Reviewer’s report

Title: A Randomized Controlled Trial of Sucrose and/or Pacifier as Analgesia for Infants Receiving Venipuncture in a Pediatric Emergency Department

Version: 1 Date: 7 December 2006

Reviewer: Mats Eriksson

Reviewer’s report:

General

Even though many others have investigated sweet solutions and/or pacifiers for pain relief, this study is interesting because it includes infants up to 6 months of age. Previous research has failed to prove any analgesic effect of sucrose above the age of 2-4 months, and that of pacifier above 1 month. Another benefit of the study is the ED setting with it’s infant population that are likely to be different of that in previous studies.

The article is well written and easy to follow, and references are up-to-date and accurate. The background is adequate. I would like to add, though, that the opioid-mediated mechanism of sweet solutions have been questioned in recent papers (Gradin M, Schollin J. The role of endogenous opioids in mediating pain reduction by orally administered glucose among newborns. Pediatrics, 2005. 115(4 Part 1): p. 1004-7, Eriksson M, Finnström O. Can daily repeated doses of orally administered glucose induce tolerance when given for neonatal pain relief? Acta Paediatrica, 2004. 93: p. 246-249).

The primary outcome FLACC is well established as a clinical and scientific tool, which is also crying time and changes in heart rate.

It is good that a follow-up to ask for adverse effect was performed.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

My main concern is that the authors need to explain the inclusion and randomization process more clearly. Some important questions are:

- Why were exactly 87 syringes prepared (when power analysis suggested a sample size of 84)(p 9 line 4)?
  - It is stated on p 11, line 4-5, that all patients aged 0-6 month were identified and that eligible patients were recruited. This gives an impression that recruitment was performed 24 hours a day, 7 days a week, but in Results (p 14, line 9-11) we find that timing of recruitment was dependent on research nurse availability. I would like to know the total number of admitted patients age 0-6 month during the two study periods, in other words, how many patients were not asked to participate? Did they differ from the included infants in any relevant way? This is discussed in the end of the article but maybe the authors can provide some additional data.
  - Were there any differences between patients from the two study periods?
  - Please describe the randomization method more in detail. Was block-randomization used due to the long recruitment-periods?

The lower age in the pacifier & placebo group is also a problem, as well as two other items that seem to differ: NPO in the pacifier & sucrose group and admission rate in the admission rate in the pacifier and placebo group. In a RCT, demographic and baseline data should preferably be similar between groups. I would like to know the variation in table 1 to be able to judge if there is a significant difference. I think the authors need to discuss more what impact this might have on the result. Age is likely to affect sensitivity both to pain and pain-relief (it is good that an age-stratified analysis is done).

I do also have a question about the fairly high sucrose concentration. In the review by Stevens et al. (ref 5 in this paper) a dose of 0.24 g sucrose = 1 ml 24 % solution is found to be effective for newborn infants: “but there did not appear to be any benefit in administering doses of sucrose greater than 0.50g”. You have
given 2 ml of 44 % solution = 0.88g. I think the authors need to explain the chosen concentration and amount.

Was all data collection performed by the same research nurse = one person? Why are the authors then talking about interrater reliability (p 14, line 19-20).

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

The name of the authors on the title page seems to be inconsequently written. Everyone is on the form Firstname I. Lastname except Terry Klassen who is presented as Klassen T.

The figures (at least in my copy) are not sharp and need to be worked with before publication. Fig 2 could be presented as a table instead.

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Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests.