Randomised Controlled Trial

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Effectiveness of facilitated tucking on reducing pain during heel stick in neonates: a randomized controlled experimental study

Rejeena Subedi, MSc[a,*], Mukesh Bhatta, MD[b], Ramananda Chaudhary, MSc[a], Basant K. Karn, MSc[a], Upendra Yadav, MSc[a], Shankar P. Yadav, MD[b]

Background: Pain in neonates is associated with adverse neurodevelopmental outcomes in the later days of life. Facilitated tucking is a nonpharmacological method of pain relief. The study aims to compare the effect of facilitated tucking in pain reduction in neonates.

Materials and methods: This was a randomized controlled experimental study conducted in the neonatal ward of a tertiary care center. There were 25 neonates randomized each in the experimental and control groups (total of 50), based on computer-generated random tables. The experimental group was placed in a facilitated tucking position during heel stick, while the control group was kept in the usual position, as done routinely. A self-structured questionnaire and Neonatal Infant Pain Scale were used. The main outcome measures were the mean Neonatal Infant Pain Scale score, and change in preprocedure and postprocedure heart rate and oxygen saturation in the two groups. Ethical clearance and informed written consent were sought.

Results: Neonates in the experimental group had significantly lesser pain (less Neonatal Infant Pain Scale score) than the neonates in the control group ($P < 0.001$). There was also a significant increment in the mean heart rate and a decrease in the oxygen saturation after the procedure in the control group, indicating significantly more pain perception ($P < 0.001$) in the control group.

Conclusions: Facilitated tucking was found to be effective in reducing the pain during heel stick procedures in neonates.

Keywords: facilitated tucking, heel stick, neonate, Neonatal Infant Pain Scale, pain

Introduction

Pain is a distressing condition associated with actual or potential tissue damage[1]. It is in the early intrauterine life that pain perception develops. Hence, neonates and small children experience pain similar to that of older children[2–4]. Repeated exposure to pain during the neonatal period may lead to altered pain threshold, behavioral disorders, and adverse neurologic and cognitive outcomes in later life[5–8].

Treatment of a neonate in the hospital setting involves a number of painful procedures meant for diagnostic and therapeutic purposes. The most common painful procedures, like routine injections, sampling, routine blood tests, heel sticks, etc., occur mostly without pain management[9,10].

Pain relief can be achieved by various pharmacological and nonpharmacological methods. The danger with pharmacological methods like side effects, overdose, the burden of extra medication, etc., always remains a concern[11,12]. Similarly, various other nonpharmacological methods exist, but their safety and efficacy over one another is still not established[13,14]. Tucking is a simple and convenient nonpharmacological method of pain relief. It is a sub-form of the method of nesting the baby where the body is brought to the midline by holding the upper and lower extremities in flexion with hands.[14,15] This position decreases the pain by enabling heat and touching stimuli, preventing painful stimuli, and stimulating the infant's regulatory systems. Additionally, this position stabilizes infants' physiological parameters, helps them gain a feeling of safety, supports their motor development, and preserves their energy[16–25].

HIGHLIGHTS

- Neonates in the experimental group (kept in the facilitated tucking position) had significantly lesser pain perception than control.
- Neonates in the experimental group (kept in the facilitated tucking position) had lesser periprocedural physiological derangements than the control group, suggesting lesser pain perception in the experimental group.
- Facilitated tucking is effective in reducing periprocedural pain during heel prick procedures in neonates.

[a]Department of Child Health Nursing and [b]Department of Paediatrics and Adolescent Medicine, B.P. Koirala Institute of Health Sciences, Dharan, Province 1, Nepal

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*Corresponding author. Address: Department of Child Health Nursing, B.P. Koirala Institute of Health Sciences, Dharan, Sunsari, Province 1 56700, Nepal. Tel.: +977 986 130 2482. E-mail: rejeenaatyou@hotmail.com (R. Subedi).

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The application of tucking in newborns prior to a painful but mandatory procedure like a heel prick will help to reduce pain in neonates. This study will help to establish the role of tucking in pain reduction in neonates prior to painful procedures like heel prick. This study will also fill the gap in the knowledge regarding the efficacy of tucking in reducing pain among nurses and health care workers, thus promoting pain-free nursing care of the newborn.

The objectives of this study were to compare the Neonatal Infant Pain Scale score and preprocedure and postprocedure physiological parameters (heart rate and oxygen saturation) between the experimental and control groups.

Methods

Study design

This was a randomized controlled experimental study design conducted in line with CONSORT criteria[26]. The study has been duly registered in the research registry (Research Registry Unique Identifying number researchregistry10145, https://www.researchregistry.com/browse-theregistry#home/registrationdetails/66067a701534c9002911d6c/).

Ethics consideration

Ethical clearance was obtained from the Institutional Review Committee (code number IRC/1285/018, December 10, 2018). Informed written consent was obtained from the parents in local language. Confidentiality was maintained throughout the study. It was made clear to parents that they could leave the study at any time.

Participants

The study population included 50 term neonates with stable vitals and birth weight above 2.5 kg, undergoing heel prick. Neonates who were born preterm; low birth weight; received analgesics/sedatives/muscle relaxants within last 24 h; those with known neurological conditions (hypoxic ischemic encephalopathy grade II or III, meningitis, etc.); those receiving positive pressure ventilation, inotropes and those with gross congenital anomalies were excluded from the study.

Study settings

The study was conducted in the Neonatal Ward of a tertiary care referral center in Nepal. The study was conducted over 12 months, from September 2018 to August 2019.

Study tools

Data was collected using predesigned proforma consisting of two parts. The first part contained sociodemographic data and clinical parameters (age, sex, birth weight, length, gestational age, heart rate, and oxygen saturation), while the second part contained the Neonatal Infant Pain Scale.

Neonatal Infant Pain Scale

This was used in the study to assess the level of pain perceived by the neonate based on certain parameters. The Neonatal Infant Pain Scale is a behavioral scale and can be useful for both term and preterm infants. Lawrence and colleagues developed this scale to evaluate the behavioral and physiological pain responses of preterm and term infants. This scale has six indicators. Each behavioral indicator is scored with 0 or 1 except 'cry,' which has three possible descriptors, therefore, is scored with a 0, 1, or 2. Each indicator need to be assessed by observing the infant for a full 1 min. Total pain scores range from 0 to 7[27,28]. The details are given in Table 1.

The validity of the tool was done by reviewing literature and consultation through subject experts[29–31]. Pretesting of the tool was done to assess its feasibility and practicability. Pretesting of the tool was done in 10% (five neonates) of the total sample size in the neonatal ward. Pretesting was done prior to the data collection period. Those infants who were included in the pretesting were not included in the study.

Sample size

The sample size was calculated using the following:

Based on a previous study done by Kucukoglu *et al.*[32], the prevalence of not experiencing pain was 50% (P1) in the intervention group, while the prevalence of experiencing pain was 96% (P2) in the control group.

The required sample size to detect the minimum difference between the proportion of those who experienced pain in the intervention group (P1) and the proportion of those who experienced pain in the control group (P2) with a 95% confidence interval ($\alpha = 5\%$) and power of 80% will be:

$$n = \frac{P1(1-P1) + P2(1-P2) \times f(\alpha, \beta)}{(P2-P1)^2}$$

$$= \frac{0.5(1-0.5) + 0.96(1-0.96) \times 15.37}{(0.96-0.5)^2}$$

$$= 20.94$$

Considering the 20% dropout rate in each case and control group, the estimated sample size comes out to be 25 in each group; 50 in total.

Intervention

Consecutive sampling was used for the selection of the sample. Neonates were randomly allocated into experimental and control groups based on a computer-generated random table in an allocation ratio of 1:1. The relevant demographic profile and clinical profile, including a brief history, general examination findings (sex, gestational age, birth weight, length, and head circumference) were entered in a predesigned proforma.

The procedure in both the experimental and control groups was done by on-duty registered nurses, whoever was posted on that particular day. The registered nurses who did the procedure had work experience of at least 1 year in the neonatal ward. The registered nurses were given an educational program 1 week prior to the data collection regarding the procedure of heel stick and facilitated tucking before the data collection, and the return demonstration was assessed by the registered nurses by the researchers.

In the experimental group, there were three on-duty registered nurses involved. The first on-duty registered nurse kept the neonate in the tucking position, the second did the heel stick, and the

Table 1

Neonatal Infant Pain Scale.

Parameters	0 point	1 point	2 points
Facial expression	Relaxed (restful face, neutral expression)	Grimace (tight facial muscles; furrowed brow, chin, jaw (negative facial expression – nose, mouth, brow)	–
Cry	No cry	Whimper (mild moaning, intermittent)	Vigorous crying
Breathing pattern	Relaxed	Change in breathing (in drawing, irregular, faster than usual; gagging breath holding)	–
Arms	Relaxed/restrained (no muscular rigidity; occasional random movements of the arms)	Flexed/extended (tense, straight arms; rigid and/or rapid extension/ flexion)	–
Legs	Relaxed/restrained (no muscular rigidity; occasional random movements of the legs)	Flexed/extended (tense, straight legs; rigid and/or rapid extension/ flexion)	–
State of arousal	Sleeping/awake (quiet peaceful, sleeping or alert, random leg movements)	Fussy (alert, restless and thrashing)	–

Pain level: 0–2 points = no pain, 3–4 points = moderate pain, > 4 points = severe pain.

third recorded the vital parameters. A heel stick was used as a part of the routine treatment, and not solely for the purpose of the study. Each neonate in the experimental group was placed in the tucking position. To implement facilitated tucking, the nurse put the neonate on his/her side, with his/her back gently bent, the legs getting up and flexion at an angle greater than 90°, and the shoulders also constricted up to 90° and the nurse's one hand placed over the arms and legs and the other hand over the neonate's head close to the mouth or on the neonate's face. The second nurse did the heel stick in the medial or lateral aspect of the planter surface of the baby's foot using a manual lancet after wiping it with cotton soaked in normal saline. The videography was done by the researcher with a camera. The researcher assessed that the on-duty nurses adhered to the study protocol. In case the baby cried during the positioning prior to the heel stick, the nurse waited till the baby calmed down, and then performed the prick. If the baby did not calm down, then the baby was excluded, as the recording of the Neonatal Infant Pain Scale and vital parameters would be inaccurate. The video recording was done from the view in which the neonate's facial expression and limb movements were best visualized. That was either from the side or the top, depending on which position is used for tucking. The video recording aimed to capture the facial expression, cry, breathing patterns, limb movements, and state of arousal of the baby. The video recording was started 15 s before, during, and up to at least 60 s after the procedure. Meanwhile the third nurse recorded the heart rate and oxygen saturation 1 min before and 1 min after the procedure from a monitor. Videography was done so that the video could be analyzed separately by the pediatrician and calculate the Neonatal Infant Pain Scale. The Neonatal Infant Pain Scale score was assessed after analyzing the video recording by a pediatrician based on certain parameters mentioned in Table 1.

The procedure in the control group was done by two on-duty nurses, whoever was posted on that particular day. The videography was done by the researcher. The first on-duty nurse did the heel stick, while the second recorded the vital parameters. Neonates in the control group were not placed in any particular position. The rest of the procedure for the heel stick, video recording, and recording of physiological parameters were the same as in the intervention group. The flow diagram for the study is shown in Figure 1. None of the subjects enrolled in either group were harmed or had an unintended effect.

Randomization and blinding

Randomization was achieved by computer-generated random tables. The researcher was involved in generating the computer-generated random tables, enrolling participants, and assigning them to intervention.

Since the study involves a particular position, which is obviously visible during the intervention, videography, and video interpretation, blinding could not be achieved. However, serial numbers were given to the video to minimize the observer bias of the pediatrician who analyzed the video and provided the Neonatal Infant Pain Scale score.

Outcome

The primary outcome of the study was the Neonatal Infant Pain Scale score after the heel prick, while the secondary outcome was the change in the heart rate and oxygen saturation before and after the heel prick.

Operational definitions

Effectiveness

It is the degree to which facilitated tucking is successful in reducing pain during heel stick. This was assessed by comparing postprocedure Neonatal Infant Pain Scale scores and preprocedure and postprocedure physiological parameters (heart rate and oxygen saturation) between the experimental and control groups.

Term neonate

Neonates who are delivered after 37 weeks of gestation.

Facilitated tucking

Holding the infant's arms and legs in flexed positions close to the midline of the torso, either in a supine or lateral position.

Pain

Pain refers to the response of the neonate to painful stimuli (heel stick) as measured by the Neonatal Infant Pain Scale, that is, Neonatal Infant Pain Scale score > 3 refers to felt pain.

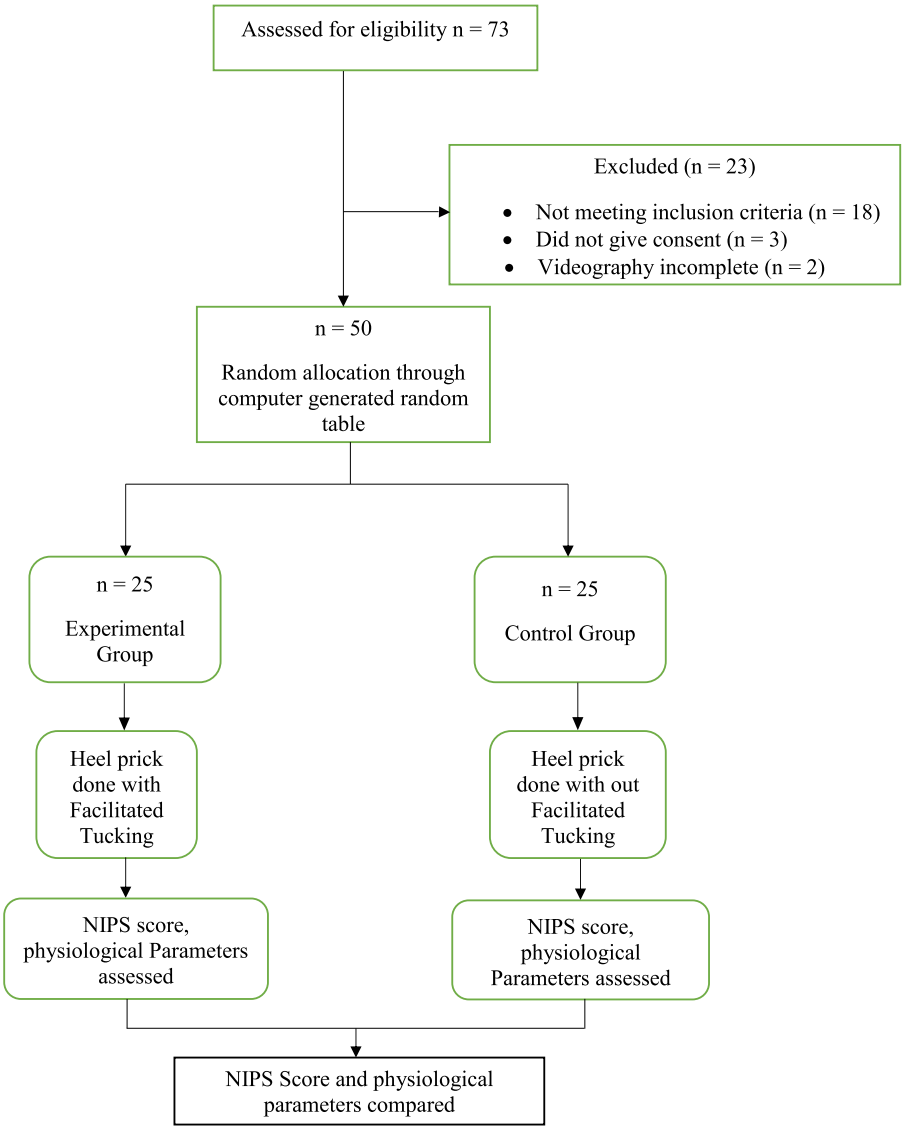

Figure 1. Flow diagram.

Heel stick

A procedure in which a newborn baby's heel is pricked with a manual lancet at the medial and lateral aspect of the plantar surface of the foot, and then a small amount (one drop) of blood is collected for glucose estimation.

Data analysis

After completion of data collection, the physiological parameters and the obtained Neonatal Infant Pain Scale score were entered in a predesigned proforma. Data was taken, and sequential coding was performed. Data was entered in MS Excel, transferred to SPSS, version 20, and analyzed. Videos were deleted after analysis of data. Descriptive statistics, such as mean, median, and SD were used to analyze the data. χ^2 test and Fisher's exact test were used for the analysis of categorical data and to compare different variables in the experimental and control groups. Quantitative data was compared among the experimental and control groups using the Student *t* test or Mann–Whitney *U* test, as per the need. After the analysis of data, the results were presented through tabulations and graphs.

Results

In the study, 73 neonates were assessed for eligibility, out of which 23 were excluded because of reasons like not meeting inclusion criteria, parents unwilling to participate, and incomplete videography. The study was done among 50 neonates meeting the inclusion criteria. There was a male preponderance. Half of the neonates were less than 3 days old. The incidence of spontaneous vaginal delivery and lower segment cesarean section were almost similar. Nearly half (48%) of the neonates had four to six painful procedures in the last 24 h. The predominant mode of feeding was mother's breast feed. The baseline demographic and clinical characteristics, including age, sex, mode of delivery, number of painful procedures in the last 24 h, and feeding pattern

Table 2

Baseline demographic and clinical characteristics of neonates.

Characteristics	Experimental group [*n* (%)]	Control group [*n* (%)]	Total [*n* (%)]	*P*
Age group (days)				
< 3	12 (48)	13 (52)	25 (50)	0.77[a]
3–28	13 (52)	12 (48)	25 (50)	
Sex				
Male	16 (64)	19 (76)	35 (70)	0.36[a]
Female	09 (36)	06 (24)	15 (30)	
Mode of delivery				
SVD	15 (60)	11 (88)	26 (52)	0.258[a]
LSCS	10 (40)	14 (56)	24 (48)	
Number of painful procedures in last 24 h				
0–3	11 (44)	09 (36)	20 (40)	0.465[b]
4–6	10 (40)	14 (56)	24 (48)	
> 6	04 (16)	02 (08)	06 (12)	
Feeding pattern				
MBF only	24 (96)	23 (92)	47 (94)	0.552
Mixed feeding	01 (04)	02 (08)	03 (06)	

LSCS, lower segment cesarean section; MBF, mother's breast feed; SVD, spontaneous vaginal delivery.
[a]χ^2 test.
[b]Fisher's exact test.

Table 3

Association of position with pain score.

Pain score	Tucking *n* (%)[b]	Nontucking *n* (%)[b]	Total	*P*
No pain (NIPS score 0–2) (%)	13 (26)	02 (4)	15 (30)	< 0.001[a]
Moderate pain (NIPS score 3–4) (%)	09 (18)	02 (4)	11 (22)	
Severe pain (NIPS score > 4) (%)	03 (6)	21 (42)	24 (48)	

[a]Fisher exact test.
[b]Percentage of total population.

(mothers breast milk only or mixed feeding) were comparable among the experimental and control groups. The details are presented in Table 2.

Anthropometric measurements of the neonates were done. The mean birth weight (kg) was 3.01 ± 0.46 in the experimental group, while it was 3.11 ± 0.4 in the control group. Similarly, the mean length (cm) of the neonates in the experimental and control groups were 50.5 ± 1.6 and 50.3 ± 1.7, respectively. Likewise, the mean head circumference (cm) in the experimental group was 33.1 ± 1.1 while that in the control group was 33.2 ± 1. The mean birth weight, length, and head circumference were comparable among the experimental and control groups with *P* value of 0.42, 0.67, and 0.77, respectively.

There were 13 neonates (26%) who had no pain in the tucking position. Nine neonates (18%) had moderate pain when kept in the tucking position, while the remaining three (6%) experienced severe pain. Contrary to the findings in the experimental group, 21 (42%) had severe pain in the control group, and the result was statistically significant. This shows that neonates who underwent tucking experienced less pain, while those who were not kept in the tucking position experienced severe pain, as shown in Table 3.

Similarly, the median (interquartile range) Neonatal Infant Pain Scale score of the neonates in the experimental group [2 (1, 4)] was lower than that of the control group [5 (5, 6.5)] and this was found to be statistically significant ($P < 0.001$).

The comparison of preprocedure (1 min prior to procedure) and postprocedure (1 and 5 min after procedure, respectively) physiological parameters (heart rate and oxygen saturation) between experimental and control groups were made. It was observed that the preprocedural heart rate and oxygen saturation were comparable among the experimental and control groups. However, the mean heart rate, 1 and 5 min after the procedure, was significantly higher in the control group ($P < 0.001$). The increase in heart rate in the control group suggests a greater perception of pain. Similarly, a statistically significant decrease in the oxygen saturation was noted in the control group both 1 and 5 min after the heel stick, while there was no such decrease in the treatment group. The decrease in oxygen saturation was, however, clinically not significant, unlike the heart rate, which showed clinically demonstrable tachycardia. The details of the physiological changes are given in Table 4.

In the study, a heel stick was used as a part of the routine treatment, and not solely for the study purpose. So, no harm or extra pain was inflicted on the participant.

Discussion

Neonates are exposed to various painful procedures, be it a healthy neonate during routine vaccinations or a sick neonate during various diagnostic and therapeutic procedures. Nonpharmacological methods for pain relief have been made due to their ease, no risk of overdose, and side effects. Facilitated tucking is one such valuable alternative for pain control during brief invasive procedures like heel sticks performed on newborns. There have been several studies done in the past to study the effectiveness of facilitated tucking among neonates undergoing various painful procedures. This study has been done to study the effectiveness of facilitated tucking in neonates undergoing heel prick.

In this study, the number of neonates in the age group of less than 3 days and between 3 and 28 days were equal. A male preponderance was noted in the study. This is in accordance with the previous hospitalization records. The possible reason for this male preponderance may be the unusual attention given to the male newborn child in our society. Spontaneous vaginal delivery and lower segment cesarean section were the modes of delivery depending on the obstetric indications, and both of them were almost equal in number. Most of the newborns had around one to six painful procedures within the last 24 h. This number of painful procedures depicts the other routinely done procedures like pushing medication from the intravenous site, blood sample collection, etc., as is being routinely done in all hospitalized neonates. The anthropometric measurements like birth weight, length, and head circumference were comparable in both experimental and control groups, suggesting the otherwise uniform distribution of the study subjects. Additionally, the age, sex, mode of delivery, feeding pattern, and number of painful procedures prior to the procedure were comparable among the experimental and control groups, which is similar to the study done by Kucukoglu *et al.*[32] in the past.

In this study, it was observed that neonates in the experimental group had lower Neonatal Infant Pain Scale scores than the ones in the control group. This suggests that tucking position significantly reduces the pain perception in newborns. The findings of our study are similar to the findings of Kucukoglu *et al.*[32] and Axelin *et al.*[17], which were done during vaccination and suctioning respectively. Likewise, Hartley *et al.*[23] demonstrated that

Table 4

Comparison of preprocedure and postprocedure physiological parameters between experimental and control groups ($n = 50$).

	Experimental group	Control group	
Characteristics	**Mean ± SD (range)**	**Mean ± SD (range)**	***P***
Heart rate 1 min prior to heel stick (beats per minute)	132 ± 7.1 (128.8–135.5)	129.5 ± 5 (126.5–137.9)	0.10[a]
Heart rate 1 min after heel stick (beats/min)	139.9 ± 6.6 (136.3–143.5)	160.6 ± 10.1 (136.6–152.12)	< 0.001[a]
Heart rate 5 min after heel stick (beats per minute)	135.3 ± 6.4 (132–138.7)	143.1 ± 7.5 (131.2–141.2)	< 0.001[a]
SPO2 1 min prior to heel stick (%)	96.2 ± 2.6 (93.1–96.4)	95.24 ± 2.1 (95.5–97.6)	0.17[a]
SPO_2 1 min after heel stick (%)	93.5 ± 2.5 (90.7–94)	90.2 ± 3.6 (92.4–95.11)	< 0.001[a]
SPO2 5 min after heel stick (%)	94.6 ± 2.1 (92.7–95.1)	92.2 ± 2.3 (93.4–96.3)	< 0.001[a]
Total	25 (50%)	25 (50%)	

[a]Independent Student *t* test.

facilitated tucking reduced the expression of pain in premature infants. Similar was the findings done by Alinejad-Naeini *et al*.[25], Ward-Larson *et al*.[15], Lopez *et al*.[19], and Obeidat *et al*.[14].

The study also aimed to find any significant change in the physiological parameters like heart rate and oxygen saturation after pain stimuli in both experimental and control groups. In the control group, there was a statistically significant increase in the mean heart rate and a decrease in the oxygen saturation 1 and 5 min after the pain stimuli. This suggests that the tachycardia and fall in oxygen saturation were due to the increased pain perception in the control group. Similar to these findings were the findings of the study done by Corff *et al*.[33]. The effects of pain on the physiological parameters were also demonstrated by Hill *et al*.[18] and Oktaviani *et al*.[34] in their study, and the findings of their studies respectively corroborate with the findings of this study.

Studies done in the past separately by Reyhani and colleagues, Axelin and colleagues, Corf and colleagues, and Oktaviani and colleagues demonstrated that facilitated tucking significantly reduced the duration of crying after the painful procedure. The duration of crying might have been reduced because of the lesser pain perception due to the facilitated tucking position. However, the duration of crying after the procedure in both groups was not studied in this study[17,33–35].

There were some studies that contradicted the findings of this study. Kaur and colleagues did a study on 60 preterm infants to assess the effects of facilitated tucking during heel prick. They concluded that facilitated tucking was not effective in reducing the level of pain among the experimental group during the heel lance procedure and at 1, 2, and 3 min after the heel lance procedure when provided just prior to the heel lance procedure[36].

There were no harms or adverse events reported during the study in both the experimental and control groups.

Limitations

There are certain limitations in this study. The procedure was done by on-duty nurses, who were posted on that particular day. The same group of nurses could not be involved in the procedure for all participants. This could have led to individual differences in the quality of the procedure performed. Also, neonates who had received painful procedures on the same day prior to the heel stick might have had a different pain perception as compared to those who had received only a single painful stimulus. This could be minimized in future studies by including only those neonates who have not received any painful stimuli on the day of intervention.

For calculating the Neonatal Infant Pain Scale score, the state of the lower limbs (relaxed or flexed/extended/tense) need to be observed. By looking at the position of the limbs, one can make out whether the child is in tucking or nontucking (classical) positioning. This might lead to bias in the expert who is analyzing the video.

Breastfeeding might decrease the pain score in some babies. However, maximum efforts were made not to do the procedure immediately after breastfeeding. No efforts were made by the authors to stop or postpone breastfeeding solely for the purpose of eliminating bias due to breastfeeding. A small sample size is also another limitation of this study.

Conclusions

Pain management is a challenging aspect of the treatment of any neonate. There has been increasing interest generated over the recent years in the nonpharmacological methods of pain management. Facilitated tucking is an effective nonpharmacological method of pain reduction in newborns undergoing any painful procedure. Facilitated tucking decreases the pain and also prevents physiological derangements like tachycardia and fall in oxygen saturation that occur due to pain. Facilitated tucking is thus a simple, inexpensive, and effective way of analgesia in newborns. Keeping this fact in mind, it can be used as a method of pain relief during painful minor procedures like heel sticks. In the near future, other similar studies comparing the efficacy of facilitated tucking with other nonpharmacological methods can be carried out.

Ethical approval

Ethical clearance was obtained from the Institutional Review Committee (code number IRC/1285/018, December 10, 2018) of B.P. Koirala Institute of Health Sciences, Dharan, Nepal.

Consent

Informed written consent was taken in the local language from the parents.

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None.

Author contribution

R.S. was involved in the literature search, data collection, analysis, interpretation, and drafting of the initial manuscript. R.C.,

B.K.K., and U.Y. were responsible for conceptualizing the study, facilitating manuscript writing, and approving the final manuscript. S.P.Y. and M.B. contributed expert input in the literature search and facilitated manuscript writing. All authors have seen and approved the final manuscript.

Conflicts of interest disclosure

The authors declare no conflicts of interest.

Research registration unique identifying number (UIN)

The researchers are from a poor, underdeveloped nation and have financial constraints when registering the research.

Guarantor

All authors.

Data availability statement

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Provenance and peer review

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