2001). By using a tool that is reliable and validated for use by clinical nurses, the appropriate management of newborn pain can become part of routine care in the NICU.

Implications for Practice

On the basis of the results of this study, the PAT is recommended for use in NICUs providing care for varying subgroups of neonates. Optimal pain assessment and management in newborn care requires a supporting education program, clinical practice guidelines, and a quality improvement process for all clinicians, both nursing and medical, as recommended by Franck et al. (2000). It is hoped that through the consistent use of a reliable and valid pain assessment tool, appropriate and effective pain

management strategies for sick, hospitalized infants can be put into place.

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