Effect of gentle manual pressure on neonatal pain during heel prick: a randomised crossover trial

Abstract

This is a randomised, open-labelled, crossover trial. The data collected came from healthy, term neonates with physiological jaundice in a neonatal unit of an acute public hospital in Hong Kong. Nine babies received 10 seconds of gentle manual pressure over the needle stick site immediately prior to the stick on the first day of the data collection. They received no manual pressure before the heel stick on the second day of the data collection. Eight babies received the intervention in the reverse order. The researcher measured the babies' reactive responses to pain with the Neonatal Infant Pain Scale (NIPS) at scheduled time slots. No adverse reaction caused by the intervention was observed. The pain score during the heel prick was significantly lower with the prior manual pressure than with the heel prick that was performed without manual pressure (p=0.01).

Keywords

Neonate | Pain | Heel prick | Experimental study | Crossover study

Heel prick tests are one of the most common needle-related painful procedures performed on neonates in hospitals (Carbajal, 2008). Various studies have suggested that acute episodic pain can cause early neurological injury in neonates. Repeated and prolonged exposure to pain may even alter subsequent psychokinetic development, as well as affect long-term neurodevelopmental, behavioural and social-emotional outcomes. Examples include increased sensitivity to pain, prolonged hyperalgesia after acute painful stimuli and decreased visual perceptual ability later in life (American Academy of Paediatrics et al, 2007; Bouza, 2009; Walker et al, 2009a; Doesburg et al, 2013). The American Academy of Paediatrics and other paediatrics organisations have jointly stated that health workers are encouraged to use nonpharmacological methods to reduce pain in minor, routine procedures such as heel prick tests (American Academy of Paediatrics et al, 2007). Many studies have been conducted aiming to reduce pain during heel prick tests by nonpharmacological means. For example, Ramenghi et al (1996) have found that sucrose solutions significantly reduce neonate crying time after heel prick. Elserafy et al (2009) noticed that a sucrose solution with a pacifier decreased pain score in neonates during simple painful procedures including heel pricks. In Liaw et al's study (2012), non-nutritive sucking was as effective as sucrose solution to reduce discomfort in painful minor procedures. Goubet et al (2007) found exposure to a familiar odour reduced crying and grimacing in neonates having heel pricks. In a study conducted by Jain et al (2006), 2 minutes of massage over the ipsilateral leg before heel prick significantly reduce pain score in neonates. Gray et al's study (2002) suggested a mother's cuddle with breastfeeding is a potent analgaesic for neonates having heel prick. Morrow et al (2010) and Castral et al's (2007) studies also suggested that swaddling and skin to skin contact can significantly reduce neonatal pain during heel pricks. Alternatively, Ozdogan et al's (2010) study suggested that expressed breast milk without cuddling was ineffective in reducing pain during heel pricks.

Despite the suggestions and evidence, the area in which this study was conducted does not utilise pain control for heel pricks. For decades, heel prick tests were considered a minor procedures in Hong Kong and few nurses would intrinsically feel the need to provide pain control for it. Moreover, the nonpharmacological methods that have been studied would either require an extra person (e.g. swaddling, breastfeeding, skin-to-skin

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contact), extra material (e.g. sucrose solution, artificial sweetener, non-nutritive sucking, familiar odour), or extra time (e.g. massage and others). In the research venue, despite the official statistic being 1 nurse per 10 neonates, in extreme cases there may be double that number of patients. It would be very unlikely, if not impossible, that any intervention asking for extra person or time would be welcomed and successfully implemented among nurses here. In this study, the researchers aimed to develop a nonpharmacological pain reduction method for heel pricks that is both effective and practical, by applying 10 seconds of gentle manual pressure on the needle stick site immediately prior to the prick. The design of this method was based on the gate control theory of pain. The gate control theory of pain suggests that the transmission of nerve impulses from afferent fibres to the central nervous system is modulated by a spinal gating mechanism. This gating mechanism is influenced by the relative amount of activity in large diameter fibres and small diameter fibres. Activity in large fibres tends to inhibit transmission (close the gate) while small fibre activity tends to facilitate transmission (Melzack, 1996) In the case of human sensory neurons, the Aα and Aβ fibres that are mainly responsible for innocuous stimuli have larger diameters than the Aδ and C fibres that are mainly responsible for noxious stimuli (Jankowski and Koerber, 2010). Therefore, stimulating the Aα and Aβ neurons with touch and pressure may suppress the transmission of noxious signals from the Aδ and C fibres during heel pricks, and reduce pain in neonates.

Methods

Overall study design

This study adopts a randomised, open-labelled, crossover design. The data collection took place in a neonatal unit of a busy public hospital in Hong Kong. When the research was being undertaken, it had a bed status of 10 and admitted noninfectious babies under the age of 1 month. Most of the babies admitted to the neonatal unit had neonatal jaundice, requiring heel pricks and phototherapy. Heel pricks were performed according to the physician's order, with the verbal consent of baby's parent. The heel pricks were usually repeated on a daily basis to monitor the baby's blood bilirubin levels. The current practice in the research venue is that no pain control for heel pricks is given. The trial consisted of four phases:

1. Subject enrolment and screening
2. Randomisation according to the sequence of enrolment to divide the subjects into an immediate intervention group (odd number) and a delayed intervention group (even number)
3. The immediate intervention group received manual pressure before the first heel prick and current practice (no manual pressure) during the second heel prick. The delayed intervention group received current practice (no manual pressure) during the first heel prick and received manual pressure before the second heel prick
4. The behavioural outcome assessments and physiological measurements were carried out within and at 1 minute after the heel pricks respectively.

Subjects

Of all the subjects in the study, 25 have been screened and 17 subjects completed the study. Of those 17, 9 were in the immediate intervention group, and 8 were in the delayed intervention group. The participants were recruited by convenience sampling when they were admitted to the SCBU. They had to meet the following criteria to participate:

- Term infant (born at 37–42 weeks of gestation)
- Under 2 weeks old
- Normal growth parameters (weight, length, and head circumference within normal range on growth chart)
- No known disease/physical abnormality other than physiological neonatal jaundice

Immediately before every heel prick, subjects also had to meet the following criteria to continue in this study:

- No ingestion of substances that may affect pain perception or expression before the heel prick (no analgesic/sedative within 48 hours, no breast milk and/or sucrose within 30 minutes)
- Free from pain immediately before the heel prick (Neonatal Infant Pain Score (NIPS) below or equal to 3)

The sample size calculations were based on the results of research conducted by Jain et al (2006) that were similar to this manual pressure study in terms of the target group (neonates), the procedure concerned (heel prick), and the rationale behind the intervention (gate control theory of pain). The effect presented by the Cohen's d value of Jain's study was calculated to be -1.54 (Ellis, 2009) when treated as parametric data as it was presented. The sample size for a crossover trial was calculated to be 9 for a two-tailed parametric test with 5% significance level and power at 0.8 (Schoenfeld, 2015). As NIPS is not a parametric factor, an extra 15% sample size was added (GraphPad software, 2015) to obtain a final sample size of 10–11.

Ethics considerations

Written informed consent was obtained from each patient's parent. No extra pain or discomfort was elicited during the data collection process. Ethics approval regarding research on human samples was obtained from the Research Ethics Committee of the Hong Kong Hospital Authority.

Data collection and measures

The baseline behavioural pain score (NIPS), heart rate, respiratory rate (RR), oxygen saturation, and inclusion criteria screening were measured by the researcher before every heel prick. The heel pricks were performed by the nursing staff in the research venue. When appropriate, the researcher pressed on the neonate's heel for 10 seconds immediately before the heel prick, using the first digital portion of the thumb. The area under digital pressure was approximately 2.5x1.5=3.75 cm^2, measured with a ruler. The researcher then pressed on a baby scale 10 times and recorded the force of every press to the nearest gram. The range and average pressure applied was converted from kg/cm^2 into kilopascal (kPa). The range of pressure was 15.68–27.85 kPa and the average pressure applied was 20.4 kPa. No adverse reaction caused by the manual pressure was observed. The NIPS was obtained by the researcher within 1 minute after the needle prick. A second set of physiological data was taken 1 minute after the heel prick. The heart rate and oxygen saturation were measured with a stethoscope and oximeter, respectively, while the researcher, aided by a watch or clock with a second hand, counted the respiratory rate. The procedures of the data collection are summarised in *Figure 1*.

Outcome measurements

Pain induces reactions in living organisms. While children and adults can express symptoms (conscious expression) of pain, neonates and infants can only express signs (unconscious or involuntary reactions) such as withdrawal from painful stimuli, increase in heart rate, change in posture or facial expressions, and crying (Bellieni, 2012).

In this study, the NIPS score was used to measure the neonates' behavioural indicators of pain and to generate the primary results of this research. Infants' facial expression, cry, breathing patterns, arm and leg movement, and state of arousal are taken into account in the neonatal and infant pain score. The minimum score is 0 and the maximum score is 7. A total score higher than 3 indicates an experience of pain by the subject (Walker and Arnold, 2009b). Physiological measurements of pain, such as heart rate (HR), respiratory rate (RR), and blood oxygen saturation level (SpO2) were collected as the secondary results. A two-tail 'Wilcoxon signed ranks test' was used within the group to analyse the NIPS scores with a confidence interval of 95%. This test was chosen based on the non-parametric nature of the NIPS score with its presentation in continuous variables. A two-tail paired t-test was used to analyse the physiological measurements with a confidence interval of 95%. A t-test was chosen because the HR, RR and SpO2 levels can be interpreted as parametric data. The effectiveness of the intervention was presented with Cohen's d (Polit, 2010).

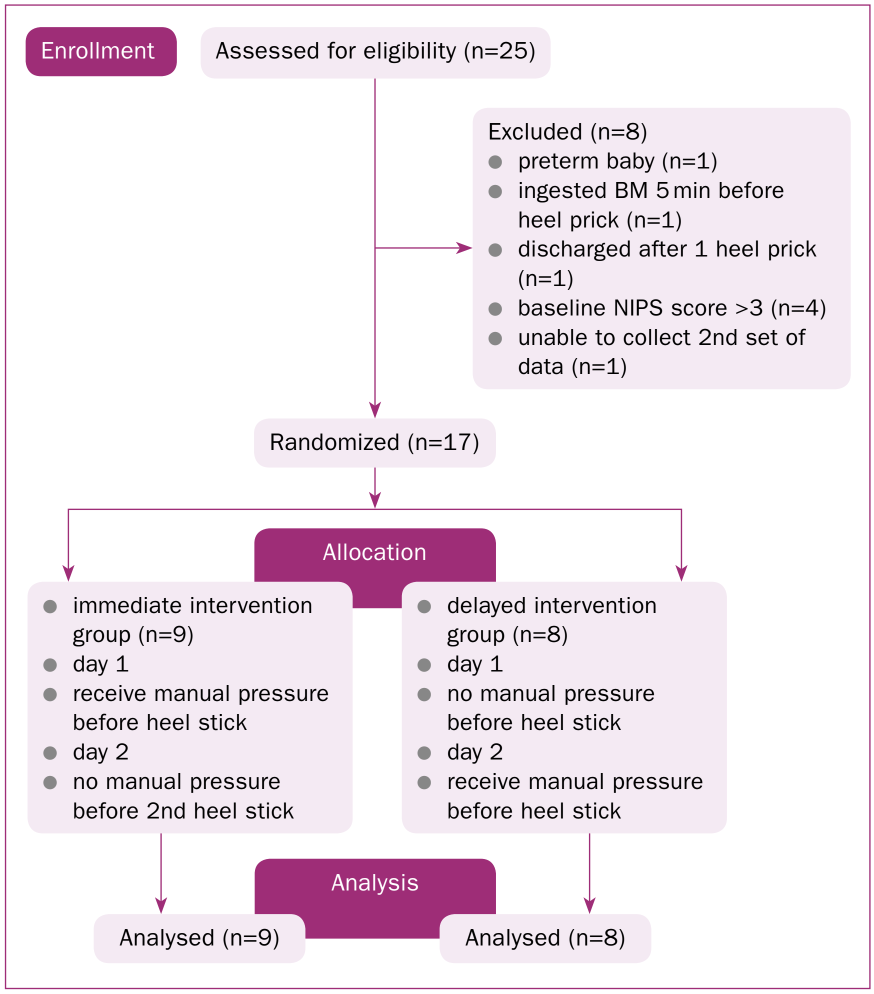

Figure 1: Data collection flow diagram

Results

Participant characteristics

The patients' demographic data on the day of recruitment appears in *Table 1*. All the patients were neonates under 2 weeks old who had only physiological jaundice.

Table 1. Distribution of demographic characters (n=17)

Growth parameters	Mean(SD)	Range
Age (day)	4.82 (1.38)	3–8
Gestational age (week)	38.71 (0.77)	37–40
Body weight (kg)	3.17 (0.32)	2.58–3.87
Body length (cm)	49.34 (1.97)	46–53.5
Head circumference (cm)	34.33 (1.43)	32.3–38
Gender		
Male	9 (52.9%)	
Female	8 (47.1%)	
Mode of feeding		
Exclusive breastfeeding	3 (17.6%)	
Mixed feed	11 (64.7%)	
Formula feed	3 (17.6%)	

Table 2: Comparison of Neonatal and Infant Pain Score with and without manual pressure					
	NIPS pain score Mean (SD)	**Pα (effect size)**	**Pβ (effect size)**	**Pγ (effect size)**	**Pδ (effect size)**
Without manual pressure					
Before heel prick	0.53 (0.87)		0.001** (-2.44)		
During heel prick	5.29 (2.62)	0.61 (NA)			0.01* (0.92)
With manual pressure					
Before heel prick	0.41 (0.87)			0.016* (-1.11)	
During heel prick	2.76 (2.86)				
P value by Wilcoxen Signed Ranks Test Effect size presented in Cohen's d					
Pα: Before heel prick (without pressure) vs Before heel prick (with pressure) Pβ: Before heel prick (without pressure) vs During heel prick (without pressure) Pγ: Before heel prick (with pressure) vs During heel prick (with pressure) Pδ: During heel prick (without pressure) vs During heel prick (with pressure)					

Table 3: physiological indicators of pain					
	Before heel prick		**After heel prick**		**p-value (effect size)**
	Without manual pressure Mean (SD)	With manual pressure Mean (SD)	Without manual pressure Mean (SD)	With manual pressure Mean (SD)	
Heart rate (beats per min)	137.5 (14.0) 137.5 (14.0) Na 137.5 (14.0) Na	137.9 (12.3) 137.9 (12.3) Na Na 137.9 (12.3)	147.9 (18.7) Na 147.9 (18.7) 147.9 (18.7) Na	148.4 (18.2) Na 148.4 (18.2) Na 148.4 (18.2)	Na 0.896 0.932 0.076 0.043* (-0.68)
Respiratory rate (per min)	38.9 (2.9) 38.9 (2.9) Na 38.9 (2.9) Na	40.4 (3.3) 40.4 (3.3) Na Na 40.4 (3.3)	42.6 (10.7) Na 42.6 (10.7) 42.6 (10.7) Na	41.7 (8.9) Na 41.7 (8.9) Na 41.7 (8.9)	Na 0.902 0.710 0.170 0.500
Oxygen saturation (%)	99.2 (0.8) 99.2 (0.8) Na	98.8 (1.0) 98.8 (1.0) Na	98.5 (1.3) Na 98.5 (1.3)	98.4 (1.2) Na 98.4 (1.2)	Na 0.030* (0.44) 0.887
	99.2 (0.8) Na	Na 98.8 (1.0)	98.5 (1.3) Na	Na 98.4 (1.2)	0.049* (0.65) 0.275
Effect size presented in Cohen's d					

Behavioural pain score (NIPS)

A comparison of the behavioural pain scores (NIPS) was the primary outcome. Four sets of NIPS scores were collected for each subject. The mean (SD) was used to present the data for easy interpretation of the results. The results obtained are persented in *Table 2*. According to the results, the participants that had manual pressure before the heel pricks experienced significantly less pain during the procedure.

Physiological measurements of pain

In general, the heel pricks increased the subject's heart rate, increased the subject's respiratory rate and decreased the subject's oxygen saturation. However, these changes were mostly statistically nonsignificant. The results are summarised in *Table 3*.

Discussion and limitations

The results of this study suggest that gentle manual pressure over the needle stick site immediately before a heel prick is a safe and effective method to reduce neonatal pain during this procedure. No adverse reaction related to the intervention (10 seconds of manual pressure) was observed during the course of the data collection. A significant increase in pain scores during the heel pricks supported the statement that a heel prick is a painful procedure for neonates. When 10 seconds of gentle manual pressure was applied over the needle stick site immediately before the heel pricks, the frequency and intensity of the pain experienced by the babies were significantly decreased, as indicated by a significant decrease in their behavioural pain scores. Compared with other nonpharmacological methods aimed to reduce heel prick pain in neonates, ten seconds of manual pressure is much more practical in the clinical setting. This method needs no additional person or apparatus except one extra piece of sterile gauze, and only takes 10 additional seconds to implement. Manual pressure also fits smoothly into the procedure of heel prick. This experiment can also be readily repeated and implemented in other settings, such as outpatient clinics and day wards. Although the differences in the physiological parameters were not statistically significant, the general trends of physiological results showed an increase in heart rate and respiratory rate and decrease in oxygen saturation after heel prick. This finding concurs with the previous findings concerning pain scores, suggesting that heel prick is a painful procedure for the neonates. There was practically no difference between the physiological data of the intervention and control groups after heel pricks. This was possibly due to:

- an inadequate sample size
- the behavioural pain scale used in this study may be much more sensitive than physiological parameters in assessing neonatal reactions to pain
- in this study, the behavioural pain score was taken at an earlier time (within 1 minute after needle stick) than the physiological parameters (at 1 minute after needle stick).

Any significant changes in physiological parameters may have diminished by then. If the effect of heel stick pain on physiological parameters is studied in the future, researchers may consider increasing the sample size (assuming a weak to moderate effect size) and trying to minimise the time lapse between the needle stick and the time to measure the physiological parameters.

This research included only healthy term neonates partly due to the limitations of the research venue. The researchers believe reducing pain during heel pricks by manual pressure could also be promising for preterm neonates and neonates requiring more intensive care. These neonates usually experience more heel pricks than healthy neonates during their hospital stay. Thus, they could receive more benefit if pain can be reduced by more practical methods in the clinical setting. Since this study only tested on two occasions of heel pricks for each patient, the possible effect of learnt reflex and reactions (Skinner, 1984) of the baby cannot be observed. Could a baby who experienced repeated episodes of manual pressure followed by painful procedure become conditioned to expect pain when manual pressure is applied? Such a patient may begin to show reactions to pain even before the painful stimuli is actually applied. Researchers may consider repeating this experiment on neonates with various characteristics to test its generalisability, remembering to take the previous point into consideration.

‘Although the differences in the physiological parameters were not statistically significant, the general trends of physiological results show an increase in heart rate and respiratory rate and decrease in oxygen saturation after heel prick’

Reducing pain by prior manual pressure may also be useful to practitioners carrying out other needle-related procedures, such as venepunctures or intramuscular and intradermal injections. Researchers may consider investigating whether prior manual pressure can reduce pain in other needle-related procedures and in populations other than neonates.

Limitations

Due to the shortage of practioners and resources, this experiment was an open-labelled study and all interventions and data collection was done by the researcher. Marker bias cannot be excluded if there is more than one rater. We can provide training to reduce individual marker disparity. Then we can have all raters to observe and rate a number of events independently; if the differences between their results are statistically insignificant, we can say that the inter-rater disparities has been minimised. The researchers suggest that further studies should blind the markers to the intervention. During the heel prick process, the researchers also observed possible painful stimuli other than needle stick pain (e.g. puncture wound rubbed by the blood collection device and forceful squeeze of the babies' heels when blood flow is inadequate). The researchers suggest further studies to determine ways to better isolate the painful stimuli to a heel prick only. These measures may include ways to standardise the time and force used to squeeze the baby's heel (e.g. temperature of the baby's foot and avoid rubbing the baby's open wound with blood collection device).

Conclusion

Heel pricks are a painful procedure for neonates. Gentle manual pressure for 10 seconds over the puncture site immediately before the heel stick can safely and significantly reduce the pain felt by healthy, term neonates during heel pricks. This can be easily implemented in the blood collection process with a minimal requirement of extra time and resources. BJM

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Key points

- The heel prick is a very common procedure that causes pain in neonates
- Repeated and prolonged exposure to pain in early life may cause long-term negative consequences
- Nonpharmacological pain control should be provided during painful procedures such as heel pricks
- Gentle manual pressure is likely to be the easiest method to implement in busy, resource-stretched clinics
- Current suggested methods such as oral sucrose solution and cuddling cannot be easily implemented in clinical areas that are very busy, because of the extra resources they require
- According to this study, gentle manual pressure over the puncture site immediate before heel prick can safely and effectively reduce behavioral pain in neonates during heel prick.

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CPD reflective questions

- Can you think of any procedures where you feel you should be providing more pain control for a neonatal patient?
- Which of the pain control methods discussed in this article would be appropriate for your clinical setting? Please take into account the ratio of nurses to patient and how much time you can afford each baby.
- Is the gentle manual pressure technique appropriate for your practice?