Reviewer's report

Title: The Minimally Effective Dose of Sucrose for Procedural Pain Relief in Neonates: A Randomized Controlled Trial

Version: 0 Date: 18 Jun 2017

Reviewer: Eva Cignacco

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The RCT aimed at determining the minimally effective dose of 24% oral sucrose for reducing pain in hospitalized neonates undergoing a single skin-breaking heel lance procedure. Although there is sound evidence that oral sucrose is an effective pain relieving agent for acute procedural pain in neonates, there is a lack of clarity and a high uncertainty in the clinical setting on the minimally dose needed to manage pain in neonates. The study addresses these current important questions.

The study is methodologically well conducted and reported in a very concise way. The reporting adheres to the CONSORT guidelines. There are few minor points to address and a critical remark on the effectiveness of oral sucrose to successfully reduce acute procedural pain.

Outcome Measures

It should be indicated how many persons were involved in the blinded coding

Results

Although statistically not significant, the dose of 0.1 ml evoked moderate pain (7 to 11.9) in 38% and severe pain (12+) in 9% of neonates, which leads to an amazing total of 47% of neonates experiencing pain beside getting oral sucrose at 30' after heel lance. The frequency of moderate and severe pain got even higher 60' after heel lance, reaching a total of 48.7% of the neonates experiencing pain. This treatment failure, particularly for severe pain, should be discussed more in depth and be combined with some recommendation for the clinical setting. Should additional doses of 0.1ml sucrose be suggested for a single painful procedure to reduce pain intensity particularly for severe pain?

It struck me that the number of sucrose doses since birth (median = 5) is obviously lower than the number of painful procedures since birth (median = 22). This could be an indicator of inconsistent clinical use of oral sucrose in the sites under investigation. I assume this
disproportion is due to the use of alternative non-pharmacologic pain strategies. This aspect should be elaborated in more detail in the discussion section.

Discussion

There was a site effect which the authors explain by contextual factors. It should be stated that these factors refer to organizational contextual factors, as the term contextual factors might refer to individual or political factors also.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.
I am able to assess the statistics

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