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An Open Access, Online International Journal Available at http://www.cibtech.org/jls.htm
2017 Vol. 7 (2) April-June, pp. 5-11/Acikgoz et al.
Research Article

A TURKISH ADAPTATION OF THE NEONATAL PAIN/AGITATION, SEDATION SCALE (N-PASS) AND ITS VALIDITY AND RELIABILITY

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ABSTRACT
This report aims to validate and reliability of a Turkish-adapted N-PASS (Neonatal Pain/Agitation and Sedation Scale) for acute pain. The scale was developed in by Hummel *et al.*, (2008). This study used an application survey approach. After the Ethical Committee approval, the study performed, between January and December 2010, at the Neonatology Intensive Care Unit of the Eskisehir Osmangazi University Research, Education and Care Hospital, in Eskisehir, Turkey. 76 N-PASS were performed at 38 newborns. 38 actual and 38 pretended injections (plasebo), thus, simultaneously video recordation were also implemented. Recorded videos are later on examined by researchers, for each baby, individually and plotted independently, by close blind metod. According to the N-PASS points; given by 4 independent research nurses and a neonatology nurse, were furthermore statistically analyzed. The SPSS-20 program is mainly used. Cronbach's alpha metod is used for the internal validation and structural confidence analysis, as well as language adaptation and validations. The evaluation of accuracy and the analyzing of inter-rater reliability and a correlation analysis between groups; the researcher nurses and the Unit nurse are also performed. Cronbach's alpha coefficient for internal consistency were; before the procedure 0.77, and after the process 0.91. The N-PASS scale is statistically indicates by this research, that it will be a reliable for neonatal pain measurements.

Keywords: *Pain, Pain Measurement, Newborn*

INTRODUCTION
Newborns also perceive pain and even they can distinguish; acute, sub-acute and chronic pain, as well at the intrauterine period (Anand *et al.*, 2006; Ball *et al.*, 2010; Derebent & Yigit, 2006; Gardner *et al.*, 2011; Ozyalcin, 2002; Ovali, 2008). Physiological, metabolic and psychological effects have been reported as a cause of pain (American Academy of Pediatrics Committee on Fetus and Newborn *et al.*, 2006; Anand and International Evidence-Based Group For Neonatal Pain, 2001; Derebent & Yigit, 2006; Gardner *et al.*, 2011; Korkmaz, 2005).

Neonatal reactions to the pain are not easily encountered, because the pain expression is obscure, as same causes and intensity as adults (American Academy of Pediatrics Committee on Fetus and Newborn *et al.*, 2006; Anand & International Evidence-Based Group for Neonatal Pain, 2001; Korkmaz, 2005; Ovali, 2008). Carbajal *et al.*, (2008) indicated that infants in neonatal intensive care units undergo an average of 115 treatments in their first 14 days, and 75.0% of these are painful treatments. Infants in neonatal intensive care units are exposed to numerous painful procedures; such as drawing blood, intubation, aspiration of intubation cannula, and chest physiotherapy and ventilation applications (Anand & International Evidence-Based Group for Neonatal Pain, 2001; Anand *et al.*, 2006; Ball *et al.*, 2010; Sivasli & Tekinalp, 2005).

In order to measure the pain, there are no reliable and easily performed physiological and biochemical tests (American Academy of Pediatrics Committee on Fetus and Newborn *et al.*, 2006; Korkmaz, 2005;

Toruner & Buyukgonenc, 2012). The behavioral attitudes are mainly used for pain assessment. Several measurement scales are indicated, however for neonatal period the verdicts must adapted to newborn infants (American Academy of Pediatrics Committee on Fetus and Newborn *et al.*, 2006; Anand & International Evidence-Based Group for Neonatal Pain, 2001; Ball *et al.*, 2010; Derebent & Yigit, 2006; Korkmaz, 2005; Ovali, 2008). Hummel *et al.*, (2008, 2010), represented at 2003, the N-PASS scale, and revised in 2009. N-PASS; Neonatal Pain, Agitation and Sedation Scale, is mainly instructed to use in full-term, as well as preterm infants. It is distinguished acute and chronic pain even the newborn infants are on ventilator support.

Hummel's acute pain Scale, N-PASS (Neonatal Pain/Agitation and Sedation Scale), is applied to the newborn infants; at the full-term and preterm newborns, with acute and chronic pain induced conditions, like ventilator support, in the Neonatology Intensive Care Unit of Eskisehir Osmangazi University. This study is for validation and realization of the N-PASS at Turkey.

MATERIALS AND METHODS

This study is for determination of the validity and reliability of the Neonatal Pain/Agitation, Sedation Scale (N-PASS), in Eskişehir, Turkey. This was an experimental study.

N-PASS was performed, between the January 2010 and December 2010, at 38 newborn infants, in the Neonatology Intensive Care Unit of Eskişehir Osmangazi University, Teaching, Training and Research Hospital.

In surveying the sample size; because of the N-PASS have 5 subgroups, in considering with 3 different Likert Scale, the summation will be 15 (5x3). For appropriation; multiply with 5, than the sample size must be at least 75 (15x5). To certify the equality between the two groups, the sample size determination is 76. Hepatitis B vaccination performed; 76 applications to 38 infants. All infants have no paralysis or neuromuscular blockade and even not administered any pain relievers or sedative drugs.

This study was approved by the Institutional Review Board of the Eskisehir Osmangazi University (IRB approval number: 2012/74). We have received permission from the owner to use the scale. The aim and the method of the study were explained to the children and their parents and they were informed that if they did not want to continue, they can leave the study without stating a reason.

N-PASS consists of two sections; a) sedation degree, and b) pain attitudes of infants. The scale has five sub-parameters; crying and irritability, behavioral state, facial expression, body tension and vital signs. 0 to positive 2 points are given for pain and 0 to negative 2 points are assigned for the evaluation of sedation, as a behavioral and a physiological criterion. If the infant was born before 30 weeks of gestation, +1 is added to the total score for the evaluation of pain. The total pain score ranges from 0 to +11, and the total sedation score ranges from 0 to +10. A high score indicates that the pain is severe. The aim is to maintain the score at or below 3. In case of over 3 points, sedation requirements; medication or oral sugar solutions, is needed to induce the desired sedation level. If there is no sign of sedation in the infant, 0 points are assigned. Slight sedation usually results in scores between -2 and -5 points, and deep sedation usually results in scores between -5 and -10 points (Hummel *et al.*, 2008; Hummel *et al.*, 2010). The average time spent implementing the scale is 1 minute.

Before testing the validity and reliability permission was obtained. First Turkish language translation and comprehension is performed. The original English scale was independently translated into Turkish by neonatologists. Two physicians have been graduated at the English educated Collage. Later on the Turkish version re translated into English by the two other colleagues, they are; one as the owner of a school that teaches a specialized English course, the other as a teacher at the school. The both translations, from Turkish back to English was compared with the original English version and statements that did not agree with the original were revised and corrected. 10 University Nurse Highschool academic nurse staffs, and 2 pediatricians at the same University Hospital academic member confirm the pilot evaluation of the N-PASS. The purpose of assessment is whether the translated N-PASS measurements were understandable or not. As a result of the evaluation and in accordance with the recommendations of the experts, inappropriate statements were corrected.

The study performed after taken the informed consent from the families, Random sampling method is used for establishing Hepatitis B vaccination or placebo interaction. After the first application, 30 minutes later, the second one is performed. Blind control process is used, applicator have no idea which is which. All immunizations performed by one NICU nurse. Placebo applications is; confirm the vastus lateralis muscle area, using the same technique as vaccination, and gently; clean the area, wipe the injection field with a 2x2 special alcohol embedded sponge, and dry the place with sponge. Make fold the skin and make vaccination, but did not include the injection at placebo.

Video recording started before the test procedures, first for basal condition recorded and later on after the two procedures, per each. Video recordings were independently evaluated; the researcher and NICU nurse, all known to use N-PASS. Neither of these individuals participates in the administration of vaccinations and plasebo applications. The videos were scored by using the N-PASS.

Validity assessment phase established while the coherence and homogeneity among the elements of the N-PASS.

Data analysis was performed using IBM SPSS for Windows version 20.0. Kolmogorov-Smirnov tests were used to test the normality of data distribution. Continuous variables were expressed as mean± standard deviation, median (25.percentiles-75.percentiles), and categorical variables were expressed as counts (percentages). Comparisons of continuous variables between the groups were performed using the Mann Whitney U Test. As for the validity study, the language and content validity and the construct validity (Cronbach's alpha analysis of the internal consistency and reliability) were examined, while the inter-observer reliability (intra-class correlation analysis) was examined in the reliability study. A two-sided *p* value <0.05 was considered statistically significant.

RESULTS AND DISCUSSION

Results

76 application of N-PASS at 38 newborns; 38 actual Hepatitis B vaccination and 38 pretended injections (plasebo) were performed to the same newborn infants, between January and December 2010, at the Neonatology Intensive Care Unit of the Eskisehir Osmangazi University Research, Education and Care Hospital, in Eskisehir, Turkey. The 38 newborn infants were; 15 female (39.5%) and 23 male (60.5%), gestational ages are distributed a range of 23.3 to 40.4 weeks of gestation, mean 34.00 gestational week. The mean postnatal age was 21 days; ranged 1 day to 88 days.

N-PASS values are; before the test procedures mean 0.00 (with 0.00-1.00 range), and after the Hepatitis vaccination the median score was 8.00 (range 6.00-9.00). N-PASS values is also same before the placebo application, mean 0.00 (range 0.00-0.25), and after the application the median score was 2.00 (range 1.00-3.00) (Table 1). While there was no statistically significant difference between the scores of the two groups before the treatment (p = .768), the scores of the groups during the vaccination or application were significantly different (p < .001).

Table 1: Comparison of Median Values of N-PASS Score and among Groups before and during the Placebo and Hepatitis B Vaccination of Neonates

	Prior to Vaccination Administration	**During the Vaccination Administration**
	The Median (25%– 75%)	**The Median (25%–75%)**
Hepatitis B Vaccine Administration Group	0 (0-1)	8 (6-9)
Placebo Application Group	0 (0-0.25)	2 (1-3)
Z	-0.295	-6.660
P	0.768	p<0.001

Mann-Whitney U test

Table 2: N-PASS Scale Content Validity Rates (CVR) and Content Validity Indexes (CVI)

Scale Dimensions	Scale Materials	CVR	CVI
Crying / Irritability	Crying / Irritability -2	0.83	1.00
CVR=0.87	Crying / Irritability -1	1.00	
	Crying / Irritability 0	0.83	
	Crying / Irritability 1	0.83	
	Crying / Irritability 2	0.83	
Behavior / State	Behavior / State -2	0.83	0.98
CVR =0.80	Behavior / State -1	0.83	
	Behavior / State 0	0.83	
	Behavior / State 1	0.83	
	Behavior / State 2	0.67	
Facial Expression	Facial Expression -2	0.67	1.00
CVR =0.63	Facial Expression -1	0.67	
	Facial Expression 0	0.83	
	Facial Expression 1	0.50	
	Facial Expression 2	0.50	
Extremities / Tone	Extremities / Tone -2	1.00	1.00
CVR =0.87	Extremities / Tone -1	0.83	
	Extremities / Tone 0	0.83	
	Extremities / Tone 1	0.83	
	Extremities / Tone 2	0.83	
Vital Signs	Vital Signs -2	0.67	1.00
CVR =0.60	Vital Signs -1	0.67	
	Vital Signs 0	0.83	
	Vital Signs 1	0.50	
	Vital Signs 2	0.33	

Table 3: N-PASS Scoring System İnternal Consistency and Analysis of Substance Reliability

Sub-Groups of the Scale	Cronbach's Alpha Coefficients for Internal Consistency	Article Total Score Correlation Coefficients
Before the Invasive Procedure		
Crying / Irritability		0.710
Behavior / State		0.849
Facial Expression	0.772	0.672
Extremities / Tone		0.720
Vital Signs		0.713
During the Invasive Procedure		
Crying / Irritability		0.884
Behavior / State		0.904
Facial Expression	0.917	0.889
Extremities / Tone		0.895
Vital Signs		0.916

Table 4: Intra-Class Correlation Analysis of N-PASS Scoring System

	Intra-Class Correlation Analysis			
	ICC	**F**	**Alpha**	**p**
Pre-Intervention	0.987	153.351	0.993	p<0.001
Administration sequence	0.990	209.043	0.995	p<0.001

Table 5: N-PASS Scale, Inter-Observer Compliance Status

	r*	**p**
Crying / Irritability	0.931	p<0.001
Behavior / State	0.909	p<0.001
Facial Expression	0.950	p<0.001
Extremities / Tone	0.940	p<0.001
Vital Signs	0.988	p<0.001
Total Score	0.991	p<0.001

*r=Pearson correlations

In the content validity phase for the N-PASS and to evaluate whether the translated measurement items were clear or not, 10 academic specialists in the Department of Nursing for Child Health and Diseases and 2 academic specialists in child health and diseases were asked to evaluate the materials in the N-PASS. Expert faculty members evaluated each item on a scale based on the following scores: 1-Not Applicable, 2-More need for correction, 3- Less need for correction, and 4-Very appropriate. In the evaluation of the 12 expert opinions, a content validity index (CVI) was used. Based on the results of the evaluation and in accordance with the recommendations of the experts, the inappropriate materials were corrected by the researcher. We determined the content validity rates (CVRs) and the content validity indexes (CVIs) for each statement in the scale applied after the modification (Table 2).

The content validity rates (CVRs) for all items were determined separately to be above 0.00. In accordance with the results obtained from the CVRs for the scale materials, a CVI=0.99 was determined.

In the construct validity (internal consistency) phase, Cronbach's alpha coefficients for internal consistency and the materials' total score correlation were calculated to examine the consistency and homogeneity among the items of the N-PASS when applied to invasive procedures. Cronbach's alpha coefficient for internal consistency obtained for the N-PASS scoring system was determined to be 0.77 prior to the invasive treatments and 0.91 during the treatment (Table 3).

During the inter-observer reliability assessment phase, the relationship between the NPASS total scores recorded from the reactions during the pretreatment and operation sequences was determined by means of the intra-class correlation coefficient (ICC).

The reactions were assessed independently from the video recordings by two individuals, one of whom is a researcher and the other is a nurse working in the neonatal unit, neither of whom participates in vaccinations. As shown in Table 4, the ICC values were determined to be 0.98 for the invasive preintervention and 0.99 for the administration sequence.

The agreement between the total scores obtained by the researcher and the nurse using the pain assessment was examined to determine the reliability of the N-PASS among the evaluators (Table 5).

Sub-groups of the N-PASS scale scores from the two observers was statistically significant when evaluated in terms of compliance was determined that a strong level of alignment (Table 5).

Discussion

The median value of N-PASS for the pain score before the both applications were 0.00, the value increases at the placebo to 2.00, while the value is 8.00 in the real Hepatitis B vaccine group. Statistically, not any differences between the two groups before the procedure ($p = .768$), the pain score N-PASS is during the treatment were significantly different ($p < .001$) versus ($p = 0.314$) (Table 1). The pain scores reported by Hummel *et al.,* (2010) using the N-PASS for the sham and real blood taking process are similar to our study results.

In our study, the content validity ratio was calculated separately for all items (Table 2). No items were removed from the scale given that this ratio was positive (greater than 0.00) (Cam and Baysan-Arabaci 2010, Yurdugul, 2005). Given that we measured a CVI of 0.99, the N-PASS sufficiently expresses the necessary characteristics for measuring pain (Grant and Davis, 1997; Yurdugul, 2005). As a result of the expert opinions, the Turkish version of the N-PASS can be said to be an appropriate measurement tool in terms of language and content validity.

Cronbach's alpha for the scale was calculated at 0.83 for acute pain. As shown in Table 3, the Cronbach's alpha coefficient for internal consistency obtained using the N-PASS scoring system was found to be 0.77 prior to the invasive treatment and 0.91 during the treatment. Cronbach's alpha coefficient for internal consistency examines whether the questions in tests and scales are consistent with each other. The higher the alpha coefficient of a scale, the more consistent the questions in the test are with each other. Generally, to be appropriate, the alpha value for internal consistency needs to be greater than 0.70 (Ozdamar, 2011). According to this information, it can be said that the internal consistency between the N-PASS elements is high during the invasive procedure.

In this study, the items' total score correlation coefficient values prior to the invasive procedure (Table 3) were the following: crying, irritability: 0.71; behavior status: 0.84; facial expressions: 0.67; hands and feet body tension (tone): 0.72; and vital signs: 0.71.

The total item score correlation coefficient values during the invasive procedure were the following: crying, irritability (irritability): 0.88; behavior status: 0.90; facial expressions: 088; hands and feet body tension (tone): 0.89; and vital signs: 0.91.

During the inter-observer reliability assessment phase, the relationship between the total N-PASS scores measured for the pretreatment and operation sequence reactions was determined by calculating the intra-class correlation coefficient (ICC).

Video recordings were independently monitored and evaluated by two individuals, one of whom is a researcher and the other is a nurse working in the neonatal unit, neither of whom participate in vaccinations (Table 4). The intra-class correlation coefficient was found to be 0.86. The ICC value was 0.98 prior to the invasive procedure and 0.99 during the invasive procedure. These results are similar to the results obtained from the study by Hummel *et al.,* (2010).

There was a statistically significant level of agreement between the sub-groups of the N-PASS scale scores from the two observers (Table 5). The average scores the two observers assigned to all sub-groups also showed a statistically significant level of agreement.

Conclusion

The validity and reliability study of the N-PASS chart was found positive for use in acute pain in infants in Eskisehir, Turkey. The N-PASS can evaluate the acute and chronic pain conditions in full-term and preterm neonatal infants, and can also be used with infants who receive mechanical ventilation support. In this respect, N-PASS has eliminated the need to use different pain scales in infants with different characteristics. For this reason, we recommend using the N-PASS in all neonatal units.

ACKNOWLEDGEMENT

Professor Doctor Ayse OCAKCI, Professor Doctor Guler CIMETE, Professor Doctor Arif AKSİT, Professor Doctor Zumrut BASBAKKAL, Professor Doctor Sema KUGUOGLU, Associate Professor Ener Çagri DINLEYICI, Associate Professor Bilal YILDIZ, Associate Professor Yurdagül ERDEM, Assistant Professor Duygu GOZEN, Assistant Professor Ozlem ORSAL, Assistant Professor Rana YIGIT, Assistant Professor Deniz SAYINER, Research Assistant Esma AKCAN, Doctor Sadi IDEM.
English Teachers: Omer Faruk Yasar, Muhammed Ozgur Yasar.

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