Laser acupuncture before heel lancing for pain management in healthy term newborns: a randomised controlled trial

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ABSTRACT

Background Healthy term newborns commonly undergo painful procedures during routine follow-up visits. Non-pharmacological strategies have currently become more important than pharmacological analgesic agents in neonatal pain management. Acupuncture is a new non-pharmacological method for preventing pain in newborns.

Objective We aimed to investigate the effect of laser acupuncture (LA) at the *Yintang* point before heel lancing as a non-pharmacological intervention for procedural pain management in infants.

Methods Forty-two term newborns, who were undergoing heel lancing between postnatal days 3 to 8 as part of routine neonatal screening, were randomly assigned to the LA group or the oral sucrose group. In the LA group, 2 min before the heel lancing, 0.3 J of energy was applied to the *Yintang* point using a Laser PREMIO-30 unit for 30 s. In the sucrose group, each infant received 0.5 mL of 24% sucrose orally via syringe 2 min before the heel lancing. Each baby's behaviour was scored using the Neonatal Infant Pain Scale (NIPS), assessed blinded to group.

Results There were no significant differences between the LA and oral sucrose groups with respect to means for gestational week of age at birth, birth weight, actual weight, or Apgar score. Mean procedure time was significantly shorter in the LA group; however, mean crying time was longer and NIPS score was lower compared to the oral sucrose group.

Conclusions Our results indicate that 0.3 J of LA at the *Yintang* point before heel lancing is less effective than oral sucrose for reducing the discomfort of this procedure.

Trial registration number KA14/09.

INTRODUCTION

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[1] Healthy term newborns commonly undergo painful procedures during routine follow-up visits.[2] Some research suggests that painful experiences can alter clinical outcome and brain development in very low birthweight neonates.[3] Numerous studies have focused on minimising neonatal pain during painful procedures, but management of pain in this patient group remains a challenge.

Non-pharmacological strategies have currently become more important than pharmacological analgesic agents in neonatal pain management. To date, the two most widely studied non-pharmacological methods are sucrose administration and non-nutritive sucking.[4] The American Academy of Pediatrics and the Canadian Paediatric Society recommend oral administration of 0.05–0.5 mL of 24% sucrose 1–2 min before the procedure to decrease neonatal pain.[4] However, knowledge gaps remain with respect to appropriate dosing for sucrose and the safety and efficacy of long-term repeated doses of this agent, especially in preterm newborns. Additional research is needed to investigate the effect of repeated sucrose administration on pain intensity and long-term outcomes since orally administered sweet solutions might only mask neonatal pain.[5] The mechanism of pain relief by sucking oral sucrose is not known for certain.[6] Studies support the

theory that sucrose (due to the sweet taste) and pain relief are interrelated through the body's endogenous opioid system which provides natural analgesia.[7] The analgesic effect of sucrose is reversed with administration of naloxone, an opioid antagonist, suggesting that sucrose activates the central endogenous opioid system, with an action similar to that of opioid analgesics.[8]

Intraoral sucrose also has a calming effect on full term newborns, eliciting mouthing and hand-mouth contact.[9] This may indicate the rapid recruitment of central endogenous opioid secretion through taste stimulation by the sugar.

Acupuncture is a well-known and effective treatment for acute and chronic pain in adults[10 11] and children but has been used only occasionally for treating pain in newborn infants.[12–14] Acupuncture has been shown to be a safe, non-pharmacological treatment option that is potentially effective for pain management in preterm and term infants.[15] This technique, originally part of Traditional Chinese Medicine, involves stimulating 'points' via insertion of thin needles, or more recently via laser as a pain-free stimulus.[16] To date, 'light needling acupuncture' has been shown to have an effect on feeding, stooling and sleeping in infants with infantile colic, and to have analgesic effects on procedural pain in preterm infants.[14 17] The efficacy and safety of paediatric light needling acupuncture has been investigated, and reviews to date have concluded that acupuncture use should be limited to clinical trials.[15 18]

Landgren *et al*[17] evaluated the effect of minimal, standardised needle acupuncture on the duration and intensity of crying in infants with colic. The authors applied standardised light stimulation of the acupuncture point LI4 twice weekly for 3 weeks. More parents in the acupuncture group observed an improvement in colic and judged the infants' sleep to be 'better' or 'much better' during the study time.

Low-level laser therapy is a light-source treatment that emits no heat, sound, or vibration, but which may act via non-thermal or photochemical reactions in cells.[19–22] Throughout the past 35 years, as an alternative to using needles, practitioners have administered low-level laser stimulation to acupuncture points via laser-emitting devices applied to the skin. In this technique, known as laser acupuncture (LA), a laser beam generated by a low-level laser diode stimulates the point. This method is painless and especially suitable for awake children. However, optimal points, power output, and duration of stimulation for the LA method remain controversial.

LA has been used with the purpose of achieving pain relief in children and adults.[23 24] Baxter *et al*[23] reviewed the clinical effectiveness of LA on adults aged over 18 years and found it effective in the treatment of myofascial pain, chronic tension headache, and postoperative nausea and vomiting. The efficacy of LA in children (17 years of age or younger) with headache was investigated, and significant decreases were documented in headache frequency, monthly cumulative headache hours, and headache pain intensity.[24]

Other research has demonstrated that LA can be beneficial for addressing vomiting in children. Schlager *et al*[25] investigated the effectiveness of this modality on postoperative vomiting in children who had undergone strabismus surgery. They found that the group receiving LA had a significantly lower incidence of vomiting than the control group not receiving this therapy.

Previous studies have commonly used the *Yintang* point. Wang *et al*[26] applied acupressure at the *Yintang* point in a group of paediatric patients 30 min before the patients underwent general anaesthesia for gastrointestinal endoscopic procedures. They observed decreased pre-procedural anxiety and reduced requirements for intra-procedural propofol. Ecevit *et al*[14] found some evidence that needle acupuncture at the *Yintang* point reduces Neonatal Infant Pain Scale (NIPS) score for minor painful procedures in preterm infants. They observed shorter crying duration and lower (better) NIPS scores in their needle acupuncture group compared to untreated controls.

We aimed to investigate whether stimulation with LA at the *Yintang* point would also provide pain relief. To date, low-level laser therapy has not been reported as a means for reducing procedural pain in children or adults. In this study, our aim was to investigate the effect of LA at the *Yintang* point before heel lancing as a non-pharmacological intervention for procedural pain management in infants, in comparison with oral sucrose administration.

METHODS

Design and participants

The prospective study involved 42 term newborns who were undergoing heel lancing between postnatal days 3 and 8 as part of routine neonatal in-patient screening for phenylketonuria and hypothyroidism. All the infants enrolled were healthy, had been delivered at Baskent University Hospital in Ankara, Turkey between the 37th and 42nd gestational weeks, and had a 5 min Apgar score ≥7. The exclusion criteria were perinatal asphyxia, birth trauma, cardiorespiratory instability, or administration of sedative medication to mother or child. The study was approved by Başkent University Ethical Research Committee, and written informed consent was obtained from the parents of each participant.

Intervention

Each participating infant was randomly assigned to the LA group or the oral sucrose group. Newborns were randomly allocated to the groups according to a blank envelope containing a card indicating one of

two groups; the envelope was opened after the newborns came for neonatal screening. Patients and the nurse were blinded to group allocation before the envelope was opened. All babies were fed at least 30 min before the heel lancing procedure. In the LA group, low-level LA was applied to the *Yintang* point, located midway between the medial ends of the eyebrows at the root of the nose. This point is traditionally indicated for insomnia, agitation, and restlessness, and stimulation produces an anxiolytic and sedative effect.[27] Two minutes before the heel lancing, 0.3 J of energy was applied to the *Yintang* point by using a Laser PREMIO-30 unit (Sedatelec, France) for 30 s (figure 1). This low-level laser has the following characteristics: 0.2 mm diameter diode pulsed laser; an average power output that can be programmed according to the required skin depth; it has a wave length of 905 nm and is capable of pulse frequency programming, scanning (applied frequency is 73 Hz), and a 75 ns pulse width. The equipment's nominal ocular hazard distance (NOHD) is 30 cm. Both infants and the physician wore special protective glasses during the procedure. A physician well trained in LA applied the technique.

In the sucrose group, each infant received 0.5 mL of 24% sucrose orally via syringe 2 min before the heel lancing. The sucrose was instilled with gentle movements of the syringe to stimulate sucking for 30 s.

In our practice, we routinely give oral sucrose before the painful procedures so we regarded the oral sucrose group as the standard care control group.

Heel lancing was carried out by wiping the heel with alcohol, pricking with a lancet (Broche Sterile Blood Lancet, manual lancet, blade width 2.5 mm and depth 1 mm), and squeezing to collect the required blood volume (0.25 mL). All 42 heel lancing procedures were done by the same experienced nurse blinded to intervention.

Neonates were videotaped during the entire procedure, though the administration of LA and sucrose was not included. A research assistant blinded to the study hypothesis and group allocation subsequently made assessments from the videotape. Each baby's reactions during the heel lancing was scored from the videotape using a behavioural pain scale known as NIPS. NIPS is recommended for assessing pain during procedures, and consists of five behavioural indicators (facial expression, movement of arms, movement of legs, crying, state of arousal) and one physiologic indicator (breathing pattern). The total score for NIPS ranges from 0 to 7, with a higher score indicating more severe pain.[28] The validation and reliability of NIPS was provided by Lawrence *et al*[28] and it was adapted for use in Turkish newborns by Akdovan *et al*.[29] In addition to the total NIPS score, procedure time was recorded in seconds.

Figure 1 Laser PREMIO- 30 unit is appropriate.

Cry duration expressed in seconds and milliseconds and duration of the procedure were recorded from the videotapes. The first cry was defined as the duration of audible distressed vocalisations with a continuous pattern before a quiet interval of 5 s from the time of the painful stimulus. We recorded the total length of cry in response to heel lancing, defined as a cry starting within 5 s of firing the lance and finishing with a gap of at least 30 s before any further cry. The score for the first 30 s after the heel prick was taken to reflect the prick pain.

No child developed any clinically visible changes on the skin and no side effects were observed.

Statistical analysis

Power analysis was calculated using PASS V.11 software packages, and showed that a sample size of n=21 per group would be required to detect a difference of 3.52 in NIPS score assuming an SD of 1.8 at 80% power and α 0.05. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS V.17.0; SPSS Inc, Chicago, Illinois, USA). A value of $p<0.05$ was considered statistically significant. Results were expressed as number of observations, mean±SD, and/or median and minimum-maximum values, as appropriate. Levene's test (homogeneity) and the Shapiro-Wilk test (normality) were used to decide which statistical methods to apply to compare the study groups' findings. Results for variables that were normally distributed and had homogeneous variances were compared between the groups using Student's t test. For variables that did not meet the assumptions for parametric testing, group results were compared between the two groups using the Mann-Whitney U test. Categorical data were analysed with Fischer's exact test and χ^2 test. When values in individual cells were ≥20% less than expected values, the 'Monte Carlo Simulation Method' was used.

RESULTS

The baseline characteristics and results are summarised in table 1. There were no significant differences between the LA and oral sucrose groups with respect to means for gestational week of age at birth, birth weight, actual weight, or Apgar score. There

were also no differences between the groups with respect to sex or mode of delivery. Mean procedure time was significantly shorter in the LA group; however, mean crying time was longer in this group. The sucrose group had a significantly lower mean NIPS score.

DISCUSSION

The main findings of our study were shorter procedure time in the LA group compared to the oral sucrose group, but longer crying time and worse NIPS scores in the LA group.

LA has been found to influence neurovegetative and neurobioelectrical parameters, such as heart rate, heart rate variability, and electroencephalogram (EEG) readings, in rats.[30] Rats' heart rates changed significantly only during 20 min red laser stimulation of the PC6 (*Neiguan*) point (located proximal to the accessory carpal pad of the forelimb, between the flexor carpi radialis and palmaris longus ligaments); thus, the experimental study showed that some effects of LA are time-dependent, and, therefore, dose-dependent. In a previous study not yet published, we compared the analgesic effects of 2 min acupressure at *Yintang* and oral sucrose before heel lancing in term newborns. Procedure time and crying time was longer in the acupressure group with higher NIPS. We also investigated the analgesic effect of acupressure at BL60 (*Kunlun*) and KI3 (*Taixi*) points before heel lancing in preterm newborns, and found that the newborns who received acupressure had shorter procedure time and shorter duration of crying.[31] As is the case with LA, this effect could be associated with duration and continuity of acupressure stimulation.

The clinical effectiveness of LA on pain management of adults (>18 years of age) was reviewed by Baxter *et al*.[23] The required dosage of LA was reported as being at least 0.5 J per point for the reduction of myofascial pain. There is no study published about the dosage of LA in newborns, so 0.3 J per point was selected in our study. Further studies are needed to find an adequate dosage for LA in newborns.

Acupuncture treatment for pain relief in children has been shown to be effective and in recent years there have been several studies concerning acupuncture procedures, especially in newborns.[13 32 33]

In our study we did not find a significant decrease in NIPS score in the LA group. There might be a significant effect of LA compared with placebo laser, but it would not be ethical for newborns to be given no intervention before painful procedures.

Yates *et al*[13] investigated the safety of non-invasive electrical stimulation of acupuncture points (NESAP) in neonates which was delivered by a transcutaneous electrical nerve stimulation (TENS) unit during routine heel pricks. Their subjects were healthy term newborn infants <3 days old and they applied NESAP with self-adhesive electrodes at ST 36 (*Zusanli*), SP6 (*Sanyinjio*), KI3, and BL60 points. They did not use any control groups but compared the effects of three different TENS settings on skin assessment, vital signs and Premature Infant Pain Profile (PIPP) evaluation. This study showed that the use of gentle electrical stimulation at selected acupuncture points is safe during invasive procedures for pain management.

Flippelli *et al*[32] studied 54 newborns diagnosed with neonatal abstinence syndrome. They examined the effects, safety and adverse effects of stimulation of seven acupuncture points by non-insertive acupuncture (NIA). They reported calming during NIA, falling asleep, and better feeding following NIA of newborns with no adverse effects.

Gentry *et al*[33] observed the effect of acupuncture on 10 infants, two of whom were neonates, for agitation, feeding, weaning from the ventilator or from analgesic medications. They found a significant decrease in need for sedative and analgesic drugs, without any complications.

The shorter heel lancing procedure time in infants who received LA compared to their counterparts who received oral sucrose is interesting. The underlying

Table 1 Comparison of demographic characteristics and clinical findings in the two groups

	Laser acupuncture group (n=21)	Sucrose group (n=21)	p Value
Gestational week at birth	38.3±0.84	38.4±0.87	0.59
Birth weight (g)	3247.6±419.29	3420.0±440.19	0.20
Age at time of procedure (postnatal days)	4.9±1.02	4.9±1.07	1.00
Weight at time of procedure (g)	3233.8±433.95	3380.4±460.76	0.29
Apgar score at 1 min	8.6±0.65	8.4±0.67	0.36
Apgar score at 5 min	9.6±0.65	9.5±0.59	0.62
Sex (female/male)	12/9	7/14	0.21
Mode of delivery (caesarean/vaginal)	20/1	16/5	0.18
Procedure time (s)	86.33±23.90	104.76±18.33	0.008*
Crying time (s)	97.95±34.23	46.66±37.82	0.000*
NIPS	4.52±0.87	3.66±1.01	0.006*

*p<0.05.
NIPS, Neonatal Infant Pain Scale.

mechanism for this effect could be associated with the vasomodulatory effect of LA on endothelium and vascular smooth muscle by the release of calcitonin gene-related peptide (CGRP).[34] However, this could be a chance finding as in our previous study we found longer a procedure time in the acupressure group.

In our group most of the infants were delivered at about 38 weeks of gestation with caesarian section. Infants were not stratified for gender, weight, mode of delivery and the duration of gestation, which is a limitation of our study.

The *Yintang* point is known to have a sedative and calming effect, and we aimed to explore whether the sedation effect might reduce the perception of pain. Our previous study's finding that needling acupuncture at the *Yintang* point reduced NIPS scores suggested that this point also has an analgesic effect.[13] Nevertheless, in our present study we found that LA at the *Yintang* point before heel lancing was less effective than oral sucrose.

CONCLUSION

To our knowledge, this is the first study to have compared the analgesic effects of administering LA as opposed to oral sucrose before heel lancing in term newborns. Our results indicate that LA at the *Yintang* point, at the dose used here, before heel lancing is less effective than oral sucrose for reducing the discomfort of this procedure. Further research is needed to evaluate potentially effective modes/doses of LA at this point, as well as the efficacy of other acupuncture points and modes of stimulation for managing procedural pain in newborns.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The study was approved by Başkent University Ethical Research Committee.

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