

# 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” [Response to Letter]

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## Dear editor

We are glad to respond to the concerns raised by Harrison and Bueno regarding our manuscript. Some mistakes and misunderstanding in the original letter need to be addressed. The surname of the first author is De Bernardo and not Bernardo. In our paper, 66 healthy newborns with a mean of 22 days of life were enrolled. This was the first novelty in the study design. Secondly, the patients were newborns discharged from hospital and readmitted for routine controls in the neonatal ward. The setting of the study was thus quite different from neonatal intensive-care units or rooming-in inpatients in the first days of life. The study aimed to test the effectiveness of sweet solutions associated with nonnutritive sucking in healthy and unhospitalized newborns. Newborns received oral 24% sucrose or 10% glucose before and during venipuncture, starting with a pacifier for nonnutritive sucking in both groups. The authors did not limit their analysis to effectiveness of the sweet solutions as nonpharmacological treatment, but they studied the efficacy of the sweet solutions in association with nonnutritive sucking in the neonatal period, during the third week of life, and in a new setting. For this reason, the study complied with the principle of equipoise. Our research team have already performed several studies on neonatal pain.<sup>1-8</sup> We are sorry that we did not cite the work of Harrison and Bueno, but the list of references reported in the manuscript was adequate for the aim of the study. In a meta-analysis, Harrison et al considered eligible 62 trials that included

term and/or preterm infants in the neonatal period, receiving sucrose, glucose, or other sweet solutions orally compared with no treatment, water, pacifier, swaddling/positioning, skin-to-skin care, formula feeding, expressed breast milk, breastfeeding, sensorial saturation, or topical anesthetics.<sup>9</sup>

Furthermore, this meta-analysis focused only on crying time and composite infant pain-intensity scores to evaluate the effectiveness of nonpharmacological treatments. Our study aimed to investigate the use of sweet solutions in association with nonnutritive

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sucking in the neonatal period (0-29 days) beyond the first 2 weeks of life in healthy unhospitalized newborns who returned to the clinic for checkup and had venipuncture requested.<sup>10</sup> Parents were fully informed about the aims of the study, and they were also able to choose to provide their newborn breastfeeding, nonnutritive sucking, or sweet solutions alone during venipuncture. To the best of our knowledge, this is the first study in the literature to investigate the efficacy of 24% sucrose as an analgesic in healthy unhospitalized newborns in the third week of life. This research reduces the gap in health assistance during the neonatal period. A pilot study can be also a way to implement non-pharmacological treatment to control pain in newborns in settings other than intensive-care units. Despite evidence existing on the efficacy of sweet solutions since the 2000s, it is still not routine analgesic procedure in neonatal care.

In conclusion, the study contributes to reducing the gap between theory and clinical practice and paves the way to encourage and implement the best clinical practice for newborns.

## Disclosure

The authors report no conflicts of interest in this communication.

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