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PAIN MANAGEMENT

Low-level laser therapy for pain relief after episiotomy: a double-blind randomised clinical trial

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Aims and objectives. To evaluate the effectiveness of a low-level laser therapy for pain relief in the perineum following episiotomy during childbirth.

Background. Laser irradiation is a painless and non-invasive therapy for perineal pain treatment and its effects have been investigated in several studies, with no clear conclusion on its effectiveness.

Design. A double-blind randomised controlled clinical trial.

Method. One hundred and fourteen women who underwent right mediolateral episiotomies during vaginal birth in an in-hospital birthing centre in São Paulo, Brazil and reported pain ≥3 on a numeric scale (0–10) were randomised into three groups of 38 women each: two experimental groups (treated with red and infrared laser) and a control group. The experimental groups were treated with laser applied at three points directly on the episiotomy after suturing in a single session between 6–56 hours postpartum. We used a diode laser with wavelengths of 660 nm (red laser) and 780 nm (infrared laser). The control group participants underwent all laser procedures, excluding the emission of irradiation. The participants and the pain scores evaluator were blinded to the type of intervention. The perineal pain scores were assessed at three time points: before, immediately after and 30 minutes after low-level laser therapy.

Results. The comparison of perineal pain between the three groups showed no significant differences in the three evaluations (p = 0·445), indicating that the results obtained in the groups treated with low-level laser therapy were equivalent to the control group.

Conclusions. Low-level laser therapy did not decrease the intensity of perineal pain reported by women who underwent right mediolateral episiotomy.

Relevance to clinical practice. The effect of laser in perineal pain relief was not demonstrated in this study. The dosage may not have been sufficient to provide relief from perineal pain after episiotomy during a vaginal birth.

Key words: episiotomy, laser therapy, lasers, low intensity, nurses, nursing, pain, perineum, postpartum period

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Introduction

Perineal pain after vaginal delivery is common and can significantly affect the quality of a woman's life. It is associated with surgical (episiotomy) or spontaneous perineal trauma, which act as mechanical triggers for inflammation and acute pain and generate considerable discomfort during the puerperium. Although perineal pain is a major complaint of women in the postpartum period, it is generally undervalued by the patient, her family and health professionals. During this period, attention to the newborn takes priority and the needs of the mother are usually pushed to the background.

Several studies have shown that perineal pain is highly prevalent in the postpartum period. A prospective study of the frequency of perineal pain and the type of trauma, which included 447 mothers one day, seven days and six weeks after delivery, reported a frequency of perineal pain between 75–100%, with the highest frequency associated with major perineal trauma. At the first and seventh days postpartum, perineal pain was reported by 75 and 38%, respectively, of women with intact perineums; by 95 and 60%, respectively, of women with first- and second-degree lacerations; by 97 and 71%, respectively, of women with episiotomies; and by 100 and 91%, respectively, of those with third- and fourth-degree lacerations. When comparing trauma type, there was no significant difference in the frequency of perineal pain among women in the sixth week after delivery (Macarthur & Macarthur 2004).

Avoiding injury and appropriately repairing any perineal trauma are the primary measures to prevent or reduce postnatal pain and discomfort (Enkin *et al.* 2000). Practices including non-pharmacological and pharmacological therapies can be employed to relieve this discomfort. Among these treatments, low-level laser therapy (LLLT) has emerged as a promising technology for treating tears and stimulating healing. Irradiation with LLLT stimulates physiological processes that are analgesic, anti-inflammatory and decrease tissue oedema, known as biomodulatory effects (Tunér & Hode 1999).

Irradiation with LBI is a painless and non-invasive therapy and its effects have been investigated in several studies. In a systematic review that included 48 studies, Bjordal *et al.* (2006) summarised the effects of LLLT on pain and biochemical markers and Hagiwara *et al.* (2007) evaluated these effects in guinea pigs. These studies found positive results for LBI in reducing pain, swelling, redness and inflammation, as well as accelerating wound healing (Bjordal *et al.* 2006, Hagiwara *et al.* 2007). Recent research has suggested that the analgesic effects of LLLT can be explained by irradiation stimulating the release of beta-endorphins, either directly or indirectly. A clinical trial showed that the level of beta-endorphins rose after the application of radiation using the diode laser as a semiconductor, with no increase in inflammatory cell numbers. This result suggests that peripheral opioids are actively involved in the LLLT mechanism of analgesia (Hagiwara *et al.* 2007). Mizutani *et al.* (2004) also observed a significant reduction in pain scores ($p < 0{\cdot}001$) and serum levels of prostaglandin ($p < 0{\cdot}05$) in women treated with a diode laser (GaAlAs). However, a study included in the systematic review found only limited evidence that the mechanism of analgesia was mediated by the release of endogenous opioids (Bjordal *et al.* 2006).

The search for methods, especially non-pharmacological methods, that relieve perineal pain and do not interfere with lactation has been a challenge for professionals who provide care for women during childbirth and the postpartum period. Two studies have investigated the effects of lasers on the relief of perineal pain, but these failed to provide conclusive results owing to methodological weaknesses, such as an absence of randomisation, a lack of standardisation of the evaluation criteria and of the dosage of the laser (Kymplová *et al.* 2003, Rzakylieva *et al.* 2006).

In a pilot study of the effectiveness of LLLT in relieving perineal pain, a protocol of radiation dosimetry was developed for this purpose. The authors observed that the studied parameters (wavelength, dose and potency) were not sufficient to reach the deeper layers of the episiotomy, although a decrease in pain scores after the application showed some promise for this intervention (Santos *et al.* 2011). In this context, this study aimed to evaluate the effectiveness of LLLT for pain relief in the perineum after episiotomy during childbirth.

Methods

Study design

This was a double-blind randomised controlled trial on the effectiveness of LLLT in reducing perineal pain after episiotomy during childbirth. The study was registered in a database, the Australian New Zealand Clinical Trials Registry (ANZCTR), which is registered in the International Clinical Trials Registry Platform of the World Health Organisation (protocol 00320866).

Settings

The study was conducted in the rooming-in unity (RIU) of the Amparo Maternal (AM), an institution located in the city of Sao Paulo, Brazil. At the AM, normal deliveries are assisted in

an in-hospital birth centre by nurse-midwives and midwives. 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 RIU along with their newborn if both are in good clinical condition. In the RIU, women are routinely given 500 mg of metamizole (dipyrone). If the pain persists, a non-steroidal anti-inflammatory (diclofenac sodium, 50 mg) is administered. Non-pharmacological therapies are not used for perineal pain relief. A detailed description of this service is part of the pilot study that supported the current study (Santos *et al.* 2011).

Participants

The study population consisted of women who had undergone right mediolateral episiotomies during a normal delivery and the participants were studied between 6–56 hours after childbirth. The following inclusion criteria were used: age ≥18 years; with a newborn in good clinical condition, born in cephalic presentation and from a single, full-term pregnancy; absence of perineal lacerations associated with episiotomy; ability to communicate well in Portuguese; without infection, haemorrhoids, bruising, swelling or varicose veins in the perineal area; no use of endogenous or exogenous photosensitising drugs; no clinical or obstetric complications; and referring perineal pain ≥3 on a numeric scale of 1–10 at the time of approach.

Sample and randomisation

The study sample consisted of 114 mothers, with 38 women in each group. The sample size calculation was performed assuming a 40% decrease in pain score, an alpha error of 0·05 and a test power of 80% (Brasjer & Brant 2007). The results indicated that a sample size of at least 36 women was necessary for each group. Randomisation of the subjects was performed using a randomisation table that identified each woman by a numerical code, generating a list of 114 numbers with 38 in each of the three groups studied (experimental infrared and red groups and a control group). The randomisation procedures were performed by a statistician who was not connected to the study. Each number in the list was individually placed in an opaque, sealed and numbered envelope, ensuring allocation concealment. The envelope was opened by the principal investigator at the time of irradiation to identify the group to which the patient belonged.

The participants were randomly divided into three parallel groups: an Infrared Experimental Group, composed of mothers who received the infrared laser wavelength; a Red Experimental Group, consisting of mothers who received laser treatment with a wavelength in the red range; and the Control Group, composed of women who received simulated treatment without irradiation from the light beam.

Intervention

The irradiation source was a portable clinical LLLT Twin Laser® (MMOptics, São Carlos, Brazil) the same model used in the pilot study. This unit is a Class 3B laser, which emits radiation in the infrared and red bands. The following protocol was used for red light irradiation beams (wavelength 660 nm) and an infrared laser diode (wavelength 780 nm): spot size of 0·04 cm^2, dose of 8·8 J/cm^2, 35 mW power, duration of irradiation of 10 seconds per point, energy 0·35 J per point and total energy of 1·05 J.

The laser current application protocol was based on data from the pilot study (Santos *et al.* 2011), which used a laser diode with only a red light beam, a dose of 3·8 J/cm^2, 15 mW power, energy of 0·15 J per point and total energy of 0·45 J per application. Data from the pilot study indicated that its irradiation protocol was not sufficient to promote perineal analgesia, which led us to propose the current protocol.

As a general rule, the longer the wavelength of the laser device, the greater the penetration of the beam into the tissue. Because infrared light has a wavelength >700 nm and red light is typically <700 nm, infrared light penetrates more deeply into the target tissue than red light. This fact does not mean that infrared light is not absorbed by the surface, but it indicates that in addition to their absorption into the tissue surface, the waves reach deeper tissue layers. Therefore, longer wavelengths are generally recommended to treat deeper lesions and shorter wavelengths are considered beneficial in the treatment of superficial target tissues (Enwemeka 2009).

The experimental groups, red and infrared, were subjected to a single application of LLLT directly onto the episiotomy. The application was performed by touching the tip of the laser device to the incision for 10 seconds at three points of the episiotomy (central, upper and lower portions), regardless of its length.

To evaluate the possible effects of placebo therapy, the control group participants were also subjected to a single application, but without the emission of radiation. The duration of the simulation of irradiation and the number of application points were the same as in the experimental groups. The laser pen tip was covered with a cotton swab and

the active external tip of the laser pen was covered with aluminium foil, ensuring that no light was emitted.

Main outcomes

The independent variable was the application of LLLT to the perineal region after right mediolateral episiotomy. The dependent variable was the magnitude of perineal pain assessed at three time points (before, immediately after and 30 minutes after the application of LLLT) using a numerical scale from 0–10, with zero representing no pain and 10 the worst pain imaginable. In this study, a two-point reduction on a numerical scale (0–10) was considered a clinically significant change in perineal pain.

Data collection

Data collection was performed from November 2009–March 2010 by two previously trained nurse-midwives (research assistants) and the lead researcher. The participants were selected using a search of maternal records, following the inclusion criteria. The research assistants were responsible for the initial approach and assessing perineal pain scores. The LLLT application was conducted by the principal investigator on the woman's bed in the RIU, with the woman in the lithotomy position. During irradiation, the principal investigator and postpartum women wore glasses for eye protection. Immediately after the application of LLLT, the principal investigator left the room and the research assistant assessed the perineal pain score. The third assessment of perineal pain occurred 30 minutes after the application of LLLT.

To be blinded for the pain score evaluation, the research assistant remained outside the room during the LLLT and was not aware of the woman's group. The subjects also were given no information about the group to which they were allocated. At the end of each treatment, the research assistant questioned the mother regarding her opinion of LLLT.

Data analysis

The Statistical Package for Social Sciences (SPSS) software for Windows, version 13.0 (SPSS Inc., Chicago, IL, USA), was used for the statistical analysis. The normal distribution of the quantitative variables was assessed using the Kolmogorov–Smirnov test. Many of the variables did not have a normal distribution and were therefore analysed with non-parametric tests. The chi-squared test was used to compare qualitative variables among the groups. An analysis of variance with two factors was used for comparing the means among the groups. In this analysis, the two independent factors were the group and the time when the irradiation was performed. Multiple comparisons were made by the Tukey-HSD (Honestly Significant Difference) test. p Values $\leq 0{\cdot}05$ were considered statistically significant. The study was approved by the Ethics Committee of the School of Nursing, University of São Paulo (process 778/2008) and participation was voluntary. The patient's signature on the consent form was obtained.

Results

During the data collection period from November 2009–March 2010, there were 2235 births in the maternity ward, of which 1720 (76·9%) were spontaneous, 511 (22·9%) caesarean sections and four (0·2%) forceps. Among the women who had vaginal deliveries, 600 (34·9%) had an intact perineum, 541 (31·4%) experienced perineal tears and 416 (24·2%) underwent episiotomies, of which 401 (23·3%) were right mediolateral episiotomies and 15 (0·9%) median episiotomies. The perineal condition was not recorded in 163 (9·5%) of the maternal records.

During the data collection period, 401 women were eligible for the study. Among these, 274 did not meet the inclusion criteria and 13 refused to participate, leaving 114 mothers who were divided randomly into three groups of 38 (control, experimental infrared and red). No follow-up loss or migration occurred between the groups (Fig. 1).

With respect to obstetric characteristics and the present delivery, we observed that most subjects were nulliparous (88·6%) and had received emotional support during the labour and delivery (94·7%). No differences were found among the groups regarding sociodemographic or obstetrical characteristics (Table 1). There were no significant differences among the three groups regarding gestational age, newborn characteristics, length of the episiotomy, number of analgesic tablets consumed or the time between analgesic tablets ingestion and irradiation (Table 2).

In the maternity service where this study was conducted, oral analgesics are routinely prescribed. Therefore, 111 women (97·4%) were treated with dipyrone, three participants (2·6%) received acetaminophen and 92 (80·7%) were given diclofenac sodium for pain control after delivery.

The subsequent within-group analysis found significant differences among the three groups when comparing the first and second pain assessments (control 4·7 vs. 3·4, $p < 0{\cdot}001$; red 4·4 vs. 3·4, $p < 0{\cdot}001$; IR 4·3 vs. 2·9, $p < 0{\cdot}001$) and the first and third pain assessments (control 4·7 vs. 2·6, $p < 0{\cdot}001$; red 4·4 vs. 2·4, $p < 0{\cdot}001$; infrared 4·3 vs. 2·1, $p < 0{\cdot}001$). A comparison among the three groups (inter group analysis) found no significant differences between the

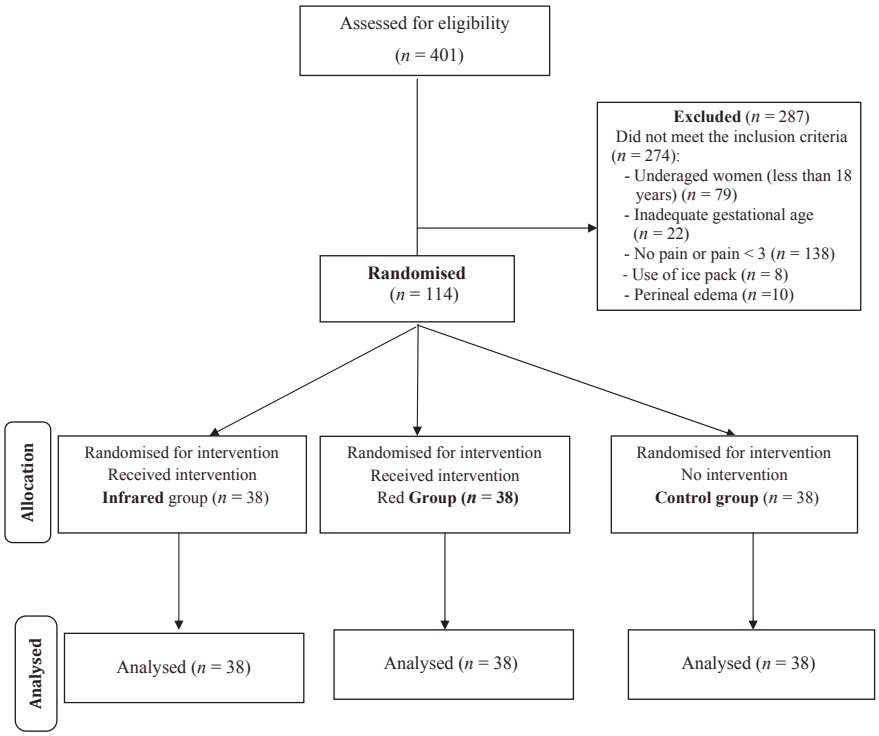

Figure 1 Participant flowchart.

three evaluations of perineal pain (p = 0·445). The means of the pain scores did not differ before irradiation between the control and red groups (4·7 vs. 4·4, p = 0·999), between the control and infrared groups (4·7 vs. 4·3, p = 0·999) or between the red and infrared groups (4·4 vs. 4·3, p = 0·999). The same result was obtained in the analysis of mean pain scores immediately after the intervention between the control and red (3·4 vs. 3·4, p = 1·000), control and infrared (3·4 vs. 2·9; p = 0·998) or red and infrared (3·4 vs. 2·9, p = 0·998) groups. There was no significant difference between the pain score means at 30 minutes after application of LLLT between the red and infrared groups (2·4 vs. 2·1, p = 0·999), control and red groups (2·6 vs. 2·4, p = 0·994) or control and infrared groups (2·6 vs. 2·1, p = 0·999) (Table 3).

According to the chi-squared test, no significant differences among the three groups were found immediately (p = 0·234) or 30 minutes after the intervention (p = 0·111), indicating that the reduction in perineal pain was similar among the groups. Immediately after treatment, fewer than half of the women (44·8%) reported perineal pain relief ≥30%, with no significant difference among the three groups. Thirty minutes after LLLT, the proportion of participants who reported a reduction in pain scores ≥30% increased to 68·4%, also without a significant difference among the three groups (Table 4). These results indicate that the decrease in pain scores obtained with LLLT was not different from the placebo treatment.

The participants were asked about their opinion of LLLT and 96·0% of them had a favourable opinion. Only three women said the practice was neutral. There were no significant differences in the views of the women between the experimental, red and infrared groups (p = 0·053). When asked about the idea of receiving LLLT again, there was no significant difference (p = 0·772) among the mothers in the three groups.

Most women considered the treatment comfortable (93·4%). Five mentioned discomfort during the procedure; among these women, one felt disturbed by the procedure and four women reported it as painful. When comparing the red and infrared groups, no significant difference was found (p = 0·464) in the comfort of the treatment. Most participants (110; 96·5%) reported that they would have the treatment again, whereas four women (3·5%) declined because they did not experience any perineal pain relief.

Discussion

This study investigated the effects of laser therapy on perineal pain owing to episiotomy during childbirth. Pain in the perineal area is the main symptom associated with local trauma and is often experienced by postpartum women. It may arise during the first hours after birth and persist for months (Declercq *et al.* 2008).

Tables 1 and 2 show that the three groups of subjects exhibited similar characteristics at the beginning of the study.

Table 1 Distribution of mothers according to age, race, education, marital status, employment and smoking habits. São Paulo, Brazil, 2010

	Groups						
	Control (n = 38)		Red (n = 38)		Infrared (n = 38)		
Variable (n = 114)	n	%	n	%	n	%	p-value
Age (years) $\bar{x}$ (SD)	22·5 (4·1)		23·3 (4·5)		22·6 (4·7)		0·616*
Parity							0·068†
Nulliparous	36	94·7	30	78·9	35	92·1	
Multiparous	2	5·3	8	21·1	3	7·9	
Skin colour							0·424†
White	15	39·5	15	39·5	8	21·1	
Black	6	15·8	6	15·8	8	21·1	
Mullato	17	44·7	17	44·7	22	57·9	
Educational level							0·899†
Primary education	10	26·3	8	21·1	12	31·6	
Incomplete secondary education	11	28·9	9	23·7	9	23·7	
Complete secondary education	14	36·8	18	47·4	13	34·2	
Higher education	3	7·9	3	7·9	4	10·5	
Employment							0·371†
No	20	52·6	26	68·4	23	60·5	
Yes	18	47·4	12	31·6	15	39·5	
Partnership							0·198†
Yes	25	65·8	31	81·6	32	84·3	
No	13	34·2	7	18·4	6	15·8	
Support in labour							0·121†
No	2	5·3	4	10·5	–	–	
Yes	36	94·7	34	89·5	38	100·0	
Smoking							0·141†
No	32	84·2	33	86·8	37	97·4	
Yes	6	15·8	5	13·2	1	2·6	
Total	38	100	38	100	38	100	

SD, standard deviation.
*Kruskal–Wallis test.
†Chi-squared test.

Table 2 Comparison of the means and standard deviations (SDs) of quantitative variables between the control, experimental infrared and red groups. São Paulo, Brazil, 2010

	Groups			
	Control (n = 38)	Red (n = 38)	Infrared (n = 38)	
Variable	Mean (SD)	Mean (SD)	Mean (SD)	p-value*
Gestational age (weeks)	39·4 (1·2)	39·2 (1·2)	39·4 (1·2)	0·825
Newborn weight (g)	3·216·3 (406·1)	3·252·0 (309·7)	3·226·3 (291·7)	0·924
Cephalic perimeter (cm)	33·8 (1·2)	33·9 (1·5)	34·0 (1·0)	0·646
Apgar score, 1st minute	8·8 (0·4)	8·5 (0·9)	8·5 (0·8)	0·296
Apgar score, 5th minute	9·6 (0·5)	9·4 (0·6)	9·5 (0·5)	0·134
Episiotomy length	3·0 (0·8)	3·1 (0·8)	3·1 (0·2)	0·889
Number of analgesic tablets	4·5 (2·2)	3·6 (1·6)	4·0 (2·1)	0·211
Time between analgesic administration and LLLT (hours)	5·4 (2·1)	5·2 (1·9)	5·5 (2·1)	0·953
Time between delivery and LLLT (hours)	29·7 (11·7)	27·2 (12·5)	24·0 (10·8)	0·110

LLLT, low-level laser therapy.
*Kruskal–Wallis test.

Table 3 Mean perineal pain scores and confidence intervals of the control, experimental infrared and red groups at the three time points. São Paulo, Brazil, 2010

	Groups		
Pain assessment	Control Mean (95% CI)	Red Mean (95% CI)	Infrared Mean (95% CI)
1st (before intervention)	4·7 (4·07–5·29)	4·4 (3·90–4·93)	4·3 (3·85–4·77)
2nd (immediately after intervention)	3·4 (2·79–3·94)	3·4 (2·69–4·09)	2·9 (2·36–3·52)
3rd (30 minutes after intervention)	2·6 (2·02–3·24)	2·4 (1·73–3·16)	2·1 (1·62–2·58)

Table 4 Percentage reduction in perineal pain immediately after and 30 minutes after LLLT in the control, experimental red and infrared groups. São Paulo, Brazil, 2010

	Groups							
	Control		Red		Infrared		Total	
Percentage reduction in perineal pain scores after LLLT	*n*	%	*n*	%	*n*	%	*n*	%
Immediately after LLLT								
Above 50%	9	23·7	10	26·3	9	23·7	28	24·6
Between 30–50%	7	18·4	4	10·5	12	31·6	23	20·2
< 30%	22	57·9	24	63·2	17	44·7	63	55·3
30 minutes after LLLT								
Above 50%	13	34·2	17	44·7	19	50·0	49	43·0
Between 30–50%	14	36·8	5	13·2	10	26·3	29	25·4
< 30%	11	28·9	16	42·1	9	2·7	36	31·6

LLLT, low-level laser therapy.

There were significant reductions in mean pain scores in the intragroup comparisons immediately after irradiation and 30 minutes after treatment in the three groups (control, experimental red and infrared). However, when comparing the mean scores of perineal pain between the three groups at the three evaluation stages, there were no significant differences, indicating that the relief of perineal pain with LLLT was equivalent to placebo treatment.

These findings can be explained by patients feeling reassured, changing their expectations or reinterpreting their symptoms when subjected to a treatment (Krogsbøll *et al.* 2009). These authors conducted a meta-analysis evaluating spontaneous improvement in clinical trials in eight different clinical conditions that included three analysis groups: no treatment, placebo and active intervention. Spontaneous improvement (24%) and the placebo effect (20%) contributed significantly to the results of effective treatment in these studies. Regarding acute pain, spontaneous improvement was responsible for 25% of the reduction in pain scores in the actively treated groups. These results have two implications for evaluating the results of clinical trials.

First, an improvement that occurs after an established treatment cannot be entirely attributed to the treatment. In the studies analysed by Krogsbøll *et al.* (2009), only approximately half of the improvement could be attributed to the treatment. In addition, the authors suggested that it would be incorrect to attribute the effect observed in the placebo group only to the placebo effect because the findings also included spontaneous improvement. Spontaneous improvement appears more important in clinical trials that include patients with high pain scores and symptom scores and do not include a placebo group, especially because the regression to the mean is likely to be more significant in such conditions.

Factors that contribute to the spontaneous improvement of pain in a clinical context are diverse: the natural history of the clinical problem, the non-specific effects of treatment (including professional attention) and the expectations of patients and health professionals about pain management. Friendship, human warmth, sympathy, empathy and positive attitude are also non-specific conditions that can directly influence the outcome of pain treatment (Turner 2001).

During data collection in the present study, the auxiliary researcher provided women with information related to breastfeeding, breast care, newborn care and perineal trauma. Therefore, the therapeutic effects obtained in this study could be attributed to the Hawthorne phenomenon, which states that people tend to modify their behaviour by being an object of attention during the trial. Thus, patients try to please the

researchers, making them feel that the intervention was successful (Fletcher & Fletcher 2005).

The clinically significant change in perineal pain (a two-point reduction on a numerical scale) stated in this study represents a 30% decrease in perineal pain, as reported by Farrar *et al.* (2001). Less than half of the women presented this reduction in perineal pain and there was no difference between groups immediately following the intervention or after 30 minutes, although the pain reduction rate had risen to approximately 70% by the latter time point.

There have been two prior studies using LLLT for the treatment of pain and healing following episiotomy. A study conducted in the Czech Republic (Kymplová *et al.* 2003) compared the effects of phototherapy using three sources of light: a low-level laser, a halogen light and a light-emitting diode (LED), along with a control group. The participants were 2436 puerperal women who had undergone episiotomy (with the continuous catgut suture method) and had been divided into four groups. Group A, with 748 women, used the LLLT with a wavelength of 670 nm once a day with an energy density of 2 J/cm^2 and a continuous alternation frequency of 10, 25 and 50 Hz. The applications were performed between the day of delivery or the next day and the discharge day, with a mean of 3·99 applications per woman. The B group, with 581 women, used lamp-polarised halogen (where light passes through a polarising filter) begun shortly after birth and maintained during hospitalisation (4–6 days); the total energy density over the course of an application was 5 J/cm^2 and there was an average of 4·37 applications. The C group, with 715 women, used an LED light with a magnetic applicator (one-second pulses alternating between light and magnetic application; the magnetic applicator was active for 60% of the period) with a total light energy density of 0·7 J/cm^2. The period of application of the pulsed magnetic field was three minutes and the average number of applications was 4·83. The K group, with 592 women, did not use any method of treatment. Phototherapy with any of the three sources used reduced the occurrence of complications during healing of the episiotomy ($p < 0{\cdot}01$). There was a reduction in the number of healing complications: 3/381 (0.8%) in group B and 8/715 (1.1%) in group C. In the control group (K), 58 more severe complications were found (including need for a complete resuture and cutaneous and subcutaneous dehiscence with purulent discharge). The best results were obtained after using the laser (group A), where two women had complications (2/748 – 0.3%) (redness of the superior pole of the incision). The authors concluded that LLLT was the best of the options studied and that it could be complemented by the application of polarised light (Kymplová *et al.* 2003). There was no assessment of the effect of the laser on perineal pain. However, some methodological aspects of this research are questionable, such as the lack of randomisation, the absence of criteria for assessing perineal healing, limited detailed description of the intervention and no explanation of possible conflicts of interest of the authors.

Another survey conducted in Azerbaijan by Rzakylieva *et al.* (2006) examined the effects of LLLT on the stimulation of perineal healing in 86 postpartum women with episiotomy or perineotomy sutured with Vicryl. The women were divided into a control group ($n = 40$), who were given topical antiseptics and a laser group ($n = 46$), who received LLLT and traditional care. The first irradiation occurred immediately after the suture and then once per day after that, which lasted for six or seven applications. The dosimetry of the laser was set individually, depending on the severity of the perineal injury, with the average frequency of pulses ranging from 80–100 Hz, power 80 mW, a magnetic induction of 20 mT and an average time of irradiation of 6–8 minutes. The authors found that LLLT reduced the intensity of perineal pain after two to three applications of therapy, improved the healing process and rapidly decreased inflammation symptoms. Some methodological aspects of this study are also questionable, however, such as a lack of randomisation, the absence of criteria for evaluating the outcomes, a lack of a detailed description of the application of the therapies, no blinding assessment and a lack of results for the outcomes evaluated. The above studies support the findings of Enwemeka (2009), which showed that more than 30% of published studies on laser therapy do not provide relevant details and use inaccurate radiation measurements and incorrect dosages of irradiation protocols, hampering the assessment of the treatment's efficacy in relieving pain.

In the maternity service studied, routinely prescribed postpartum medications include oral analgesics and anti-inflammatory drugs. The mean time between the administration of analgesics and irradiation with LLLT was more than five hours in all three comparison groups, with no significant differences. However, we observed that even after the administration of oral analgesics, all women reported perineal pain ≥3 on the numeric scale, confirming the findings of a clinical trial conducted by Steen *et al.* (2000) showing that drug treatment alone is not sufficient to relieve perineal pain.

The women included in the present study were not approached before the study because in the Brazilian National Health System, they are not offered a choice of birthing facility. Therefore, it was not possible to randomise the women during the pregnancy period. As in the pilot study, the use of analgesics may be considered both a limitation of this study and a pragmatic condition because

there is usually no way to avoid women receiving routinely prescribed medication (Santos *et al.* 2011). This study considered the pragmatic elements of reality and strengthened the external validity of the results, increasing the possibility of applying these findings to clinical practice.

For the relief of perineal pain, there is a need for the concurrent use of systemic and localised treatments (Steen 2005). With this in mind, we sought to evaluate the effectiveness of LLLT in reducing perineal pain without restricting the intake of oral analgesics.

The findings of this trial suggest that when promoting an analgesic treatment using LLLT, the care provider must consider several factors: the wavelength, power, power density, energy density and energy emitted by the device, as well as the spot size and characteristics of the woman and the trauma, including the location, size and depth of the lesion to be treated. In addition, the manner, frequency, time, dose and cumulative dose of radiation application should be considered (Chow *et al.* 2009, Enwemeka 2009). These authors state that the success of the analgesic treatment with LLLT is intrinsically related to dosimetry and the correct selection of the aforementioned parameters.

It is known that the length and depth of episiotomies vary considerably among women and the incision penetrates skin, subcutaneous tissue, muscle and vaginal mucosa at the superficial or deeper tissue layers by up to 3–5 cm (Kettle 2005). Given the depth reached by the beams of the LLLT, both red and infrared and the characteristics of episiotomy, it is believed that the single dose of radiation used in this study was not sufficiently powerful to promote the relief of perineal pain. Accordingly, these data suggest that further research involving mothers with perineal trauma is required to investigate the effectiveness of LLLT for the relief of perineal pain and to define an effective irradiation protocol.

In 2009, the Regional Nursing Board of São Paulo released a regulation for the use of LLLT by nurses in the clinical treatment of wounds, providing assurances that this treatment was legal (CAT No 011/2009) (Carrara & Harada 2009). The construction of a scientific study was the first step in increasing our knowledge about the applicability of laser therapy in obstetrical practice in Brazil.

Conclusion

LLLT did not decrease the intensity of perineal pain reported by women who underwent right mediolateral episiotomy. The dosage may not have been sufficient to provide relief from perineal pain after episiotomy during a vaginal birth. New research proposals comprising multiple LLLT therapeutic protocols are required to determine an effective protocol for the relief of perineal pain and discomfort among postpartum women.

Relevance to clinical practice

The findings indicate that a significant number of mothers who underwent LLLT had a favourable opinion regarding the procedure. For most women, the procedure was considered comfortable, with no significant difference between the groups. Although the results of this study do not indicate benefits of LLLT for the relief of perineal pain when comparing the experimental groups with the control, we believe that with the expansion of knowledge of the laser and the appropriateness of therapeutic protocols in obstetrics, this technology might be useful for the treatment of perineal trauma.

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Contributions

Study design: JOS, SMJVO, MRCN, data collection and analysis: JOS, RHO, MLGR and manuscript preparation: JOS, SMJVO, FMBS, MRCN.

Conflicts of interest

None.

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