Republic of Turkey

Black Sea Technical University Rectorate

Directorate of the Institute of Health Sciences

Number: 27863166-302.14.04- 02/22/2024 22.02.2024

Subject: Thesis Proposal (Berrin GÖGER)

TO THE DEPARTMENT OF NURSING

Regarding the “Doctoral Thesis Proposal” of Berrin GÖĞER, a doctoral student in your department, a copy of the Institute Management Board decision dated 14.02.2024 and numbered 160 is attached. I kindly request your attention and action.

Assistant Professor Efnan ABDIOĞLU FAZLI

Director a.

Deputy Director of the Institute

DETAİLED DESCRİPTİON OF THE WORK

Title of the study

The effect of mechanical vibration and flicking methods on reducing pain during the Hepatitis B vaccine administration in infants

General Information

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage” (1). The International Classification of Nursing Practice (2019) defines pain as “perceptual disorder: increased unpleasant sensations in the body, subjective reporting of pain, grimacing, changes in muscle tone, self-protection.” It has been defined as “behavior, narrowing of attention focus, altered perception of time, withdrawal from social contact, impaired thought processes, distracting behaviors, restlessness, and loss of appetite” (2).

The American Pain Society has defined pain as the fifth vital sign and emphasized that healthcare professionals should systematically assess pain in the same way they assess temperature, pulse, respiratory rate, and blood pressure (3). The Turkish Language Association (TDK) defines pain as a feeling of discomfort arising from the intense stimulation of nerve endings anywhere in the body (4). Although pain is subjective, its definitions are based on previous pain experiences, and it is noted that early life experiences related to pain shape future pain responses (5, 6).

Short-term effects of untreated procedural pain in infancy and early childhood include delayed wound healing, changes in immune system function, endocrine and biochemical changes, increased cortisol and catecholamine release, increased glucagon, growth hormone, aldosterone, renin, and antidiuretic hormone levels, and decreased insulin secretion. In addition, physiological changes such as apnea, bradycardia, tachycardia, skin color changes, hypertension, sweating of the palms, increased intracranial pressure, respiratory rate, and muscle tone, as well as behavioral changes and crying, are also present (7). It is also noted that it causes long-term sequelae, including anticipatory anxiety (8). These effects include decreased analgesic efficacy, increased sensitivity to pain and needle phobia, avoidance of routine health care checkups, and a tendency not to comply with medical treatment and preventive measures (6).

From birth and throughout infancy, they are routinely exposed to painful procedures as part of routine preventive care (15). Depending on their stage of development, they may lack the communication skills and cognitive development necessary to describe the nature, location, severity, or intensity of their pain. It is a complex, multidimensional, and subjective condition that can be difficult to assess and manage, especially in infants and young children (16).

However, ensuring a thorough assessment of their physiological status during painful procedures and developing evidence-based, appropriate pain control strategies with an understanding of the effects of pediatric pain is both a medical and ethical responsibility for pediatric nurses (1, 17). The World Health Organization (WHO) estimates that 12 billion It is estimated that injections are administered, with approximately 5% of these being childhood vaccinations (6). Pain associated with vaccination is considered a significant adverse event following vaccination and therefore pain management should be part of every vaccination (9).

To minimize these adverse events, the American Academy of Pediatrics and the International Neuropsychiatric Pain Group recommend reducing pain in infants and using non-pharmacological pain relief methods as the primary option in newborns (18, 19). Studies indicate that non-pharmacological tactile stimuli such as vibration may have the potential to reduce pain due to the presence of numerous large fibers in the skin (11, 20-22). Infants are exposed to mechanical vibration through vibrating infant seats or swings to calm them in both hospital and home settings (23). However, it is known that vibration applied with a mechanical hand vibrator is also used as a method of chest physiotherapy in Neonatal Intensive Care Units (NICUs) to calm colicky infants (24, 25).

It has been suggested that manipulations such as rubbing, applying pressure, and tapping directly on or below painful areas may also alleviate pain by releasing beta-endorphins into the bloodstream (13). It has been suggested that simple manual pressure applied to the injection site (similar in effect to the fiske method) may be a useful technique for reducing injection pain (7, 13, 26). The current literature shows that non-pharmacological mechanical vibration and fiske applications may be effective in reducing injection pain (7, 11).

Based on this information, the aim is to evaluate the effect of mechanical vibration and fiske tapping methods in reducing pain during vaccination in one-month-old infants receiving healthcare as part of routine primary preventive healthcare services.

Aim

This study aims to investigate the effect of tapping the injection site prior to the second dose of Hepatitis B vaccine administered to the anterior surface of the vastus lateralis muscle during infancy and the application of mechanical vibration to the injection site throughout the vaccination procedure on acute pain, crying duration, and physiological parameters that may occur due to intramuscular injection.

Research Hypotheses

Main Hypotheses

Hypothesis 0a (H0a): There is no difference in pain between the control group and the study groups when mechanical vibration is applied during Hepatitis B vaccination in infants compared to routine Hepatitis B vaccination.

Hypothesis 1a (H1a): There is a difference in pain between the control group and the study groups when mechanical vibration is applied during Hepatitis B vaccination in infants compared to routine Hepatitis B vaccination.

Hypothesis 0b (H0b): There is no difference in pain between the control group and the study groups when comparing the routine Hepatitis B vaccination with the tap method applied during Hepatitis B vaccination in infants.

Hypothesis 1b (H1b): There is a difference in pain between the control group and the study groups in infants during routine Hepatitis B vaccination and during Hepatitis B vaccination administered using the finger-prick method.

Method

Type of Research

The research is planned to be conducted as a randomized controlled trial to examine the analgesic and physiological effects of mechanical vibration and fiske methods in infant vaccinations.

Location and Timing of the Research

Research data will be collected at Gümüşhane Kelkit No. 1 ASM. According to the study schedule, ethical committee and institutional approval will be obtained before starting the research, following the submission and acceptance of the thesis proposal, and then the data collection process will begin. Data collection, obtaining expert opinions, and data entry will take place over a 12-month period. Data analysis and thesis report writing will be completed within a three-month period, and the research is expected to be carried out according to the planned schedule.

Ethical Aspects of the Study

Before starting the study, the necessary permissions will be obtained from the Scientific Research Ethics Committee of Karadeniz Technical University Health Sciences. After obtaining permission from the ethics committee, institutional permission will be obtained from the Gümüşhane Provincial Health Directorate, to which Gümüşhane Kelkit No. 1 ASM is affiliated, in order to carry out the study. All parents of newborn babies included in the study will be informed about the purpose, type, implementation process, and content of the study, the purpose for which the video images taken during the data collection process will be used, the fact that all data will be stored on the researcher's personal computer, and where the obtained data will be used. Verbal and written consent will be obtained from the parents.

Study Population and Sample

The study population will include infants whose mothers, who agreed to participate in the study, applied for the second dose of the Hepatitis B vaccine at the end of the first month as part of routine preventive care at Gümüşhane Kelkit No. 1 ASM and who met the inclusion criteria for the study.

A power analysis was performed to select the patients to be sampled. The G*Power 3.1.9 program was used to calculate the number of participants to be included in the study. During the calculation, the effect size was taken as 0.31 based on Kanbur's (2021) study for the parameters specified according to the type of test, the margin of error was taken as 0.05, the power value was taken as 0.80, the number of groups was taken as 3, and the number of measurements was taken as 3. The calculation resulted in a minimum participant number of 72. Accordingly, it was planned to include a minimum of 24 participants in each group (27).

Research Inclusion Criteria

The parent agrees to participate in the study/volunteers to participate,

The gestational age is between 38 and 42 weeks,

The birth weight is between 2500 g and 4000 g,

No pain medication is administered prior to vaccination,

Body temperature is within normal limits,

Exclusion Criteria

Parents who do not consent to participate in the study,

Gestational age below 38 weeks or above 42 weeks,

Infants with congenital diseases or birth defects will not be included in the study.

Data Collection Tools

Newborn Baby Identification Form

The newborn infant information form created by the researcher consists of a total of nine questions, including the infant's group number, gender, gestational age, mode of delivery, birth weight and length at birth, postnatal age, current weight and height, and feeding method (27, 29).

Parent Information Form

The parent information form created by the researcher consists of a total of six questions, including the parent's group number, mother and father's ages, education status, and occupation information (27).

Newborn Baby Observation Form

The observation form prepared by the researcher is a form on which physiological parameters will be recorded, including the baby's group, crying time with the start of the vaccination procedure, the baby's body temperature before and after the procedure, the baby's respiratory rate before and after the procedure, and oxygen saturation and heart rate before, during, and after the procedure. This information about the infant before, during, and after the procedure **will be observed by the researcher and recorded on this form (27, 29).**

Neonatal Infant Pain Scale (NIPS)

Developed by Lawrence and colleagues, it is used to measure the behavioral responses to pain in preterm and term infants during the first six weeks after birth. The scale ensures that the infant's behavior, which is the first step in meeting the newborn's needs, is objectively assessed at the bedside. The scale's reliability coefficient has been found to be between 0.92 and 0.97. It is stated that the scale can be used reliably and can measure the effectiveness of the intervention, and six behaviors in response to pain are evaluated (27). Facial expression, breathing pattern, arm movements, leg movements, and alertness are scored as 0 or 1, while crying is scored as 0, 1, or 2. The total score ranges from 0 to 7, with a high score indicating severe pain. The Turkish adaptation of the scale was performed by Akdovan and Çiğdem in 1999 (28).

Application Tools

Mechanical Vibrator

The Norco NC70209 brand mini vibration device, which is lightweight, portable, and battery-operated, with silicone heads for small areas, vibrates at 5500 rpm and is intended for use on infants in the mechanical vibration group.

Video Camera

The digital camera of the Samsung Galaxy M31 phone is planned to be used to determine pain levels before, during, and after the Hepatitis B vaccination procedure in infants, to evaluate physiological parameters, to accurately calculate crying times, and to check for inter-observer agreement in the evaluation of pain scores. The camera has an 8-megapixel video resolution and features that allow images to be reviewed on a wide screen.

Pulse Oximeter

An ACCURATE handheld rechargeable pulse oximeter device is planned to be used at the patient's bedside to easily view measurement trends on the screen for determining oxygen saturation and heart rate in infants. The device is designed to monitor pulse and blood oxygen levels in premature infants, newborns, children, and adults. Values can be tracked by attaching it to the adjustable wrist, ankle, or finger.

Thermometer

A KANGJI brand, model GQ-129, non-contact infrared digital screen thermometer is planned to be used to measure the body temperature of infants. Body temperature measurement will be taken from the forehead, and the thermometer will be held 3-5 cm away from the infant's forehead.

Data Analysis

IBM SPSS 27 software will be used to analyze the data in this study. Continuous data will be presented as mean ± standard deviation, while categorical data will be presented as frequency and percentage. If the values obtained from the measurements taken for each variable throughout the study show a normal distribution, the parametric test ANOVA test will be used to compare repeated measurement results. If the values do not show a normal distribution, the non-parametric Friedman test will be used. For intergroup analyses, the parametric test, one-way ANOVA, will be used for those showing a normal distribution, and the non-parametric test, Kruskal Wallis H test, will be used for those not showing a normal distribution. Statistical significance will be accepted as $p<0.05$ for all analyses.

Research

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