

Research Article

Breastfeeding: Non-Pharmacological Analgesia for Reducing Procedural Pain in Healthy Full-Term Infants

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• Neonatal pain; Heel prick; Breastfeeding; Non-pharmacological analgesia

Abstract

Background: Some routine painful diagnostic procedures are performed even in healthy full-term neonates. Neonates feel pain and non-pharmacologic interventions can reduce this unpleasant experience. However, it is not already established which is the optimal measure.

Research aim: To evaluate the efficacy of non-pharmacologic interventions in relieving pain response during heel prick in healthy full-term neonates.

Methods: The neonates (N=61), at 72 hours of life during the metabolic screening test, were assigned into three groups: Breastfeeding with Skin-to-Skin Contact Group, Oral Glucose Group and Maternal Holding with Swaddling Group. Physiological parameters variations (heart rate and peripheral oxygen saturation) were evaluated using pulse oximeter at three times (T₀: 10 minutes before; T₁: during and T₂: 10 minutes after heel prick). Neonatal Infant Pain Scale was assessed at T₁.

Results: All groups showed a significant heart rate increase at T₁ respect to T₀ (Breastfeeding with Skin-to-Skin Contact Group p=0.001; Oral Glucose Group p<0.0001; Maternal Holding with Swaddling Group p<0.0001) and a tendency towards a higher heart rate at T₂ compared to T₀. At T₁ respect to T₀, oxygen saturation decreased only in Maternal Holding with Swaddling Group (p=0.0001), whereas in the first and in the second Group it remained stable. Median Neonatal Infant Pain Scale score was significantly lower in Breastfeeding with Skin-to-Skin Contact Group compared with other groups (value=1, 4 and 4.5, respectively). No neonate of Breastfeeding with Skin-to-Skin Contact Group showed Neonatal Infant Pain Scale score>5.

Conclusion: Breastfeeding provides superior analgesia than the other non-pharmacologic measures.

ABBREVIATIONS

HP: Heel Prick; SS: Sensorial Saturation; BF: Breastfeeding; GA: Gestational Age; BW: Birth Weight; BF + SSC: Breastfeeding + Skin to Skin Contact; OG: Oral Glucose; MH + SW: Maternal Holding + Swaddling; HR: Heart Rate; SpO₂: peripheral Oxygen Saturation; NIPS: Neonatal Infant Pain Scale; SGA: Small for Gestational Age; SD: Standard Deviation.

INTRODUCTION

The word "pain" was defined in 1986 by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" [1]. Physical pain sensation is generated by the massive activation of peripheral receptors caused by mechanical, chemical or thermal stimuli, transmitted by communicating neurons to the Central Nervous System, where they are processed. It is hypothesized that an immaturity of such a network of communication implies the impossibility of perceiving pain; consequently, until 1980s it was claimed that "pain" was a subjective experience not perceptible by neonates. Now it is

known that neonates feel pain [2,3], and its management is a relevant issue in neonatal period because of the short-term [4,5] and long-term consequences [7].

Routine medical care includes, even for healthy full-term neonates, some painful diagnostic procedures, such as heel prick (HP). It is a simple procedure, but it can result more painful than venipuncture, especially when multiple pricks and foot squeeze are performed for blood flowing well. HP provokes pain-related stress with a consequent increase of the biomarkers of oxidative stress [5], it is therefore mandatory to prevent and alleviate needle-related procedural pain and Italian clinical guidelines recommend adopting Sensorial Saturation (SS) (Grade A recommendation) [7].

SS is a non-pharmacological analgesic technique that involves the use of pleasant sensory stimulation to compete with the arrival of the painful stimulus to the brain [8]: the "gate control theory" explains the interaction and mutual modulation existing between nociceptive and non-nociceptive nerve fibers [9]. Breastfeeding (BF) inducing gustative, auditory, visual, olfactory, thermal, tactile and proprioceptive inputs at the same time should be considered like SS.

Our main objective was to evaluate the healthy full-term neonates' reaction to the painful stimuli due to HP and to investigate the analgesic effect of BF in addition to Skin-to-Skin Contact (SSC) versus other non-pharmacological interventions.

METHODS

The study was conducted at the "Fondazione Policlinico Agostino Gemelli, IRCCS" in Rome, Italy, from February to September 2018. The number of deliveries was 4090 during 2018; and, in the Department of Obstetrics and Neonatology, Rooming-in is expected to sustain mother-father-infant bonding and to provide an initial support to parents before discharge.

A convenience sampling was applied, and the target population was healthy full-term neonates that had to undergo HP for metabolic testing. Inclusion criteria were the following: (1) written parental informed consent, (2) vaginal birth, (3) gestational age (GA) between 37 weeks + 0 days and 41 weeks + 6 days, (4) clear amniotic fluid, (5) premature rupture of membranes less than 18 hours, (6) CTG Category I or II during delivery stage, (7) single fetus in cephalic presentation, (8) Apgar score at least 7 at 1' and 5' after birth and (9) birth weight (BW) between 2500 g and 4500 g. Exclusion criteria were: a) any maternal condition that do not allow breastfeeding, such as (1) severe cardiopathies, nephropathy or severe acute anemia, (2) pre-eclampsia, eclampsia, HELLP syndrome, (4) HIV, HBV, HCV infections in active phase, (5) hematopathy and malignant neoplasm, or b) administration of analgesic or sedative drugs to neonate.

The first day of the last menstrual period and the early ultrasound estimation were used to define the GA. In case of weigh-for-gestational-age at birth less than the 10th percentile the neonate was defined Small for Gestational Age (SGA), respect to the Italian anthropometric newborn curves [10,11].

1. The neonates were assigned to three groups according to the non-pharmacologic intervention adopted: In the Breastfeeding and Skin-to-Skin Contact Group (BF+SSC Group) the newborn infant was placed naked on the mother's bare chest and breastfeed during the whole procedure. BF started 1 minute before blood sampling to allow the infant to focus on it, and it continued in T₂ phase.
2. In Oral Glucose Group (OG Group), the neonate received oral glucose 10% during HP. At the end of the procedure, carried out on the changing table, the newborn stayed there alone for at least 30 seconds before being comforted by his/her mother.
3. In Maternal Holding and Swaddling Group (MH+SW Group), the neonate was gently wrapped with his/her sheet to smell his/her perfume, and he/she was held by the mother.

Data collected for each neonate were: Heart Rate (HR), peripheral Oxygen Saturation (SpO₂) and Neonatal Infant Pain Scale (NIPS) score. HR and SpO₂ were recorded using Masimo Radical-7® pulse oximeter (Masimo Corporation, Irvine, CA, USA) with the probe positioned at right wrist. NIPS score was assigned by a single examiner, who evaluated each of the following items: facial expression, cry, breathing pattern, arms, legs, and state of

arousal. This neonatal pain scale assessment was adopted since it is specific for full-term newborn and it has high degree of sensitivity to analgesia [12,13]. NIPS score >5 was considered as moderate-to-severe pain.

All data were stored in the quiet inpatient room barred to other people and had no identifying names. The only people approved into the room were the skilled pediatric nurse or midwife, the observer and parents, who must not interfere before sampling and 30 seconds after HP. The neonatal pain response was analyzed at 72 hours of life during the sampling for mandatory metabolic screening test performed before discharge with a standard procedure by skilled pediatric nurses or midwives. NIPS score was calculated referring to the first puncture if multiple pricks were required.

Three-time points were considered: T₀ (baseline: 10 minutes without stimuli before HP); T₁ (procedure: HP and squeezing) and T₂ (recovery: 10 minutes after the end of the procedure). HR and SpO₂ were collected during all time-points, while NIPS score was assessed at T₁.

Results are presented as mean ± standard deviation (SD) for continuous variables or as median (interquartile range) and as number (percentage) for categorical variables. Unpaired Student's t test was used for parametric data, Wilcoxon rank-sum test (Mann-Whitney U test) for nonparametric data, and χ^2 test for categorical variables. Analyses were performed using "Stata Statistical Software: Release 10" (StataCorp LP, College Station, Tx). A p < 0.05 was considered statistically significant.

RESULTS

Sixty-four neonates were selected for this study. Three of them were excluded because their mothers refused participation (Figure 1): the first mother gave her consent, but at the beginning of the procedure she withdrew what she said; the second referred to be very impressionable; the third mother just didn't want to take part of this study. The participation rate was 95%.

There were no significant differences among the groups in terms of maternal age, gravidity and parity, GA, BW, sex, number of SGA or Apgar score at 1' and 5' (Table 1).

The median NIPS score for each group, as well as HR and SpO₂ is shown in the Table 1. All groups showed a significant increase in HR at T₁ compared to T₀ (BF+SSC Group, p=0.001; OG Group, p<0.0001; and MH+SW Group, p<0.0001). At T₂, HR decreased in all groups respect to T₁, but a significant decrease was assessed only in MH+SW Group (p=0.0001). At T₂ respect to T₀ a tendency towards a higher HR was observed in all groups (Figure 2A).

SpO₂ decreased in MH+SW Group (p=0.0001) at T₁ compared to T₀, whereas in BF+SSC Group and OG Group it remained stable. At T₂ respect to T₁, in all groups SpO₂ increased, but significantly only for MH+SW Group (p<0.0001) (Figure 2B). Comparing SpO₂, a significant difference was observed between BF+SSC Group and MH+SW Group at each time-point (T₀, p=0.06; T₁, p=0.002; T₂, p=0.09).

The median NIPS score was significantly lower in BF+SSC Group than the other groups. As evidenced in Figure 3, no neonate of BF+SSC Group showed a NIPS score >5, whereas 5

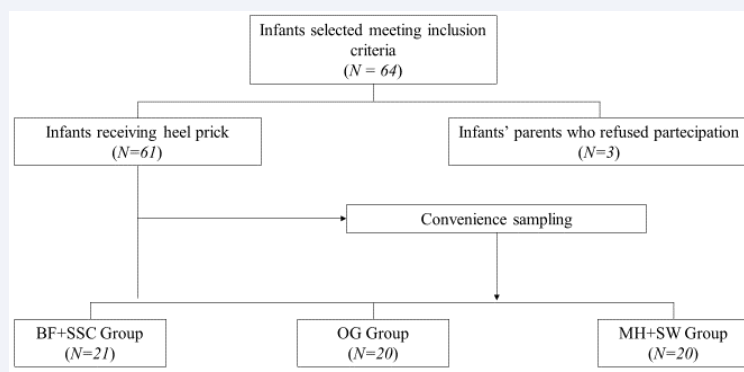


Figure 1 Flowchart of participant recruitment

BF+SSC Group = Breastfeeding and Skin-to-Skin Contact Group; OG Group = Oral Glucose Group; MH+SW Group = Maternal Holding and Swaddling Group.

Table 1: Maternal and neonatal characteristics (N=61).

	BF+SSC Group (N=21)	OG Group (N=20)	MH+SW Group (N=20)
Age, years*	33.9 ± 5	32.5 ± 5	33.0 ± 5
Gravidity = 1 n (%)	11 (52)	9 (45)	9 (45)
Gravidity > 1 n (%)	10 (48)	11 (55)	11 (55)
Parity > 0 n (%)	8 (38)	7 (35)	11 (55)
GA, wks*	39 ± 1	39 ± 1	39 ± 1
BW, g*	3414 ± 327	3320 ± 368	3261 ± 390
Male, n (%)	11 (52)	9 (50)	12 (70)
SGA, n (%)	2 (9.5)	2 (10)	3 (15)
Apgar 1*	8.9 ± 0	9 ± 1	8.7 ± 1
Apgar 5*	9.9 ± 0	9.8 ± 0	9.7 ± 1

* Results expressed as mean ± SD

BF+SSC Group= Breastfeeding and Skin-to-Skin Contact Group; OG Group= Oral Glucose Group; MH+SW Group= Maternal Holding and Swaddling Group. GA= Gestational Age; BW= Birth Weight; SGA= Small for Gestational Age.

of 20 (25%) of OG Group and 7 of 20 (35%) of MH+SW Group assessed moderate-to-severe pain (BF+SSC Group vs OG Group, $p=0.04$; BF+SSC Group vs MH+SW Group, $p=0.01$).

DISCUSSION

The effectiveness of non-pharmacological analgesic techniques for neonatal pain management is demonstrated; although it is not already established which measure is the optimal one.

Oral glucose is recommended in reducing procedural pain [14]; swaddling results a complementary measure during painful procedures [15]. Several studies report that both expressed milk and BF can be considered effective analgesics for minor procedures; however, supplemental human milk, that is mother's own milk given by oral or nasogastric tube or with syringe, seems to provide inferior analgesia than BF [16,17]. Breastfed infants demonstrate significantly lower pain responses respect to babies who are held by their mothers, swaddled, or receive oral glucose,

a pacifier, placebo, or no intervention [17]; they also show lower variations of HR and SpO₂ when compared with neonates who receive oral sucrose [18]. Moreover, neurophysiological assessments by two-channel near infrared spectroscopy (NIRS) showed that breastfeeding analgesia, differently from glucose, is associated with a generalized cortical activation overwhelming pain perception [19].

The results of our study confirm that HP induces pain in healthy full-term neonates, and that none of non-pharmacologic agents completely eliminate pain, since the HR increase in all groups during the procedure. In addition, our data illustrate that breastfed neonates in SSC experienced less pain than the infants who received oral glucose 10% and those who were held by their mothers and swaddled.

According to Gabriel et al. [20], NIPS score was lower in BF+SSC Group than the other groups. Nevertheless, we observed an increase of HR without SpO₂ decrease either in BF+SSC Group and OG Group. This variation of HR alone in absence of

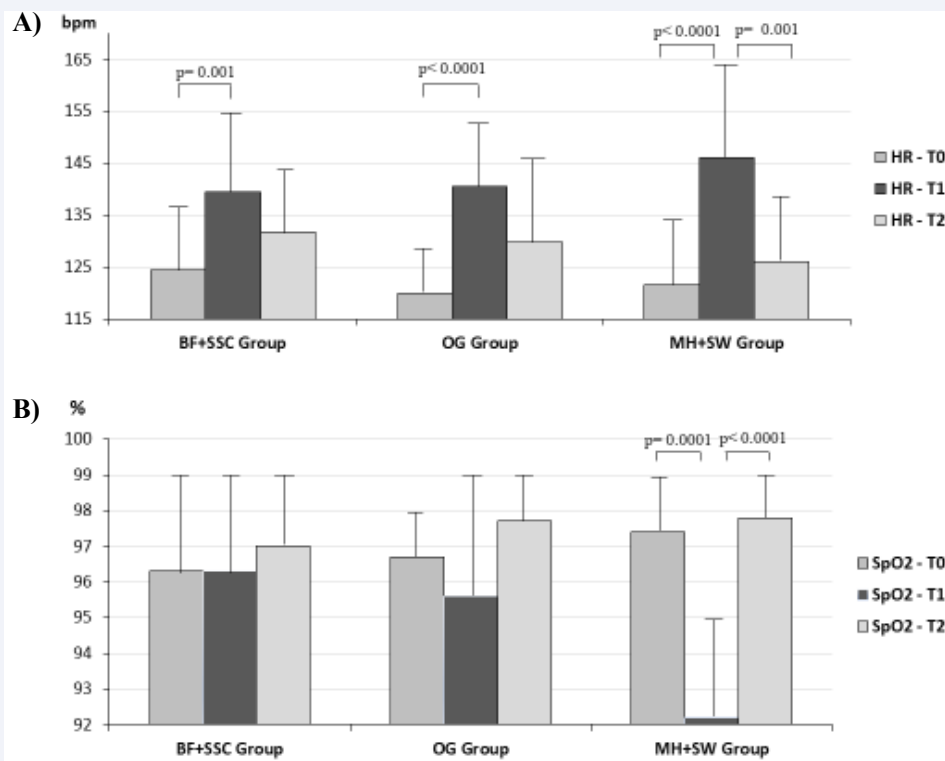


Figure 2 (A and B): Heart Rate and Oxygen Saturation at T₀, T₁ and T₂ for each study group
 T₀ (baseline: 10 minutes without stimuli before heel stick); T₁ (procedure: heel prick and squeezing) and T₂ (recovery: 10 minutes after the end of the procedure). HR= Heart Rate; SpO₂= perypheral Oxygen Saturation; BF+SSC Group = Breastfeeding and Skin-to-Skin Contact Group; OG Group = Oral Glucose Group; MH+SW Group = Maternal Holding and Swaddling Group.

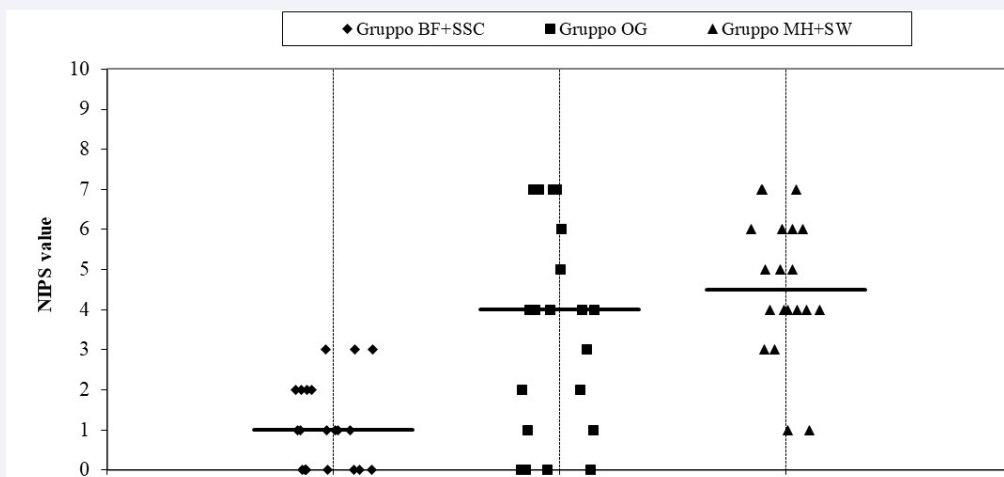


Figure 3 NIPS Score during procedure in the three groups
 BF+SSC Group = Breastfeeding and Skin-to-Skin Contact Group; OG Group = Oral Glucose Group; MH+SW Group = Maternal Holding and Swaddling Group.

desaturation could mean that both BF+SSC and OG provide more effective analgesia and that pain is contained, but not totally overwhelmed. Greater pain sensation resulted in neonates of MH+SW Group since in these neonates the HR and SpO₂ variation simultaneously occurred.

Although recent studies highlight the relevance of maternal-

infant relationship, our data do not allow us to evaluate if it is human milk itself or its combination with SSC to provide this deeper analgesia. Neurophysiological study and clinical assessment of nociceptive interventions showed that the main analgesic factor in BF is the relational experience rather than the breast milk itself [21]. Starting from these findings, on the basis of our results, we may assert that the mother-infant relationship

established during maternal-holding is efficient only if combined with other non-pharmacological measures. In fact, NIPS score and physiological parameters variations show that the neonates who perceived both maternal-infant relationship, realized with the SSC and oral stimulation with BF, experienced a less intensive pain sensation than the neonates who perceived or the only maternal-infant relationship through swaddling and holding, or the only oral stimulation through glucose solution.

LIMITATIONS

The present study has some limitations, such as the small sample. The absence of blindness of the observer and the paediatric nurses about the groups was limited by their unknowledge of the purpose of the study. Finally, the absence of recording did not allow an evaluation from different observers and in different circumstances.

CONCLUSIONS

It is evident how important is a deep multisensorial stimulation to make a non-pharmacologic intervention effective in reducing neonatal pain sensation and our results show that BF is the measure able to reach that analgesic strength. In conclusion, our results suggest that BF+SSC provides superior analgesia respect to OG and MH+SW, highlighting that the maternal-infant relationship can be considered like an "analgesic amplifier" when combined with other non-pharmacologic interventions rather than an analgesic intervention itself. The combination of maternal-infant relationship with other measures realizes the multisensorial stimulation that minimizes painful stimuli and allows faster recovery. Considering this natural multisensorial stimulation, as suggested by Bembich, BF+SCC should be preferred to the other non-pharmacological analgesic measures for minor painful procedures in healthy full-term neonates [21].

CLINICAL IMPLICATIONS

Neurophysiological studies [21] underline the complexity of its mechanism of action, so we think that the evaluation of analgesic effectiveness of non-pharmacological measures can need a multidimensional approach: it could be useful making a comparison among functional neuroimaging study, NIPS score and SpO₂ and HR variations, in order to clarify even the mechanism of action of non-pharmacologic interventions and maternal-infant relationship especially.

AUTHORS' CONTRIBUTIONS

GC, MPDC and RS designed the study. MPDC and GC performed the statistical analysis. MPDC, RS and MD participated in the design of the study. GC and MPDC wrote the discussion and reviewed the results. GC submitted the manuscript. MPDC, RS, MD and AL revised the manuscript. All authors read and approved the final manuscript.

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