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Analgesic effect of breast feeding in term neonates: randomised controlled trial

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Abstract

Objectives To investigate whether breast feeding is effective for pain relief during venepuncture in term neonates and compare any effect with that of oral glucose combined with a pacifier.

Design Randomised controlled trial.

Participants 180 term newborn infants undergoing venepuncture; 45 in each group.

Interventions During venepuncture infants were either breast fed (group 1), held in their mother’s arms without breast feeding (group 2), given 1 ml of sterile water as placebo (group 3), or given 1 ml of 30% glucose followed by pacifier (group 4). Video recordings of the procedure were assessed by two observers blinded to the purpose of the study.

Main outcome measures Pain related behaviours evaluated with two acute pain rating scales: the Douleur Aiguë Nouveau-né scale (range 0 to 10) and the premature infant pain profile scale (range 0 to 18).

Results Median pain scores (interquartile range) for breast feeding, held in mother’s arms, placebo, and 30% glucose plus pacifier groups were 1 (0-3), 10 (8.5-10), 10 (7.5-10), and 3 (0-5) with the Douleur Aiguë Nouveau-né scale and 4.5 (2.25-8), 13 (10.5-15), 12 (9-13), and 4 (1-6) with the premature infant pain profile scale. Analysis of variance showed significantly different median pain scores (P < 0.0001) among the groups. There were significant reductions in both scores for the breast feeding and glucose plus pacifier groups compared with the other two groups (P < 0.0001; two tailed Mann-Whitney U tests between groups). The difference in Douleur Aiguë Nouveau-né scores between breast feeding and glucose plus pacifier groups was not significant (P = 0.158).

Conclusions Breast feeding effectively reduces response to pain during minor invasive procedure in term neonates.

Introduction

In healthy infants, the most common painful procedures are heel lance and venepuncture. Pharmacological treatments are rarely used during these procedures because of concerns about their effectiveness and potential adverse effects. Therefore, non-pharmacological interventions are valuable alternatives.

Recent studies have reported that pain can be reduced with simple interventions such as sweet oral solutions and non-nutritive sucking or multisensory stimulation. Skin to skin contact between mothers and infants can also be effective. Environmental and behavioural strategies have been considered essential to the prevention and management of neonatal pain. As breast feeding probably constitutes the most potent pleasant stimulation a newborn infant can experience, we hypothesised that breast feeding could have analgesic properties in neonates.

We investigated the efficacy of breast feeding for pain relief during venepuncture in term neonates and compared any effect with that of oral glucose combined with a pacifier.

Methods

Protocol

We included infants who were born at ≥37 weeks’ gestation; had APGAR scores ≥ 7 at 5 minutes; were aged ≥ 24 hours; were undergoing venepuncture as part of routine medical care; were breast fed; and had not been fed for the previous 30 minutes. We excluded infants with medical instability, those who had received naloxone during the previous 24 hours, and those who had received a sedative or a major analgesic during the previous 48 hours.

Procedures and masking

Participating infants and their mothers were taken to a quiet nursery room for venepuncture. SV opened a consecutively numbered envelope, which contained the treatment assigned to each infant. Infants were allocated to one of four groups: in group 1 they were breast fed, starting two minutes before the procedure and continuing throughout; in group 2 they were held in their mother’s arms without breast feeding, starting two minutes before the procedure; in group 3 two minutes before the procedure infants were laid on a table and given 1 ml of placebo (sterile water) without a pacifier; and in group 4 two minutes before the procedure infants were laid on a table and given 1 ml of 30% glucose followed by sucking a pacifier. The infant’s legs and feet were uncovered to allow observation of movements. Infants in groups 3 and 4 lay supine on an examination table during procedures.

The water or 30% glucose was administered for about 15 seconds by a sterile syringe into the infant’s mouth. In group 4 the pacifier (standard nipple stuffed with a gauze square for resistance) was held gently in
the infant’s mouth by an assistant throughout the procedure. Infants’ heart rate and oxygen saturation were monitored with a Nellcor monitor (model N-395). The infants and the monitor screen were video recorded during the procedure. Venepuncture was performed on the dorsal aspect of the infant’s hand by one of three experienced nurses.

Two specially trained observers independently assessed the recordings using the Douleur Aiguë Nouveau-né (DAN) scale (primary outcome measure) and the premature infant pain profile (PIPP) scale (secondary outcome measure). They assessed arousal state using Prechtl’s observational rating system. Assessment of pain started when the needle was inserted and ended when it was removed. Observers were blinded to the purpose and hypothesis of the study. They had been told that we were assessing agreement of their scores in four different situations. For the DAN scale there was good agreement between both observers on initial evaluation. The two observers independently re-evaluated all the procedures for which scores had not been identical during their first assessment, and obtained perfect interobserver agreement.

Sample calculation
We calculated that we would need 40 infants in each group to detect a 2 point difference in DAN scale with 80% power and at 1% significance. We decided to include 45 neonates in each group to cover potential problems with video recordings.

Pain scales
The DAN scale is a behavioural scale developed to rate acute pain in term and preterm neonates. Scores range from 0 (no pain) to 10 (maximum pain). It evaluates three items: facial expressions, limb movements, and vocal expression. The PIPP scale is a multidimensional measure developed to assess acute pain in preterm and term infants. It measures gestational age, behavioural state, heart rate, oxygen saturation, and three facial reactions (brow bulge, eye squeeze, nasolabial furrow). In term infants, scores range from 0 (no pain) to 18 (maximum pain).

Statistical analysis
We used one way analysis of variance on ranks to compare overall differences among four groups. We compared median pain scores of all groups using two-tailed Mann-Whitney U tests. Because five pairwise planned comparisons were made we considered P<0.01 as significant. We used χ² tests to compare categorical variables.

Results
During the study period (February to June 2001) 351 infants met the inclusion criteria. Of these, 180 were allocated to one of four equal sized groups. The perinatal characteristics of neonates not included in the study were similar to those included. There were no substantial differences among the groups except for arousal state—the median score for state of arousal was lower in the breast fed group. The reasons for venepuncture included tests for hypothyroidism and phenylketonuria screening, bilirubin, C reactive protein, sickle cell disease screening, calcium, and blood typing.

The median pain scores (interquartile range) during venepunctures for group 1 (breast feeding), group 2 (mother’s arms), group 3 (placebo), and group 4 (30% glucose plus pacifier) were 1 (0-3), 10 (8.5-10), 10 (7.5-10), and 3 (0-5) with the DAN scale and 4.5 (2.25-8), 13 (10.5-15), 12 (9-13), and 4 (1.6) with the PIPP scale. Analysis of variance showed that median pain scores were significantly different (P<0.0001). Tables 1 and 2 show pairwise comparisons of median pain scores.

Discussion
We have shown that breast feeding throughout a painful procedure is analgesic in term neonates. Of 44 infants in the breastfeeding group, 16 showed no indication at all that the venepuncture and blood sampling had even occurred; 35 had a DAN pain score ≤3, which can be considered as reflecting minimal or no pain. Our findings are clinically important as they show that natural protective mechanisms may safely and non-invasively be activated by breast feeding during medical procedures.

We detected no reduction in response to pain in infants who were simply held in their mother’s arms, possibly because these infants were dressed and did not have a skin to skin contact with their mothers. Gray et al found that 10 to 15 minutes’ skin to skin contact between a mother and baby reduces the infant’s response to pain during heel stick.9 To our knowledge, there have been only two previous reports on the analgesic effect of breast feeding. Bilgen et al compared the analgesic effects of sucrose, expressed breast milk, and breast feeding during heel pricks. Breast feeding was allowed for two minutes and stopped before a heel prick.10 There was no analgesic effect of this type of intervention, possibly because breast feeding was not continued during the procedure. Gray et al reported that breast feeding before, during, and after heel prick markedly reduced crying and grimacing and prevented the increase in heart rate in term neonates compared with swaddled infants in their cots.12 No other groups were included in their study design. The infants were held in full body skin to skin contact during the entire procedure.

Study limitations
Firstly, observers obviously recognised the four groups when they were evaluating the recordings. However,
they did not know the purpose of the study. Moreover, high agreement among observers during initial evaluations indicates objectivity. Secondly, although the DAN scale has been shown to discriminate pain in term newborn infants, no study has yet proved that it can grade the degree of perception of pain. We assumed that the more pronounced the facial expressions, limb movements, and vocal expressions, the higher the pain in the infant. Nevertheless, the robustness of pain evaluation was supported by the fact that the simultaneous use of the PIPP scale yielded similar results. Finally, median score for state of arousal was lower in the breastfeeding groups than in the other groups. This difference was slight and in our opinion was insufficient to explain all differences observed in pain scores among groups.

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References

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