Analysis of the infant's acute pain assessment using developed conductance skin electric instrument compared to the behavioural and faces pain scale in painful injected vaccine

Correspondence: Yeni Rustina, Department of Pediatric Nursing, Faculty of Nursing, Universitas Indonesia, Jalan Prof. Dr. Bahder Djohan, UI Campus, West Java, 16424, Indonesia.
Tel.: +62.21.78849120; Fax: +62.21.7864124.
E-mail: y_rustina@ui.ac.id

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Arie Kusumaningrum,[1] Yeni Rustina,[2] Tomy Abuzairi,[3] Nurhadi Ibrahim,[4] Nurdina Widanti,[3] Gita Rindang Lestari[3]

[1]Faculty of Nursing, Universitas Indonesia, West Java, Indonesia; [2]Department of Pediatric Nursing, Faculty of Nursing, Universitas Indonesia, West java, Indonesia; [3]Faculty of Engineering, Universitas Indonesia, West Java, Indonesia; [4]Faculty of Medicine, Universitas Indonesia, West Java, Indonesia

Abstract

This study compared the scale of infant pain during vaccinated injection using conductance skin electric (Skin Conductance), the Wong-Baker Faces Scale (WBFS) instrument, and Face Leg Activity Cry and Consolability (FLACC) instruments. It was observational cohort study with pre-experimental design using vaccinated injection as pain stimuli. This study investigated 121 infants (59 boys, 62 girls), age/PNA 4.37 ± 2.97 months, and current body weight 6522 ± 1378.65 grams). Most infants had adequate birth weight 71 (89.9%) about 2985.74 ± 405.83 kg and mature infants as 67 (84.4%), about 38,52 ± 2,09 weeks. Pain measurement of all three instruments was do simultaneously using a developed Skin Conductance (SC) apparatus and video recording (to assess behaviour and face). WBFS, FLACC and SC have the same significance in measuring infants' pain scale during vaccination injection. Statistical analysis showed a significant difference in the three pain measurement instruments between before and during injection with a p value of <0.001. So that SC can be recommended for pain measurement.

Introduction

The pain assessment procedure is the first step to assessing the infant's pain scale where nurses play a very huge substantial role in pain management. One of the obstacles in pain assessment procedures is that it involves subjective experience that depends on several idiosyncratic factors such as observer cognitive bias, gender, past pain experience, knowledge, culture, and patient background.[1]

Currently, instruments attempt to change the subjective pain scale to be objective with the infant' pain assessed using machine-based tools to improve consistency and effectiveness.[2] Several studies have been conducted to assess verbal and nonverbal pain in infants faced by the health sector.[2] This led to developing a unidimensional (describe measures of pain intensity of one-dimensional). and multidimensional pain measurement tool (measures of multiple dimensions of pain) that is revised and updated regularly.

Several measuring instruments for infant pain use a single

modality indicator, namely facial expressions such as the WBFS However, it has been reported that some infants have limited ability to express pain due to clinical disorder or physical activity problems such as in infants with neurological immaturity problems and the presence of serious diseases (such as Moebius syndrome, paralysis, and weakness).[3] Therefore, it is important to consider behavioral and physiological pain indicators to complete the assessment process, since infant's pain indicators include behavioral, physiological and contextual.[4] Behavioral indicators such as facial expressions, crying sounds and changes in body movements. Face Leg Activity Cry and Consolability (FLACC) is a pain measurement instrument using behavioral indicators as parameters. The WBFC and FLACC instruments are commonly used in hospital clinical settings, including in Indonesia.

Meanwhile, one of the physiological indicators is skin conductance activity. This SC instrument does not exist in hospital clinical settings in Indonesia yet. Currently, the Skin Conductance is being studied a lot due to its potential as a basis for noninvasive methods for measuring pain in infants.[5] Furthermore, over the last few years, research publications have shown increasing SC use to measure infant pain.[6] Many recent studies have found SC as an objective, simple, noninvasive, fast-response, and accurate tool to detect the neonate's autonomy reflex function.[7,8] Almost all previous studies used the Med-Storm Innovation SC Apparatus to measure SC activity in order to measure infant pain. Schubach used the Varioprot B SC apparatus, Zimmerman used the Q Sensor SC, and Petterson used the Sensormedic SC apparatus.[7,9-14] In this study, the PaIncare-UI SC apparatus was used. The first reason is because this tool hasn't been comparing with other measuring instruments yet. Other, this tool is a simple, non-invasive, portable, easy to use and rapid method of detecting objective pain based on skin conductance or galvanic skin response. This result will indicate the possibility of PainCare-UI's recommendation for the future as a pain intrument. The name of Paincare UI is an abbreviation of Pain Instrument Care by the Universitas Indonesia. This tool has been used by several researchers to detect pain in adult and infant patients.[15,16]

The studies that analyze pain measurement using the FLACC, WBFS and PaIncare-UI was unknown. Therefore, this study aims to compare the scale of infant pain during immunization injection using the FLACC, Wong-Baker Faces Scale and skin conductance by PaIncare-UI instrument.

Materials and Methods

Population

It was an observational cohort study, and an experiment design. The intervention is the injection procedure of administering the vaccine which is a routine procedure for infants. The measurement was carried out by comparing the pain score before and during injection. Data samples were obtained from Imogiri I, Dlingo I, and Dlingo II Public Health Centers in the Yogyakarta Province area, from July to August 2020. Infants were recruited by midwives at the public health center, with written informed consent from their parents/guardians according to the ethical committee protocol at FIK UI (the Ethics Committee of Faculty of Nursing, Universitas Indonesia Registry Number SK-273/UN2.F12.D1.2.1/ETIK.FIK. 2019), followed by taking demographic data and explaining the procedures utilized. Demographic data and clinical information were collected from interviews with mothers, such as sex, postnatal age, birth weight, gestational age at birth, maternal age and MCH book (maternal and child health book also known as the pink book).

The study populations were all infants below 20 months that received immunization injections in a thigh area, and willing to participate in research as inclusion criteria. A total of 121 babies met the inclusion criteria. However, the exclusion criteria were i) infants that received analgesics during the last 10 hours, ii) although the video was unable to show their face expression and motor activity, iii) skin conductance data were unreadable, with iv) incomplete profile data.

Procedure

All recruited infants underwent a painful procedure such as vaccine injection as a routine procedure of infants in public center area. Of all types of vaccine injections, intramuscular injection in the thigh area was selected by the researcher, as a form of homogeneity. The standard protocol for vaccine injection involved such as laying the infant to bed in the supine position, removing the shirt and socks, applying a skin conductance patch, while another staff: preparing the vaccine in a syringe, squeezing the baby's right thigh, then administering the vaccine to the infant. The standard protocol of vaccine injection included cleaning the site with an alcoholic solution, in the area of the infant's thigh, applying the vaccine solution and then removing the syringe. In this study there were no other interventional approaches to distraction of pain (orally administered sweeteners and breast feed), because this approach had not been implemented as a standard procedure in this setting.

The skin conductance was measured using low-frequency electrical conductance, which reflects the ionic conduction in the stratum corneum and largely determined by sweat duct filling. PaInCare-UI is the skin conductance tool developed and used in this study. Furthermore, the skin conductance analysis parameter in this study was the peak score (voltage). The SC measurement method assessed the electrical current generated on the two skin sites with electric potential. The 2-electrode system used in this research were measuring electrode (M) and a countercurrent electrode (C), which ensured a constant applied voltage across the stratum corneum, placed in the plantar of the right foot. SC was measured by placing 2 electrodes in the palm of the infant's foot that connect to SC apparatus. SC peak was shown on the mobile phone monitor installed by GSR application. Bluetooth would connect SC apparatus with android.

The PainCare-UI was developed by steps, designing circuit technical specifications, simulating with software, circuit assembly and troubleshooting, and human testing. In this case the author already has a certificate of good clinical practice. The Instrument was designed by compiling hardware and software designs for skin conductance measurement units. The design of the circuit technical specifications was intended to obtain a sensor circuit and output signal. Circuit simulation with software related to signalling and data transfer. This tool used Proteus software. Data transfer on this prototype used Bluetooth iTead HC-05 to make it easier for users to monitor remotely. Digital data was recorded on a spreadsheet along with the time period for which it was recorded. The measurement display was in the form of a spreadsheet table containing two variables: recording time and voltage. The led indicator would display a graph of y voltage and x running time in real time. The pain category in infants would show a red led for severe pain, yellow if moderate pain and green if no pain/mild pain. Troubleshooting was done on Adruino IDE Web Editor hardware and Mit App Inventor software. Tool testing starts from the function of the tool in the laboratory, Bluetooth connection and Android software. After that proceed with testing on humans.

The infants' behavior was observed in 2 phases, with the first carried out in 20 seconds, while the second was carried out in the next 20 seconds during the immunization injection process. Infant activity was continuously recorded in all phases using videotaped.

Recording using the Xiaomi Yi Discovery Kit action Camera 4K touchscreen with a maximum video frame rate of 4K@20fps is about 1-meter from the infant and using a standing tripod. However, blankets were not used to evaluate their leg movement and activity according to the FLACC scale parameter.

Pain assessment instruments included the WBFS and FLACC scale. Each instrument was equipped with a sheet of paper in a format filled in by the nurse in the form of a score for each assessment parameter. Two nurses independently and blindly assessed the results of the videotape recordings obtained with the differences in assessment between the two raters, discussed. All raters were pediatric nurses with a minimum of bachelor's degree in nursing education and at least 2 years' experience using WBFS and FLACC. The video recordings that have been obtained were screened to determine the feasibility of the image, and then randomly renamed in phases. However, the rater did not know all clinical information concerning the infant.

Statistical analysis

The study's statistical analysis was performed using computer software (SPSS 16). Furthermore, the subjects' demographic data and clinical information were described using the frequencies distribution with categorical data and the mean (standard deviation) determined. The mean differences between before dan along during pain stimuli of FLACC, WBFC and skin conductance were analyzed using a non-parametric test (WBFC, FLACC, and SC). Meanwhile, the independent sample Kruskal Wallis Test was used to examine the mean differences in the 3 groups.

Results

The result showed that out of the 121 infants that selected the public health center to get immunized, they had appropriate demographic and skin conductance data (59 boys, 62 girls, age (Post Natal Age/PNA) 4.37 ± 2.97 month, and current weight 6522 ± 1378.65 gram). Almost all infants were full-term, and 97, 6% were previously exposed to pain through injection or take blood sampling, as shown in Table 1. Pain measurement of all three instruments was done simultaneously using a developed Skin Conductance (SC) apparatus and video recording (to assess behaviour and face).

The Peak of SC was significantly higher during injection immunization (3.43±0.966) than before the insertion of the needle (2.79±1.240; $p < 0.05$). Furthermore, the FLACC (1.42±1.558 VS 7.71±1.301; $p<0.05$) and WBFS scales (1.79±1.71 VS 4.96±0.204; $p<0.05$) was significance higher during injection than before the immunization injection, as shown in Table 2.

The WBFS, FLACC scale and SC Peak analysis results were shown in Table 2. Independent sample of Kruskal Wallis analysis indicated a significant difference, both WBFC - SC, WBFC - FLACC, and SC - FLACC ($p<0.05$), as shown in Table 2.

The correlation analysis between contextual factors and demographic data with all NIPS and SC scales is shown in Table 3. The results of this analysis show that there is no significant relationship between all pain scale with gestational age, current weight, head circumference, age (post-natal age), gender and vaccine type ($p>0.05$). Similar results are shown in the correlation analysis between the SC scale with all contextual variables and demographic data ($p>0.05$).

There is a significant relationship between Birth weight ($p<0.05$) and height ($p<0.05$) with the FLACC pain scale. Further analysis showed that the greater birth weight ($r=-0.45$), and the higher baby ($r=-0.47$), had a lower FLACC scale ($r=-0.45$).

Discussion

Wong-Baker Face Scale (WBFS)

Facial scales in pain assessment are frequently used as expressions of pain in clinical research and practice, and the Royal College of Nursing has identified WBFS.[17] This scale has a numerical score ranging from 0 to 10.[18] This pain scale is described using 6 facial scales which describe the range of pain ratings from "no pain" to "very painful" equivalent to a score from left to right, namely 0, 2, 4, 6, 8, and 10.

This result is in accordance with previous studies, that found a significant increase in the pain scale between two phases (before

Table 1. Demographic data of infant and mother.

Variable	N	Mean	SD	Minimum	Maximum
Parity	121	1.92	0.87	1	4
Birth weight	121	2985.74	405.83	1900	3800
Gestational age	121	38.52	2.09	28	42
Weight	120	6699.42	1746.04	3600	13100
TB	120	66.83	7.92	55	87
Age (PNA)	121	6.28	753	1	21
Mother age					
<35	102	-	-	-	-
>35	19	-	-	-	-
Gender infant					
Female	62	-	-	-	-
Male	59	-	-	-	-
Immunization					
Pentabio	35	-	-	-	-
BCG	12	-	-	-	-
MR/Boster	18	-	-	-	-
IPV	56	-	-	-	-

and during the vaccination procedure).[19] Furthermore, this study found that WBFS was not associated with gestational age, postnatal age, current weight, birth weight, sex, previous pain history and type of injection (p>0.05). This contrasts with Savino's findings, which stated that WBFS is influenced by age and previous venipuncture experience.[20] Evidence shows differences in WBFS between children under 8 years with venipuncture experience and those that never had venipuncture. The report of Tomlinson *et al.* on previous painful events, play a role in the anticipation and evaluation of future pain experiences.[17] Furthermore, the repeated events of pain could alter the neurological response, thereby leading to changes in the neurobehavioral reactions and subsequent pain.[18] These changes are associated with a decrease in the pain threshold during the development period.

These different findings in this study also show of due to anxiety factors and types of injection/vaccination procedure. Younger infants tend to show no anxiety from the start and respond to pain when there is stimulus, in contrast to older babies that tend to cry more even when entering the examination room. In addition, this study cannot rule out mothers' distraction techniques during pain stimulation, through the skin-to-skin contact, breastfeeding, embracing, and holding.

Face Leg Activity Cry Consolability (FLACC)

The Face, Legs, Activity, Cry, and Consolability (FLACC) is one of the most commonly used pain instruments scales. Therefore, a pain measuring scale that is impractical, long, difficult to assess and remember, such as the FLACC is structured to be more practical, simple and short.[19]

This study's findings indicated a significant increase in the FLACC score between the pre and injection phases of immunization (1.42 ± 1.558 VS 7.71 ± 1.301; p<0.05). This is in line with the previous research, which performed distractions in babies immunized using light & sound-producing toys and cartoon movies.[20] The behavioral pain measurement in this study used FLACC. Tamvaki's (2020) stated that this pain assessment instrument is suitable for a sample of children in Greece.[21]

The FLACC scale is reliable and pain-sensitive for assessing procedural pain.[14,22] The study involves 26 physicians that performed a FLACC scale rating on 100 video segments of children aged 6 to 42 months undergoing the procedure. The video segment was rated by 4 reviewers. The results showed high results on the interrater (0.92) and interrater (0.87) reliability coefficient. It also supports the use of the FLACC for the assessment of procedures in children. However, a systematic review stated that the FLACC is adequate for use in assessing postoperative pain in infants and children, with insufficient data used to support its use in all circumstances.[19]

Almost all demographic and contextual factors in infants have no relationship with the FLACC scale (p>0.05). This study compared of 2 variables; birth weight (p=0.02) and height (p=0.03), with a significant relationship. A lot of studies have shown that contextual factors affect pain in infants including age (gestational/postnatal age), gender/sex, health status, behavioral status, history of previous pain stimulation, and therapeutic interventions.[23] Therefore, based on this, the baby's anthropological status like birth weight and height are not mentioned as a contextual factor that affects the infant's pain. The result showed that infants had a relationship between birth weight and height with the FLACC scale. Furthermore, at the time of heavier infants tended to express less behavioral pain. However, this is not demonstrated in WBFS and SC result.

Table 2. Infant's pain scale using WBFC, FLACC and SC during immunization injection.

	WBFC		FLACC		SC	
	Before	During	Before	During	Before	During
Mean ± Deviation Standard	1.63±1.60	4.92±0.27	1.76±2.59	4.96±0.20	2.72±1.11	3.36±1.11
Median	1	5	1	5	3	5
Min - Max	0-5	4-5	0-7	4-5	1-5	4-5
P-value	<0.05		<0.05		<0.05	
Comparison of group WBFC, FLACC and SC p-value						
WBFC - FLACC	<0.05	-	-	-	-	-
FLACC - SC	<0.05	-	-	-	-	-
SC - WBFC	<0.05	-	-	-	-	-

Table 3. Correlation demographic factor with WBFC, FLACC dan SC.

	WBFC		FLACC		SC	
	p-value	r	p-value	r	p-value	r
Gestational age	0.81	0.05	0.11	0.33	0.57	-0.09
Birth weight	0.25	-0.24	0.03	-0.45	0.33	0.15
Weight	0.53	0.14	0.33	-0.21	0.15	-0.23
Height	0.44	-0.17	0.02	-0.47	0.22	-0.19
Age/PNA	0.99	0.00	0.11	-0.34	0.18	-0.21
Gender	0.11	-0.18	0.52	0.14	0.17	0.21
Type of Vaccine	0.42	-0.17	0.65	-0.10	0.24	-0.18
Previous pain	-	-	-	-	0.48	-0.11

Skin Conductance (SC)

Measurement of SC are SC Activity (SCA), Skin Conductance Response (SCR), Electrodermal Activity (EDA), Electrodermal Response (EDR), or Galvanic Skin Response (GSR).[24] Skin conductance is more desirable than heart rate, as it attempts to assess a purely emotional response initiated in the central nervous system. The measurement results adjust to variations in the electrical conductance of the skin and have an acceptable correlation with the activity of the nervous system which indicates an emotional state accompanied by stress. The central nervous system controls the sweat glands, so when the person is stressed or frightened, greater electrical conductance is seen in measuring the Galvanic Skin Conductance (GSR).

In previous studies, med-storm innovation tool was used to measure infant skin conductance with three electrodes attached to the neonates' heels.[17,24] Furthermore, Schubach *et al.* used the Varioport-B system with two electrodes, placed in a similar manner.[12] However, only the adhesive materials used by Med-Storm and Varioport-B were different from the adhesive material wrapped to remove any unwanted artefact movements capable of affecting the SCM. In this study, infants were placed in the open bed before the application of electrodes, and wear nappies, which opened the cover of both legs and the cable secured with a band around the ankle area.[17,25] The collection time in this study was 20-30 s before and during injection pain stimuli.

Many previous studies showed that SC increased significantly during painful procedures. Infants that received immunization injections, showed a significant increase in the skin conductance scale (NWPS, $p<0.05$) before and during the injection, with NIPS used as another measurement parameter of pain.[24-26]

This study's analysis showed no significant relationship between SC scores with contextual factors, such as gestational age, birth weight, bodyweight at the examination, gender, and significant previous history of pain ($p>0.05$). This is different from preliminary studies, which stated that there is a relationship with contextual factors; sex (female, male), number of previous injections, current age, gestational age, and postnatal age 1–21 month age, also range of current weight range (3600–13100) and birth weight range (1900–3800).[23]

Conclusions

WBFS, FLACC and PainCare-UI as skin electrical conductance have the same results for measuring pain regularly used to assess pain during vaccination injection. WBFS and FLACC are directly used during immunization while skin conductance is measured by applying the device's electrode and connecting it to the monitor. However, skin conductance is more beneficial for an infant without clear pain expression using tele-diagnosing/tele-monitoring. The next investigation will more controlling contextual factors affecting pain like age (gestational/postnatal age), gender, health status, behavioural status, history of previous pain stimulation, and therapeutic interventions. Furthermore, testing the validity and reliability of these instruments will increase the accuracy of the tool.

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