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The effect of Buzzy application on pain and comfort level during heel stick in newborns: a randomized controlled study

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ABSTRACT

Aims: The aim of this study was to evaluate the effects of the Buzzy device application on pain levels and comfort in newborns during heel stick procedures.

Methods: This randomized controlled experimental study was conducted at a Family Health Centre affiliated with the Public Health Directorate in a province in eastern Turkey between September and November 2024. The sample included 80 newborns born at 37–42 weeks of gestational age within the first 28 days of life (Buzzy group: n=40; control group: n=40). In the Buzzy group, the Buzzy device was applied approximately 30 seconds before the heel stick procedure. In the control group, the procedure was performed without any intervention. Data collection tools included the neonatal introduction form, the neonatal infant pain scale (NIPS), and the neonatal comfort behavior scale (NCBS). Ethical principles were adhered to throughout the study.

Results: Pain levels and comfort scores during the heel stick procedure were significantly better in the Buzzy group compared to the control group ($p<0.001$). Analysis revealed that, in the control group, pain levels increased significantly, and comfort levels decreased markedly during the procedure. In contrast, the Buzzy group exhibited a more limited increase in pain levels and a less pronounced decrease in comfort. After the procedure, the pain scores were significantly lower, and comfort levels were higher in the Buzzy group compared to the control group ($p<0.001$).

Conclusion: The Buzzy device was found to be an effective method for significantly reducing pain and maintaining comfort in newborns during heel stick procedures. These findings suggest that the Buzzy device can be a valuable tool for pain management and enhancing comfort in clinical settings. Future studies could explore the effectiveness of the device in larger populations and compare it with other pain management strategies.

Keywords: Buzzy, newborn, pain, comfort, heel stick, nursing

INTRODUCTION

Heel stick blood collection is a critical preventive health service performed globally.[1] However, it causes significant pain and stress in newborns[2], which disrupts their comfort.[3] Invasive procedures that impair comfort can negatively affect the biopsychosocial development of newborns.[2] Due to their higher density of nociceptors compared to adults, neonates perceive pain more intensely[4,5], making pain a more pronounced stressor for this age group.[6,7]

Pain during medical procedures can lead to adverse physiological consequences, including decreased blood oxygen saturation (SpO_2), increased heart rate, heightened oxygen demand, and elevated intracranial pressure, which raises the risk of intraventricular haemorrhage.[8] Furthermore, pain and stress can weaken an infant's immune system, increasing susceptibility to infections.[5] Research indicates that painful experiences during infancy may negatively affect brain development and predispose individuals to inadequate pain responses later in life. Repeated exposure to pain in early life may also hinder the healthy development of organs.[9,10]

Reports suggest that newborns undergo approximately 98 painful procedures within the first 14 days of life, with most performed without drug-based or non-drug pain management interventions.[11] Evidence highlights that healthcare providers address pain management in only 20% of these procedures[12], and more than half are performed without any measures to alleviate pain.[5,13] Heel pricking is a common painful procedure used for screening, diagnostics, and emergencies. Repeated punctures may have long-term negative effects on pain processing and stress responses in infants.[5,14]

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Non-pharmacological interventions have demonstrated efficacy in reducing pain and regulating physiological and cognitive responses in infants.[15-17] However, many non-pharmacological methods are underutilised by healthcare professionals due to the need for preparation, complexity of application, and the potential to extend procedural time.[18,19] The Buzzy device offers a simple, time-efficient solution. This device combines vibration and cold application to naturally block pain within seconds. By physiologically suppressing pain signals through the combination of cold and vibration, the Buzzy device effectively reduces acute procedural pain.[20-22] The Buzzy device has been found to be effective in minimizing pain and anxiety during immunizations, blood draws, and sample collections in children aged 2 to 18 years.[20,23-25] However, there is limited information in the literature on its use in infants under 2 years of age.[26]

Based on the gate control theory, vibratory stimuli compete with pain signal transmission along the spinal cord-thalamic pathway, potentially reducing the perception of pain in neonates.[27] Providing comfort, ensuring safety, and protecting health are core professional and ethical responsibilities of nurses, particularly when caring for neonates. However, effectively reducing pain and maintaining comfort in newborns continues to be a major difficulty for nurses.[3,27,28] Among pain management strategies, drug-free methods are prioritized in neonatal nursing.[25]

Thus, this study aims to evaluate how effective the device is in this age group, focusing on newborns' pain experience and overall comfort. In this regard, it seeks to provide scientific evidence for the potential application of Buzzy as a drug-free pain relief method in neonatal nursing.

Study hypotheses;

H_1: There is a notable variation in the pain measurements of newborns in the Buzzy group relative to the control group.

H_2: There is a notable variation in the comfort levels of newborns in the Buzzy group relative to the control group.

METHODS

Ethics

Ethical approval was granted by the Van Yüzüncü Yıl University Non-interventional Clinical Researches Ethics Committee (Date: 16.06.2023, Decision No: 2023/06-02). Written and verbal informed consent was obtained from the parents. The randomized controlled study followed CONSORT guidelines, ensuring adherence to ethical principles throughout the research. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Design

This research utilized a randomized controlled experimental design.

Place and Time

The research was carried out between September and November 2024 in a Family Health Centre, selected through a lottery method, under the Public Health Directorate in an eastern region of Turkey.

Population and Sample

The study population consisted of 80 newborns registered at the Family Health Centre, born at 37–42 weeks of gestation, and presenting at the health institution for routine heel prick blood collection within the first 28 days of birth.

The sample size was estimated with the G-power 3.1 software. Considering an effect size of 0.5 and a power of 0.95, at least 35 infants were required per group. To account for potential losses and ensure group homogeneity, the final sample size included 40 infants in both the control and Buzzy groups (**Figure 1**).

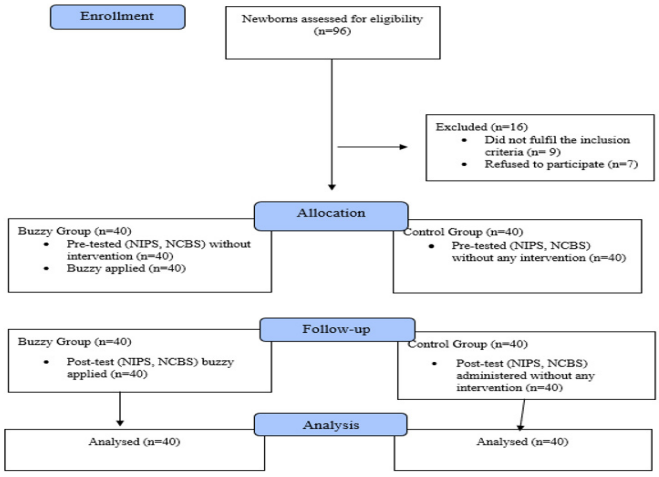

Figure 1. CONSORT 2022 flow diagram[29]

Inclusion Criteria

Newborns fulfilling the following conditions were enrolled in the research: neonates aged 0–28 days, having a gestational age ranging from 37 to 42 weeks, with vital signs within normal limits, and whose parents voluntarily consented to take part in the study.

Exclusion Criteria

Infants were excluded from the study if they had compromised skin integrity at the application site of the device, if they exhibited nerve impairment or deformity in the limb where the heel blood was to be drawn, or if they had inherited conditions, congenital abnormalities, metabolic disorders, or osteogenesis imperfecta. Additionally, infants who required cardiopulmonary resuscitation, had failed the first attempt at heel blood collection, had received analgesics within the last six hours, or had other conditions deemed unsuitable for the study were excluded.

Data Collection Tools

The instruments used for data collection comprised the neonatal introduction form, the neonatal infant pain scale (NIPS), and the neonatal comfort behaviour scale (NCBS).

The Neonatal Introduction Form

The Neonatal Introduction Form was created based on an analysis of existing studies in the field.[18,22,27] This form

includes questions regarding gestational age, gender, type of delivery, length, birth weight and the age of the mother.

The Neonatal Infant Pain Scale (NIPS)

The NIPS, created by Lawrence et al.[30], assesses pain responses in preterm and term newborns. Scores range from 0 to 7, with values above 3 indicating pain. The Turkish adaptation, validity, and reliability of the NIPS were established by Akdovan[31], with Cronbach's alpha values reported as 0.83 before and during the procedure, and 0.86 afterward.

Neonatal Comfort Behaviour Scale (NCBS)

NCBS, created by Ambuel et al.[32], evaluates comfort, pain, and stress in neonates on mechanical ventilation in intensive care. The Turkish adaptation of the scale was validated by Kahraman et al.[33] It includes items rated from 1 to 5. A total score below 13 indicates comfort, while 14 or higher suggests discomfort, requiring further intervention.

Implementation of the Intervention

The heel blood collection room was specially prepared to ensure the comfort of the infants and their stability during the procedure. The room temperature was kept between 24-26°C, and measures were taken against air flow and sudden temperature changes to prevent babies from getting cold. Lighting was adjusted so that it was neither too bright nor inadequate, and harsh lights shining directly into the infants' faces were avoided. Instead, diffused and soft light sources were used to create an environment that does not disturb the eyes of the babies. A comfortable environment was created for the babies, and care was taken to ensure that the babies could not see each other during the procedure. Parents were allowed to be with their babies throughout the process. The procedure took place in the unit's designated blood collection room. Infants meeting the sampling criteria were initially assessed by a family physician.

In order to ensure equal distribution between the groups, buzzy and control groups were determined by simple randomisation method using Random Allocation Software.[34]

Buzzy Group

Mothers of eligible infants for heel prick were informed by the observation nurse, and verbal and written consent were obtained. The procedure's purpose and details were explained. Then, the data collection form was completed. For Buzzy use, a deep-frozen ice pack was left at room temperature for 10 minutes before being attached to the device. During the procedure, it was placed below the knee, aligning with the sural nerve, 30 seconds before the heel prick. One nurse performed the procedure, while another recorded videos before, during (15-20 seconds), and five minutes after.[35] These recordings were evaluated by two experts NIPS and the NCBS to analyze the effectiveness of the procedure. After use, the ice pack was cleaned with 70% alcohol and placed back in the deep freezer for re-freezing (**Figure 2**).

Control Group

No pain relief device or method was used for the control group during the heel prick. The first nurse performed the procedure by collecting blood directly from the heel, while the second nurse recorded videos before, during (15-20 seconds), and five minutes after. Two experts analyzed the recordings using NIPS and NCBS to evaluate pain levels and comfort in the control group infants.

Figure 2. Buzzy device

Statistical Analysis

All statistical analyses were conducted using SPSS 26.0 for Windows. Continuous variables were summarized as mean, standard deviation, minimum, and maximum values, while categorical variables were presented with frequency and percentage distributions. Chi-square analysis was used to compare categorical variables between the control and Buzzy groups. The skewness and kurtosis values of the study scales were within ±1.5 in both groups, indicating normal distribution. Therefore, an Independent-samples T-test was applied to compare scale scores between groups. ANOVA was used to analyze variations in scale scores before, during, and after the heel prick, with the Bonferroni test applied for post-hoc comparisons. A p-value of <.05 was considered statistically significant.

Clinical Study Registration

The randomized controlled study was registered on the ClinicalTrials.gov website under ClinicalTrials ID No. NCT06773325 (https://www.clinicaltrials.gov) on January 2, 2025, with the Clinical Trial Registry.

RESULTS

In the control group, 30% of the babies were born at the 38th and 40th gestational weeks, 57.5% were female, 57.5% were born vaginally, 72.5% weighed between 3000-3490 g, and 85% had a birth length between 46-50 cm. Additionally, 65% of the mothers were aged between 26-35 years. In the Buzzy group, 32.5% of the babies were born at 39 weeks, with a 50% distribution between girls and boys, 55% were born by caesarean section, 65% weighed between 3000-3490 grams, and 85% were 46-50 cm tall. Furthermore, 67.5% of the mothers in the Buzzy group were aged between 26-35 years.

These findings revealed that there was no statistically significant difference between the Buzzy and control groups in variables such as gestational week, gender, mode of delivery, birth weight, birth length, and maternal age, indicating a general similarity between both groups (p>0.05, **Table 1**).

There was no significant difference between the NIPS scores observed before the heel prick in the control and Buzzy groups, with both groups having a pain level of zero. However,

Table 1. Demographic characteristics of the participants

Variable	Category	Control group		Buzzy group		Total		X^2	p
		n	%	n	%	n	%		
Gestational week	37th week	6	15.0	6	15.0	12	15.0	.820	.845
	38th week	12	30.0	12	30.0	24	30.0		
	39th week	10	25.0	13	32.5	23	28.7		
	40th week	12	30.0	9	22.5	21	26.3		
Gender	Girl	23	57.5	20	50.0	43	53.8	.453	.501
	Boy	17	42.5	20	50.0	37	46.3		
Birth type	Vaginal birth	23	57.5	18	45.0	41	51.2	1.251	.263
	Cesarean birth	17	42.5	22	55.0	39	48.8		
Weight	2500-2990 g	6	15.0	8	20.0	14	17.5	.540	.763
	3000-3490 g	29	72.5	26	65.0	55	68.8		
	3500-4000 g	5	12.5	6	15.0	11	13.8		
Length	46-50 cm	34	85.0	34	85.0	68	85.0	.000	1.000
	51 cm and above	6	15.0	6	15.0	12	15.0		
Mother's age	18-25 years	9	22.5	10	25.0	19	23.8	.571	.751
	26-35 years	26	65.0	27	67.5	53	66.3		
	36 years and above	5	12.5	3	7.5	8	10.0		

when the pain levels during the procedure were analyzed, the NIPS scores of the infants in the control group (6.00±0.93) were significantly higher than the NIPS scores of the infants in the Buzzy group (3.33±0.73) (t=14.276; p<0.001). Similarly, the NIPS scores of the infants in the control group (4.57±0.84) were significantly higher than the NIPS scores of the infants in the Buzzy group (1.58±0.68) (t=17.557; p<0.001). The ANOVA test results also indicated significant differences between the measurement times for both groups (p<0.001). The Bonferroni multiple comparison test following the repeated measures ANOVA test revealed the time periods during which these differences occurred.

These findings show that the pain level during the procedure was lower in the Buzzy group compared to the control group, and the pain decreased more after the procedure (**Table 2**).

Table 2. Comparison of NIPS scores of control and Buzzy groups

Time	Control group $\bar{X}$±SD	Buzzy group $\bar{X}$±SD	t	p
Before heel stick procedure	a.00±.00	a.00±.00		
During heel stick procedure	b6.00±.93	b3.33±.73	14.276	<.001*
After heel stick procedure	c4.57±.84	c1.58±.68	17.557	<.001*
F	942.896	417.309		
P	<.001*	<.001*		
Difference	a<c<b	a<c<b		

*p<.05, a,b,c.: Indicates the statistical difference between procedures according to the Bonferroni multiple test result, NIPS: Neonatal infant pain scale, SD: Standard deviation

It was determined that the NCBS scores of the babies before the heel stick blood collection were significantly lower in both the control (6.53±0.87) and Buzzy (6.78±0.92) groups, and the comfort levels of the babies were statistically similar (p>0.05). When the NCBS scores during the procedure were analysed, it was found that the mean score of the infants in the control group (26.43±2.39) was significantly higher than the mean score of the infants in the Buzzy group (13.73±1.54) (t=28.319; p<0.001). These results show that the comfort levels of the infants in the control group during heel prick were significantly lower than those in the Buzzy group. In fact, the mean score of the Buzzy group (13.73±1.54) was smaller than the cut-off score of 14 for the scale, and it was concluded that the comfort of the babies in this group did not deteriorate at all according to the scale evaluation criteria.

Similarly, the NCBS scores of the infants in the control group (17.15±3.01) were significantly higher than the mean score of the infants in the Buzzy group (9.63±1.85) after the procedure (t=13.233; p<0.001). These results show that the comfort levels of the babies in the control group were significantly lower than those in the Buzzy group after the procedure (**Table 3**).

Table 3. Comparison of comfort-NCBS scores of control and Buzzy groups

Time	Control group $\bar{X}$±SD	Buzzy group $\bar{X}$±SD	t	p
Before heel stick procedure	a6.53±.87	a6.78±.92	-1.245	.217
During heel stick procedure	b26.43±2.39	b13.73±1.54	28.319	<.001*
After heel stick procedure	c17.15±3.01	c9.63±1.85	13.233	<.001*
F	4588.194	229.135		
P	<.001*	<.001*		
Difference	a<c<b	a<c<b		

*p<.05, a,b,c.: Indicates the statistical difference between procedures according to the Bonferroni multiple test result, NCBS: Neonatal comfort behavior scale, SD: Standard deviation

In addition, according to the ANOVA test results, it was observed that there were significant differences between the measurement times for both groups in NCBS (p<0.001). The Bonferroni multiple comparison test performed after the

repeated measures ANOVA test determined between which time periods this differentiation occurred. The decrease in comfort level was less in the Buzzy group compared to the control group. Furthermore, it was found that the comfort level in the Buzzy group reached a level closer to the pre-procedure level in the post-procedure period (**Table 3**).

DISCUSSION

Heel stick is one of the most painful procedures performed in newborns.[36] The fact that their nervous systems are not fully developed makes newborns vulnerable to the neurodevelopmental effects of pain.[5] Various non-drug techniques are commonly utilized to manage pain during heel stick blood collection. These include swaddling, breastfeeding, heel warming, non-nutritive sucking, skin-to-skin contact, positioning strategies, therapeutic touch, foot massage, reflexology, and vibration therapy.[35,37-44] However, these applications may create additional time, effort, and stress on parents and nurses.[45]

Therefore, research supports the use of Buzzy, a device that is easy to use, reusable, cost-effective, and fast, as it has positive effects on pain management, especially by combining mechanical vibration and cold application. These mechanisms are believed to block pain messages and temporarily alleviate pain.[20,46,47] These effects can be explained within the framework of the pain gate theory, which suggests that the brain has the ability to 'switch off' or 'switch on' pain signals, and that external stimuli (e.g., cold or mechanical vibration) can influence this process.[48] The Buzzy device appears to alleviate pain based on this theory, with newborns reporting lower pain scores during procedures.[49,50] Buzzy has been found effective in managing pain in children and has been used in various settings such as intramuscular[20,51], subcutaneous[21], intravenous[47], blood sampling[48,52] and dental extractions.[53] There are also studies that demonstrate pain reduction with mechanical vibration alone[35,54] or cooling alone.[55,56]

However, no studies have been found in the literature evaluating the effectiveness of the Buzzy device in alleviating pain during the heel prick procedure. In this study, the Buzzy device was observed to significantly reduce pain during and after the procedure compared to the control group ($p<0.05$) (**Table 2**). These results support the hypothesis H1: "There is a notable variation in the pain measurements of newborns in the Buzzy group relative to the control group". It is believed that this effect can be explained by the gate control theory, which prevents the transmission of pain messages to the nervous system. Additionally, this device was found to be effective in alleviating pain in newborns during the heel prick procedure and is expected to make a significant contribution to the literature on this topic.

In neonatal nursing care, ensuring the comfort of the baby is a basic requirement to prevent the negative effects of pain and stress.[57] Many non-drug methods used during painful procedures in newborns help enhance comfort by alleviating pain.[58] Some studies have shown that skin contact, auditory interventions, holding, breastfeeding, foot massage, and heel warming effectively enhance infant comfort during heel blood collection.[3,43,59-61] Newborns react to pain severity with body movements such as crying, alertness, and changes in muscle tone. Tension in the body, along with facial and bodily movements, plays a key role in assessing their comfort. Multisensory stimuli have been found effective in soothing newborns and enhancing comfort during painful procedures.[60,61]

This study found that the Buzzy device significantly improved neonatal comfort levels compared to the control group during and after the procedure ($p<0.001$) (**Table 3**). These findings support the research hypothesis. H2: "There is a notable variation in the comfort levels of newborns in the Buzzy group relative to the control group" The Buzzy device was found to be effective in providing comfort to newborns by blocking pain messages with mechanical vibration and cold applications, and this effect is thought to be supported by the pain gate theory.

Limitations

This study possesses several notable strengths. First, it employed a randomized controlled trial design, widely regarded as the gold standard for evaluating intervention effectiveness. The sample size was calculated using robust statistical methods to ensure sufficient power, and strict inclusion criteria were applied to minimize confounding variables. The use of validated tools such as the NIPS and NCBS ensured the reliability and validity of the findings. Moreover, the analysis of video recordings by two independent evaluators enhanced the objectivity of the data.

However, the study is not without limitations. The sample was derived from a single center, which may limit the generalizability of the results to other settings or populations. The short follow-up period restricted the ability to assess the long-term effects of the Buzzy device on neonatal pain perception and comfort. Additionally, the intervention was not blinded, as the use of the Buzzy device was visually apparent, which could introduce observer bias despite independent evaluation. Finally, the study did not consider the psychological or physiological responses of parents, which could have provided a more comprehensive understanding of the intervention's broader impact.

CONCLUSION

This study demonstrated that the Buzzy device effectively reduced pain and enhanced comfort in newborns during heel blood collection. These findings suggest that the Buzzy device should be integrated into neonatal pain management protocols in clinical settings The pain-relieving and comfort-enhancing effects of mechanical vibration and cold applications, which influence the nervous system according to the pain gate theory, support the clinical use of the device. The preference of healthcare professionals for such non-pharmacological interventions in painful procedures can significantly contribute to minimizing pain and stress in newborns. Future studies should investigate its effectiveness in procedures such as venipuncture, lumbar puncture, or vaccination. Widespread use of the Buzzy device in nursing care could enhance care quality, improve pain management, and increase patient satisfaction.

ETHICAL DECLARATIONS

Ethics Committee Approval
Ethical approval was granted by the Van Yüzüncü Yıl University Non-interventional Clinical Researches Ethics Committee (Date: 16.06.2023, Decision No: 2023/06-02).

Informed Consent
Written and verbal informed consent was obtained from the parents.

Referee Evaluation Process
Externally peer-reviewed.

Conflict of Interest Statement
The authors have no conflicts of interest to declare.

Financial Disclosure
The authors declared that this study has received no financial support.

Author Contributions
All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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