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Case Series

Evaluating reliability and validity of the infant distress scale for distress assessment during and after intramuscular injection

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ABSTRACT

The infant distress scale (IDS) was developed to assess the unpleasant feeling (distress) triggered by intramuscular injection where the child experiences pain. Numerous pain scale exists to measure pain during painful procedure, but only a few scales measuring the distress, So the investigator intended to evaluate the reliability and validity of the IDS in assessing distress both during and after intramuscular injection. The methodological research design was used to test and evaluate the research instrument. The study was conducted at an immunization clinic. Twenty infants aged between 1 to 6 months who received intramuscular vaccination were included in this study. Two observers measured the distress using separate Infant Distress Scale by observing the video recordings. In total around 120 observations were made. Face validity and content validity were established for the tool. Internal consistency of the scale was calculated using Cronbach's alpha, with values ranging from 0.731-0.821 and the content validity index is 0.89. The study concluded that the IDS is statistically valid and reliable.

Keywords: Distress, Pain scale, Reliability, Validity, Infant

INTRODUCTION

Intramuscular (IM) injections are a widely used technique for delivering vaccines, hormonal agents, antibiotics, and high-viscosity medications directly into the muscles. This route of administration improves drug absorption and bioavailability compared to oral and certain other parenteral methods.[1] Currently, vaccines are most commonly administered via intramuscular injection. Vaccination is considered one of the greatest achievements in medical science, preventing an estimated 2–3 million deaths worldwide each year.[2] Despite their benefits, vaccinations represent one of the earliest and most frequent painful procedures experienced by children, with "getting a needle" often reported as one of the most feared and painful medical experiences.[3] According to 2023 data, approximately 134 million babies are born globally each year, with around 25 million births in India and approximately 1.1 million in Karnataka alone.[4] Among these, about 13.4 million births worldwide are premature, based on 2020 estimates.[5] Furthermore, nearly 19.8 million infants are born with low birth weight annually.[6] Although routine vaccinations-typically three to four injections are a universal and essential medical experience, they are often painful, and children commonly exhibit behavioral distress in response to them.[7-9] Despite the clear benefits of immunization, the pain associated with vaccination remains a major source of anxiety and distress for many children.[10,11] Physiological responses to vaccination-related anxiety can manifest in several ways. These include an increased metabolic rate and body temperature, elevated cardiac output and contractility leading to high blood pressure and heart rate, sodium retention, bronchodilation, and an accelerated respiratory rate.[12] Anxiety also stimulates the adrenal (suprarenal) glands and activates the sympathetic nervous system, which further contributes to elevated blood pressure,

breathing, and heart rate.[13,14] Infant may feel distress due to pain or other stressful experiences. Pain is now more clearly recognized in babies through regular use of standard pain assessment tools. However, identifying distress in infants also needs attention to signs beyond just pain. This can be challenging because such infants may not yet have developed the normal behaviours. Although numerous scales exist to measure pain during painful procedures, few are specifically designed to assess the distress caused by pain. Therefore, the investigators aimed to develop the Infant Distress Scale and evaluate its reliability and validity in assessing distress during intramuscular injections.

CASE SERIES

The methodological study design was adopted. The study was conducted in an immunization clinic at AJ Institute of Medical Sciences, Mangaluru, Karnataka. Data were collected from January 12th 2025 to March 24th 2025. A total of 20 infants who received intramuscular injections were included. Eligibility criteria required that male and female infants aged 1 to 6 months undergoing their first needle prick, be medically stable, and have parents willing to provide consent, Infants were excluded from the study if they had received subcutaneous, intravenous, or intradermal injections, were uncooperative, had used topical anesthetics at the injection site, or had been administered sedatives, analgesics, or opiates within the preceding 24 hours. IDS was developed by Shanthi et al items were generated using inductive and deductive approach. By reviewing the relevant literature and of the phenomenon to be investigated and ensured content adequacy in the final scales. The content adequacy assessment was done by using experts they categorized or sort items based on their similarity to construct definitions.

The instrument includes seven parameters, categorized into physiological and behavioral indicators, Physiological indicators: Heart rate, oxygenation, and respiration. Behavioral indicators: Changes in state, cry, body movements, and facial expressions. Each physiological indicator is rated from 0 to 2, except for oxygenation, which has only two possible descriptors (0 or 1). Each behavioral indicator is rated from 0 to 2, except for changes in state, which also has only two possible descriptors (0 or 1). The total score ranges from 0 to 12. And the scale is interpreted as 0 to 1: Some distress,1 to 4: Mild distress,5 to 8: Moderate distress: More than 8: Severe distress. The validity refers to the degree to which an instrument measures what it is intended measure more of tents applied in test of knowledge measurement content validity was obtained from five experts like Pediatrician, Neonatologist, Pediatric Nurse, Pediatric Intensivist, and Pediatric Nurse Educator. Permission for tool validation was obtained by acceptance letter. Experts are requested to give their suggestions regarding each item in the tool in terms of strongly agree (SA), agree (A), disagree (DA) and strongly disagree (SD) validation suggestion were incorporated in the tool. They were requested to give their remarks for each item. The item in the tool were modified according to the recommendation and suggestions of the experts an acceptable agreement index was calculated prior to administration of the items and the content validity index is 0.89.

Written consent was obtained from the parent/care givers. Parents/care givers of infants were interviewed to collect baseline data. A calibrated pulse oximeter was used to measure oxygen saturation and heart rate. To assess the behavioural responses to distress, a video recorder was used. The observer scored the responses during, immediately 1 minute and 5 minutes after the needle prick by reviewing the video. Observer 1 was a nursing faculty member, while Observer 2 was a senior nurse working in an immunization clinic. Both observers conducted their assessments independently, without communicating with each other or being aware of the scores assigned by the other. Each observer completed 20 assessments, resulting in a total of 120 observations.

The research data were analysed using the statistical package for the social sciences (SPSS). Descriptive statistics on frequency, percentages, mean and standard deviation were used in assessing the study data. The content validity ratio and content validity index were calculated to determine the content validity. Correlations of total item scores and Cronbach's alpha coefficients were calculated to determine the reliability of the scale. Kappa analysis was conducted to assess the consistency between the observers and an inter- scale correlation.

In the present study 55% were female and 45% were male. Regarding gestational age at birth, 20% of the infants were born preterm while 80% were born full-term. The average birth weight was 2.70±0.46 kg. The average current weight of these neonates was 3.30±0.27 kg. In the study population, 80% of the births were normal deliveries, while 20% were caesarean sections. Additionally, 75% of the infants' parents lived in urban areas and 25% lived in rural areas.

Examining the reliability of the tool

Internal consistency: Cronbach's alpha coefficient was calculated to assess the internal consistency of the scale. Based on the observer assessments, the cronbach's alpha value was found to range from 0.731-0.821 for the observer one and 0.775 – 0.862 for the observer two.

Intraclass correlation coefficient of infant distress scale

The intraclass correlation for the scale was found to be in the range 0.91-0.94 during the intramuscular injection, 0.81-0.88 immediately one minute after injection and 0.82-0.84 five minutes after the injection ($p<0.001$) (Table 5). The kappa test determined the good concordance between the observer.

Table 1: Sample characteristics.

S. no.	Demo variables	N	%
1	**Gender**		
	Female	11	55
	Male	9	45
2	**Gestational age during birth**		
	Preterm	4	20
	Term	16	80
3	**Mode of delivery**		
	Normal	16	80
	Caesarean section	4	20
4	**Place of living**		
	Urban	15	75
	Rural	5	25
5	Annual income		
	<10,000	0	0
	10,001–50,000	2	10
	50,001-1,00,000	4	20
	>1,00,001	14	70
6	Mean birth weight of an infant (in kg)	2.70±0.46	
7	Mean current weight of an infant I (in kg)	3.30±0.27	

Table 2: Mean, standard deviation and Cronbach's alpha coefficient for the reliability of the IDS.

Observers	Time	Number of items	Mean±SD	Cronbach's alpha coefficient
Observer 1	During injection	7	9.15±1.38	0.731
	One minute after injection	7	2.35±0.89	0.892
	Five minutes after injection	7	1.25±0.33	0.821
Observer 2	During injection	7	9.10±1.26	0.775
	One minute after injection	7	2.01±0.92	0.823
	5 minutes after injection	7	1.10±0.42	0.862

Table 3: Intraclass correlation coefficient of infant distress scale.

Intra class correlation coefficient 'r'	Observer 01			Observer 02		
	During injection	**One minute after injection**	**Five minutes after injection**	**During injection**	**One minute after injection**	**Five minutes after injection**
	0.91	0.88	0.82	0.94	0.81	0.84

DISCUSSION

The present study found the internal consistency of the IDS ranged between 0.831-0.921 for observer 1 and 0.875–0.962 for the observer 2. and the content validity index is 0.89. A similar study conducted by Elliott C.H., which developed the observational scale on behavioural distress Revised (OSBD-R) to measure reported Cronbach's alpha values of 0.68 (before) and 0.72 (after).[16]

Another study by Tucker et al on the reliability and validity of the brief behavioural distress scale (BBDS) in children (aged between 2 to 10 years) during invasive medical procedures found that total distress scores were highly correlated with six of seven concurrent validity measures from multiple sources (i.e., OSBD, parent ratings, two nurse ratings, child self-report, and a physiological arousal measure, heart rate) (range r =0.57-0.76, p <0.001-0.0001).

A robust association was found between the BBDS distress scores and OSBD total distress scores (r=0.72, p<0.0001).[17] The study concluded that IDS is statistically reliable and valid for measuring infant distress.

This study has a few limitations. Since the raters observed and scored the infants' distress in real time, they

were not able to use another distress scale at the same time for comparison.

CONCLUSION

Neonates express pain during the first needle prick, and with subsequent pricks, they exhibit increasing discomfort in response to the pain experience. Several scales have been developed to assess neonatal pain; however, only a few specifically evaluate the distress experienced by infants. The infant distress scale was designed to address this gap by measuring the level of distress during painful procedures. The scale has demonstrated good reliability, indicating its potential usefulness in accurately assessing infant distress associated with pain.

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