Reliability and Validity of the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale in Assessment of Acute Pain in Healthy Newborn Infants

Cynthia Anderson Elverson, PhD, RN, NNP-BC
College of Nursing, South Dakota State University, Brookings, SD
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INTRODUCTION

The FLACC Behavioral Scale was originally developed and evaluated for post-operative pain assessment in children (Merkel, Voepel-Lewis, & Malviya, 2002), but has limited validation in acute procedural pain with infants younger than 2 months. Reliability and validity were studied with immunization in infants 2-6 months (Taddio et al., 2011) and 12-18 months (Gomez et al., 2013).

The purpose of the study was to evaluate the FLACC Behavioral Scale with newborn infants experiencing a heel lance for newborn metabolic screening.

FLACC SCALE

Categories	Score		
	0	1	2
Face	No particular expression or smile	Occasional grimace, frown, withdrawn, or disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, or tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, or tense	Arched, rigid, or jerking
Cry	No cry	Moans, whimpers, or occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

Each of the five categories is scored from 0-2, which results in a total score between zero and ten.

METHODS

Design
- Sub-study within a clinical trial related to pain management during heel lance

Sample
- Healthy newborn infants

Setting
- Procedure room in hospital

Measures
- Four trained observers scored FLACC Behavioral Scale and Neonatal Facial Coding Scale (NFCS) once before, every 60 seconds during the heel lance, and every 60 seconds during the first three minutes after the heel lance.
- Audiotapes were scored for crying during the heel lance by the investigator who was masked to FLACC and NFCS scores.

INTER-RATER RELIABILITY

Time	Face	Legs	Activity	Cry	Consolability	Total
	Percent Agreement Kappa	Percent Agreement Kappa	Percent Agreement Kappa	Percent Agreement Kappa	Percent Agreement Kappa	ICC (95% CI)
Before (*n*=10)	100% 1.00	90% .70	80% .50	100% 1.00	90% .75	.98 (.95,.99)
During						
60 s (*n*=10)	80% .67	90% .73	90% .73	70% .50	60% .33	.94 (.77,.98)
120 s (*n*=9)	55.5% .30	55.5% 0	66.6% .18	88.8% .82	66.6% .50	.94 (.77,.98)
180 s (*n*=7)	71.4% .57	71.4% .30	71.4% .30	71.4% .57	71.4% .56	.86 (.29,.97)
After						
60 s (*n*=9)	100% 1.00	88.8% .70	100% 1.00	77.7% .43	88.8% .75	.99 (.96,.99)
120 s (*n*=9)	100% 1.00	88.8% .74	88.8% .74	100% 1.00	100% 1.00	.99 (.97,.99)
180 s (*n*=9)	100% 1.00	100% 1.00	88.8% .70	100% 1.00	88.8% .70	.99 (.97,.99)

FLACC AND NFCS SCORES

Time	Face	Legs	Activity	Cry	Consolability	Cronbach's alpha	FLACC Total (0-10)	NFCS Total (0-4)	Kendall's tau (two-tailed significance)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)		*M* (*SD*)	*M* (*SD*)	
Before (*n*=47)	.19 (.57)	.19 (.53)	.19 (.49)	.19 (.57)	.19 (.49)	.96	.95 (2.51)	.59 (1.27)	.89 (*p*<.001)
During									
60 s (*n*=47)	.74 (.84)	.38 (.64)	.48 (.68)	.68 (.78)	.59 (.74)	.92	2.89 (3.28)	2.70 (1.70)	.62 (*p*<.001)
120 s (*n*=42)	.88 (.86)	.47 (.74)	.54 (.77)	.73 (.76)	.66 (.81)	.94	3.30 (3.61)	2.54 (1.81)	.74 (*p*<.001)
180 s (*n*=31)	1.06 (.85)	.67 (.83)	.64 (.79)	1.00 (.85)	.83 (.89)	.95	4.22 (3.93)	2.51 (1.87)	.73 (*p*<.001)
After									
60 s (*n*=47)	.46 (.68)	.25 (.56)	.27 (.53)	.38 (.60)	.31 (.55)	.94	1.70 (2.71)	1.59 (1.75)	.74 (*p*<.001)
120 s (*n*=47)	.38 (.67)	.21 (.54)	.19 (.49)	.29 (.54)	.21 (.50)	.95	1.29 (2.57)	1.02 (1.58)	.71 (*p*<.001)
180 s (*n*=47)	.29 (.62)	.21 (.58)	.23 (.59)	.19 (.57)	.17 (.52)	.98	1.06 (2.77)	.78 (1.36)	.59 (*p*<.001)

RESULTS

- Inter-Rater Reliability: adequate for most categories and excellent for total score
- Internal Consistency: Cronbach's alpha above 0.8 at all time periods
- Construct (Convergent) Validity: FLACC scores were related to NFCS scores (Kendall's tau, .59-.89, p<.001, two-tailed)
- Construct (Convergent) Validity: mean FLACC score was related to mean percent time crying during the heel lance (Kendall's tau, .81, p<.001, two-tailed)
- Construct (Discriminative) Validity: FLACC scores were highest during the heel lance and lower before and after the heel lance

DISCUSSION

- Preliminary evidence of reliability and validity of FLACC Behavioral Scale for acute procedural pain in healthy newborn infants

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South Dakota State University
College of Nursing