Amethocaine gel reduced pain during venipuncture in newborn infants


QUESTION: Does topical amethocaine gel reduce pain during venipuncture in newborn infants?

Design
Randomised (allocation concealed), blinded (patients, clinicians, outcome assessors), placebo controlled trial with follow up immediately after the procedure.

Setting
Postnatal wards and the neonatal intensive care unit at the Nottingham City Hospital, Nottingham, UK.

Patients
40 newborn infants (median age 7 d, median gestational age 33 wks) who required venipuncture as part of their routine care. Infants who were unwell, ventilated, or sedated were excluded. Follow up was 98%.

Intervention
20 infants were allocated to 1.5 g of placebo gel and 20 were allocated to 1.5 g of amethocaine gel. The gel was applied to the dorsum of the hand or foot and covered with an occlusive dressing. After 1 hour, the dressing was removed, the gel was wiped away, and the infant was left to settle for 5 minutes. A neonatal senior house officer or an advanced neonatal nurse practitioner did the venipuncture using a 21-ST needle.

Main outcome measures
2 authors independently assessed pain reaction at 1 second intervals, beginning 5 seconds before needle insertion and ending 5 seconds after insertion using the neonatal facial coding system (NFCS) (maximum cumulative score of 25 over a 5 second period). Main outcomes were proportion of infants who showed no or minimal pain reaction to venipuncture (NFCS score ≤ 10 in the 5 seconds after needle insertion) and proportion who did not cry in the 5 seconds after needle insertion. Other outcomes included number of attempts to obtain the blood sample and number of local skin reactions.

Main results
More infants who received amethocaine gel had minimal or no pain compared with infants who received placebo gel, and more did not cry at all (table). The groups did not differ for proportion of blood samples collected on the first attempt (79% vs 65%, p = 0.3), and no local skin reactions were observed.

Conclusion
Topical amethocaine gel reduced pain during routine venipuncture in newborn infants.

Topical amethocaine gel v placebo during venipuncture in newborn infants*

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Amethocaine</th>
<th>Placebo</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion who had little or no pain with needle insertion</td>
<td>84%</td>
<td>30%</td>
<td>181% (52 to 490)</td>
<td>2 (2 to 5)</td>
</tr>
<tr>
<td>Proportion who did not cry at all in the 5 seconds after needle insertion</td>
<td>79%</td>
<td>25%</td>
<td>216% (56 to 624)</td>
<td>2 (2 to 5)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RBI, NNT, and CI calculated from data in article.

COMMENTARY
Venipuncture is a painful, invasive procedure commonly performed on newborn infants in hospital. Few options have been available to clinicians for reducing the pain associated with such procedures. Until recently, studies evaluating the use of amethocaine gel were done solely in adult and paediatric populations. The study by Jain and Rutter is the first to assess the effectiveness of this new topical anaesthetic in newborn infants.

Amethocaine gel is a potential therapeutic breakthrough for procedural pain management in infants. When compared with EMLA (eutectic mixture of local anaesthetics), amethocaine gel has the added benefits of a shorter application time, longer duration of effect, and lower cost; however, it is only licensed for use in full term infants > 1 month old.

This study is important and well designed. Strengths include the use of an identical placebo control and good inter-rater reliability among the researchers who assessed pain. More research is needed, however, before we can safely use amethocaine gel in newborn and preterm infants. The ideal dose and application times for infants need to be safely established; doses used in published studies range from 0.5–1.5 g with application times of 30–60 minutes. Many infants, especially those in neonatal intensive care, require multiple venipunctures and intravenous insertions during their hospital stay, and the effect of repeated dosing in a short period is not known. Additional research addressing these outstanding issues would be required before using amethocaine gel in clinical practice with newborn and preterm infants.

Marilyn Ballantyne, RN, MHSc
Clinical Nurse Specialist/Neonatal Nurse Practitioner
The Hospital for Sick Children
Program Director, Post Masters NP Diploma
Faculty of Nursing, University of Toronto
Toronto, Ontario, Canada