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Validity and Reliability of Acute Pain In Infants

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Abstract: **The newborn care, immense importance for the proper development and healthy life of a baby. Pain is a subjective phenomenon that is difficult to quantify and qualify. The need for pain measure is a clinically important issue for substantiating a therapeutic decision and evaluating the effectiveness of a particular intervention. Medical and social scientists routinely create scales to measure phenomena that are not directly observable but reveal themselves through several closely related variables containing both subjective and objective ones. Sometimes a scale in a different socio-geographic arena already exists and scientists attempt to modify and adapt the scale in a similar situation in another part of the planet. The above process typically needs the newly proposed scale to be validated and reliable confirmed. Validity and Reliability are important concepts in medical practice because it can be used to reduce errors during diagnostic evaluations, during the analysis of responses to questionnaires, and even during surgical procedures. Various statistical methods can be used to test reliability according to the characteristics of the data (categorical or continuous) and the contexts of testing variables. So far scientists have used Pearson correlation or the spearman's rank correlation to validate the medical tools. Canonical Correlation used in this research to validate the newly proposed scales on two different medical areas of Baby Pain measurement by the neonatologists. This research is going to provide that the PIPP (Premature Infant Pain Profile) Proposed tool and NPASS (Neonatal Pain Assessment Scale) Proposed tool are valid and reliable tool for assessing acute pain in infants.**

Keywords: **Infant Pain: PIPP, NPASS; Validity, CCA, Cronbach's Alpha.**

I. INTRODUCTION

All persons with pain deserve prompt recognition and treatment. Pain should be routinely monitored, assessed, reassessed, and documented clearly to facilitate treatment and communication among health care clinicians (Gordon et al., [10]). In patients who are unable to self-report pain, other measures must be used to detect pain and evaluate interventions. The PIPP and NPASS are composite tools developed to assess acute pain in preterm and term neonates. The complex nature of pain in infants suggests that pain is best assessed by more than a single indicator. This is especially true as professionals are becoming increasingly aware of the immediate and long-term effects of pain in preterm and term infants. The PIPP and NPASS have been tested for construct validity by using multiple test data sets including infants of a variety of gestational ages and levels of illness acuity (Stevens *et al*. 1994; Johnston *et al*. 1995; Stevens *et al*. 1996; Stevens *et al*. 1999a) [20]. PIPP, NPASS and their proposed methods observable data collected from Dr. Mehta Hospital Pvt. Ltd., Chennai, India. Neonatal and Premature infant pain study is in collaboration with Dr. Bhaswati Ghoshal, Neonatologist, Dr. Mehta Hospital, Chennai.

II. MOTIVATION OF THE STUDY

It is widely recognized that newborns undergoing intensive care are necessarily subjected to numerous painful procedures. Despite the availability of clinical guidelines the majority of painful procedures on neonatal intensive care units are still carried out without any form of analgesia. If neonatal pain or localized inflammation truly produces these long term changes, then analgesia or anti-inflammatory treatment should prevent or to reduce the expression of the reported cellular and behavioral changes. Preliminary evidence for the beneficial effects of pre-emptive morphine analgesia in preterm infants in a placebo controlled randomized controlled trials suggests a reduced incidence of early neurologic injury in the morphine treated infants. The pattern and magnitude of abnormalities will depend on genetic variability as well as the timing, intensity and duration of adverse environmental experiences. Thus, cumulative brain damage during infancy will finally lead to reductions in brain volume, abnormal behavioral and poor cognitive outcomes during childhood and adolescence. So protocols to combat infant's pain are very justified [1].

The different scoring systems are available to assess pain in newborn like PIPP and NPASS for prolonged and acute pain, CRIES (Crying Requires oxygen Increased vital signs Expression Sleep), NIPS (Neonatal Infant Pain Scale) etc. In the present study a new scoring system for assessment of pain in infants is prepared, which includes gestation, responses of AGA (Appropriate For Gestational Age), SGA (Small For Gestational Age), LGA (Large For Gestational Age) neonates and whether any appreciable difference in response among different groups. We have accounted for the sedation also while calculating the pain score. The present proposed score is compared with a valid score of PIPP and NPASS [20], both for acute and prolonged pain [13].

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It is important to understand that the inability to communicate verbally or nonverbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment. Pain can be acute, established, or chronic. It can further be classified as physiologic, inflammatory, neuropathic, or visceral, with each of these categories further divided according to the degree of severity. Pain in newborns is very commonly overlooked, under recognized, and under-treated. Health care providers must evaluate, recognize, prevent and manage pain in the newborn infant. Nurses play a key role in identifying sources of pain, minimizing exposure to painful procedures, and proactively assessing and treating neonatal pain. If they have make any mistake than it will result in a wrong treatment of the patient. The challenges are numerous, but the opportunity to maximize the comfort and health of the newborn is great [21]. In the statistical way we are facing problem to continue to do convergent validity with spearman- rank correlation. Because according to the categorical data sets using spearman rank correlation is give us less information. So, for more information and more details of variables we used canonical correlation instead of spearman rank correlation.

III. THE INFANT PAIN PROFILE

Pain and sedation assessment are an important aspect of medical care of the hospitalized patient of all ages. Inadequate pain assessment contributes to sub-optimal pain management leading to morbidity and mortality. A clinically useable, reliable, and valid pain and sedation tool is needed to improve patient care and clinical outcomes. The currently available PIPP and NPASS were created for procedural pain.

The PIPP and NPASS are behavioral measure of pain for premature infants. If the patient is continually asking for the physician to increase their pain medication or increase the frequency then they need further evaluation by both a nurse and a physician. There is a good possibility the patient is in pain. There is also a possibility that they are becoming addicted to prescribed medication. The patient's history must be taken into account as well. Medical conditions such as cancer and rheumatoid arthritis are chronic condition and can be very painful. In long-term care facilities three non-drug interventions need to be attempted before administering anti-anxiety or anti-psychotic medications. These interventions can be giving the patient food, drinks, one on one care, back rub, changing the patient's position in bed, adjusting the temperature, and redirecting the patient's mental focus. Many times these interventions work, but many times the medication may still need to be administered [1]. The patient's history and diagnosis are helpful in deciding whether or not the patient is developing a substance abuse problem. A patient having social or relationship problems may need to meet with a crisis counselor.

A. PIPP Existing and Proposed data set:

Pain and sedation assessment are an important aspect of medical care of the hospitalized patient of all ages. Inadequate pain assessment contributes to sub-optimal pain management leading to morbidity and mortality. A clinically useable, reliable, and valid pain and sedation tool is needed to improve patient care and clinical outcomes. The currently available Premature Infant Pain Profile was created for procedural pain. The Premature Infant Pain Profile is a behavioral measure of pain for premature infants [15].

PIPP existing variables are Behavioral state, Heart rate maximum, Oxygen saturation minimum, Brow bulge, Eye squeeze, Nasolabial furrow. The scoring range is 0 to 3. The PIPP pain assessment criterion shown is at Table II. And a proposed method criterion shown is at Table III.

B. NPASS Existing and Proposed data set:

The N-PASS is a valid and reliable clinical pain/agitation and sedation tool for neonates. Nurses find the N-PASS easy to use clinically, facilitating documentation and management of pain and sedation [16]. Neonatal Pain, Agitation and Sedation Scale was developed in response to the need for a clinically useable, consistent, age appropriate assessment and documentation methodology for ongoing infant pain.

In NPASS Existing tool we are continuing with variables Crying irritability, Behaviour state, Facial Expression, Extremities Tone, Vital Signs (HR, RR, BP, SaO2). All five variables carrying the scoring instruction of -2 to +2, where -2 and -1 follows sedation, 0 follows sedation/pain, 1 and 2 follows pain/agitation.

The Proposed method scoring structure is 0 to +2. In this newly proposed method we can find out the variables and scaling differences. Variable are used Cry, Expression, SpO2, Heart rate, Posture, Blood Pressure.

In this data set we are carrying 353 observations for further analysis. The NPASS pain assessment criteria shown at Table IV. And proposed methods criterion is shown at Table III.

IV. STATISTICAL METHODS & INTERPRETATIONS

The collected data were analyzed by Minitab version 14, SPSS 20 and SAS software using Microsoft EXCEL. The mean, standard deviation and coefficient of variation, standard error of mean of the collected data will be calculated. The level of significance will be calculated by 95% confidence interval. The relationship among different variables will be calculated by linear regression analysis.

In this experiment used Canonical correlation instead of Spearman rank correlation for checking convergent validity [20] [21]. According to canonical correlation structure, more details about each variable observed [19]. The Canonical correlation analysis (CCA) is a way of measuring the linear relationship between two multidimensional variables. It finds the two bases in which the correlation matrix between the variables is diagonal and the correlations on the diagonal are maximized [6].

After clustering the path parameter is interpreted as the maximal possible probability of a current cluster containing a vertex, and it monotonically increases as evolution process proceeds. Normality Significance tests used in cluster analysis assumes variables are univariate, bivariate and multivariate normally distributed. Cluster analytic solutions may also be improved when normality holds in the data. Hence, we wish to carry out such an analysis on the averages of such variables, so that the central limit theorem can be taken advantage of. So we form several clusters from the original data using the variables from the existing scale. Then use the cluster averages of the variables for our analysis [12].

Table I: Convergent Validity using Canonical Correlation based of existing method and proposed method of PIPP & NPASS.

Tools	Correlation Coefficient (Existing Method Vs Proposed Method)	
	Canonical Correlation	
	R	R^2
PIPP	0.994	0.989
NPASS	0.997	0.996

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Regression analysis used to fitting a model and explore the relationships among the variables. Is there a significant relationship between PIPP and NPASS with Proposed methods? Linear models were used to the differences between the interventions in PIPP values and the other continuous variables (Proposed method).

The regression equation is

Total (PIPP) = 0.750 + 1.25 Total (Proposed method)

R-Sq = 52.2% , r = rank correlation coefficient.

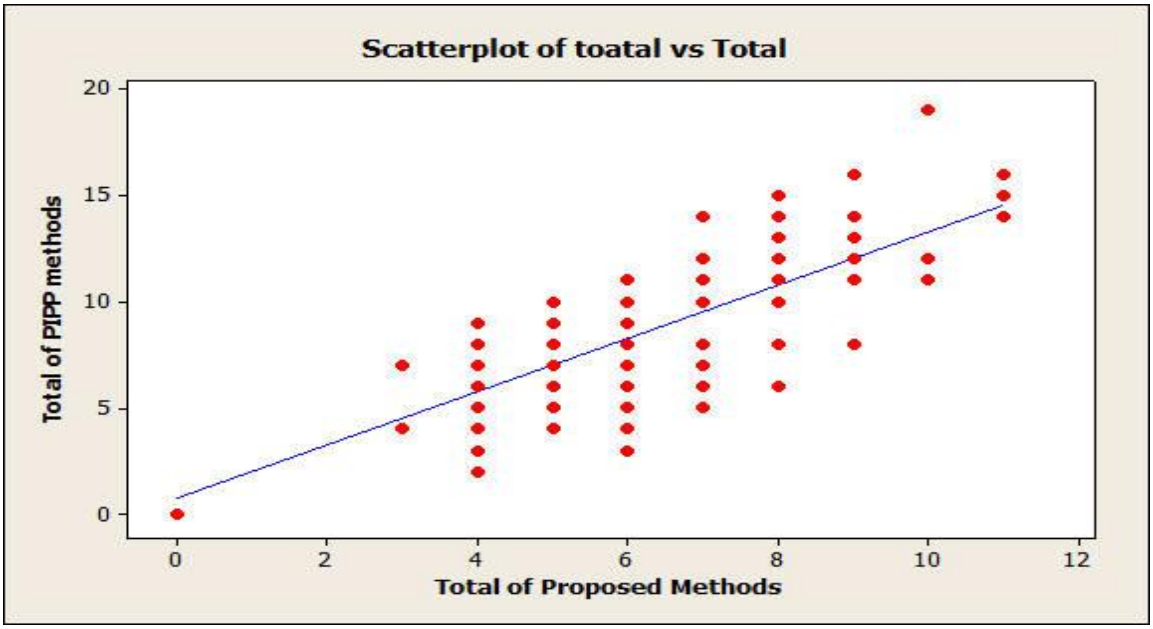

Figure A: Graphical representation of regression plot based on the total score of PIPP and total score of proposed method

The regression equation is

Total1(NPASS) = 1.85 + 0.835 Total2 (NPASS Proposed Method)

R-Sq = 67.2%

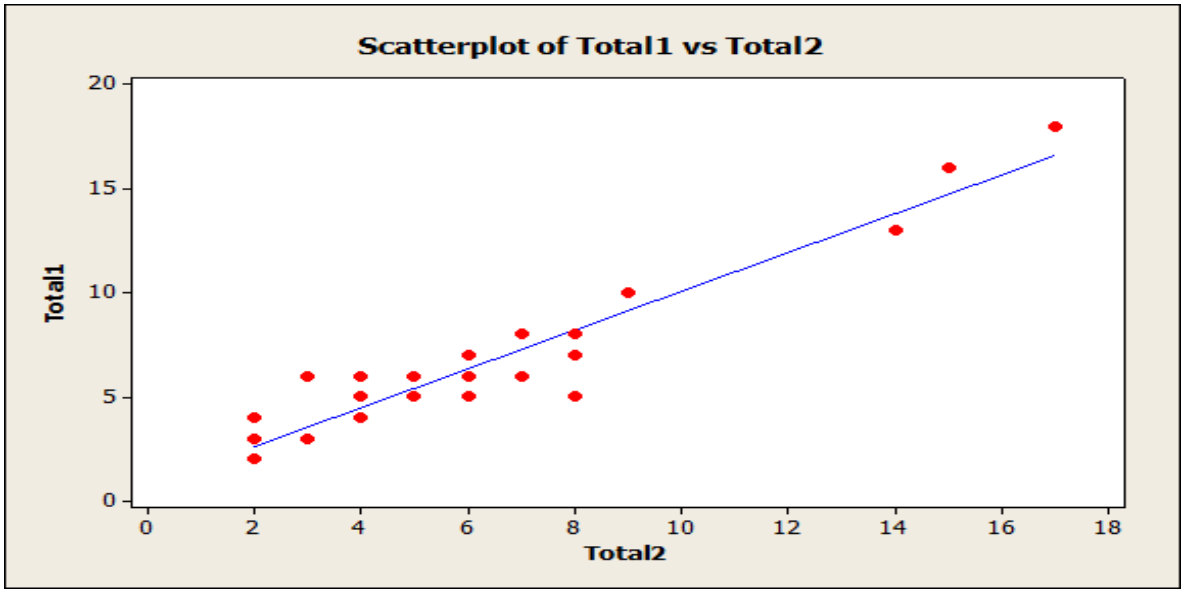

Figure B: Graphical representation of regression plot based on the total score of NPASS (Total1) and total score of proposed method (Total2)

To check, is there any significant difference of pain responses between PIPP and NPASS total score and proposed method total score based on this three criteria's [11] [20].

a. Female babies Total Score, Male babies Total Score

b. AGA babies Total score, SGA babies Total score

c. Preterm babies Total Score, Term babies Total Score

a. Female babies Total Score, Male babies Total Score:

To check, is there is any difference of pain responses between male babies and female babies based on PIPP and NPASS with their proposed methods total score. The non parametric Mann-Whitney Test used to check difference of pain responses on male and female babies [9].

In the case of PIPP Proposed method *P* value is 0.935 and case of PIPP existing method is 0.201. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in male and female babies. But compare to existing method, proposed method showing better result. In case of NPASS Proposed method *P* value is 0.800 and case of NPASS existing method is 0.330. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in male and female babies. But here also compare to existing method, proposed method showing better result.

b. AGA babies' Total score, SGA babies Total score:

Here to check the is there is any difference of pain between AGA babies(weight lies between 2.5 kg to 4kg) and SGA babies(weight less than 2.5 kg) based on PIPP and NPASS with proposed methods total score. To do this again applied the non parametric test, Mann-Whitney Test to check difference of pain on AGA and SGA babies.

In the case of PIPP Proposed method *P* value is 0.535 and case of PIPP existing method is 0.404. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in AGA and SGA babies. But compare to existing method, proposed method showing better result. In case of NPASS Proposed method *P* value is 0.945 and case of NPASS existing method is 0.735. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in AGA and SGA babies. But here also compare to existing method, proposed method showing better result.

c. Preterm babies Total Score, Term babies Total Score:

To find out the effect of pain response between preterm and term babies based on the score of PIPP and NPASS proposed methods tool. A non parametric test i.e. Mann-Whitney Test between total score of preterm babies (age less than 20 weeks) and term babies (age greater than 20 weeks).

In the case of PIPP Proposed method *P* value is 0.379 and case of PIPP existing method is 0.373. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in AGA and SGA babies. But compare to existing method, proposed method showing better result. In case of NPASS Proposed method *P* value is 0.17 and case of NPASS existing method is 0.52. In both the cases *P* value is greater than 0.05. Hence there is no difference of pain in AGA and SGA babies. But here also compare to existing method, proposed method showing better result.

To measure of reliability of tools the most commonly used Cronbach's alpha [3]. Cronbach's alpha is used to estimate the proportion of variance that is systematic or consistent in a set of test scores. To check the internal consistency of the variables we have used Cronbach's alpha [14].

The alpha value of PIPP proposed method studies is 0.663 and for NPASS proposed method is 0.704.

In the case of Item total statistics the value of alpha does not differ too much. Basically, all items are consistences with each other's i.e. there are internal consistency among the variables.

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A. TABLES:

Table II: PIPP Score for Assessment of Pain

Indicator	Finding	Points
Behavioral state	active/awake eyes open facial movements	0
	quiet/awake eyes open no facial movements	1
	active/sleep eyes closed facial movements	2
	quiet/sleep eyes closed no facial movements	3
Heart rate maximum	0-4 beats per minute increase	0
	5-14 beats per minute increase	1
	15-24 beats per minute increase	2
	>= 25 beats per minute increase	3
Oxygen saturation minimum	0 to 2.4% decrease	0
	2.5 to 4.9% decrease	1
	5.0 to 7.4% decrease	2
	7.5% decrease or more	3
Brow bulge	none (<= 9% of time)	0
	minimum (10-39% of time)	1
	moderate (40-69% of time)	2
	maximum (>= 70% of time)	3
Eye squeeze	none (<= 9% of time)	0
	minimum (10-39% of time)	1
	moderate (40-69% of time)	2
	maximum (>= 70% of time)	3
Nasolabial Furrow	none (<= 9% of time)	0
	minimum (10-39% of time)	1
	moderate (40-69% of time)	2
	maximum (>= 70% of time)	3

Table III: PIPP & NPASS Proposed Score for Assessment of Pain

Score	0	1	2
CRY-	No	Consolable	Incessant
Color	Pink	Dusky	Pale
Expression	None	Grimace	Grunt
SpO2	No change	Fall in saturation up to 10%	Fall in saturation>10%
Heart Rate	No change	Increase<20% baseline	Increase > 20%baseline
Change of posture	No change of posture	Flexed or extended	Arching
reathing pattern	No change	Tachypnea	Retractions
Blood Pressure	No change	Increase of systolic BP<10mmHg	Increase of systolic BP>10 mmHg
Serum cortisol			

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Table IV: NPASS Score for Assessment of Pain

Assessment Criterion	Sedation		Normal	Pain / Agitation	
	-2	-1	0	1	2
Crying Irritability	No cry with painful stimuli	Moans or cries Briefly with painful stimuli	Little crying Not irritable	Irritable or crying at intervals Consolable	High pitched or silent continuous cry. Inconsolable
Behaviors state	No arousal to any stimuli. No spontaneous movement	Arouses minimally to stimuli. Little spontaneous movement.	Appropriate for GA	Restless sleep. Awakens frequently.	Constantly awake or arouses minimally.
Facial Expression	Mouth is lax No expression	Minimal expression with stimuli	Relaxed	Any pain expression intermittent	Any pain expression continual
Extremities	No grasp	Weak grasp	Relaxed	Intermittent	Continual
Tone	Reflex. Flaccid tone	Reflex. Decreased tone	Hand and feet. Normal tone.	Clenched toes/fists or finger splay. Body is not tense.	Clenched toes/fists or finger splay. Body is tense.
Vital signs HR, RR, BP. SaO2 change with stimulation	No variability with stimuli. Hypoventilation or apnea.	<10% variability with stimuli from baseline	Within baseline in normal for GA	Increase 10-20% from baseline, SaO2 decrease to 76-85% with stimulation, quick rise	Increase > 20% from baseline, SaO2 decrease to < 75% with stimulation, slow rise

V. CONCLUSION

Pain is a subjective phenomenon that is difficult to quantify and qualify. The need for a pain measure is a clinically important issue for substantiating a therapeutic decision and evaluating the effectiveness of a particular intervention. Many acute-procedural pain assessment tools have been validated; But we must have to notice that is there the tool is easy to use or not, it's reduces the pain procedure or not. The PIPP and NPASS Proposed method can used for the assessment of ongoing pain in infants; therefore it is appropriate to validate the scale for use in acute-procedural pain, contributing to the clinical ease of using one tool for both ongoing and acute pain. The impact of prior painful stimuli or stressful events on the reactivity of infants to acute pain has been researched. The other research with healthy preterm and full-term newborns showed an increased reactivity to subsequent painful procedures. The addition of points to the premature infant's pain score is based on the research-supported premise that premature infants are less able to exhibit signs of pain than the term infant. Correlation between gestational age and PIPP and NPASS Proposed method pain score supports these findings, significant correlation. Mean scores for each gestational age group are similar without prematurity points added, with no significant differences in mean pain scores between gestational age groups. This statistics support the current proposed method for further used.

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