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Title:

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Date:

2019-01-01

Citation:

Harrison, D. & Bueno, M. (2019). Ethics of conducting the study “oral 24% sucrose associated with nonnutritive sucking for pain control in healthy term newborns receiving venipuncture beyond the first week of life” [letter]. *Journal of Pain Research*, 12 (0), pp.1913-1914. <https://doi.org/10.2147/JPR.S203526>.

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Ethics of conducting the study “Oral 24% sucrose associated with nonnutritive sucking for pain control in healthy term newborns receiving venipuncture beyond the first week of life” [Letter]

This article was published in the following Dove Press journal:
Journal of Pain Research

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Dear editor

We refer to the pilot study by De Bernardo et al,¹ in which 66 healthy infants were randomized to 24% sucrose or 10% glucose during venipuncture. Findings were 24% sucrose statistically significantly reduced pain compared to 10% glucose. This is not surprising as the efficacy of sweet tasting solutions in reducing pain in newborn infants has been known since the early 2000s,² and less concentrated solutions, including the 10% glucose used in this study had already been shown to be ineffective. Therefore, this trial, which studied an already known effective intervention compared to an already known ineffective intervention, does not comply with the principle of equipoise.^{2,3}

Clinical research trials require equipoise, defined as “a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial”.³ This requires that the investigator is fully aware of the current knowledge regarding benefits of intervention and control arms and existing knowledge gaps before planning a trial. Unfortunately, it is evident the authors were not aware of the knowledge concerning analgesic effects of sweet solutions before they commenced their study.

The authors state “The study was conducted in accordance with the Declaration of Helsinki”. However, this implies that: “Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature...”.⁴ As stated earlier, this had obviously not occurred as evidenced by the omission in the reference list of key systematic reviews on the topic. Another concern with this paper relates to parental informed consent. The authors stated that informed consent from the families was obtained. However, were parents truly informed about the study? Were they informed of the fact that there was already abundant evidence to support 25% sucrose during venipuncture? Were they informed about analgesic effects of other strategies they could use during their infants' venipuncture, such as breastfeeding?⁵ Engaging with and involving parents of hospitalized infants from the beginning of the study may have resulted in more relevant research being conducted.

In conclusion, extensive research conducted over the past two decades has clearly demonstrated that sweet solutions, if sufficiently sweet, reduce acute

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procedural pain in newborns, while less sweet solutions, including expressed milk and low concentrations of sucrose or glucose, are less effective. Further trials of sweet solution analgesia in medically stable newborns and infants beyond the newborn period are not ethically justified and do not address any knowledge gap. As clinicians, researchers, student supervisors, ethics committee members, and health-care organizations, we need to ensure that ethically responsible research is being conducted; parents are fully informed about research and preferably, involved in the research processes, and relevant evidence is used in practice. Ethical conduct relating to infant pain research must improve. In the meantime, we have a responsibility to implement existing best evidence into clinical practice while continuing to address true knowledge gaps about ways to consistently reduce newborn pain.

Disclosure

The authors report no conflicts of interest in this communication.

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