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Facilitated Tucking on Pain in Pre-Term Newborns During Venipuncture

A Randomized Controlled Cross-Over Trial

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SUMMARY

IMPORTANCE The preterm infant is more vulnerable to painful experiences during early life, resulting in long-term developmental and psychological problems. Venipuncture is a common invasive procedure in neonatal care and can elicit significant pain in preterm infants. Pain management, such as facilitated tucking (FT), becomes a vital component of neonatal care.

AIMS The purpose of this study was to evaluate the effectiveness of FT in preterm neonates during the venipuncture procedure.

METHODS A randomized controlled crossover study was conducted in perinatology units at hospitals in East Java, Indonesia, from 23 October to 20 November 2019. Preterm neonates requiring venipuncture were included. Each participant received facilitated tucking (FT) and non-facilitated tucking (NFT) in alternating order, with a minimum 24-hour washout period between interventions. Infant characteristics were obtained from medical records, and pain responses were assessed one minute after venipuncture using the Neonatal Infant Pain Scale (NIPS). Data was analyzed using SPSS, with the Wilcoxon test used to compare pain scores between intervention conditions ($p < 0.05$)).

FINDINGS Eighteen preterm infants were included, with gestational ages of 30–34 weeks (median 32 weeks) and birth weights of 840–2358 g (median 1610 g). The FT condition resulted in significantly lower pain scores than the NFT condition (median NIPS 5 [IQR 5] vs. 6 [IQR 0]; $p = 0.009$; $r = 0.62$).

CONCLUSION Facilitated tucking (FT) is effective intervention for relieving pain during the venipuncture procedure among preterm neonates.

RELEVANCE TO CLINICAL PRACTICE Facilitated tucking (FT) should be integrated into standard neonatal nursing protocols for procedural pain relief during venipuncture.

ETHICS APPROVAL AND FUNDING This study was obtained from the ethical committee of DR. Saiful Anwar Hospital by ethical clearance number 400/184/K.3/302/2019.and no specific funding.

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1. INTRODUCTION

Globally, approximately 19.8 million babies are born preterm each year, accounting for 14.7% of total live births—about one in every seven babies (UNICEF-WHO, 2023). In low- and middle-income countries, the prevalence can reach up to 40%, and Indonesia ranks fifth worldwide, with around 779,000 preterm births annually, representing 15% of all live births. About 15% of these neonates are born before 32 weeks of gestation and require intensive care in the Neonatal Intensive Care Unit (NICU) (Lee et al., 2019). Preterm infants frequently undergo numerous invasive and painful procedures necessary for survival and optimal outcomes (Lopez et al., 2015). Studies report that preterm neonates experience 34 painful procedures in the first two weeks of life and up to 14 painful procedures per day, yet only 40–60% receive adequate pain management (Bellieni et al., 2018; Simons et al., 2003).

Repetitive procedural pain during the neonatal period can have serious implications. Evidence shows that repeated painful stimuli may cause brain atrophy, altered pain reactivity, and adverse neurodevelopmental outcomes (Bayat, 2021; Cignacco & Sellam, 2015; Hartley et al., 2015). Preterm neonates, due to immature neurological systems, are particularly vulnerable to the long-term consequences of uncontrolled pain, including lowered pain thresholds, cognitive impairment, and behavioral disorders (Lopez et al., 2015). Physiological instability, such as fluctuations in heart rate, blood pressure, and oxygen saturation, can also occur during painful stimuli (Bayat, 2021). Based on the recommendation of the American Academy of Pediatrics (AAP), painful procedures in the NICU should be minimized, and that clinicians receive proper training in neonatal pain assessment and management (Davari et al., 2018; Lavoie et al., 2015). Thus, effective pain management constitutes a crucial component of neonatal intensive care.

Pharmacological management of pain in preterm infants remains controversial due to potential side effects such as respiratory depression, dependence, and seizures (Hartley et al., 2015). Therefore, non-pharmacological methods are increasingly emphasized as safer and cost-effective alternatives for procedural pain management, particularly for reducing pain associated with repeated invasive procedures during hospital treatment. One commonly used method, non-nutritive sucking, carries the drawback of potential nipple confusion, highlighting the need for other simple, non-invasive interventions (Lopez et al., 2015).

Facilitated tucking (FT) is a gentle, non-pharmacological intervention involving supportive containment of the infant with the limbs flexed toward the midline while maintaining comfort and mobility (Lopez et al., 2015; Yang et al., 2023). As tactile sensitivity develops by the 32nd week of gestation, this method provides both physiological and emotional stabilization during stressful procedures (Pekyiğit & Açıkgöz, 2023). Some relevant studies have proven that FT can decrease physiological deterioration and enhance behavioral regulation during painful interventions (Hartley et al., 2015). However, studies examining FT's effect on pain among preterm neonates in Indonesia are scarce. A quasi-experimental study by Oktaviani et al. (2018) assessed FT during blood collection, focusing on heart rate, oxygen saturation, and crying duration (Oktaviani et al., 2018). Building upon this evidence, the current study adopts a randomized cross-over design and incorporates the Neonatal Infant Pain Scale (NIPS) to comprehensively assess behavioral pain responses. This study aims to evaluate the effectiveness of facilitated tucking in relieving pain among preterm neonates during venipuncture procedures in the NICU.

2. METHODS

2.1 Study Design and Participants

The randomized cross-over trial experimental study design means that all samples receive two interventions, namely facilitated tucking (FT) and routine care or non-facilitated tucking (NFT). This study recruited 18 preterm neonates with gestational age are ranging from 32 to 36 weeks who needed venipuncture, and from whom parental consent was obtained after explaining the study and procedure by the researcher. Neonates who were breathing unassisted by positive airway pressure, receiving paralytic or sedative medication within 48 hours, having any surgery, having intraventricular hemorrhage (grade III-IV), disorders of the extremities, Downey Score ≥ 6, and who died or were discharged from the hospital during the data collection procedure were excluded. The minimum sample size was determined using the numerical comparative research formula of the two-group crossover with significance at the 0.05 level, 80 % power, and using data from the previous similar study (standard deviation 2,9; mean of first group 95,5; mean of second group 94,05, and 20 samples) (Oktaviani et al., 2018). The minimum sample size obtained from this formula was 15 samples. Data collection was conducted from 23 October to 20 November 2019.

2.2 Features

2.2.1 Study Tools

The demographics data were collected from neonates' the medical record to assess gender, gestational age, weight. The neonates' pain responses during venipuncture were collected from the Neonatal Infant Pain Scale (NIPS) observational sheet. NIPS is a valid instrument for assessing pain response in infants and this instrument has often been used in research (Campbell-Yeo et al., 2022; Hartley et al., 2015). NIPS was used to evaluate the behavioral responses (facial expression, cry, arms, and legs movement, and state of arousal) of preterm and term infants. All indicators are scored between 0 and 1 point, except crying and heart rate indicators, which have 3 possible scores of 0 to 2 points. The total score ranges from 0 to 10 points, and a higher score indicates more pain. The NIPS score was divided into 3 pain levels: 0 to 3, mild to no pain, 4 to 6, mild to moderate pain, and greater than 6 signifies severe pain (Hartley et al., 2015).

2.2.2 Intervention

The venipuncture for blood sampling in the perinatology unit based on the physician's judgment. At the time of the study, pain management only used verbal comfort during painful interventions. Before the intervention, the second author gave a full explanation to the parents about the procedure of this study, and the pain management using FT would only be applied if the parents consented. Procedures in this study consist of the implementation of facilitated tucking, the administration of venipuncture, and pain observation using the NIPS observational sheet. All procedures were conducted by the trained nurse of the perinatology unit with a minimum of a bachelor's degree in nursing, having a Nursing Professional Registration Certificate (STR), a Neonatology Nursing Training Certificate, and a minimum of 5 years of working experience in the neonatology unit. The inter-rater reliability test was calculated for agreement analysis among two independent observers, and a good result was found (Kappa coefficient = 0,6)

All infants were placed in a supine position for at least 10 minutes before the administration of the intervention. During venipuncture procedures without FT, neonates did not receive any pain management and only received verbal comfort from the nurse. While the venipuncture procedure with FT intervention, three nurses perform assigned roles for each participant's preterm infant. One nurse implements facilitated tucking (FT) by positioning the baby on one side. One nurse's hand flexes the baby's arms and legs more than 90 degrees to the body axis and holds the buttocks, while the other nurse holds the baby's head. This intervention was performed 2 minutes before venipuncture. One other nurse performed venipuncture under the hospital standard operating procedure (SOP), and other nurses, as observers, assessed pain experience by the NIPS instrument. Observers scored the NIPS by evaluating the pain experience 1 minute after the venipuncture procedure.

2.2.3 Randomization

All of the preterm newborns participating in this research received two interventions. Participants were alternately allocated to the intervention (FT) and control (NFT) groups based on the order of venipuncture procedures. The first infant received FT, followed by the next infant receiving the control condition (NFT) first. In the subsequent venipuncture (after a minimum 24-hour washout period), participants received the alternate intervention. This sequence procedure continued until all participants were included.

2.3 Data Preparation

Data were prepared by editing, coding, data entry, and data cleaning to ensure completeness and consistency of data from all the respondents. The data editing process was done by ensuring the completeness of demographic data from patient medical records and reviewing the Neonatal Infant Pain Scale (NIPS) observation sheets filled out by observers and clarified with the observers when necessary. Next, coding was performed by assigning each participant a code to maintain confidentiality and to facilitate tracking of intervention sequences within the crossover design. For categorical data, codes were assigned based on the measurement scale of each variable (gender, gestational age, birth weight, pain level).

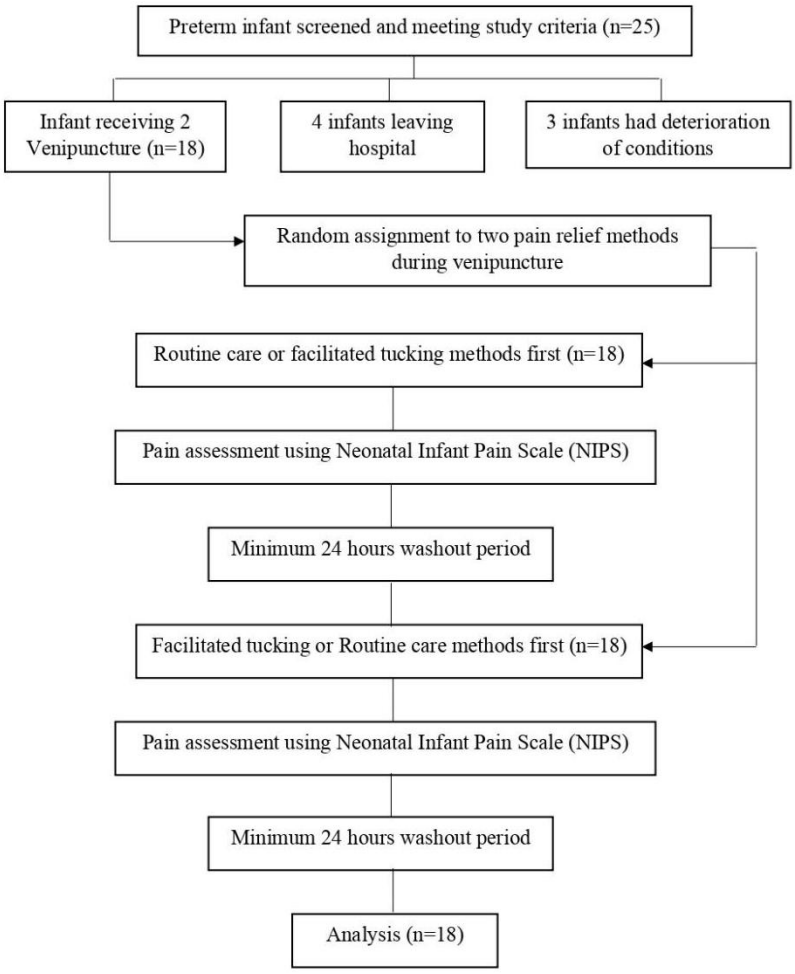


Figure 1. Flowchart of participants' recruitment

2.4 Statistical Tests

Data management and analysis were performed using SPSS 21.0. The Shapiro-Wilk test was used to assess the normality of NIPS scores, and the data were not normally distributed. Differences in pain scores were tested using the Wilcoxon test, with a significance level of $p < 0.05$.

3. RESULTS

3.1 Basic Characteristics of Participants

The demographic characteristics of participants included in this study were provided in Table 1, where each neonate served as their own control in a crossover design. The variables consist of sex, prematurity category, birth weight category, mean birth weight, and median gestational age.

Table 1. Demographic characteristics (neonates served as their control)

Characteristics	Statistic
Sex – n (%)	
Male	8 (44.4)
Female	10 (55.6)
Prematurity category – n (%)	
Moderate preterm	11 (61.1)
Late preterm	7 (38.9)
Birth weight category – n (%)	
ELBW	1 (5.5)
VLBW	5 (27.8)

Characteristics	Statistic
LBW	12 (66.7)
Birth weight – mean (SD)	1647 (454.4)
Gestational age – median (SD)	32 (30-34)

ELBW: Extremely low birth weight; VLBW: Very low birth weight; LBW: Low birth weight

In the study, 25 neonates met criteria as participants, of whom 4 neonates were excluded because of leaving the hospital before completing the intervention, and 3 neonates had deterioration of their conditions. The final participants who participated in this study were 18 neonates with a mean birth weight of 1647 grams. Other characteristics were that the majority of samples were female (55.6%), and the rest were male. Their gestational age varies from 30 to 34 weeks (median 32 weeks), consisting of 61% moderate preterm (32-34 weeks) and 39% late preterm (34-36 weeks). The birth weights (BW) of participants ranged from 840 to 2358 grams (mean 1610 grams), and consisted of 5% extremely low birth weight (ELBW, < 1000 g), 28% very low birth weight (VLBW, 1000-1499 g), and 67% low birth weight (LBW, 1500-2499 g) (Table 2).
(Table 2 is around here.)

3.2 Comparison of mean NIPS scores of the groups

The univariate analysis of the pain level on both interventions, facilitated tucking (FT) and non-facilitated tucking (NFT), was provided in Table 3. The pain levels were categorized into three scales: no pain to mild pain, mild to moderate pain, and severe pain, that presented in frequency and percentage.

Table 2 Pain level frequencies during venipuncture procedure with and without facilitated tucking

Pain Level	FT group		NFT group	
	n	%	*n*	%
No pain to mild	7	38.9	*0*	*0*
mild to moderate pain	10	55.6	16	88.9
Severe pain	1	5.6	2	11.1

The group that received FT during the venipuncture procedure had a higher proportion of no pain to mild pain compared to the NFT group (38.9% vs 0%), while the NFT group had a higher proportion of moderate and severe pain compared to the FT group (88.9% and 11.1% vs 55.6% and 5.6%) (Table 3).

Table 3 Comparison of Neonatal Pain Scores (NIPS) Between FT and NFT group

Variable	FT group Median (IQR)	NFT Group Median (IQR)	p-value	Effect Size
NIPS	5 (5)	6 (0)	0.009	0.62

The pain response in the FT group was lower than the NFT group, as indicated by the median NIPS score being lower in the FT than in the NFT group (5 [IQR 5] vs. 6 [IQR 0]). The Wilcoxon rank test also showed a statistically significant difference between the two conditions ($p = 0.009$), with a large effect size ($r = 0.62$). The large effect size indicates that facilitated tucking had a substantial impact on reducing pain in preterm neonates during venipuncture.

4. DISCUSSION

The characteristics data showed a slightly higher proportion of female neonates than male (55.6% vs 44.4%), indicating a relatively balanced distribution of sex. This result was different from previous studies, which state that preterm birth is more common in males, with around 55% of all preterm births, and is associated with a higher risk of dying when compared to girls born at a similar gestation (Kent et al., 2012). Research on the gender influences on the differences in efficacy for non-pharmacological therapy stated that newborn and preterm males tolerate fewer painful stimuli, such as a painful procedure. This may be due to bilateral somatosensory cortical activation being less frequently found in females (Migliori et al., 2023).

In terms of birth weight, most of the respondents were neonates with low birth weight (1500–2499 grams) of 66.7%, with a mean birth weight of 1647 g (SD 454.4). Birth weight is one of the important factors in neonatal pain perception, as lower birth weight may contribute to increased sensitivity to pain and altered physiological responses. Regarding the prematurity, the majority of participants were

classified as moderate preterm (61.1%). Moderate and late preterm infants generally have more mature neurological and physiological systems, which may influence their capacity to respond to painful stimuli and non-pharmacological interventions (Campbell-Yeo et al., 2022).

Preterm infants are more vulnerable to pain exposure, and they have ineffective coping with pain exposure, as shown by their physiological and behavioral changes. The Changes in infant response during venipuncture were used to evaluate the effect of the FT intervention in the study, in the form of the NIPS score. The reduction of the NIPS score reflected an infant's adaptation to painful stimuli. The presence of someone who can provide calmness and a gentle touch can help minimize the pain response. Pre-term newborns experience multiple painful procedures during their hospital stay for various diagnostic and therapeutic procedures (Assefa et al., 2022). One of the most commonly painful procedures performed in the neonatal unit is venipuncture for blood collection. Nonpharmacological methods for pain relief have been developed due to their ease, no risk of overdose, and minimal side effects; however, with varying degrees of efficacy. Facilitated tucking is one of the most frequently used nonpharmacologic interventions for pain relief during invasive procedures like venipuncture performed on preterm newborns. Some previous studies had been done to investigate the effect of facilitated tucking to relieve pain in neonates during invasive procedures, and this study was conducted to determine the effect of facilitated tucking in premature infants during venipuncture procedures.

The higher proportion of neonates who experienced a lower pain level was found in the FT group compared with those in the NFT group during the venipuncture procedure. This is based on the distribution of pain levels, which showed that neonates suffering no pain to mild pain during venipuncture were higher in the FT group compared to the NFT group (38.9% vs 0%). Conversely, the proportion of neonates with mild to moderate pain and severe pain was observed to be higher in the NFT group (88.9% and 11.1% vs 55.6% and 5.6%) (Table 3).

The Wilcoxon test results revealed that the facilitated tucking intervention (FT) can alleviate pain effectively during the venipuncture procedure. This can be observed from the NIPS median score of the FT group, which was lower compared to the routine care group 5 (IQR 5) vs 6 (IQR 0), with p value p.009 (p value > 0.05). Furthermore, the effect size of 0.62 indicates that the effect of FT on pain reduction is included in the large category, so this finding is not only statistically significant but also clinically meaningful. The results of our study are consistent with the findings of (Kucukoglu et al., 2015), which were done during vaccination and research from Axelin et al., (2006) during the suctioning procedure.

Recent research has shown that pain experienced in the newborn during the first life period can negatively impact an infant's brain, neurodevelopment, and pain reactivity (Ranjbar et al., 2020). This effect should be managed by pharmacological and non-pharmacological methods. The developmental care techniques and an environment organization as a non-pharmacological method can support the infant's ability to cope with stress and pain stimuli, which can help infants feel pain relief (Kucukoglu et al., 2015). This study used facilitated tucking, including a developmental care technique that helps infants preserve their energy, feel safe, calm themselves, and reduce their oxygen consumption (Axelin et al., 2006; Hill et al., 2005). The facilitating tucking (FT) procedure was conducted by placing infants on their sides, and their legs were in a flexion angle of greater than 90 degrees. Preterm infants have an ineffective ability to put themselves in a flexion position during pain stimuli; they cannot use this comfort position by themselves to cope with stress during painful procedures (Alinejad-Naeini et al., 2014).

Facilitated tucking is a non-pharmacological intervention that is feasible, safe, and beneficial for infants of all gestational ages in managing pain during a repeated painful procedure such as venipuncture, thereby minimizing the adverse effects caused by pharmacological agents (Cai et al., 2023). Facilitated tucking involves gentle touching and positioning of the baby (Pekyiğit & Açıkgöz, 2023). The gentle touching through FT causes an endogenous release of endorphins and reduces the level of cortisol and adrenaline, which helps to regulate pain impulses and has the effect of relieving pain (Cai et al., 2023). Because of that, babies can calm down more quickly after the pain procedure because this method contributes to the babies' recovery after the painful procedure (Bayat, 2021), as indicated by the improvement of physiological and behavioral responses after the pain procedure (Axelin et al., 2006). FT alleviates pain stimulation by preventing nociceptive transmission by distracting babies' attention from the painful stimulus (Hatfield et al., 2019). FT ensures tactile-kinesthetic stimulation for relieving procedural pain and declining behavioral stress during care procedures (Sundaram et al., 2013). The Baby positioning in FT helps infants to get that comfortable position like a utero posture, resulting in both pacifying the baby through tactile stimuli by a gentle touch and allowing the baby to assume the physiological position that will provide the best protection (Alinejad-Naeini et al., 2014; Hartley et al., 2015; Pekyiğit & Açıkgöz, 2023). In addition, the nurse's gentle touch without strong restraining also allows the baby to use the self-regulation skill, such as bringing hands to mouth and grasping, to better

cope with minor pain and stress (Pekyiğit & Açıkgöz, 2023) In the context of family-centered care, health workers can encourage parents in providing FT during invasive intervention, which can benefit both infants and parents (Lavoie et al., 2015).

4.1 Strengths and Limitations

The cross-over design provides methodological advantages in which each participant serves as their own control, thereby minimizing inter-individual variability. This approach improves efficiency by requiring a relatively small sample size. However, our study had some limitations, including the absence of physiological measurements and the inability to blind the nurses who performed the venipuncture procedure. Furthermore, pain responses were measured only once after venipuncture. Future research should include post-intervention measurements at multiple times. which would have answered the further research question of the effect of FT during the recovery phase of venipuncture.

4.2 Implications for Practice and Policy

The findings of this study demonstrate that facilitated tucking (FT) is an effective non-pharmacological intervention for reducing pain during venipuncture in preterm infants. These results have important implications for practice, education, and policy. In clinical practice, FT can be integrated into routine pain management procedures in neonatal intensive care units (NICUs) due to its feasibility, safety, and low cost. From an educational perspective, FT should be incorporated into nursing curricula and clinical training programs to ensure healthcare providers are competent in its application. At the policy level, these findings support the development of standardized guidelines and protocols that promote the use of FT and other evidence-based non-pharmacological interventions, as well as encourage family involvement in neonatal care.

5. CONCLUSION

The Conclusion should provide a concise summary of the overall contribution of the study, directly reflecting the main findings and their significance. This section should not introduce new results or interpretations but should clearly state what the study adds to existing knowledge, emphasizing its relevance to nursing and healthcare practice while remaining consistent with the observational nature of the research.

Author Contributions

SA: Conceptualization; Writing – original draft; Writing – review & editing; Formal analysis; ND: Methodology; Formal analysis; Investigation; Project administration; RE: Supervision; Methodology; Writing – review & editing.

Ethical Approval and Consent

The approval of this study was obtained from the ethical committee of DR. Saiful Anwar Hospital by ethical clearance number 400/184/K.3/302/2019.

Generative AI Transparency Statement

The authors acknowledge the use of Generative AI tools (ChatGPT Plus) to assist in language refinement and to help identify relevant content with a percentage of less than 10%. All authors are fully responsible for the content and accuracy of the research results.

Conflict of Interest Disclosure

The authors declare that they have no conflict of interest.

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Data Availability Statement

All data resulting from this study are available for academic purposes on request of the corresponding author, [SA]. The data is not available publicly to maintain the confidentiality of respondents' information

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