STUDY PROTOCOL

Title: The Effect of Using Crochet Octopus in Reducing The Pain Developed During The Process of Heel Lance İn Neonates: A Randomized Controlled Study

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Objectives: The main objective of this study was to determine the effect of using a crochet octopus to reduce acute pain that develops during a heel lance in neonates.

Design: This study used a randomized controlled design.

Methods:

Participants: Neonates born between May 1, 2020, and August 15, 2020, were included in the study. The study was conducted at a well-child unit in a research and training hospital with healthy, term neonates. The neonates were not hospitalized during the research. All blood samples for the Guthrie test were routinely taken at the well-child unit in this hospital.

Measurements: Descriptive data of participant neonates were documented in the neonatal identification form using hospital records. The pain score measured with Neonatal Infant Pain Scale.

Intervention: The crochet octopus was delivered to the hands of the neonates in the experimental group 10 min before the heel lance process occurred, and the neonates were in contact with the crochet octopus for up to 10 min after the procedure (Figure 3). In this procedure, the neonates were dressed. The procedure was carried out under a radiant heater in baby mode, and neonates were placed in a supine position. A pulse oximeter device was used

to monitor oxygen saturation and heart rate. The device probe was attached to the neonates' wrists during the time under the radiant heater. The respiratory rate was counted by one researcher for 1 min. The body temperature was measured by researcher with an infrared thermometer. The observation form was completed before the procedure began (0^{th} min). No intervention was performed beforehand to better draw the heel blood, and the blood was drawn from the left heel for each neonate because of the researcher's holding position. A fine lancet was used for heel lancing; before the procedure, the heel was wiped with 70% isopropyl alcohol wipes in a circular motion and then wiped with dry cotton. Blood was drawn from the heel while the neonate was on the mother's laps. The observation form was completed again during the procedure and after the procedure (at 2^{nd} and 10^{th} min).

The total data collection time took an average of 20 min, and the entire process was recorded on video. After the process, researcher performed the heel lance procedure with video recording. After the procedure was completed, video recordings were assessed by two observers—a neonatal nurse specialist and researcher—together to eliminate bias. Neonatal durations of crying and NIPS scores were calculated at 0 min (before the procedure) and at 2^{nd} and 10^{th} min after the process, and the scores were recorded on the data collection form. During the procedure, neonates remained with the mothers. Neonates who cried before the procedure were held by mothers until they calmed down; approximately 15 min later, they could be included in the study.

Before collecting the data, 50 crochet octopus were crocheted by three researchers according to the standards noted in the Methods' Instruments section. A new crochet octopus was used for each neonates during the heel lance procedure; the octopus was then washed in a washing machine with an organic detergent for neonates in $60^{\circ}C$ (hot) water.

The control group of neonates underwent the heel lance process without a crochet octopus.

Ethical Considerations: Ethical approval was obtained from the Clinical Researchers Ethical Committee of Giresun University (Approval No. 06.02.2020/20). Institutional permission was obtained from the Public Hospitals Association of Giresun. In addition, parents of the neonates were asked for written informed consent forms for the data collection, procedure, and video recording.

Statistical Analysis Plan

The Number Cruncher Statistical System (NCSS 2007; Kaysville, UT, USA) was used for statistical analysis. Descriptive statistical methods (average, standard deviation, median, quartiles, frequency, rate, minimum/maximum) were used to assess relevant data. Normal distribution characteristics of the study parameters were examined with the Kolmogorov-Smirnov test. Heart rate, oxygen saturation, and body temperature had normal distributions, but respiratory rate, duration of crying, and NIPS pain scores did not have normal distributions. The independent *t*-test was used for the cross-group comparison of variables with normal distributions, and the Mann-Whitney *U* test was used for those without normal distributions. Cohen's kappa coefficient was calculated for the interrater reliability of observers. Significance was assessed in the range of 95% reliability.