Validity and Reliability of New Indian Neonatal Pain Score for Detecting Acute Procedural Pain in Newborn

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Method: The present pain score is a multidimensional instrument prepared to measure the pain response to acute procedural pain. The physical changes of newborn with acute pain along with physiological changes are used as pain indicator. The parameters were selected by discussion with experts as neonatologists, psychometric specialists and by following the previous studies. 157 neonates of more than 28weeks stable neonates admitted in level III NICU was scored during heel lance. The new score has 8 parameters as cry, color change, facial expression, change of posture, breathing pattern, heart rate,SpO2,blood pressure

Results: By factor analysis the factors have commonality more than 0.3. The mean pain score in pain situation is (0.84+1.29)and on heel lance it increases to (6.05+2.18).By Man Whitney U test the pain and no pain situation shows significant difference(p=.00). Cornbachs alpha value was 0.704 showing good internal consistency of the parameters. Interclass correlation coefficient among scoring by two independent raters. Intraobserver reliability was proved by looking at the same video by same observer at two different occasions and calculating the score and comparing the values. Results: By factor analysis all the factors have commonality more than 0.3. The mean pain score in no pain situation is (0.84+1.29)and on heel lance it increases to (6.05+2.18).By Man Whitney U test the pain and no pain situation shows significant difference(p=.00). Cornbachs alpha value was 0.704 showing good internal consistency of the parameters. Interclass correlation coefficient 84%, score cut-off for pain is Conclusion: So the present Indian neonatal pain scoring system has significant concurrent and divergent validity to differentiate between pain and no pain situation. New Indian Neonatal pain score is a valid and reliable score for acute procedural pain in newborn.

Keywords: Pain score, newborn, validity, reliability.

INTRODUCTION

Pain in neonate is defined as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage [1]”. The improvement in neonatal care has prolonged the stay in NICU and exposure to an average of 12-16 painful procedures per day [2]. Research suggests that though there is adequate knowledge of pain, it is taken care of only in 35% of the cases [3]. Inadequately managed pain from repetitive painful events during the critical period of brain development can compromise neuronal and synaptic organization permanently [4] and predispose the newborn to significant immediate neurophysiologic adverse events such as intraventricular hemorrhage and long-term neurobehavioral and cognitive sequelae throughout the developmental spectrum of childhood [5]. Pain can be assessed by single dimensional or multi-dimensional approaches [6]. Though PIPP score is commonly used, there is no gold standard. Present study is planned to prepare a new multidimensional pain scoring system for acute procedural pain in newborn.

METHOD

Present study is a prospective observational study done in Dr Mehtas Hospital, Chennai, 25 bedded level III NICU with average 900 admissions per year, study period was from month of August 2019- Dec2020. Inclusion criteria was Stable neonates having acute procedural pain induced by heel lance in NICU. Exclusion criteria were neonates on anticonvulsants and analgesic drugs (phenobarbitone, fentanyl, and morphine), comatose neonates, and neonates less than 28wks. The indicators taken into consideration were pain indicators. The scoring was done by factor analysis all the factors have commonality more than 0.3. The eigen value of the component factors were significance of the factors varies from 2.5-0.5. The mean pain score in no pain situation is (0.84+1.29)and on heel lance it increases to (6.05+2.18). By Man Whitney U test the pain and no pain situation shows significant difference (p=0.00). Cornbach’s alpha value was 0.704 showing good internal consistency of the parameters. Interclass correlation coefficient 84%, score cut-off for pain is Conclusion: So the present Indian neonatal pain scoring system has significant concurrent and divergent validity to differentiate between pain and no pain situation. New Indian Neonatal pain score is a valid and reliable score for acute procedural pain in newborn.
pain score as physical parameters on acute pain as cry, color change, facial expression, change of posture, breathing-pattern and noninvasive blood pressure, heart rate, SpO2 noted from monitor. The parameters were selected by discussion with experts as neonatologists, psychometric specialists and by following the previous studies [7, 8]. Initially 12 indicators were selected and after discussion with experts and after factor analysis and component extraction 8 factors were chosen. The monitor used as Star50N monitor (Larsen and Tubro) with probe attached to the right hand of the baby. Data collected as video recording of physical and monitor parameters by digital camera. The scoring was done by looking at the video in both the proforma (new score and PIPP score) by the same senior nursing staff. The video was not showing the procedure done as much as possible and concentrating on the neonate’s physical condition and monitor parameters. All the parameters are scored as 0, 1, 2 (table1). Inter-observer reliability was proved by comparing the same pain response video scored by two raters using the new score proforma independently. Intra observer reliability was proved by scoring the same video by same senior nursing staff in two different occasions. Pilot study was done at Mehta Childrens Hospital for 100 samples. Sample size required was calculated at 95% confidence level, taking alpha error as 5% and power 80% as 126. The sample size in present study is 157.

**Statistical Analysis and Result**

Statistical analysis was done by minitab and SPSS version 16 software. In the dataset 84 cases were male and 73 were female, 120 was AGA and 37 was SGA, 106 was preterm (gestation 28-36wks) and 51 cases were term. The mean birth weight of preterm neonates in the present data set is 1.5kg and mean birth weight of term neonates are 2.8kg. Factor analysis of the 8 parameters of new score was done and communalities were calculated as more than 0.30 for all the factors (table2).The degree of variance of component factors by applying orthogonal rotation and loading is cumulative 29.02% and 49.19%. Principal component analysis was done and eigen values of components were plotted in Scree plot (range 3-0.5) (figure1). The mean new score before intervention in no pain situation was 0.84±1.29 and compared to mean heell lance score of 6.05±2.18(p=0.00).

The regression equation was prepared to detect relation of PIPP score and new score, (PIPP = 0.750 + 1.25 new score) which shows good strength of association. Pearsons correlation coefficient found 72.2% positive correlation between the PIPP score and new score. The reliability of the present scoring system is proved by estimating internal consistency by Cornbach’s alpha value (0.704(p=0.00)). The inter-observer reliability was proved by estimating interclass correlation coefficient showing 84% correlation which is a sign of good agreement among raters. The intra-observer reliability was 0.72 which indicates good agreement. Taking PIPP score(cut off 6) as a gold standard ROC curve(figure2) was prepared (area under the curve 64%(CI .55,.77)) new pain score cut-off is 5. The score 0-5 is defined as no pain, 6-10 moderate pain requiring non-pharmacological intervention and more than 10 is taken as severe pain requiring pharmacological intervention. The sensitivity of new score is 73.9%, specificity of 40%, positive predictive value of 80.9% indicates that new pain score is a good screening tool for acute procedural pain.

**Discussion**

Multidimensional pain score include both behavioral (facial expression, crying, gross motor movement, changes in behavioral state and functioning) and physiologic indicators (e.g. heart rate, blood pressure, etc). Even though these two dimensions do not correlate yet when they exist together in a single pain scale it increases its importance [6]. Present study is formulated to produce a multidimensional pain score in Indian scenario has good content validity as it is covering all domains of pain sign. The present score has good discriminant validity as it is able to differentiate pain –no pain situation and has good concurrent validity as it has good sensitivity and specificity to detect pain. The present pain score is validated by looking at factor structure of the scoring system –as a measure of construct validity. The eigen value was calculated and six factors have eigen value more than 1. The PIPP score [8] also have done factor analysis for selection of factors. Indicators considered for retention in scale if they have communality of at least 0.30 and a loading of 0.40 or greater on any factor [8]. In the present scoring system all the factors have communality more than 0.3. The present score is showing positive correlation with PIPP [8] score (Pearsons coefficient 72.2%) which proves convergent validity of the new score. The data of the present scoring system is collected in level III NICU and neonates with 28-36wks 6days needs NICU admission more, so the present data set is showing the predominance of preterm neonates. In the present data set the pain score of preterm and term neonates during heel lance not revealed any significant difference (p=0.37). Despite being unable to express pain [11, 12], the premature infant reacts to painful stimuli with activation of the highest level of sensory function in somatosensory cortex as seen by infrared spectroscopy [4, 9], have lower threshold of pain due to delayed maturation of descending inhibitory fibers [10]. In the present study, pain response of SGA and AGA neonates (p=0.4) and male and female neonates (p=0.2) not showing statistically significant difference. Valeri et al. found higher heart rate rise and maximum heart rate in male neonate than female preterm neonate [15]. Pearsons correlation coefficient was calculated between the new pain score with NPASS score for acute pain [7] was 0.65(p=0.00) showing good convergent validity of the new score. The NPASS score for acute pain has...
Pearsons correlation coefficient of 0.74 with PIPP score [7]. The NIPs score has Pearsons correlation of 0.53-0.84 at different time of observation with Visual analogue scale [13]. The present score tested for reliability by calculating internal consistency by cornbachs alpha value. The cornbachs alpha is 0.69-0.72 in the present score showing good internal consistency (cry 0.65, color0.71, expression0.68, SpO20.63, heart rate 0.63, posture0.71, breathing 0.67, BP0.67). The NIPs score [13] has good internal consistency with cornbachs alpha value of 0.87-0.91. The PIPP score [7] has cornbachs alpha value of 0.76 for eye squeeze, 0.74 for brow bulging, 0.72 for nasolabial furrow, 0.66 for oxygen saturation, 0.64 for heart rate and 0.59 for behavioral state—which is in moderate range. The degree of agreement between two independent raters varies from 83% to 91% which is a sign of perfect agreement and good reliability of the new Indian neonatal pain score. This proves that the present score is a reliable score. The NIPs score has intra-class correlation coefficient value of >0.90 [14]. The inter-class correlation coefficient in NPASS score for acute pain [7] is 0.79-0.88. The new score is a unique tool for estimating acute procedural pain of newborn with good inter-observer reliability, internal consistency and proved validity is the first Indian study to prepare a pain score, should be used in all Indian NICUs to prove its external validity.

What is already known
There is no gold standard pain score for acute procedural pain in the newborn.

What this study adds?
The new Indian Neonatal pain score is a valid and reliable tool for detecting acute procedural pain in newborns.
Table-1: Showing the pain score

PROFORMA FOR INDIAN NEONATAL PAIN SCORE

Name-Date of birth-Sex--Gestational age---Procedure-AGA/SGA/LGA

PAIN ASSESSMENT SCORE

| Score | 0      | 1          | 2          |
|-------|--------|------------|------------|
| CRY-  | No     | Consolable | Incessant  |
| Color | Pink   | Dusky      | Pale       |
| Facial Expression | None | Grimace     | Squeeze of eyes and lips |
| SpO2  | No change | Fall in saturation upto 10% | Fall in saturation>10% |
| Heart Rate | No change | Increase<10% baseline | Increase >10%baseline |
| Change of posture | No change of posture | Flexed or extended | Arching |
| Breathing pattern | No change | Tachypnea | Retractions |
| Blood Pressure | No change | Increase of systolic BP<10mmHg | Increase of systolic BP>10 mmHg |

Maximum Score-16 0-5—no pain, 6-10—moderate pain, >10— severe pain

Table-2: Analysis of factor structure and communality by principal component analysis

| Factors         | Mean  | Std deviation | Communalities |
|-----------------|-------|---------------|---------------|
| Cry             | 0.89  | .568          | .597          |
| color           | 0.09  | .296          | .480          |
| expression      | 1.05  | .260          | .425          |
| spO2            | 1.17  | .452          | .560          |
| Heart rate      | 1.30  | .483          | .625          |
| Posture change  | 0.83  | .414          | .466          |
| Breathing pattern | 0.30 | .512          | .389          |
| Blood pressure  | 1.21  | .520          | .393          |

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