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Pain relief effect of breast feeding and music therapy during heel lance for healthy-term neonates in China: A randomized controlled trial

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ABSTRACT

Objectives: to test the effectiveness of breast feeding (BF), music therapy (MT), and combined breast feeding and music therapy (BF+MT) on pain relief in healthy-term neonates during heel lance.
Design: randomised controlled trial.
Setting: in the postpartum unit of one university-affiliated hospital in China from August 2013 to February 2014.
Participants: among 288 healthy-term neonates recruited, 250 completed the trial. All neonates were undergoing heel lancing for metabolic screening, were breast fed, and had not been fed for the previous 30 minutes.
Interventions: all participants were randomly assigned into four groups – BF, MT, BF+MT, and no intervention – with 72 neonates in each group. Neonates in the control group received routine care. Neonates in the other three intervention groups received corresponding interventions five minutes before the heel lancing and throughout the whole procedure.
Measurements: Neonatal Infant Pain Scale (NIPS), latency to first cry, and duration of first crying.
Findings: mean changes in NIPS scores from baseline over time was dependent on the interventions given. Neonates in the BF and combined BF+MT groups had significantly longer latency to first cry, shorter duration of first crying, and lower pain mean score during and one minute after heel lance, compared to the other two groups. No significant difference in pain response was found between BF groups with or without music therapy. The MT group did not achieve a significantly reduced pain response in all outcome measures.
Conclusions: BF could significantly reduce pain response in healthy-term neonates during heel lance. MT did not enhance the effect of pain relief of BF.
Implications for practice: healthy-term neonates should be breast fed to alleviate pain during heel lance. There is no need for the additional input of classical music on breast feeding in clinic to relieve procedural pain. Nurses should encourage breast feeding to relieve pain during heel lance.

Introduction

Currently, in many countries around the world, routine medical care for healthy-term neonates involves heel lance for taking blood samples, which is a common source of pain experienced

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by healthy neonates (American Academy of Pediatrics, 2006). Painful stimuli in neonates may induce short-term physiological and behavioural changes such as excessive crying and vomiting (Mainous and Looney, 2007; Meek, 2012), as well as long-term consequences such as altered pain response in later infancy (Grunau et al., 2006).

The objective assessment of pain in neonates is difficult due to the subjective nature of pain and the inability of neonates to communicate. Recently, a number of reliable and valid measurement tools have been developed to assess pain for preterm or term infants (Cignacco et al., 2007). The Neonatal Infant Pain Scale (NIPS) has been successfully used with preterm and full-term infants for objective evaluation of the pain experience (Yilmaz and Arikan, 2010; Gabriel et al., 2013). The first cry following pain was also found to be the most sensitive response to noxious stimuli (Grunau and Craig, 1987). Previous studies have used latency to first cry and duration of first crying as a primary measure of pain (Upadhyay et al., 2004; Ou-Yang et al., 2013).

Significant progress in understanding the consequences of procedural pain and great advances in pain assessment for neonates have resulted in more attention to pain management (Gallo, 2003; Golianu et al., 2007). However, pain in healthy-term neonates caused by heel lance is still not treated in mainland China. Health care professionals' lack of knowledge about pain, the neonates' inability to express pain, and the short duration of the heel lance may contribute to the disregarding of pain (Liaw et al., 2010; Zhu et al., 2012). Thus it is important to examine the effectiveness of pain relief of different interventions for healthy-term neonates during heel lance.

Pharmacological treatments are rarely used to alleviate neonatal pain during heel lance because of doubtful efficacy (Shah et al., 1998; Jain et al., 2001) and potential adverse effects for the medically fragile neonates (Golianu et al., 2007). A variety of non-pharmacological methods of pain management have been evaluated for the treatment of pain in neonates undergoing venepuncture or heel lance, including sucrose (Liaw et al., 2013), non-nutritive sucking (Liaw et al., 2010; Fernandes et al., 2011), swaddling (Prasopkittikun and Tilokskulchai, 2003), breast feeding (Gabriel et al., 2013), kangaroo care (Campbell-Yeo et al., 2013), and sensorial saturation or music (Hartling et al., 2009). These approaches have been proved to be beneficial for the management of mild to moderate pain in the neonates (Golianu et al., 2007). Given the efficacy and cost-effectiveness of non-pharmacological intervention in the management of pain, Fernandes et al. (2011) pointed out that non-pharmacological intervention should be the first choice for common painful procedures such as heel lance. Regardless of the available evidence, appropriate systematic pain management is often underused for some minor procedures (American Academy of Pediatrics, 2006; Campbell-Yeo et al., 2011).

Music is increasingly being used in neonatal units to improve behavioural or physiological outcomes or to manage pain during common medical procedures. A systematic review published in 2009 included nine randomised trials to examine the efficacy of music for procedural pain management and concluded that music was beneficial in terms of physiological parameters, behavioural states and pain for heel lance procedures (Hartling et al., 2009). However, due to the poor quality of some studies included in the review and the large variation in reported outcomes, Hartling et al. (2009) indicated that additional methodologically rigorous, randomised, controlled trials were warranted to confirm the benefits of music for pain relief in neonates.

Breast feeding is a natural, readily available, and potentially risk-free measure which has been assessed for management of neonate pain in many studies (Efe and Savaşer, 2007; Codipietro et al., 2008; Leite et al., 2009; Okan et al., 2010; Gabriel et al., 2013). A Cochrane review included 20 randomised controlled trials to evaluate the effect of breast feeding or supplemental breast milk on procedure pain in neonates (Shah et al., 2012). This review found that neonates in the breast fed group had a significantly lower increase in heart rate, reduced proportion of crying time, and less pain during heel lance and venepuncture. Thus, Shah et al. (2012) recommended that breast feeding or breast milk should be used to alleviate procedure pain in neonates undergoing a single painful procedure. However, breast feeding has not been universally implemented to alleviate procedural pain (Gray et al., 2006; Codipietro et al., 2011). In mainland China, nurses still do not suggest breast feeding during heel lance because of lack of knowledge about the pain relief of breast feeding (Zhu et al., 2012). More randomised clinical trials are warranted to establish evidence for breast feeding practice during heel lance in China.

To the best of our knowledge, no research has been conducted to compare the effects of pain relief of breast feeding (BF), music therapy (MT), and combined breast feeding and music therapy (BF+MT) for healthy-term neonates during heel lancing. Therefore, the aim of this study was to investigate the pain relief of BF, MT, and combined BF+MT versus no intervention on latency to first cry, duration of first crying, and NIPS during blood sampling through heel lance in healthy-term neonates. The hypotheses of this study were as follows:

1. When compared with the no-intervention group, neonates in the BF, MT, and BF+MT groups would have a reduction in pain levels over time.
2. When compared with the no-intervention group, neonates in the BF, MT, and BF+MT groups would have longer latency to first cry, shorter duration of first crying, and lower pain levels during and after heel lance.
3. BF+MT would be more effective in pain relief than MT or BF alone for healthy-term neonates during heel lance.

Methods

Design

This is a prospective, randomised, controlled study involving pre-testing and post-testing of four groups.

Setting and participants

In total, 288 neonates were recruited by the Head Nurse from the postpartum units of a university-affiliated hospital. Eligible neonates were all born at $\geq$37 weeks gestation, had APGAR scores $\geq$7 at five minutes after childbirth, were aged $\geq$24 hours, weighed between 2000 g and 4000 g, had passed the hearing screen, were undergoing heel lancing for metabolic screening between three and five days after childbirth, were breast fed, and had not been fed for the previous 30 minutes. Multiple births and operative deliveries were also included in this study if the neonates met the above inclusion criteria. Exclusion criteria were as follows: at-risk pregnancy, neonates with medical instability, those receiving artificial feeding, those who were subjected to any painful stimulus other than intramuscular vitamin K injection, those who had received a sedative and a major pain relief during the previous 48 hours, and those who received heel lance twice due to an unsuccessful first procedure.

Sample size calculation

In order to detect a medium effect size at 0.5 to achieve a power of 80% with an α level at 0.05 (two-sided), a total of 256