World Journal of Pediatrics (2022) 18:398–403
https://doi.org/10.1007/s12519-022-00531-7

ORIGINAL ARTICLE

Analgesic effect of inhaled lavender essential oil for frenotomy in healthy neonates: a randomized clinical trial

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Received: 9 December 2021 / Accepted: 21 February 2022 / Published online: 4 April 2022

Abstract

Background Neonatal pain may affect long-term neurodevelopment and must be treated. Frenotomy is a painful procedure wherein a common strategy to relieve pain (sucking) cannot be used because the technique is performed on the tongue. Lavender essential oil (LEO) has sedative and antispasmodic properties and has been successfully used to treat pain during heel puncture and vaccination. Our aim was to demonstrate if the use of inhaled LEO is effective in reducing pain during frenotomy in healthy, full-term neonates.

Methods We conducted a randomized clinical trial in neonates who underwent a frenotomy between August 2020 and April 2021. We assessed pain using pre and post-procedure heart rate and oxygen saturation, crying time and Neonatal Infant Pain Scale (NIPS) score. Patients with type 3 tongue tie were randomized into the "experimental group" and "control group". In both groups, we performed swaddling, administered oral sucrose, and let the newborn suck for two minutes. In the experimental group, we also placed a gauze pad with one drop of LEO under the neonate's nose for two minutes prior to and during the frenotomy.

Results We enrolled 142 patients (71 per group). The experimental group showed significantly lower NIPS scores (1.88 vs 2.92) and cried almost half the amount of time (14.8 vs. 24.6 seconds, $P=0.006$). Comparing with the control group, we observed no side effects in either of the groups.

Conclusions We observed a significant decrease in crying time and lower NIPS scores in the neonates who received inhaled LEO and underwent a frenotomy for type 3 tongue-ties. Thus, we recommend using inhaled LEO during neonatal frenotomies.

Keywords Ankyloglossia · Aromatherapy · Frenotomy · Lavender · Neonate · Neonatal pain · Tongue-tie

Introduction

According to the International Association for the Study of Pain, "pain" is an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage [1]. During the last several years, neonatal units have shown an increasing interest in studying neonatal pain. Historically, newborns were thought to have no pain owing to the immaturity of their nervous system [2, 3]; however, the evidence demonstrated that they feel pain and they may be more sensitive to it and to its long-term negative effects. Repeated, unrelieved pain can cause adverse physiological effects in all systems, including the brain, potentially affecting long-term development [4]. This fact has driven development-based care, which promotes individualized care based on the observation of the neonates' behaviors and the knowledge of their physical and family environment and which focuses on avoiding painful procedures as much as possible, grouping interventions to minimally manipulate the newborn, and managing pain with analgesia, swaddling, or combining both [5]. It is important to recognize and relieve pain because it may lead to hemodynamic instability, decreased oxygen saturation, and increased intracranial pressure [6]. Non-pharmacological pain relief is important in neonatology owing to the potential adverse effects of drugs. This type of relief includes sensory stimulation (positioning or swaddling, vestibular action or rocking, aromatherapy,

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non-nutritive sucking, musical therapy) and nutritive (oral sweet solutions) and maternal interventions (maternal odor and voice, breastfeeding, skin-to-skin contact) [4, 5, 7]. Oral sucrose solutions reduce but do not eliminate the signs of pain; thus, they should be used in combination with other non-pharmacological interventions [5, 8–10]. Lavender essential oil (LEO), of all the essential oils, has been studied most by healthcare professionals [11]. LEO has sedative, antispasmodic and anticolic properties and may relieve pain [7, 12, 13] by inhibiting nociceptive stimuli by stimulating the olfactory system, inducing relaxation and stimulating endogenous opioids [5]. Lavandula angustifolia ssp angustifolia, the main component in LEO, has demonstrated benefits in reducing pain during neonatal blood sampling or heel puncture [5, 7, 14] and vaccination at two months [15].

In our service, we perform painful techniques following administration of oral sucrose, swaddling, and allowing neonates to breastfeed or suck, which help prevent crying. However, these measures are not sufficient during frenotomies because the procedure is performed in the mouth and patients cannot suck during the procedure. We have observed a high prevalence of ankyloglossia (32.5%) among our neonates, for which frenotomy is a common treatment [16]. The aim of this study was to demonstrate that inhaled LEO is effective in reducing pain during frenotomy. Our hypothesis was that signs of pain [mostly crying time and Neonatal Infant Pain Scale (NIPS) score] would be different between the experimental and the control groups. We chose LEO because it is the fragrance that has been studied the most in neonates and infants [4, 5, 7, 12, 14, 15, 17]. There are scarce studies that compare the effectiveness of LEO vs. sucrose on neonatal pain relief during blood sampling [5], and to the best of our knowledge, none has studied the potential benefit of LEO to relieve pain in neonatal frenotomy.

Methods

Study design

We conducted a single-blinded randomized clinical trial (registered at https://clinicaltrials.gov with the identifier NCT04877392, under the title "Analgesic Effect of Inhaled Lavender Essential Oil for Clipping of Tongue-ties"). We chose this design because randomized clinical trials are the gold standard for clinically testing treatments and drugs. Our hospital Ethics Committee reviewed and approved this study on August 13, 2020. This study was conducted according to the ethics code of the Barcelona Medical Association, to the principles of the Helsinki-Fortaleza Declaration 2013 and to the Declaration of the World Medical Association.

Setting

This clinical trial was conducted at the neonatal unit of a tertiary care hospital in Barcelona, Spain, within a service area covering about 400,000 persons. The hospital experiences approximately 1400 births per year. We treat a multiethnic population at our hospital (with Spain, Pakistan and Bangladesh being the most frequent nationalities among our patients) [18], and we have breastfeeding rates at discharge from the maternity ward of about 85% (86.8% in 2018) [16] and of about 82% at the age of 3 months and of about 54% at the age of six months.

Participants

The target population for this study, and thus, inclusion criteria, were healthy full-term neonates born at Hospital del Mar (Barcelona, Spain) during their stay at the maternity ward, or less than 15 days old, who underwent a frenotomy for ankyloglossia due to a type 3 tongue-tie according to Coryllos classification [19] (supplemental Fig. 1) during the study period (August 2020 to April 2021). We chose type 3 tongue-ties because they are the most common in our population [16]; and type 3 tongue-tie characterized anatomical features (thick and submucosal) seem to make breastfeeding more difficult. We excluded patients who were isolated in their hospital room due to an active maternal COVID-19 infection because those frenotomies were performed in their room instead of at the neonatal unit. Furthermore, the study conditions could not be reproduced there, so they were not offered to participate in the study. There was no compensation or payments made to participants.

We assess the presence of ankyloglossia as part of the routine neonatal evaluation. We offer a frenotomy to all symptomatic tongue-tied patients who have difficulties breastfeeding. The examiner classifies ankyloglossia based on Coryllos's criteria [19] and uses the Hazelbaker tool to assess its impact on tongue movement and breastfeeding [20]. A lingual frenulum is symptomatic if it scores eight points or less in appearance and/or 11 points or less in function according to the Hazelbaker tool. Advice and help with positioning and attachment for breastfeeding are provided to all the mothers by lactation support providers. During the study period, if we identified a symptomatic patient with a type 3 tongue-tie that affected breastfeeding, we offered the patient's parents the opportunity to participate in this study. We did not perform any frenotomies on asymptomatic patients, where the frenotomy was not indicated. Accepted patients were allocated into the experimental group or the control group by simple random sampling using the program OxMAR (Online Minimization and Randomization for Clinical Trials) with an allocation

ratio 1:1 [21]. Prior to the recruitment, we generated a list of 142 numbers, where each number was randomized to either the "aromatherapy" or "control" groups. Patients were enrolled in numerical order and assigned into the predetermined group by the neonatologist that was going to perform the frenotomy. The group into which a patient had been enrolled was not known by the attending personnel until the moment of performing the frenotomy.

To perform the frenotomy, the neonate was taken to the neonatal unit and was monitored with a pulse-oximeter (COVIDIEN Nellcor Portable SpO2 Patient Monitoring System PM10N, Covidien Ireland Limited, IDA Business and Technology Park, Tullamore, Ireland) before, during and after the procedure. For both groups, we swaddled, administered 1 mL of oral sucrose, and let the newborn suck for two minutes prior to the procedure. The experimental group also had a 7×7 cm gauze pad with one drop (43.75 mg) of 100% pure LEO (Pranarôm España S.L.) placed 2 cm under their nose for two minutes prior to the frenotomy and during the procedure; the control group had a dry gauze placed instead. The bottle of LEO has a dropper that always dispenses the same amount of oil per drop. We did not start the procedure until the patients were calm and had a NIPS score of 0. Frenotomy was performed by one of the three staff neonatologists and was conducted by placing a sterile groove director under the tongue straddling the frenulum, holding the frenulum in place with visualization of tongue base and frenulum, and snipping the frenulum with a blunt tip scissor along the underside of the tongue to its base just proximal to the genioglossus muscle until a full release was achieved [19]. Once the procedure was completed, we removed the gauze pad.

We assessed pain by means of crying time and the highest NIPS score in the five minutes post procedure [22], and whether there was an increase in heart rate (HR) and a decrease in oxygen saturation (*SatO2*). NIPS evaluates a facial expression, crying, breathing pattern, arm and leg position, and state of arousal on a scale from 0 to 7, where 0–2 means no pain to mild pain, 3–4 mild to moderate pain, and > 4 severe pain [22]. A blinded neonatologist who did not perform the frenotomy evaluated vital signs through the screen of the pulse-oximeter, NIPS score and crying time from a neighboring room through a glass, for which he/she could not smell whether LEO was being used or be able to determine whether the gauze was dry. Vital signs, whether the baby cried or not, the seconds crying lasted, and the post-procedure NIPS score were recorded on a data collection sheet. If a neonate cried, the attending staff who performed the frenotomy provided calming techniques, such as holding, swaddling, and sucking, regardless of whether LEO was used or not. These persons were not blinded; however, they were not the ones who collected data. Following the frenotomy, we returned the neonate to the mother for breastfeeding.

Calculation of sample size

In an exploratory preliminary study prior to the intervention, we observed a mean (SD) crying time of 19.80 (21.14) seconds. We took those data as our baseline. To detect a difference of 10 seconds in crying time, we calculated that we needed a sample size of 71 patients per group to draw conclusions with a confidence interval (CI) 95% and a power of 80%. We used the crying time to calculate sample size because it is an objective way to measure pain, whereas NIPS could be more person-specific.

Data collection

Data were collected between August 18, 2020 and April 15, 2021. Patients were offered to participate at the time the frenotomy was indicated, and they were enrolled if their parents agreed to and signed a written informed consent prior to the procedure. The attending neonatologist who performed the frenotomy recorded demographic data (sex, gestational age, birth weight, age in hours at the time of frenotomy), and the observer recorded clinical data on a data collection sheet (HR and SatO2 before, during, and after the procedure, whether the patient cried or not during the procedure, length of crying time in seconds, presence of side effects during the procedure (apnea, desaturation, others) and highest NIPS score within the first 5 minutes after the procedure). The independent variable was the use or non-use of aromatherapy during frenotomy. The dependent variables were: HR and SatO2 pre and post procedure, presence of crying and duration, and the NIPS score. The controlled variables were gestational age, sex, hours of life at the time of the frenotomy, and birth weight. The primary outcome was shorter crying time in the experimental group compared with the control group. The secondary outcomes were reduction of NIPS score, HR and SatO2 pre and post-procedure in the experimental group compared to the control group. Participants' confidentiality was maintained because neither the name nor the medical record number was kept in the data collection sheet.

Statistical analysis

Quantitative variables (gestational age, birth weight, age at frenotomy, heart rate pre and post-procedure, increase in heart rate post-procedure, oxygen saturation pre and post-procedure, decrease in oxygen saturation post-procedure, and duration of crying) are described using the mean, standard deviation, and 95% CI; the experimental and the control groups were compared with a Student's *t* test. Qualitative variables (sex, the presence of crying and of adverse effects) are presented in percentages and compared using Fisher's exact test. We compared NIPS scores between the

experimental and the control group using the Wilcoxon rank-sum (Mann–Whitney) test. Statistical significance was set for a $P < 0.05$. To perform statistical analyses we used STATA version 15.1 (StataCorp, College Station, TX, USA).

Results

We enrolled 142 patients (71 in the experimental group, 71 in the control group) from a total of 157 potential candidates between August 18, 2020 and April 15, 2021. There was no follow-up period, so we did not lose any participants to follow-up. Fifteen patients were excluded for the following reasons: three parents refused to participate in the study, there was a language barrier with nine parents, a pulse-oximeter did not measure HR and SatO2 properly during the procedure in one case, and two were isolated because of maternal COVID-19 infection. We enrolled patients until we reached 71 patients in each group. All the patients were analyzed for the primary and secondary outcomes. Table 1 shows the demographic characteristics of both groups. There were no differences between the two groups in terms of sex, birth weight, gestational age, or age at the moment of the frenotomy.

Mean (SD) HR pre-procedure was 128.2 (15.6) beats per minute (bpm), and post-procedure 158.0 (16.4) bpm; mean (SD) HR increase was 29.9 (15.7) bpm. Mean (SD) SatO2 pre-procedure was 99.3 (1.4) %, and post-procedure, 95.9 (3.5) %; mean (SD) SatO2 decrease was 3.4 (3.2) %. 139 patients cried (97.9%) with a mean (SD) crying time of 19.5 (21.2) seconds. Mean (SD) NIPS score was 2.39 (1.15). There were no differences between the two groups in terms of baseline HR and SatO2. Table 2 presents the outcomes of the experimental and control groups.

The experimental group had a higher but non-significant HR increase, no differences on SatO2 decrease, significantly shorter crying time (14.8 vs. 24.6 s) ($P = 0.006$) and significantly lower NIPS scores (1.88 vs 2.92) ($P < 0.001$). Almost all patients cried in both groups, but neonates in the experimental group cried almost half the length of time (9.8 seconds less) compared with the control patients. The presence of side effects from the frenotomy was low and similar in both groups. Four patients bled lightly during the procedure and required compression (three of them in the experimental group, one in the control). One patient in the experimental group had nausea prior to the procedure that persisted during the frenotomy. We observed no adverse effects with the use of LEO in any of the patients.

Table 1 Demographic characteristics of the aromatherapy and control groups

Variables	Aromatherapy group *n* (%)	Control group *n* (%)	*P* value
Male newborn	39 (54.9)	36 (50.7)	> 0.99[a]
Birth weight (g) (mean, SD)	3304.53 (482.25)	3371.43 (446.51)	0.393[b]
Gestational age (wk) (mean, SD)	$39^{5/7}$ ($1^{2/7}$)	$39^{5/7}$ ($1^{1/7}$)	0.977[b]
Age at frenotomy (h) (mean, SD)	49.6 (48.6)	42.3 (40.3)	0.332[b]

[a]Fisher's exact test. [b]Student's *t* test

Table 2 Outcomes of the aromatherapy group and the control group

Variables	Aromatherapy group *n* (%)	Control group *n* (%)	*P* value	95% CI
Heart rate (bpm) pre-procedure (mean, SD) post-procedure (mean, SD)	127.8 (17.4) 159.9 (16.4)	128.6 (13.4) 156.0 (16.3)	0.773[b] 0.159[b]	− 4.43; + 5.94 − 9.33; + 1.55
Increase in heart rate post-procedure (bpm) (mean, SD)	32.1 (15.6)	27.5 (15.6)	0.079[b]	− 9.83; + 0.54
Oxygen saturation (%) pre-procedure (mean, SD)post-procedure (mean, SD)	99.3 (1.3) 95.9 (3.3)	99.2 (1.5) 95.9 (3.7)	0.680[b] 0.973[b]	− 0.56; + 0.37 − 1.18; + 1.14
Decrease in oxygen saturation post-procedure (%) (mean, SD)	3.4 (3.3)	3.3 (3.1)	0.887[b]	− 1.14; + 0.99
Crying (yes, %)	71 (100%)	68 (95.8%)	> 0.99[a]	–
Crying (seconds) (mean, SD)	**14.8 (10.8)**	**24.6 (27.6)**	**0.006[b]**	**2.86; 16.63**
Presence of adverse effects (yes, %)	0 (0.0%)	0 (0.0%)	–	–
NIPS score (mean, SD) (range)	**1.88 (1.03) (0–4)**	**2.92 (1.02) (0–5)**	**< 0.001[c]**	–

[a]Fisher's exact test. [b]Student's *t* test. [c]Wilcoxon's rank-sum (Mann-Whitney) test. *bpm* beats per minute, *SD* standard deviation, *95%CI* 95% confidence interval, *NIPS* Neonatal Infant Pain Scale. Words in bold font indicating significance between the groups

Discussion

Aromatherapy uses the healing effects of volatile essential oils in different ways and has been widely used for centuries in traditional and modern medicine as complementary therapy [4, 12, 23]. Aroma stimulates the olfactory bulb, anatomically close to the limbic system and responsible for emotions. Effects of essential oils on the limbic system lead to encephalin, endorphin and serotonin release [13]. Absorption of the oil molecules through the skin via massage, bath, foot bath or compresses occurs within 20–40 minutes depending on the chemical nature of the oil [13]. Goubet conducted the first study of aromatherapy with neonates in 2003 [24]. Aromatherapy has been used to treat pain in infants, showing an objective improvement in neonatal pain scale scores, decreased heart rate, and prevention of decreased oxygen saturation [4, 5, 7, 12, 14]. The main aromas used in neonatology are lavender, vanilla, and human milk [4].

LEO has antibacterial, antifungal, sedative, and antidepressant properties as well as antispasmodic and anticolic properties. As a result, LEO is capable of relieving the symptoms of pain [7, 12]. LEO's sedative and local anesthetic effects stem from linalool and linalyl acetate, the main monoterpenes present in LEO. LEO may alter the perception of pain by inhibiting nociceptive stimuli by means of stimulating the olfactory system and inducing relaxation, providing a pleasant environment, distracting the mind from the pain, and stimulating endogenous opioids [5]. The anxiolytic and antidepressant effects of lavender may be attributed to an antagonism on the NMDA (n-methyl-D-aspartate)-receptor and to inhibition of SERT (serotonin transporter) [23]. LEO can be used inhaled, in massage, by dripping oil and bathing [7]. It has been used in massage to reduce the symptoms of infantile colic [12], in bath oil to decrease stress and crying and to enhance sleep in infants between one week and four and a half months of age [17], and inhaled to decrease pain from blood sampling in term neonates [7].

Previously, other authors have demonstrated the benefits of LEO in reducing pain during neonatal blood sampling or heel puncture [5, 7, 14] and during vaccination at the age of 2 months [15]. To the best of our knowledge, this is the first study to evaluate the effect of inhaled LEO on pain relief and its minimization during neonatal frenotomy. We would like to highlight the fact that both crying time and NIPS scores decreased significantly in the experimental group, which demonstrates the usefulness of inhaled LEO to help relieve pain during neonatal frenotomy.

None of the prior aromatherapy studies performed in infants has described any side effects, such as nausea, vomiting or chills [17, 25]. Consistent with these studies, we also have observed no side effects from the use of LEO. Three patients presented with light bleeding post procedure that was not related to LEO. Therefore, we concluded that using inhaled LEO is safe and cost-effective for relieving pain during frenotomy. Given the lack of adverse effects and the ease of using inhaled LEO, we recommend its use when performing neonatal frenotomies. We acknowledge that the study has limitations. The team who performed the frenotomies was not blinded, primarily because the smell of LEO is too obvious to ignore. However, the person who recorded the data was blinded, as described in the "patients and methods" section. Some candidates (7.01%) were not eligible to participate, primarily because three parents did not consent and nine parents had language barrier issues. Another limitation is that more than one person performed the frenotomies, for which the technique could have minimal variations; however, all three staff neonatologists have similar experience and training.

In conclusion, we observed a significant decrease in crying time and lower NIPS scores in the neonates who received inhaled LEO and underwent a frenotomy for type 3 tongue-ties. We observed no side effects from its use. Thus, we recommend the use of inhaled LEO when performing a neonatal frenotomy.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12519-022-00531-7.

Acknowledgements We would like to thank Dr. Mercè Comas-Serrano for calculating the necessary sample size and performing the statistical analyses. We would like to thank Jennifer Bricker-Bolton for proofreading this manuscript and helping with the English language. We would like to thank Pranarôm España S.L. for providing the samples of lavender essential oil used in the present study at no cost.

Author contributions SM: Conceptualization, data curation, formal analysis, investigation, methodology, project administration, supervision, validation, visualization, writing–original draft, writing–review and editing; MF: conceptualization, formal analysis, methodology, project administration, resources, supervision, writing–review and editing; RL: investigation, methodology, project administration, supervision, writing –review and editing; JC: data curation, investigation, methodology, supervision, writing–review and editing; JG: Data curation, investigation, writing–review and editing; ML: investigation, methodology, supervision, writing–review and editing.

Funding We declare that we have not received any funds or grants for this research. Pranarôm España S.L. (Barcelona, Spain) provided the samples of lavender essential oil used in the present study free of charge. Pranarôm España S.L. had no role in study design, data collection, analysis, decision to publish, or preparation of the manuscript.

Data availability The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval Our Ethics Committee (CEIm-PSMAR) approved the study (reference number: 2019/8537/I), which was conducted in accordance with the Declaration of Helsinki. Informed consent to participate in the study has been obtained from the participants' parents or legal guardians.

Conflict of interest The authors declare that they have no conflict of interest. This research was not sponsored. No financial or non-financial benefits have been received or will be received from any party related directly or indirectly to the subject of this article. None of the authors serves as a current Editorial Team member for any journals.

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