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Efficacy of Mechanical Vibration of Heel Stick Pain in Neonates

Yenidoğanlarda Topuk Delme İşleminde Ağrı Kontrolü ve Mekanik Vibrasyonun Etkisi

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Abstract

Objective: One of the most frequently observed painful procedures during newborn hospitalization is the neonatal heel prick. The use of vibration therapy in newborn pain control can be a preferred method for its non-invasive, cheap, and easy applicability. This study aimed to evaluate effectiveness of mechanical vibration application to avoid pain sensation during heel puncture in newborns.

Methods: This was a prospective single-center, placebo-controlled,, prospective randomized study. The study sample composed of healthy neonates born between 37 and 42 weeks of gestation in Medeniyet University Göztepe Training and Research Hospital. Sixty healthy neonates born in the study hospital between September 2012 and March 2013 and who matched the inclusion criteria after parental consent was obtained were included in the study. Heel puncture was applied to the infants during routine testing for phenylketonuria. It was recorded that all of the newborns demographic characteristics, heart rate,oxygen saturation and body tempature measurement at the process. All applications was saved to video camera, then displayed followed and the NIPS was scored by the investigator. The Cronbach's alpha coefficient for the NIPS scoring system was 0.85 during the procedure and 0.87 after the procedure in this study.

Results: Before procedure and during procedure the NIPS point average of the experiment group is calculated by (0.967±1.771) and (1.733±2.050) . For the control group, before and during application the NIPS point average is (3,567±1,775) and (4,533±1,907), respectively ($p<0.05$). In both groups Newborns post-procedure NIPS score results was higher than during procedure NIPS score and it was statistically significant ($p<0.05$).

Conclusion: Mechanical vibration is found to be effective in decreasing pain sensation in neonates.

Keywords: Pain, pain scale, sucrose, mechanical vibration, newborn

Öz

Amaç: Topuk kanı alınması işlemi; yenidoğanların hastanede kaldığı sürede en sık uygulanan ağrılı girişimlerdendir. Mekanik vibrasyon yenidoğan ağrı kontrolünde tercih edilebilecek invaziv olmayan, ucuz ve kolay uygulanabilir bir yöntemdir. Çalışmamız yenidoğanlarda topuk delme işlemi sırasında oluşabilecek ağrı hissini engellenmek için mekanik vibrasyon uygulamasının etkinliğini test etmek amacıyla yapılmıştır.

Yöntem: Araştırma randomize kontrollü, tek merkezli prospektif bir çalışma olarak Medeniyet Üniversitesi Göztepe Eğitim Araştırma Hastanesi'nde, 37-42 GH' nda doğan sağlıklı term 60 yenidoğanda, Eylül 2012- Mart 2013 tarihleri arasında yapılmıştır. Çalışma alınma kriterlerini karşılayan yenidoğanların ebeveynlerinden onam alınmıştır. Topuk delme işlemi her yenidoğana yapılan fenilketonüri testi sırasında uygulanmıştır. Hastaların tamamının demografik özellikleri, işlem sürecindeki KTA, SPO2, vücut ısısı ölçümleri kaydedilmiştir. Tüm uygulamalar kameraya kaydedilmiş, sonrasında görüntüler izlenerek araştırmacı tarafından NIPS skorlaması yapılmıştır. Bu çalışmada NIPS puanlama sisteminin Cronbach's alpha katsayısı işlem sırası için .85, işlem sonrası için .87 olarak bulunmuştur.

Bulgular: Deney grubunun NIPS puan ortalaması işlem sırası ve işlem sonrası için (0,967±1,771) ve (1,733±2,050), kontrol grubunda ise sırası ile (3,567±1,775) ve (4,533±1,907) olarak belirlenmiştir ($p<0,05$). Her iki gruptaki yenidoğanların işlem sonrası NIPS puan sonuçları işlem sırasındakilerden istatistiksel olarak anlamlı yüksek bulunmuştur ($p<0,05$).

Sonuç: Yenidoğanlarda ağrı algısının azaltılmasında ve ağrı kontrolünde mekanik vibrasyon yöntemi etkili bulunmuştur.

Anahtar Kelimeler: Ağrı, ağrı ölçeği, sukroz, mekanik vibrasyon, yenidoğan

INTRODUCTION

According to "International Association for the Study of Pain," pain is a sensory, affective, and unpleasant sense stemming from any part of the body with real or possible tissue damage and related to experiences of the patient (1).

This study has been presented in a 5th Congress of the European Academy of Paediatric Societies (EAPS) as poster presentation, 17 - 21 October 2014, Barcelona, Spain,

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Pain receptors on fetus' skin appear at the seventh week in the perioral region for the first time, and by the twentieth week, they disperse over the entire body and mucosa. Synapses between the sensory fibers and medulla spinalis posterior horn cells appear around the sixth week and are fully developed by the thirtieth week. The cerebral cortex starts to develop by the eighth week and ceases its growth by the twentieth week. The development of the links between the thalamus and cortex along with pain perception in the upper centers occur in the twenty-fourth week. Hence, while a substantial portion of the pain is received by the cerebral cortex, perception can occur at the subcortical level as well. The absence of myelin sheath across nerves does not indicate a dysfunction of nerves, but only a slowness in communication. This shows that a newborn feels and remembers pain (2, 3).

Pain threshold is the mildest level of pain perceivable by an individual and may be different between and within an individual. The causes of this difference are factors, such as the psychological status, cultural differences, religious beliefs, fatigue, and pain memory (1). One of the most important sources of pain prevention is pain memory. In newborns, using non-pharmacological methods for pain control during invasive operations would increase the pain threshold (4).

Many proven non-pharmacological methods exist for newborn pain prevention. Pseudo-pacifier, oral sucrose, and kangaroo care are some of the examples (5). A portion of the non-pharmacological methods prevents pain perception and memory in a newborn based on gate control theory.

Vibration creates a strong stimulation, which became a recognized therapy for pain. Since 1940, vibration therapy has been used in different fields. Currently, studies are being performed on vibration used in medical fields, such as sports medicine, dentistry, dermatology, and orthopedics. Moreover, a study was performed by Baba et al. (6) in the field of neonatology concerning the analgesic effect of mechanic vibration, which has been found effective. However, studies focusing on the effect of vibration therapy for pain treatment in newborns are insufficient (6).

The use of vibration therapy in newborn pain control can be a preferred method due its noninvasive, cheap, and easy applicability. The vibration theory is supported by the gate control theory developed by Melzack and Wall. By providing non-painful stimuli of skin touch, the transmission of a painful stimulus is blocked (7).

One of the most frequently observed painful procedures during newborn hospitalization is the neonatal heel prick. Therefore, the efficiency of mechanical vibration application will be tested in the prevention of pain sense during this procedure.

METHODS

This is an experimental clinic study performed in the nursery of a teaching hospital. The study population consists of healthy newborns born between the thirty-seventh and forty-second week of gestation in a research and training hospital. The number of babies born in 2012 was 2.590 in this hospital.

The sampling group consisted of newborns born in the above-mentioned hospital between September 2012 and March 2013, who qualified the sampling selection criteria, and whose parents agreed to participate.

Sample exclusion criteria;

- Existence of significant medical and surgical congenital anomaly
- Cardiopulmonary resuscitation during birth
- Opioid and non-opioid analgesic and sedative intake 12 hours before procedure
- Apgar score of ≤6 at the fifth minute
- Low birth weight compared to birth week
- Heel lance prior to study for any reason were determined as exclusion criteria

Neonates who did not meet the given criteria were excluded thereof.

The sample size was 60: 30 in the experimental group and 30 in the control group. For using paramedical measurement tests, the number 30 was specifically heeded in the determination of sample size (8).

In sample selection, grouping was performed using the raffle method of basic random sampling. In the grouping of newborns within the sample group, 60 papers were reserved; on one-half of which was scribed "study" and on the other half as "control," and the newborns were randomly assigned to either group based on the lottery method.

Newborns in the experimental group were given sucrose + mechanic vibration during heel prick and those in the control group were given only sucrose.

Data Gathering Tools

In our research, the devices along with their function for data gathering are as follows: participant identification form to assess demographic properties; Thermo Flash LX-26 (Visiomed, Shenzhen, China) thermometer to determine temperature; Med-Lab (Germany) Nano 10 pulse oximetry deviceto determine oxygen saturation and heart rate (HR); 24% sucrose solution with proven efficiency and Wollex LC-2002 AB-1 massage device to provide mechanic vibration, whose efficiency is tested in the experimental group for heel prick; Broch blood lancet for heel prick; and Neonatal Infant Pain Scale (NIPS) to evaluate behavioral response to heel pricking procedure and for visual evaluation (video) of the behavioral response by the same observer, Blood collection from the heel and pain assessment were performed by the same personnel. Hence, both the procedures were recorded using a camera Canon EOS 1100D photograph machine along with a tripod to fix the camera were used.

Participant Identification Form

Prepared by the researcher in concert with literature, this form consists of 7 open-ended questions and sections with vital results that contain sociodemographic data of the newborns.

Neonatal Infant Pain Scale (Table 1)

Neonatal infant pain scale (NIPS) was developed by Lawrence et al. in 1993. In this scale, Pearson correlations ranged from 0.92 to 0.97 across successive minutes of observation. The six component scores of the NIPS had high internal consistency: Cronbach's alphas were 0.95, 0.87, and 0.88 for before, during, and after the procedures, respectively. Lawrence et al. (9) the scale was adapted to Turkish in 1999 by Akdovan (10) and Cronbach's alphas were 0.83-0.86 for during and after the procedures, respectively (10, 11).

Table 1. HR Mean Score in Experimental and Control Groups

	Control (n=30)		Experimental (n=30)			
Groups	**Mean**	**SD**	**Mean**	**SD**	**T**	**p**
Pre-Sucrose NIPS	131.400	14.457	130.467	15.651	0.240	0.811
Preprocedural NIPS	135,.500	17.055	130.100	15.623	1.279	0.206
Periprocedural NIPS	133.267	18.502	130.733	16.360	0.562	0.576
Postprocedural NIPS	132.700	17.720	130.000	15.687	0.625	0.534

T: t test value; SD: standard deviation; NIPS: Neonatal Infant Pain Scale; HR: heart rate

Table 2. Working pattern

Experimental Group	**Control Group**
1. NIPS, HR, and SPO_2 evaluation	1. NIPS, HR, and SPO_2 evaluation
2. 2 mL oral sucrose application wait 2 minutes	2. 2 mL oral sucrose application wait 2 minutes
3. Second NIPS, HR, and SPO_2 evaluation after 2 minutes	3. Second NIPS, HR, and SPO_2 evaluation after 2 minutes
4. 60 Hz vibration application on the heel for 5 seconds using an LC-2002 AB-1 massage device	
5. Heel prick after vibration and a third NIPS, HR, and SPO_2 evaluation	4. Heel prick after vibration and a third NIPS, HR, and SPO_2 evaluation
6. Fourth NIPS, HR, and SPO_2 evaluation postprocedure	5. Forth NIPS, HR, SPO_2 evaluation postprocedure

In the scale, the maximum and minimum scores were 7 and 0, respectively. The evaluation performed as follows: 0-2 points: no pain; 3-4 points: mild, intermediate pain; >4: severe pain (9-11).

Data Gathering Method

For each newborn included in the study, a participant identification form was filled by the researcher. In the form, the gestation week, postnatal age, birth weight, and birth head circumference were obtained from infant files. Height, weight, and head circumference were obtained using the percentile chart according to the week. Last feeding time was noted from mothers.

The heel prick procedure was performed in the room where newborns stay with their mothers. Blood for the phenylketonuria (PKA) test was drawn at 8:00 a.m. to avoid disrupting the clinical routine. Saturdays and Sundays were preferred to minimize negative environmental factors (visiting noise, etc.).

Newborns' heels were checked for possible prick, and those who had had the procedure were excluded.

Newborns were laid on infant beds with their snap suits to prevent heat loss and maintain open feet. They were monitored using a saturation probe prior to the procedure, and a mechanic vibration device was placed next to newborns in the experimental group.

The camera for video recording was placed in front of the newborns on a tripod in a specific angle that sees the infant clearly. Video recording was performed to obtain objective evaluation by having the same person watch for a physiological response to pain from infants.

The body heat was measured to determine its stability prior to the procedure and thereafter the procedure was initiated. In addition, the total pain score was determined to be 0 in all samples before starting with the procedure in both the study and control groups.

Steps of procedure in experimental group are as follows:

1. NIPS, HR, and peripheral capillary oxygen saturation (SPO_2) evaluation
2. 2 mL oral sucrose application
3. Second NIPS, HR, and SPO_2 evaluation after 2 minutes
4. 60 Hz vibration application on the heel for 5 seconds using an LC-2002 AB-1 massage device
5. Heel prick after vibration and a third NIPS, HR, and SPO_2 evaluation
6. Fourth NIPS, HR, and SPO_2 evaluation postprocedure (Table 2)

Steps of procedure in control group are as follows:

1. First NIPS, HR, and SPO_2 evaluation
2. 2 mL oral sucrose application
3. Second NIPS, HR, and SPO_2 evaluation after 2 minutes
4. Heel prick and third NIPS, HR, and SPO_2 evaluation
5. Fourth NIPS, HR, and SPO_2 evaluation postprocedure (Table 2)

All applications were recorded on video camera. NIPS evaluation was performed later by the researcher by watching the recordings. Blood collection from the heel and pain assessment were performed by the same personnel. Hence, both the procedures were recorded using a camera. All heel pricks were carried out by the researcher. The heel prick procedure was performed to draw blood for the PKA test executed routinely for scanning each newborn. No procedure was performed redundantly.

Table 3. SPO_2 mean score in experimental and control groups

Groups	Control (n=30)		Experimental (n=30)		T	p
	Mean	SD	Mean	SD		
Pre-Sucrose NIPS	96.333	8.786	95.333	2.963	0.591	0.557
Preprocedural NIPS	95.200	3.818	95.400	3.201	-0.220	0.827
Periprocedural NIPS	95.433	3.626	94.933	2.791	0.598	0.552
Postprocedural NIPS	94.900	3.907	95.300	2.961	-0.447	0.657

T: t test value; SD: standard deviation; NIPS: Neonatal Infant Pain Scale

Table 4. NIPS mean score in experimental and control groups

Groups	Control (n=30)		Experimental (n=30)		T	p
	Mean	SD	Mean	SD		
Pre-Sucrose NIPS	0.000	0.000	0.000	0.000	-	-
Preprocedural NIPS	0.000	0.000	0.000	0.000	-	-
Periprocedural NIPS	3.567	1.775	0.967	1.771	0.000	0.000
Postprocedural NIPS	4.533	1.907	1.733	2.050	0.000	0.000

T: t test value; SD: standard deviation; NIPS: Neonatal Infant Pain Scale

Statistical Analysis

Data were evaluated using descriptive statistical methods (number, percentage, average, standard deviation). In the study, the variants were detected to display normal distribution by applying the normal distribution Kolmogorov–Smirnov test. The relationship between qualitative grouped variants was determined using chi-square analysis. For comparing quantitative data, the t-test was used for intergroup differences, while the matched group t-test was used for intra-group comparison of measurements. Collected data were evaluated in 95% confidence interval with 5% significance level.

Limitations and Difficulties

Mechanic vibration for pain control was applied to term newborn infants for 5 seconds right before heel prick. It is posited that continuous mechanic vibration application throughout the heel prick procedure would yield a higher efficiency. Unfortunately, this assumption was not realized throughout the procedure since all the phases of the application were performed by a single researcher, and no assistant personnel was available. Throughout, mechanic vibration is suggested for further studies.

Ethical Aspects of the Study

Prior to the study, Ethical Committee Approval and Application Permission Letter were received from Training and Research Hospital's Research Evaluation Commission (No:23.06.2012,23D).

Written consent was received from the mothers of newborns included in the sample group, having informed all custodians about the objective and method of application of the study in detail and that the entire procedure will be recorded on camera solely for scientific purposes.

Oral sucrose 24% was applied to both groups. Both groups were also applied a non-pharmacological method routinely used in clinics in painful procedures with proven analgesic effect and ethical guidelines were followed.

RESULTS

In the study, newborn infants in both groups were homogenous in terms of descriptive properties. No statistically significant difference was found with respect to gestation age, postnatal age, gender, mean weight, mean height, mean head circumference and last feeding time between newborn infants in both groups ($p>0.05$).

Findings Related to Physiological Alterations

For all the newborn infants included in the study, HR and SPO_2 values were measured using oximetry for four times: pre-sucrose, preprocedural, periprocedural, and postprocedural. The difference between HR and SPO_2 values was found to statistically insignificant for both groups ($p>0.05$; Table 1 and 3).

Findings Related to Behavioral Response

NIPS was used to evaluate newborn pain response. According to mean scores derived from the scale, an intergroup comparison was performed. Pre-sucrose and preprocedural NIPS mean scores were 0 in both groups due to the hold off until newborns were tranquilized prior to application (Table 4).

The difference between groups' median scores were found to be statistically significant in the outcome of the t-test carried out to determine a difference in terms of the group variant in the periprocedural NIPS mean scores of the newborns ($t=0.000$; $p=0.000<0.05$). Peripro-

cedural NIPS mean scores of the control group (x=3.567) was found to be higher compared to the experimental group (x=0.967; Table 4).

The difference between groups' median scores was found to be statistically significant in the outcome of the t-test carried out to determine a difference in terms of group variant in the postprocedural NIPS mean scores of participants (t=0.000; p=0.000<0.05). Postprocedural NIPS mean scores of the control group (x=4.533) were found to be higher compared to the experimental group (x=1.733; Table 4).

Reliability and validity coefficient for NIPS were calculated using the Cronbach alpha method. Periprocedural Cronbach alpha coefficient of NIPS scoring system was 0.85, while postprocedural coefficient was 0.87.

DISCUSSION

The sample was selected by considering the homogeneity of both groups. Therefore, criteria were formed to determine certain traits in all included newborn infants. Sample selection criteria developed during the study show resemblance with other examples in literature (6, 12, 13).

The effective factors concerning pain perception and response in newborn infants include the gestational age, postnatal age, gender, type of labor, environmental factors, type and duration of painful stimuli, severity of disease, experiences, and feeding status (11, 14). In our study, no significance was shown between the gestational age, postnatal age, gender, type of labor, birth measurements, type and last status of feeding, and homogeneity.

The most important problem in pain response evaluation in newborn infants is the inability of verbal expression. This problem is resolved through observing physiological and behavioral changes. In the study, HR and SPO_2 values were measured using pulse oximetry. No statistically significant result was obtained with regard to HR and SPO_2 mean values between both the groups in pre-sucrose, preprocedural, periprocedural, and postprocedural phases (p>0.0). This outcome shows the effect of sucrose on both groups.

As in similar studies in literature, no statistically significant difference was found between both groups with respect to HR and SPO_2 mean scores in our study (12).

Physiological parameters are not solely sufficient for evaluation of pain response. Behavioral aspects must also be evaluated besides physiological output. Several validated and reliable scales were developed for use in clinics to cope with the diagnosis problem in the measurement of pain response. One of these scales is NIPS.

In our study, the behavioral pain response was evaluated four times: pre-sucrose, preprocedural, periprocedural, and postprocedural. Pre-sucrose and preprocedural NIPS total mean scores were 0 for both the groups because pre-application parameters had been set to no pain for evaluation purposes.

In our study, the periprocedural NIPS total mean scores were 0.9±1.7 for the experimental group and 3.5±1.7 for the control group. The difference between the mean scores of both groups was statistically significant. In addition, the pain score of control group was not drastically high, as an indication of sucrose. Use of mechanic vibration alongside sucrose caused NIPS total scores to decrease even further.

Postprocedural NIPS total mean was 17±2.0 in the experimental group and 4.5±1.9 in control group, indicating a statistically significant difference in terms of comparative mean scores of both groups. This outcome again indicates the increased efficacy of mechanic vibration used in combination with sucrose.

In a study comparing emla and oral sucrose solution in pain prevention for intravenous blood draw in term newborn infants, Karaayvaz (12) and Unaldı (13) found the NIPS mean scores to be in favor of sucrose (12, 13).

Baba et al. (6), in her study combining sucrose and mechanic vibration similar to the present study, found the NIPS mean score to be 0.10±0.32 in pre-sucrose experimental group and 0.70±1.49 control group. While mean score was 0.00±0.00 in the preprocedural experimental group, it was 0.90±1.52 in the control group. The mean scores for the periprocedural experimental group was 1.70±1.70, while the control group was 3.30±2.54. Postprocedural results were 0.10±0.32 for the experimental group and 0.60±0.84 for the control group (6).

Results of our study are similar to that of Baba et al. (6), where sucrose efficiency as non-pharmacological pain prevention method was bolstered when combined with another non-pharmacological method, namely mechanic vibration.

The reliability and validity coefficient for NIPS were calculated using the Cronbach alpha method. Periprocedural Cronbach alpha coefficient of NIPS scoring system was 0.85, while postprocedural coefficient was 0.87. According to the study by Lawrence et al (9), for NIPS, the Pearson correlations ranged from 0.92 to 0.97 across successive minutes of observation. The six component scores of the NIPS had high internal consistency: the Cronbach's alpha values were 0.95, 0.87, and 0.88 for before, during, and after the procedures, respectively. In the study adapted to Turkish by Akdovan (10), the Cronbach's alpha values were 0.83 and 0.86 for during and after the procedures, respectively (10, 11). These values indicate that the study is highly reliable.

CONCLUSION

Importance of multiple non-pharmacological pain prevention methods have been understood and effect of mechanic vibration in decreasing pain perception have been detected. Mechanic vibration can be recommended in newborn infants to decrease pain perception. Hence, pain prevention would be managed with a cheap, easily available, and applicable instrument.

The Cronbach's alpha coefficient for NIPS scoring system was 0.85 periprocedurally, and 0.87 post procedurally; reliability of the study was found to be high. NIPS can be applied as a reliable measurement device for pain perception in newborn infants.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Medeniyet University Göztepe Reseacrh and Education Hospital (No:23.06.2012,23D).

Informed Consent: Written informed consent was obtained from the parents of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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