



Efficacy of facilitated tucking combined with non-nutritive sucking on very preterm infants' pain during the heel-stick procedure: A randomized controlled trial

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ABSTRACT

Background: Reducing acute pain in premature infants during neonatal care improves their neurophysiological development. The use of pharmacological and non-pharmacological analgesia, such as sucrose, is limited per day, particularly for very preterm infants. Thus, the usual practice of non-nutritive sucking is often used alone. Facilitated tucking could be an additional strategy to non-nutritive sucking for reducing pain. To the best of our knowledge, no randomized trial has compared the combination of facilitated tucking and non-nutritive sucking to non-nutritive sucking alone.

Objectives: To compare the efficacy of facilitated tucking in combination with non-nutritive sucking (intervention group) to non-nutritive sucking alone (control group) in reducing pain during the heel-stick procedure in very preterm infants.

Design: Prospective, randomized controlled trial.

Settings: Level III and II neonatal care units, including the neurosensory care management program.

Methods: Very preterm infants (gestational age between 28 and 32 weeks) were randomly assigned by a computer programme to the intervention or control group during a heel-stick procedure within the first 48 h of life. In both groups, infants were placed in an asymmetric position on a cushion; noise and light were limited following routine care. A heel-stick was performed first in the care sequence. In the intervention group, facilitated tucking was performed by a nurse or nursing assistant. The procedure was video recorded from 15 s (T-15 s) before the procedure until three minutes (T + 3 min) after the end of the procedure. Pain was blindly assessed by two independent specialist nurses. The primary outcome was the pain score evaluated 15 s before the procedure and 30 s immediately after by the premature infant pain profile (PIPP) scale. The secondary outcome was the pain score evaluated between T-15 s and T + 3 min by the DAN scale (a French acronym for the acute pain of a newborn).

Results: Sixty infants were included (30 in each group). The PIPP pain scores did not differ between the intervention group (median: 8.0; interquartile range (IQR): 6.0–12.0) and the control group (median: 9.5; IQR: 7.0–13.0, $p = 0.32$). Pain assessed by the DAN scale at T + 3 min was lower in the intervention group than in the control group (median: 0.3; IQR: 0.0–1.0 and 2.0; IQR: 0.5–3.0, respectively, $p = 0.001$).

Conclusions: The combined use of facilitated tucking and non-nutritive sucking did not significantly alleviate pain during the heel-stick procedure. However, the addition of facilitated tucking facilitated faster pain recovery following the heel-stick procedure.

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What is already known about the topic?

- Infants in intensive care units receive numerous painful procedures daily, including heel-sticks. During care procedures, it has been observed that only half of all newborns receive specific pain relief based on pharmacological and non-pharmacological treatment.
- The use of pharmacological and non-pharmacological analgesia, such as sucrose, is limited per day, particularly for very preterm infants. Thus, non-nutritive sucking is often used alone in this population and is not sufficiently effective in alleviating pain.
- Facilitated tucking can easily be used by health care givers or parents and might help reduce behavioural and physiological manifestations of pain.

What this paper adds

- Relative to non-nutritive sucking, manifestations of very preterm infants' pain evaluated before the heel-stick procedure and 30 s after were not significantly reduced by the addition of facilitated tucking.
- Facilitated tucking combined with non-nutritive sucking may reduce pain at three minutes post-procedure. Whereas non-nutritive sucking is often used when sucrose can no longer be administered, the combination of facilitated tucking and non-nutritive sucking is a notable alternative that merits further exploration.

1. Introduction

Preterm infants are those born alive before 37 weeks of pregnancy are completed. They represent an estimated 15 million infants per year worldwide (World Health Organization, 2018). In many countries, an increase in preterm births has been observed in recent years, e.g., France, where preterm births increased from 5.9% in 1995 to 7.5% in 2016 (Enquête Nationale Périnatale, 2016). Among preterm infants in France, 10% are very preterm, born between 28 to 32 weeks of gestational age (Ancel and Rozé, 2015).

The gap between the intrauterine and intensive care unit environments is distressing for preterm infants at a crucial time in their cerebral maturation (Grunau, 2013). Preterm infants are subjected to noise, light, touch and frequent painful procedures. A mean of 16 (range: 0–62) painful procedures per day per infant was observed during a 2-week study in neonatal intensive care units, of which cutaneous procedures, including the heel-stick, were one of the most frequent procedure types (Carbajal et al., 2008). Early nociceptive stimulations are remembered, particularly in very preterm infants, enhancing later sensitivity to pain, with more pronounced painful behavioural manifestations in childhood and consequences on cognitive development (Brummelte et al., 2012; Grunau, 2013; Ranger and Grunau, 2014; Valeri et al., 2016; Vederhus et al., 2012; Vinnall et al., 2014; Zwicker et al., 2012).

Despite important improvements in techniques leading to a better survival rate of premature infants, pain management greatly varies among neonatal units. To reduce pain during a heel-stick procedure, intermittent doses of opioid analgesics may be administered but are not efficient (Axelin et al., 2009). The use of topical anaesthetic cream is recommended only once a day because of its toxicity, and it is not often used (Carbajal et al., 2008). A large spectrum of non-pharmacological analgesia is available (Pillai Riddell et al., 2015). A prospective observational study in intensive care units including 562 preterm infants showed that only half of the infants received specific pre-procedural analgesia with pharmacological and non-pharmacological methods, including nutritive sucking with a sweet solution, such as sucrose, and non-nutritive sucking with sterile water (Courtois et al., 2016). Sucrose is an efficient pain reliever for procedural pain, but its administration is limited to four times a day since sucrose can be harmful for muscle tone, motor development, vigilance and orientation (Johnston et al., 2002). The long-term effects of sucrose administration on preterm

infants have been extensively studied, showing deleterious impacts on cortical and subcortical grey and white matter (Holsti and Grunau, 2010; Tremblay et al., 2017). Non-nutritive sucking is also used for reducing pain in preterm infants. This strategy reportedly has superior pain-relieving effects compared with those of controls, routine comfort or gentle touch and verbal comfort (Liaw et al., 2012, 2010), but has lower efficacy than sucking with sucrose (Stevens et al., 2016).

Supportive care for sensorimotor development, also called developmental care, aims to improve the environment of the premature infant and adapt care interventions in response to his/her physiological needs (Bullinger, 2015). These developmental care methods are based on environmental and behavioural strategies and the involvement of the parents in the care of their infant. The main objective of developmental care is to reduce sensorimotor adverse stimulations (Bullinger, 2015). Among the different techniques, the facilitated tucking position may improve the self-regulation of stress and may reduce pain in preterm infants (Lopez et al., 2015). This method requires placement of the infant in the foetal position using the hands of health care givers or parents, maintaining an asymmetric position (Bullinger, 2015). This method is straightforward to implement. Infants are contained but not restrained in their movements, which might reassure them and support a fast return to the baseline state after a painful procedure (Axelin et al., 2009).

Several studies have evaluated the efficacy of the facilitated tucking method on preterm infants' pain during the heel-stick procedure with contrasting results (Axelin et al., 2009; Cignacco et al., 2012; Gerull et al., 2013; Gitto et al., 2012; Huang et al., 2004; Liaw et al., 2012; Peng et al., 2018; Yin et al., 2015). Among them, two randomized studies showed no benefits to infants born between 24 and 32 weeks of pregnancy (Gerull et al., 2013; Gitto et al., 2012), whereas four other studies conducted in infants born between 24 and 37 weeks favoured facilitated tucking in conjunction with other methods (Cignacco et al., 2012; Liaw et al., 2012; Peng et al., 2018; Yin et al., 2015).

When sucrose can no longer be administered daily to very preterm infants, non-nutritive sucking is often the only possible procedure to reduce pain during a heel-stick. In that situation, combining facilitated tucking with non-nutritive sucking may have interesting pain-relief effects. However, only one study evaluated the combination of facilitated tucking and non-nutritive sucking in infants born between 27 and 37 weeks, and no benefit was reported relative to gentle touch (Yin et al., 2015). No randomized study has evaluated the combination of facilitated tucking and non-nutritive sucking relative to non-nutritive sucking alone specifically in the very preterm infant population. The Babydoul study [French study name for 'baby' and 'pain'] was designed to evaluate the efficacy of adding facilitated tucking to non-nutritive sucking to reduce pain in very preterm infants. This study aimed to address the following research question: do pain scores between very preterm infants receiving non-nutritive sucking alone and infants receiving facilitated tucking combined with non-nutritive sucking differ during the heel-stick procedure?

2. Methods

2.1. Design and settings

This prospective randomized controlled trial was conducted from April 2014 to August 2015 in the level III and level II neonatal intensive care units of a French hospital (Paris), totalling 1670 admissions per year. The very preterm infants included in this study were assigned to either the intervention group (facilitated tucking combined with non-nutritive sucking) or the control group (non-nutritive sucking alone).

2.2. Randomization and allocation

Centralized block balanced randomization in a 1:1 ratio was computer generated by an independent statistician. After obtaining parental

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