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A randomised clinical trial of the effect of low-level laser therapy for perineal pain and healing after episiotomy: A pilot study

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ABSTRACT

Objective: to evaluate the effects of low-level laser therapy for perineal pain and healing after episiotomy.
Design: a double-blind, randomised, controlled clinical trial comparing perineal pain scores and episiotomy healing in women treated with low-level laser therapy (LLLT) and with the simulation of the treatment.
Setting: the study was conducted in the Birth Centre and rooming-in units of Amparo Maternal, a maternity service located in the city of São Paulo, Brazil.
Participants: fifty-two postpartum women who had had mediolateral episiotomies during their first normal delivery were randomly divided into two groups of 26: an experimental group and a control group.
Intervention: in the experimental group, the women were treated with LLLT. Irradiation was applied at three points directly on the episiotomy after the suture and in three postpartum sessions: up to 2 hrs postpartum, between 20 and 24 hrs postpartum and between 40 and 48 hrs postpartum. The LLLT was performed with diode laser, with a wavelength of 660 nm (red light), spot size of 0.04 cm^2, energy density of 3.8 J/cm^2, radiant power of 15 mW and 10 s per point, which resulted in an energy of 0.15 J per point and a total energy of 0.45 J per session. The control group participants also underwent three treatment sessions, but without the emission of radiation (simulation group), to assess the possible effects of placebo treatment.
Main outcomes: perineal pain scores, rated on a scale from 0 to 10, were evaluated before and immediately after the irradiation in the three sessions. The healing process was assessed using the REEDA scale (Redness, Edema, Echymosis, Discharge Aproximation) before each laser therapy session and 15 and 20 days after the women's discharge.
Findings: comparing the pain scores before and after the LLLT sessions, the experimental group presented a significant within-group reduction in mean pain scores after the second and third sessions ($p=0.003$ and $p<0.001$, respectively), and the control group showed a significant reduction after the first treatment simulation ($p=0.043$). However, the comparison of the perineal pain scores between the experimental and control groups indicated no statistical difference at any of the evaluated time points. There was no significant difference in perineal healing scores between the groups. All postpartum women approved of the low-level laser therapy.
Conclusions: this pilot study showed that LLLT did not accelerate episiotomy healing. Although there was a reduction in perineal pain mean scores in the experimental group, we cannot conclude that the laser relieved perineal pain. This study led to the suggestion of a new research proposal involving another irradiation protocol to evaluate LLLT's effect on perineal pain relief.

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Introduction

Perineal pain is a frequent morbidity in the postpartum period. It is usually associated with instrumental deliveries and episiotomies (Christianson et al., 2003). It can result in difficulties with self-care, breast feeding and newborn care and can also interfere with sleep, rest, movement, urination, evacuation and even appetite (Alexandre et al., 2006).

A cohort study of 241 postpartum women revealed that 173 (92%) of them reported perineal pain in the first days after birth, regardless of the perineal trauma suffered (Andrews et al., 2008). In a study conducted in the United States of America, reporting the experience of 1,573 women with pain two months after delivery, perineal pain was cited by 48% of mothers who delivered vaginally. Among these women, 68% had an instrumental delivery (forceps and vacuum), 63% underwent an episiotomy and 43% had vaginal deliveries without an episiotomy (Declercq et al., 2008).

Despite the high prevalence of perineal pain in the postpartum period, there is no available evidence on the best method for its relief. Conventionally, oral analgesics, local anaesthetics, cooling and hot topical applications have been employed, along with the use of low-level laser therapy (LLLT). Scientific studies examining the effectiveness of these therapies have been developed (Hill, 1989; East et al., 2007; Hedayati et al., 2005; Chow et al., 2009; Derry et al., 2009).

Irradiation with LLLT involves the emission of light energy, which is absorbed by and dispersed throughout the tissue, thereby stimulating or inhibiting enzyme activities and chemical reactions. These reactions result in physiological and therapeutic processes that generate analgesic, anti-inflammatory and tissular actions. Such effects are known as biomodulatory effects (Brugnera et al., 2007; Genovese and Barreira, 2007).

The mechanisms of these photobiological effects are still unknown. A controlled clinical trial conducted in Japan showed that the levels of beta-endorphin, a natural opioid substance that reduces pain, increase after the application of irradiation with a gallium aluminium arsenide (GaAlAs) laser diode. These findings suggested that peripheral opioids are actively involved in the mechanism of LLLT-mediated analgesia (Hagiwara et al., 2007). However, a study included in a systematic review found limited evidence supporting the idea that the mechanism of analgesia involves the release of endogenous opioids (Bjordal et al., 2006).

A systematic review that included 15 randomised controlled trials and 33 controlled laboratory studies found that LLLT reduces the levels of biochemical markers, such as prostaglandin E2 (PGE2), cyclooxygenase-2 (COX 2) messenger ribonucleic acid (mRNA), interleukin 1β (IL-1β) and tumour necrosis factor (TNFα). It also inhibits the cellular influx of neutrophils and reduces oxidative stress, oedema and haemorrhage in a dose-dependent manner (median: 7.5 J/cm^2; range: 0.3–19 J/cm^2) and therefore modulates inflammatory pain. Seven randomised placebo-controlled trials found no significant pain reduction after irradiation at a single point at the lesion site or after using a total energy dose below 5 J (Bjordal et al., 2006).

A randomised, controlled trial of low-intensity CO_2 laser for pain relief in oral ulcers caused by stomatitis showed decreased pain scores immediately after laser irradiation, with a statistically significant difference between the laser and placebo groups ($p < 0.001$) (Zand et al., 2009).

In recent studies (Bjordal et al., 2006; Hagiwara et al., 2007; Chow et al., 2009), the analgesic effects observed in clinical trials in the dentistry field (Zand et al., 2009) and some structural similarities between oral and vaginal mucous membranes suggest that these outcomes could also be obtained for perineal pain relief after episiotomy. The histological findings also indicate that irradiation with LLLT can accelerate the healing process (Enwemeka et al., 2004).

Based on these considerations, the present study was proposed, with the aim of evaluating LLLT's effects on the relief of postpartum perineal pain and the episiotomy healing process in women who had undergone this procedure.

Methods

Study design

This was a double-blind, randomised, parallel, controlled trial. The study was conducted by the principal investigator (JOS), who was responsible only for LLLT application, for which she was not blinded to the study group. A previously trained nurse (research assistant) blindly assessed the degree of perineal pain and healing. The participants were also blinded to the study group to which they were assigned.

Study setting

The study was conducted at an in-hospital Birth Centre and a rooming-in unit in Amparo Maternal, a maternity service located in the city of Sao Paulo, Brazil, which uses active labour management. This institution is part of the Brazilian National Health System and serves women of low socio-economic status with low to medium pregnancy risk. According to the institution's statistical report, in August 2008, there were 762 deliveries, of which 80.2% (611) were normal deliveries, 19.4% (148) were caesarean sections and 0.4% (3) were forceps-assisted. Regarding perineal outcomes, 42.9% (262) of women had an intact perineum, 13.3% (81) underwent an episiotomy, 34.9% (213) had first-degree lacerations, 8.6% (52) had second-degree lacerations, and 0.3% (3) had third-degree lacerations.

Assistance during labour, normal delivery and the postpartum period is provided by nurse midwives, with a team of obstetricians in charge of the women's admission examinations, operative deliveries and cases involving clinical and obstetric problems. Episiotomy is selectively practiced in normal deliveries and is preceded by an infiltration of local anaesthesia with lidocaine and no vasoconstrictor. During data collection, perineal repair was performed continuously using catgut sutures for all women.

Approximately two hours after birth, mothers are transferred to the rooming-in units along with their newborn if both are in good clinical condition; they are discharged after 48 hrs. In the rooming-in unit, women are routinely given 500 mg of metamizole (dipyrone). If the pain persists, a non-steroidal anti-inflammatory (diclofenac sodium, 50 mg) is administered every eight hours. Non-pharmacological therapies are not used for perineal pain relief, and there is no scheduled follow-up visit for the mother or the newborn after hospital discharge.

Participants

The participants included postpartum women with mediolateral episiotomies. Inclusion criteria included the following: age $\geq$ 18 years; no previous vaginal deliveries; vaginal delivery with a mediolateral episiotomy; full-term pregnancy with a single live fetus with cephalic presentation; no infectious diseases, haemorrhoids, bruising or varicose veins on the perineum; no perineal preparation in pregnancy; no use of photosensitising endogenous or exogenous drugs; and no clinical or obstetric complications. We excluded mothers who had used any product other than soap and water in the vulvoperineal region during their hospital stay.

Sampling and randomisation

Sample size calculation was based on data obtained from a preliminary study conducted by the principal investigator comparing the means of perineal pain in a group of 10 women who had undergone LLLT and a control group of 15 women who received no treatment.

In this preliminary study, there was a reduction of 2.0 points in the perineal pain scores mean, after laser irradiation (from 3.4 ± 2.7 to 1.4 ± 1.6) in the intervention group, whereas the mean pain score was 2.8 ± 1.7 in the control group. The sample size was calculated assuming a clinically relevant pain score reduction of 2.0 points when comparing the mean pain scores of the experimental and control groups. Based on a significance level of 5% and a test power of 90%, the study sample size was at least 24 women in each group.

The final sample was composed of 52 women who were randomly divided into two groups: an experimental group ($n=26$) subjected to low-level laser irradiation and a control group ($n=26$) that received a simulation of the treatment without the irradiation.

The women were allocated to the control or experimental groups using a computer-generated randomisation list. Each number was placed in an opaque, numbered, sealed envelope by an individual who was not involved in the research. The envelope was opened by the principal investigator upon the woman's inclusion in the study to identify her group, and the women were assured an equal chance of being assigned to either group.

Intervention

The source of irradiation was a clinical model, portable LLLT Twin Laser (MMOptics®, Brazil), registered with the National Agency for Sanitary Surveillance (Number 80051420007) and certified by the National Institute of Metrology, Standardisation and Industrial Quality (Number 2756/05 NCC). The unit is classified as a Class 3B laser, which emits irradiation in the infrared and red bands. To develop this stage of the research, the following conditions were used: a laser diode with an AlGaInP semiconductor, a wavelength of 660 nm, a spot size of 0.04 cm^2, a dose of 3.8 J/cm^2, a power of 15 mW, an irradiation time of 10 s per point, an energy of 0.15 J per point and a total energy of 0.45 J per session.

During the study, the laser was submitted to weekly power transmission assessments using a Power Meter (Coherent, Inc., Santa Clara, CA, USA), to ensure that a consistent amount of energy was used throughout the study.

The experimental group underwent three sessions of irradiation with a low-level laser placed directly on the episiotomy. The first session occurred immediately after suturing or up to two hours after delivery, the second session occurred between 20 and 24 hrs postpartum and the third one occurred between 40 and 48 hrs postpartum. The irradiation was performed touching the laser pen tip on three points of the episiotomy (central, upper and lower portions), regardless of its length.

Similar to the experimental group, the control group participants also underwent three treatment sessions, but without the emission of irradiation, which facilitated the assessment of possible placebo effects (simulation group). To ensure that no light was emitted, the laser pen tip was covered with a cotton swab, and the active external tip of the laser pen was covered with aluminium foil. The time of simulation and the number of points irradiated were the same as those of the experimental group.

This therapy was based on the application protocol for treating ulcers in the oral mucosa, which aimed to eliminate pain and accelerate tissue repair (Genovese and Barreira, 2007). The first laser irradiation session occurred at the birth centre, with each patient in the delivery room in the lithotomy position. The other two sessions were performed on the woman's bed in the postpartum rooming-in unit, where the researcher asked her to be in a lithotomy position. Both the principal investigator and the woman used individual protection equipment (goggles) during irradiation.

Main outcomes measurement

The main outcomes were perineal pain intensity and the healing process.

Assessment of perineal pain and healing

Perineal pain intensity was assessed before and immediately after each session of irradiation using a numerical scale from 0 to 10, with zero indicating no pain and ten indicating unbearable pain. A representation of this scale was shown to each postpartum woman, and she was asked to point to the value that best represented the intensity of her pain.

The healing process was assessed with the REEDA scale (Redness, Edema, Ecchymosis, Discharge Approximation) before each of the three irradiation sessions and between 15 and 20 days after discharge. The REEDA scale comprises five items that assess healing: hyperaemia, oedema, ecchymosis, level of wound discharge and approximation of the skin edges at the site of episiotomy. Each item is given a score from zero to three, with 0 indicating no trauma and 3 the most trauma. The maximum value of 15 corresponds to the worst perineal condition (Hill, 1990).

The Peri-Rule™[1] was used to evaluate the healing process and the length of episiotomy. It is a measuring device 105 mm long and 10 mm wide made of soft plastic with a millimetre scale imprinted on one side (Tohill and Metcalfe, 2005).

Data collection

Data collection occurred from March to June 2009. The researchers (principal and assistant) remained in the maternity ward for eight hours daily to identify women eligible for the study.

Medical and registration records were searched to obtain information about the women included in the study. To be invited to participate in the study, eligible women were approached up to two hours after delivery in the observation room of the birth centre. The research objectives, the procedure and the possibility of being allocated to either of the two groups, which would be determined by random drawing, were explained. After obtaining the woman's agreement, a data collection form containing her identification, obstetric history and data related to the birth and the newborn was filled out.

Before the first treatment session (up to 2 hrs after delivery), the research assistant assessed the magnitude of the perineal pain, the episiotomy length and the progress of perineal healing. After the main outcomes were evaluated, the research assistant left the room. Then, the principal investigator opened the envelope containing the group randomisation information to identify the woman's group assignment. The principal investigator then conducted the laser therapy or simulation, according to the assigned group. Immediately after this session and after the

[1] http://www.peri-rule.bham.ac.uk/.

principal investigator left the room, the assistant again evaluated the participant's perineal pain.

The same procedure was conducted for the second (20–24 hrs postpartum) and third (40–48 hrs postpartum) LLLT sessions.

At the end of the third irradiation session, the research assistant (still blinded) assessed the 52 women's opinions regarding the treatment. Then, the researcher requested the women's return to the maternity service 15–20 days after delivery for a perineal pain and healing assessment.

Treatment and data analysis

The Statistical Package for Social Sciences (SPSS) for Windows, version 13.0, was used for statistical analyses. First, a descriptive data analysis was performed to describe the women, their labour and the newborns' characteristics. In the quantitative variables analysis, student's *t*-test and the Mann–Whitney test were performed. For qualitative variables, the χ^2 or Fisher exact test was used to compare the groups regarding proportions, following the Monte Carlo approach. This method yielded *p*-values in the case of expected frequencies less than 5 (Peat and Barton, 2005). A two-factor analysis of variance was used to compare means between groups, with the group as one independent factor and the time when irradiation was performed as the other factor. Multiple comparisons were made with the Tukey's highly significant differences test. The results were considered statistically significant when *p*-values were less than 0.05.

Ethical aspects

This research project was approved by the Research and Ethics Committee of the School of Nursing, University of São Paulo (process 778/2008). The researchers did not have any relationship with the manufacturers or distributors of the equipment used in the study.

Findings

Data collection occurred in the maternity unit sites, where 2,395 births took place, of which 21.8% (523) were caesarean sections and 78.2% (1,872) were normal vaginal deliveries. Among these normal births, 40.9% (766) of women had an intact perineum, 39.4% (737) had spontaneous lacerations, and 18.8% (351) had episiotomies. In 0.9% (18) of the cases, the perineal condition was not reported.

During the study period, 351 women were eligible, 100 did not meet the inclusion criteria, 187 underwent an episiotomy while the researchers were not in the maternity ward, 10 were excluded and 2 refused to participate, leaving 52 participants with 26 in each group (Fig. 1).

In both groups, the mean age of the participants was 23.4 ± 4.9 years, with a median of 22 years and minimum and maximum ages of 18 and 39 years, respectively. Eight participants had had a previous caesarean section; most women were nulliparous (84.6%), non white ethnic group (51.9%) and non-smokers (86.5%) and lived with their partner (76.9%) (Table 1).

The similarity of the groups in terms of obstetric history, ethnicity and education was noted. A statistically significant difference in marital status and smoking ($p < 0.05$) is shown in Table 1.

The length of the episiotomy ranged from 1.7 to 5 cm, with a mean length of 3.2 ± 0.8 cm, and catgut thread was used in all perineal suturing, using a continuous suture technique in 88.5% (46) of cases. All deliveries included in this study were attended by nurse midwives. Infant birth weight ranged from 2,570 to 4,160 g, with an average of $3,257.3 \pm 394.6$ g. Infant head circumference ranged from 31 to 37 cm with a mean of 33.6 ± 1.3 cm (Table 2).

The data in Table 2 show that there was no statistically significant difference between the groups regarding maternal age, episiotomy length, infant birth weight and head circumference or metamizole administration during the hospital stay, which demonstrates that the groups were equivalent. Only three women in the control group received an oral anti-inflammatory (diclofenac) to treat perineal pain.

Based on analysis of the intragroup perineal pain scores (Table 3), there was a statistically significant reduction in perineal pain level in the control group after the first irradiation session ($p = 0.043$). In the experimental group, a significant reduction in mean pain scores occurred after the second and third sessions ($p = 0.003$ and $p < 0.001$, respectively).

No statistically significant differences were observed when comparing the mean pain scores of the experimental and control groups either prior to each of the three LLLT sessions or immediately after the three irradiation sessions (Table 3).

From 15 to 20 days after delivery, none of the 29 women (16 controls and 13 experimental) who returned for a postnatal evaluation reported any perineal pain. No research participants reported pain during the irradiation sessions.

Regarding the healing process assessment, there was no significant difference in the mean healing scores between the two groups in the three different time points during the hospital stay or within 15–20 days postpartum (Table 4).

All participants (52) stated that the procedure was comfortable and that they would be willing to undergo the treatment again. Of the participants, 96.1% (50) reported that the therapy was 'very good' or 'good'. In the control group, one woman considered the treatment 'neutral', and another had no opinion.

Discussion

This study aimed to evaluate the effect of LLLT on alleviating perineal pain and accelerating perineal wound healing after episiotomy for a vaginal birth. Postpartum women were offered three sessions of irradiation during hospitalisation, regardless of whether they complained of perineal pain.

Although an intragroup pain reduction was observed in both groups, the comparison between the experimental and control groups (intergroup) did not show significant differences in perineal pain. The therapeutic effects observed in the groups may have resulted from personal care involved in the treatment, (Hawthorne effect), which occurs when participants in clinical research change their behaviour when they are targets of interest or receive special attention, regardless of the specific nature of the intervention (Fletcher and Fletcher, 2005).

These findings are corroborated by a controlled study conducted in the Czech Republic with 2,436 women with episiotomies, comparing the analgesic effects of phototherapy using three light sources, LLLT, a halogen light and a light-emitting diode (LED). It was concluded that LLLT was the best option and that it could be complemented by the application of halogen light (Kymplová et al., 2003). However, some methodological aspects of the research are questionable, such as the lack of randomisation, evaluation criteria, and a detailed description of the therapies' application and omitted details about possible conflicts of interest.

Other studies have examined the influence of laser irradiation on wound healing, such as the study conducted at the College of Dentistry, University of São Paulo - Brazil, to evaluate the effectiveness of LLLT in preventing and reducing the severity of injuries caused by labial herpes; that study used the same equipment used in the current study, with one session per week

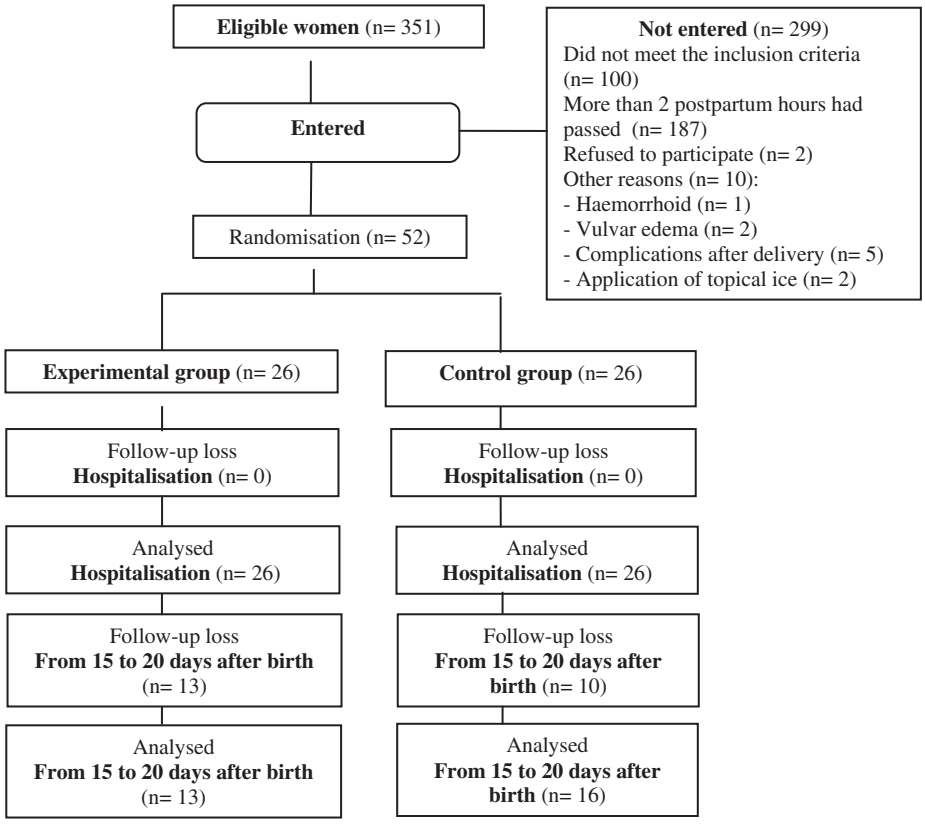

Fig. 1. Flow chart of the study participants.

Table 1
Study subjects characteristics.

Variable	Groups				*p-Value**
	Control		Experimental		
	n	%	n	%	
Number of pregnancies					0.211
First pregnancy	17	65.4	21	80.8	
Second or more	9	34.6	5	19.2	
Parity					1.000
Nulliparous	22	84.6	22	84.6	
Primiparous	4	15.4	4	15.4	
Ethnicity					1.000
White	9	34.6	9	34.6	
Other ethnic group	17	65.4	17	65.4	
Education level (Ω)					0.773
Primary	10	38.5	9	34.6	
High school or higher	16	61.5	17	65.4	
Habitation status					**0.021**
With partner	19	73.1	25	96.2	
Without partner	7	26.9	1	3.8	
Smoker					**0.049**
Yes	6	23.1	1	3.8	
No	20	76.9	25	96.2	
Total	**26**	**100**	**26**	**100**	

* χ^2 and Fisher's exact test for expected frequencies of less than 5 (Ω). Includes the completion or non-completion of high school

for ten weeks. The subjects were randomly divided into a control group (30 patients) treated with topical acyclovir and an experimental group (41 patients) treated with laser irradiation at 780 nm, 60 mW and 3.0 J/cm^2 in punctual mode. A significant decrease in lesion size (p=0.013) and local oedema (p=0.031)

Table 2
Study subject and newborn characteristics.

Variable	Groups		*p-value**
	Control $\bar{x}$ (SD)	Experimental $\bar{x}$ (SD)	
Age (years)	23.9 (5.0)	22.8 (4.7)	0.402
Length of episiotomy (cm)	3.1 (0.7)	3.3 (1.0)	0.598
Birth weight (g)	3,228.1 (451.2)	3,286.5 (335.3)	0.349
Head circumference (cm)	33.4 (1.4)	33.8 (1.2)	0.277
Analgesic use (tablets)	3.8 (1.4)	3.4 (1.5)	0.291

* Student's *t*-test and Mann–Whitney test.

Table 3
Mean and standard deviation (SD) of perineal pain before and immediately after each LLLT session.

LLLT session	Perineal pain		*p-Value**
	Control $\bar{x}$ (SD)	Experimental $\bar{x}$ (SD)	
Up to 2 hrs			
Before	2.4 (2.4)	2.2 (2.4)	0.999
After	1.6 (2.3)	1.7 (2.3)	0.999
*p-Value**	**0.043**	0.161	
20–24 hrs			
Before	3.0 (2.0)	2.5 (2.3)	0.934
After	2.3 (1.9)	1.5 (2.1)	0.758
*p-Value**	0.072	**0.003**	
40–48 hrs			
Before	2.8 (2.3)	2.3 (2.4)	0.925
After	2.5 (2.3)	1.5 (1.9)	0.662
*p-Value**	0.116	< **0.001**	

* Tukey's test.

Table 4
Mean and standard deviations (SD) scores of healing, according to the evaluation period.

Evaluation period	Healing scores		*p-Value**
	Control $\bar{x}$ (SD)	Experimental $\bar{x}$ (SD)	
Up to 2 hrs	3.4 (1.6)	3.1 (1.3)	0.227
20–24 hrs	4.3 (2.7)	4.5 (2.6)	0.601
40–48 hrs	4.5 (2.9)	4.5 (2.3)	0.458
15–20 days	0.7 (0.9)[a]	0.7 (1.9)[b]	0.503

[a] $n=16$.
[b] $n=13$.
* Student's *t*-test.

was observed in the experimental group compared with the control; however, no significant reduction in pain ($p=0.051$) was observed (Carvalho et al., 2010).

Systematic reviews of LLLT's effectiveness in reducing the pain of rheumatoid arthritis (Brosseau et al., 1998), osteoarthritis (Brosseau et al., 2000) and non-specific low back pain (Yousefi-Nooraie et al., 2007) have not led to definitive conclusions, due to the heterogeneity of the populations studied and the treatments applied. Chow et al. (2009) reported that the effectiveness of this intervention depends on several factors, such as the wavelength used and the location, duration and dose of the LLLT.

It is possible that a combination of systemic and localised treatments is necessary to achieve adequate pain relief that will meet individual women's needs (Steen, 2005; East et al., 2007). The use of analgesics can be considered a limitation of the current study, but it also can be seen as a pragmatic condition because the medication is usually given routinely. Pragmatic studies consider the elements of reality and strengthen the external validity of results, increasing the possibility of their applicability.

The healing process is influenced by several factors, such as the extent of tissue damage, the intensity and duration of the stimulus, nutritional status and the presence of conditions that inhibit this process (Kumar et al., 2005). Regarding the effects of LLLT in accelerating the healing process, experimental studies in vitro and in vivo suggest that this benefit can be triggered by the promotion of cell proliferation and the formation of granulation tissue, by stimulating collagen synthesis and adenosine triphosphate (ATP) in the mitochondria and by activating lymphocytes (Karu, 1988; Enwemeka et al., 2004).

In this study, we observed that the groups were similar in ethnic origin, extent of perineal injury, technique and suture material used, and the professional who attended the birth, indicating that these factors that could influence healing were equivalent.

In the current study, no significant difference was found between the experimental and control groups regarding perineal wound healing in the four assessments. Similar findings were found in a systematic review, which showed no evidence of any benefit associated with LLLT on the healing of venous ulcers in lower limbs (Flemming and Cullum, 1998).

The only significant difference between groups was smoking status ($p<0.05$). The association between smoking and deficiences in healing is known and it has been reported in some clinical trials (Biondo-Simões et al., 2009). However, there was no significant difference in perineal wound healing between the two groups.

In the maternity service studied, routine postpartum care includes the administration of oral analgesics; therefore, all participants in this pilot study were treated with dipyrone, which is used to treat pain and fever. The analgesic and antipyretic effect of this drug starts between 30 and 60 mins after administration and usually lasts approximately four hours.

However, we observed in this study that even after the administration of oral analgesics, a large number of postpartum women (30–57.7%) reported perineal pain, corroborating the findings of another clinical study (Steen et al., 2000) and indicating the insufficiency of that medical treatment for perineal pain relief.

Another limitation of the current study was the reduced period for healing assessment, which was limited to the hospital stay of the women, approximately 48 hrs after the perineal suture. This period is considered insufficient for an appropriate assessment of healing. The acute inflammatory response, characterised by pain, redness, swelling and heat, begins only the third day after injury (Kumar et al., 2005). The high values on the REEDA scale observed between 20 and 48 hrs after delivery correspond to the inflammatory reaction expected in this period.

Postnatal women should be offered a check up consultation from one week to fifteen days after the delivery. This contact would be ideal for evaluation of healing. However, the women in this study were living far away from the maternity service, which influenced their ability to return for the consultation.

Therefore, the women were offered the results of their neonatal phenylketonuria screening test on the 15–20th postpartum day, when the late assessment was performed by the researchers. However, only 16 mothers in the control group and 13 in the experimental were able to return to the unit. There were no differences in the healing process between the groups and the women did not report any perineal pain.

Despite the reduction in perineal pain when the control and experimental groups were compared, the dosimetry and the wavelength of LLLT used in this pilot study was not effective. The red light beam was probably not powered to reach the muscle layers affected by the episiotomy. According to the literature, lasers emitting red light (660 nm) penetrate less into the tissue, reaching a depth of 0.5–2.5 mm, whereas the infrared light beam increases the power of penetration to 8–10 mm, reaching deeper tissues (Enwemeka, 2001).

Given the depth reached by the LLLT beams used in this study, the type of injury and the tissues to be irradiated, we propose developing a randomised controlled study employing a new dosimetry and adding the infrared wavelength of 780 nm, to allow comparisons of results and better evaluation of LLLT for the relief of perineal pain.

Conclusions

In this pilot study, LLLT did not accelerate the healing of episiotomies. The study allowed the researchers to identify some difficulties related to evaluating the healing process after LLLT use. Although the intragroup comparison indicated a significant reduction in pain score means in the experimental group (at 20–24 hrs and 40–48 hrs postpartum) and in the control group (up to 2 hrs postpartum), there was no statistical difference between the groups at any of the evaluated time points. We cannot conclude that the laser provided perineal pain relief.

A new research proposal to examine the effectiveness of the therapy in reducing perineal pain in the perineum could be developed based on another irradiation protocol. Red and infrared irradiation wavelengths could be employed in a new research proposal, and the study could be conducted using a single session that would enrol only women with an episiotomy who reported perineal pain greater than or equal to three; the study could be used to evaluate pain immediately after treatment with LLLT and 30 mins after irradiation.

Randomised controlled trials using non-pharmacological techniques and non-invasive LLLT are required to develop more effective adjuvant treatments for the relief of perineal pain, which is a common problem in the postpartum period.

Conflict of interest statement

The authors have no conflicts of interest to disclose.

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