

論 文 内 容 要 旨

Effect of music (Brahms lullaby) and non-nutritive sucking on heel lance in preterm infants:
A randomized controlled crossover trial
(早期産児の踵穿刺における音楽（ブラームスの子守歌）とおしゃぶり併用の疼痛緩和効果：無作為化クロスオーバー試験)

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Introduction

Preterm infants are exposed to a large number of painful procedures, which have been linked to poor early neurodevelopment and altered brain development. Oral sucrose solutions are commonly administered to infants for managing acute procedural pain. However, the long-term effects of repeated oral sucrose usage have not been systematically studied. Non-nutritive sucking (NNS), facilitated tucking and swaddling are also effective for immediate pain control preterm infants, but yield a Premature Infant Pain Profile (PIPP) score higher than 6 points. PIPP scores of 6 or less generally indicate minimal or no pain.

Although the mean PIPP score of 21 preterm infants with music and facilitated tucking during heel lance indicated some still had pain. Also, a reduction in the heart rate (HR) and facial expression of pain during heel lance with a Brahms lullaby appeared to only occur in infants at minimum 32 weeks' postconceptual age (PCA). However, the sample size of the two studies was small.

To develop a more effective pain management method than oral sucrose, this study evaluated the pain alleviation effect and the time to return to homeostasis facilitation effect of a Brahms lullaby combined with NNS for heel lance in preterm infants.

Methods

This non-blinded, randomized controlled, two-period, two-sequence crossover trial was approved by the institutional review board at the A hospital (approval number 14-008). Inclusion criteria of infants were as follows: (a) 28 - 35 weeks PCA at birth (infants born at < 36 weeks PCA heel lance), (b) 32 to 35 weeks PCA at the time of the intervention, based on the infant's ability sucking and listening to the voice version of lullabies, (c) Apgar score of 6 or more at 5 minutes after birth, (d) intraventricular hemorrhage grade of 2 or less, (e) 48 hours or older in the case of birth by cesarean operation, and (f) permission of the attending physician. Exclusion criteria included: (a) a congenital anomaly or a serious condition, and (b) sedative or analgesic drug usage within 48 hours prior to the heel lance. Using the Wilcoxon signed-rank test in G*power 3.1.9.2, we estimated that 25 preterm infants would be needed to detect the effect size of 0.6 an alpha level of 0.05 and a power of 80%.

Twenty-five infants were randomly allocated to intervention (a Brahms lullaby with NNS, facilitated tucking and holding) or standard care (facilitated tucking and holding). The primary outcome variable was PIPP, and secondary outcomes were heart rate (HR), oxygen saturation, abnormal HR, the frequency of abnormal HR and potential stress O₂ Sat. HR, O₂ Sat and the preterm infant's facial expressions were measured from before baseline (before intervention) until five minutes (every 30 seconds) post heel lance. The interrater reliability of the PIPP of six preterm infants by two coders ranged from 0.851 to 1.0, which was considered satisfactory.

After the baseline score was measured for one minute, a pacifier was placed in the mouth, the infant was held and facilitated tucking was used. Then a Brahms lullaby by a Japanese female vocalist with instrumental music was played. The lullaby volume was below 65 - 75 dB (scale C). One minute after the lullaby was started, the practitioner performed the heel lance to the

infants. The intervention was continued until five minutes post heel lance. Infants in the standard care group received only facilitated tucking and holding.

Differences in PIPPs, HRs and O₂ Sats were tested using a 2-sided type 3 F test of the intervention effect in a general linear mixed model, where the final model included fixed-effects for intervention, sequence, period, and with random effects for participants. The protocol-defined model included evaluation of carry-over effect, period effects, and intervention effect. The difference-in-differences model was selected as the appropriate strategy comparing change from baseline or 30 seconds post heel lance between the 2 groups. The PIPP reduction rate was calculated by dividing the value of subtracting the PIPP at each point from the PIPP at 30 seconds by the PIPP at 30 seconds. The Mantel-Haenszel Test was used to compare the frequencies of abnormal HR, potential stress O₂ Sat and abnormal O₂ Sat between the 2 groups.

Results

The infants were 33.8 weeks gestational age at birth, 1983.7 grams birth weight, and 32 - 35 weeks post-conceptual age. At all 10 measurement points, constructed of every 30 seconds post heel lance, mean PIPP of infants during the intervention (3.6 - 2.4) was significantly lower than during the standard care (8.0 - 4.6) (range, $P < 0.0001 \sim P = 0.0039$). All PIPP reduction rates from the 30 seconds point were similar between the 2 groups. The HR of preterm infants at the 120 seconds points were significantly lower ($P = 0.0151$), and the HRs of 6 points were considerably lower during the intervention than during the standard care (range, $P \leq 0.0879 \sim P \geq 0.049$). The abnormal HR total number was significantly lower during the intervention (2) than the standard care (23) (frequency ratio=0.087, $P < 0.0001$).

Discussion

In the intervention group, all mean PIPP scores post heel lance were less than 6 points, which suggests minimal or no pain. The mean PIPP scores in the current study were lower than those of previous interventions such as NNS, swaddling, Kangaroo mother care, and facilitated tucking. Although the PIPP scores of the preterm infants receiving sucrose with or without NNS were lower than 6, sucrose usage has some problems such as a risk of oxidative stress. The HRs were considerably lower in the intervention group than in the standard care group. The incidence of abnormal HR was less than 10% of that with standard care. The current study demonstrated stronger pain relief and the maintenance of homeostasis for heel lance in preterm infants. The results showing no adverse events detected from the intervention in the current study indicate the safety of this intervention.

Conclusion

A new pain management method, the addition of a recorded Brahms lullaby to non-nutritive sucking, facilitated tucking and holding, demonstrated stronger analgesia and maintenance of homeostasis on heel lance in preterm infants.