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ORIGINAL ARTICLE

Low-level laser therapy improves pain in postcesarean section: a randomized clinical trial

Alane Macatrao Pires de Holanda Araujo[1] · Kassio Rafael Rocha de Sena[2] · Edson Meneses da Silva Filho[3,4] · Rodrigo Pegado[3] · Maria Thereza Albuquerque Barbosa Cabral Micussi[1]

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Abstract

This study aimed to evaluate the effect of low-level laser therapy (LLLT) on immediate postpartum pain relief during cesarean section. A randomized, parallel controlled trial was carried out. In total, 88 women with immediate postpartum were divided into 4 groups: control group ($n = 22$), placebo group ($n = 22$), experimental group I ($n = 22$, dose of 4 J/cm^2), and experimental group II ($n = 22$, dose of 2 J/cm^2). The pain measured by Numeric Rating Scale (NRS), algometry, and Global Change Perception Scale (GCPS) was assessed at 12, 20–24, and 44–48 h postpartum. Two LLLT sessions were performed at 12 and 24 h postpartum. A significant interaction was observed between time versus group for NRS F (2.40) = 36.80, $p < 0.001$ and algometry F (1.70) = 27.18, $p < 0.001$. GCPS revealed a significant difference between the groups during second ($p = 0.04$) and third evaluation ($p = 0.04$). The NRS and algometry presented a large effect size for the experimental groups. LLLT is an efficient method to reduce pain and enhance the GCP in postcesarean section. No significant clinical differences were found between the laser doses.

Keywords Low-level laser therapy · Cesarean section · Analgesia · Phototherapy

Introduction

Cesarean section has immensely increased in the industrialized and developing countries, such as Brazil, which presents the highest cesarean section rates worldwide, with 80–90% of births in private hospitals and 40% in the public health system [1, 2]. Women who undergo cesarean delivery prefer avoidance of pain during and after surgery; therefore, effective postoperative analgesia is crucial [3]. Severe postoperative pain is associated with persistent pain, rater opioid use, delayed functional recovery, and postpartum depression [4]. Moreover, acute postoperative pain has proven to be one of the most consistent and strongest predictors of chronic postsurgical pain after undergoing various surgical procedures including hernia repair [5], limb amputation [6], and coronary artery bypass [7]. Present evidence indicates a relatively low incidence of pain chronification after cesarean delivery, ranging between 1 and 18% [8, 9].

Women experiencing severe acute postpartum pain had a 2.5-fold increased risk of insistent pain and 3-fold augmented risk of postpartum depression compared with women with mild acute childbirth pain [10]. The pain after cesarean delivery can disrupt normal mother–infant physical contact and the care provided to the mother [11]. This situation may affect breast-feeding performance during the puerperium, thus impacting the mother's feed and care ability [12, 13].

It is essential to identify the patients at risk for high acute postpartum pain and address the need for more careful pain treatment after childbirth [13]. Multimodal analgesia includes scheduled nonsteroidal anti-inflammatory drugs and acetaminophen opioids to be administered for severe pain [14]. Studies suggest that nonpharmacological resources for optimizing postpartum pain management include hypnosis, transcutaneous electrical nerve stimulation, and low-level laser therapy (LLLT) [14–17].

✉ Edson Meneses da Silva Filho
meneses.edson@yahoo.com.br

[1] Health Science Center, Federal University of Rio Grande do Norte, Natal, RN, Brazil

[2] Faculdade Estácio, Natal, RN, Brazil

[3] Faculty of Health Science of Trairí, Graduate Program in Rehabilitation Science, Federal University of Rio Grande do Norte, Santa Cruz, RN, Brazil

[4] Graduate Program in Rehabilitation Science, Federal University of Rio Grande do Norte, Santa Cruz, RN 59200-000, Brazil

LLLT refers to a noninvasive, phototherapy, or photobiomodulation method that uses photons at a nonthermal irradiance in order to stimulate the biological activity and has been classified as a safe, noninvasive treatment modality [18]. It is used to treat numerous conditions that require healing stimulation, pain/inflammation relief, and function restoration [19]. Several mechanisms have been proposed for LLLT, including increased endogenous opioid neurotransmitter production, thermal pain improvement, increased adenosine triphosphate production, increased production of anti-inflammatory cytokines, and local neoangiogenesis [20–23]. One such LLLT mechanism includes photon absorption by cytochrome c oxidase in the mitochondrial respiratory chain that catalyzes oxygen reduction for energy metabolism, thereby leading to higher oxygen consumption and metabolic energy production via mitochondrial oxidative phosphorylation [24]. LLLT alters the cellular redox state, which further activates numerous intracellular signaling pathways and alters the affinity of transcription factors concerned with cell proliferation, survival, tissue repair, and regeneration [25–27]. These biological effects may prove efficient in various clinical settings including the treatment of acute and chronic pain [18].

LLLT could be an effective, economic, and deployable therapy to enhance functionality in postpartum patients, thus aiming to reduce pain and promote faster cesarean scar regeneration. Therefore, for the effective administration of LLLT, the optimal dosage should efficiently reach an enough volume of regenerative target tissue. Further studies are warranted to optimize its therapeutic value to determine if the effects of photobiomodulation can be made more reliable and extensive in treating postpartum pain.

Considering these assumptions, this study aimed to evaluate the effect of LLLT on immediate postpartum pain during cesarean section. We hypothesized that LLLT can significantly reduce the pain in postpartum women.

Methods

This is a randomized, double blind, controlled, and parallel clinical trial that followed the CONSORT's recommendations [28]. All women were informed about the study procedures, and that they could be randomized into any of the study groups and their participation would be voluntary as per resolution No. 466/12 of the National Health Council. This study was approved by the local institutional ethics committee from Federal University of Rio Grande do Norte (number: 1.998.386). The study was registered in the REBEC platform (Identifier: RBR-6B8HCC). All the participants signed the informed consent term, accepting to participate in the study. Data were collected from March 2017 to June 2018.

In total, 88 women in the immediate postpartum stage of cesarean section were included in this study. The participants were recruited by spontaneous demand in accommodation of Divino Amor Maternity located in the county of Parnamirim, state of Rio Grande do Norte and regarded as suitable to participate in this study, if they fulfilled the following criteria: (1) women over 18 years and absence of clinical or obstetric intercurrences (hypertension or diabetes) and (2) mean pain score of at least 3 on the Numeric Rating Scale (NRS). Exclusion criteria were (1) women with ineffective communication during the postpartum period, (2) hospital discharge before the end of intervention, and (3) those who presented intercurrences (as hemorrhage, postcesarean wound dehiscence, or sepsis).

Portable low-intensity gallium-aluminum-arsenide (GaAlAs) laser device, Laserpulse IBRAMED®, was used during the interventions. The laser was previously evaluated by an independent researcher to confirm its power emittance. LLLT was performed in two sessions: at 12 and 20–24 h postpartum. The interventions were carried out via two different protocols: in the experimental group I, an LLT dose of 4 J/cm^2 and 0.24 J/point in 8 s was used. In the experimental II group, the LLLT dose of 2 J/cm^2 and 0.12 J/point in 4 s was used. Spot diameter was 0.06310 cm^2 and irradiance was 0.47 W/cm^2. In the placebo group, LLLT was performed in presence of electricity, but without energy emission of energy. Furthermore, as the device produces insufficient heat, the patients will be unable to understand whether active or placebo PBMT was administered. Besides that, patient and researcher used the same protection glasses. Details of LLLT parameters are described in Table 1. This protocol was preferred due to its feasibility and was be previously established for wound healing in other surgical scars including healing after episiotomy and to relieve pain after fracture surgery [16, 35].

An expert physiotherapist performed the technique. The application form was punctual, non-contact, and with spot laser positioned perpendicular to the skin in the line of the cesarean incision. The number of points applied depended on the surgical wound extension, considering the distance of 1 cm between the application points (Fig. 1). The laser source tip was cleaned between the sessions of irradiation with 70% alcohol and was wrapped with a flexible plastic material (polyvinyl chloride). The physiotherapist and the patient used specific glasses for further protection in the placebo, experimental I, and experimental II groups. The positioning of the patient was in neutral supine position. For the placebo laser, all sites were treated with the lasers in turn-off mode with the same duration.

The study presented three phases: first phase (I): 12 h after cesarean: includes gynecological and obstetric history and primary and secondary outcomes (first evaluation); second phase (II): interventions were performed in 2 consecutive days; third phase (III): two evaluations were performed between 20 and 24 h postpartum (second evaluation) and 44–48 h postpartum (third evaluation). The overview of all procedures is presented in Fig. 2.

Table 1 Parameters of the LLLT used in the study

Groups	Parameters	Values
	Laser active	GaAlAs
	Mode	Continuous
	Wavelength	660 nm
	Power	30 mW
Experimental I	Dose	4 J/cm^2
	Energy/point	0.24 J
	Energy/session	2.4 J
	Total energy	4.8
	Irradiation time/point	8 s
	Number of points	10
	Area	1 cm^2
	Laser active	GaAlAs
	Mode	Continuous
	Wavelength	660 nm
	Power	30 mW
Experimental II	Dose	2 J/cm^2
	Energy/point	0.12 J
	Energy/session	1.2 J
	Total energy	2.4
	Irradiation time/point	4 s
	Number of points	10
	Area	1 cm^2

J Joules, *J/cm*^{2} Joules per centimeter square

Pain was defined as the primary outcome evaluated by numeric rating scale (NRS) and algometry. The NRS is a segmented numeric version of the visual analog scale, in which the respondents select a whole number (0–10 integers) that best reflects the intensity of their pain. The pain NRS is a single 11-point numeric scale with 0 representing one pain extreme (e.g., "no pain") and 10 representing the other pain extreme (e.g., "pain as bad as you can imagine") [30].

The digital algometry (Force Gage model Wagner FDM®) was used to assess the pain threshold. The equipment had a rubber disk of a 1 cm^2 connected to a pressure gage (values in kgf/cm^2). The rubber disk was coated with PVC plastic wrap and was sanitized with 70% alcohol. The volunteer was encouraged to stop the process when the pressure with the tip of the equipment evoked pain. The threshold record was measured at the time of the "stop" report. Three measurements of algometry were recorded at the extremities and midpoint of the operative wound. For calculating the algometry, the average of the 3 points was considered [31].

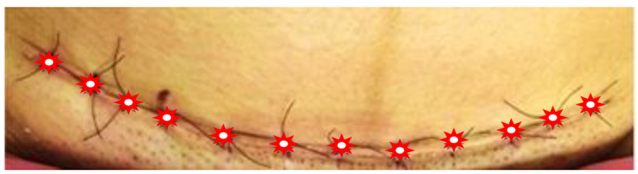

Fig. 1 Laser therapy target points with a distance of 1 cm between them. The number of points was determined based on the cesarean incision size

The secondary outcome was measured using the Global Change Perception Scale (GCPS). The evaluation occurred at 20–24 h and 44–48 h postpartum. The scale is a one-dimensional measure in which the individuals can classify the improvement of pain symptomatology by associating the intervention to seven factors, distributed as follows: 1 = no changes, 2 = almost the same, 3 = slightly better, 4 = with certain improvements, 5 = moderately better, 6 = better, 7 = considerably better. This instrument is validated in the Portuguese version and is easy and quick to apply. It is often used in individuals undergoing interventions to determine the clinically important minimal differences during pain assessment, physical function, and quality of life [32].

The sample calculation was performed according to the Miot [33] formula based on the stage of pain in the region of the surgical incision (as a reference the visual analog scale of the pain graded from 0 to 10 and presented a reduction of 3 points in the graded pain score). The alpha error was 0.05 and test power was 80%. The sample size calculation indicated that 72 participants were necessary. We decided to add 16 additional patients to account for attrition. Thus, 88 patients were recruited and randomized into 4 groups of 20 patients.

Randomization was performed through by using the software originated by the site www.randomization.com in a 1:1:1:1 sequence by an independent researcher who was not involved with either stimulation or assessments. All volunteers were randomized and divided into four groups: control group (no LLLT, n = 22), experimental I (n = 22), experimental II (n = 22), and placebo group (equipment turned on without irradiation emission, n = 22) (see Fig. 3). Both participants and evaluator researcher involved in the assessments were blinded to the group allocation throughout the trial. Moreover, all participants were blinded to the intervention group, with no information of the applied dose.

Data were analyzed using SPSS software 20.0 (Statistical Package for the Social Sciences) for Windows, and in all statistical analyses, p values < 0.05 were considered as statistically significant. We performed Shapiro–Wilk test and Levene for normality of the data distribution and equality of variances. Descriptive statistics were presented using the measures of central tendency. Mauchly's test of sphericity was used to validate the correlation of the repeated measures, and if the assumption of sphericity was violated, the Greenhouse–Geisser correction was applied. A two-way repeated measures ANOVA was used to compare the effects of LLLT between groups over time on a primary outcome. The independent fixed variables were time (1st, 2nd, and 3rd evaluations), stimulation groups (control, placebo, experimental I, and experimental II), and the interaction term. When appropriate, post hoc comparisons were carried out using Tukey's post hoc correction for multiple comparisons. The one-way ANOVA

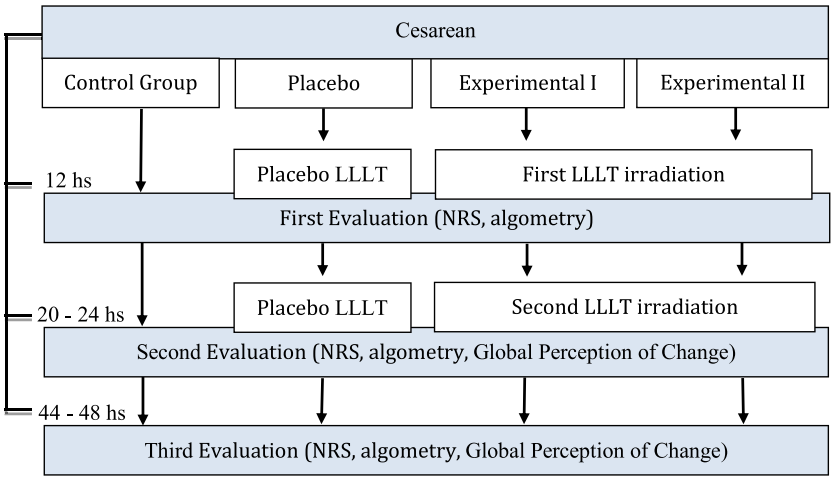

Fig. 2 Stages of data collection and groups of intervention. Low-level laser therapy. NRS: numeric rating scale

was used to assess the pain outcome at each assessment and the overall perception of change (secondary outcome) in the reassessments along with the Tukey's post hoc test to identify the difference between groups. The minimum clinically significant difference was demonstrated by calculating the effect size with Cohen's *d* formula. For the missing data, intention to treat analysis was used.

Results

A total of 1320 individuals were screened for eligibility and 1232 were excluded as they did not meet the inclusion criteria. In this study, 88 patients were divided into 4 groups and 11 volunteers abandoned the study. The reasons for exclusion included discontinued intervention due to bleeding, painless, withdrawal, and difficult communication. No significant differences were observed in the sociodemographic and clinical variables in the baseline values between groups (Table 2). LLLT did not reveal any side effects during the study.

A significant interaction between time versus group was found for NRS $F(2,140) = 36.80$, $p < 0.001$ and algometry $F(1,70) = 27.18$, $p < 0.001$ (Table 3). A significant difference was observed between groups in the third evaluation of NRS ($p = 0.03$) and algometry ($p = 0.04$). GCP was evaluated at 20–24 h (first evaluation) and 44–48 h (second evaluation) postpartum and revealed a significant difference between groups in the first ($p = 0.04$)

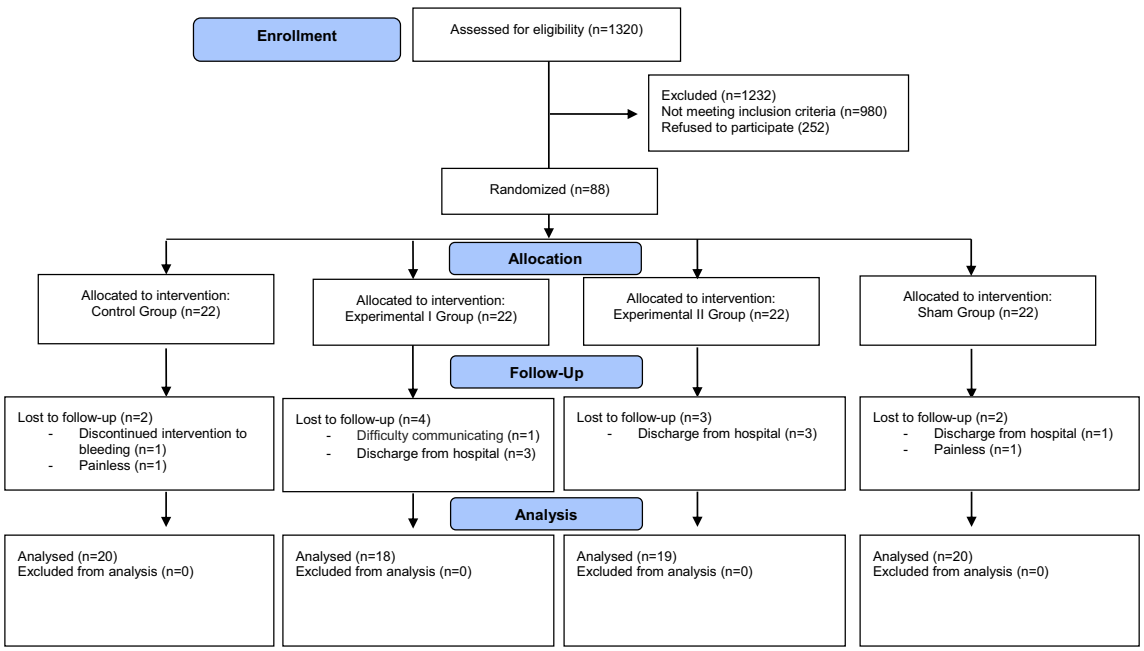

Fig. 3 Flowchart of the study

Table 2 Comparison of baseline characteristics between groups

Variables	Control (n = 20)	Placebo (n = 20)	Experimental I (n = 18)	Experimental II (n = 19)	p value
Numeric rating scale	5.75 ± 1.44	3.90 ± 2.40	5.24 ± 2.42	5.47 ± 2.00	0.06
Pain threshold (kgf/cm^2)	0.77 ± 0.47	0.72 ± 0.54	0.58 ± 0.30	0.67 ± 0.33	0.08
Number of pregnancies	1.63 ± 0.83	2.08 ± 1.28	2.10 ± 1.11	1.79 ± 0.82	0.17
Gestational age (week)	39.00 ± 1.44	39.17 ± 1.47	38.80 ± 2.04	38.47 ± 2.31	0.21
Age groups (years)					0.42
18–28	25% (n = 5)	40% (n = 8)	33.33% (n = 6)	31.58% (n = 6)	
29–39	65% (n = 13)	40% (n = 8)	38.89% (n = 7)	47.37% (n = 9)	
30–39	10% (n = 2)	20% (n = 4)	27.78% (n = 5)	21.05% (n = 4)	
Marital status					0.65
With partner	90% (n = 18)	95% (n = 19)	100% (n = 18)	94.74% (n = 18)	
Without partner	10% (n = 2)	5% (n = 1)	0% (n = 0)	5.26% (n = 1)	
Educational level (%)					0.77
Illiterate	0% (n = 0)	0% (n = 0)	0% (n = 0)	0% (n = 0)	
4 years of study	0% (n = 0)	0% (n = 0)	5.55% (n = 1)	10.52% (n = 1)	
8 years of study	10% (n = 2)	10% (n = 2)	11.12% (n = 2)	10.52% (n = 1)	
11 years of study	90% (n = 18)	90% (n = 16)	77.78% (n = 14)	78.96% (n = 15)	
More 11 years of study	0% (n = 0)	10% (n = 2)	5.55% (n = 1)	0% (n = 0)	

Experimental group I (LLLT with dose of 4 J/cm^2). Experimental group II (LLLT with dose of 2 J/cm^2)

and second (p = 0.02) evaluation (Table 3). Pain intensity indicated a significant difference at 44–48 h between groups in the third evaluation (p = 0.04; Fig. 4).

The effect sizes for NRS in placebo and control groups were 0.11 and 0.43, respectively. Experimental I presented an effect size of 0.71, and for experimental II, it was 0.69. Algometry revealed an effect size of 0.26 and 0.27 for the placebo and control groups, respectively. The experimental I and experimental group II presented large effect sizes of 0.91 and 0.88 for algometry, respectively.

Tenoxican, scopolamine butylbromide, dipyrone, and simethicone were administered. In the placebo group, 5% patients (n = 1) were administered tenoxicam and scopolamine butylbromide and 25% (n = 5) were given simethicone. In the control group, 5% (n = 1) were administered tenoxicam and dipyrone and 10% (n = 2) were given scopolamine

Table 3 Comparison of means and standard deviation in pain and clinical perception between groups

	Evaluation	Control (n = 20)	Placebo (n = 20)	Experimental I (n = 18)	Experimental II (n = 19)	p value
Numerical rating scale	12 h	5.47 ± 2.00 (4.44–6.50)	3.90 ± 2.40 (2.77–5.02)	5.23 ± 2.41 (3.99–6.47)	5.75 ± 2.00 (5.07–6.42)	0.12
	20–24 h	6.05 ± 2.07 (4.99–7.13)	4.75 ± 1.55 (4.02–5.48)	4.17 ± 1.74 (3.28–5.07)	4.10 ± 1.86 (3.22–4.97)	0.23
	44–48 h	3.94 ± 1.91^b (2.74–4.55)	3.65 ± 1.92^a (2.74–4.55)	1.88 ± 2.08$^{a.b}$ (0.81–2.95)	2.70 ± 1.38 (2.05–3.34)	0.03*
Pressure pain threshold (kgf/cm^2)	12 h	0.61 ± 0.19 (0.54–0.88)	0.72 ± 0.54 (0.47–0.98)	0.57 ± 0.31 (0.41–0.73)	0.66 ± 0.33 (0.50–0.84)	0.07
	20–24 h	0.61 ± 0.74 (0.46–0.77)	0.61 ± 0.36 (0.44–0.78)	0.90 ± 0.48 (0.65–1.15)	0.89 ± 0.40 (0.68–1.10)	0.07
	44–48 h	0.76 ± 0.14$^{b.d}$ (0.46–1.07)	0.84 ± 0.22$^{a.c}$ (0.74–0.95)	1.49 ± 1.11$^{a.b}$ (1.01–1.82)	1.45 ± 0.75$^{c.d}$ (1.03–1.80)	0.04*
Global change perception	20–24 h	2.60 ± 1.28 $^{a.b}$ (1.87–3.01)	3.95 ± 1.93 (2.93–5.01)	5.11 ± 1.31 ^{a} (4.75–6.37)	5.52 ± 1.21^b (4.44–6.54)	0.04*
	44–48 h	1.40 ± 1.60 $^{b.c}$ (1.15–3.16)	3.70 ± 2.22 $^{a.d}$ (2.89–4.96)	6.18 ± 0.90 $^{a.b}$ (5.99–6.91)	6.00 ± 0.69 $^{c.d}$ (5.32–6.68)	0.02*

*Significant, $p < 0.05$—ANOVA one-way and Tukey's post hoc. Data is presented in means, standard deviation, and 95% confidence interval. The same letters indicate significant difference between the groups

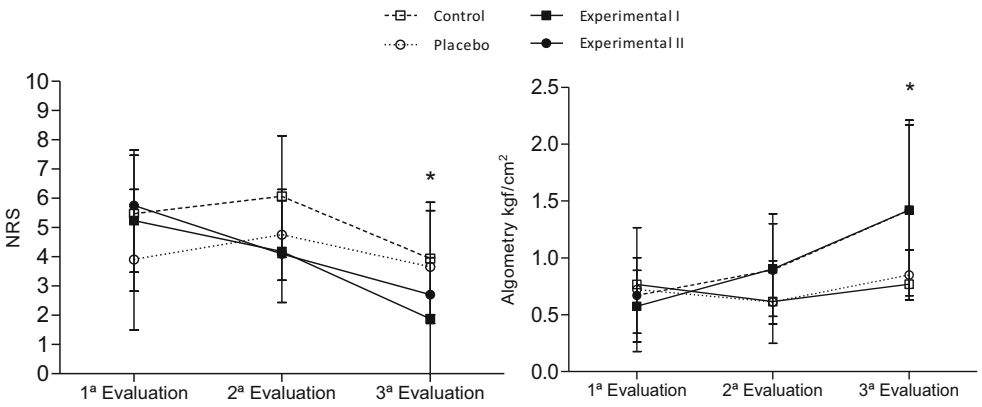

Fig. 4 Pain intensity after 12 h (1st evaluation), 20–24 h (2nd evaluation), and 44–48 h (3rd evaluation) post cesarean. Numeric rating scale (NRS). *Significant difference between groups

butylbromide. In experimental I and II, 10.53% were administered simethicone ($n = 2$) and 5.55% were given dipyrone ($n = 1$).

Discussion

The primary objective of this study was to evaluate the effect of continuous GaAlAs laser with wavelength of 660 nm on immediate postpartum pain in cesarean incision. The secondary aim was to assess the GCP after the intervention. The results revealed that LLLT improved pain and GCP after cesarean incision. No significant difference was observed between the dosimetry of 2 J and 4 J.

LLLT is clinically a well-accepted tool in rehabilitation and has been used to restore functionality in various clinical conditions, thus aiming to improve pain, enhance wound healing, and promote tissue regeneration with more quality [18, 34]. Studies suggest LLLT for tissue regeneration in postoperative surgery, periodontal treatment, pain and inflammation control [35–37]. Pain relief promoted by LLLT is related to reduced E2 prostaglandin, which prevents the onset of pain by stimulating compounds and also controls inflammation process [34]. Analgesia is caused by the release of endogenous endorphins and hyperpolarization of nerve endings, which inhibit the transmission of painful stimuli to the central nervous system. Additionally, the biological effects produced due to the energy absorption by the tissues allow the light of the photons to interact with the cellular structure [25]. An increase in cellular energy is observed, which alters the permeability of the cell membrane, causes reduction in the interstitial fluid, wound healing, muscle relaxation, modulation of the immune system, and nerve regeneration [25]. Only one clinical trial was reported in literature regarding the use of LLLT in pain after elective cesarean section [29].

Poursalehan et al. (2018) [29] studied 80 patients after an elective cesarean with an objective to investigate the effect of low power laser on acute pain. The authors used two different wavelengths (GaAlAs: 804 nm and GaAlInP: 650 nm) applied in the surgery room postsurgery and before the bandage. The incisions were treated by the red laser (1 J/cm^2 for 10 s) and IR laser (2 J/cm^2 for 10 s). Thereby, only one LLLT session was performed and pain was measured at 1, 4, 8, 12, 16, and 24 h after the end of cesarean section. The authors found that the pain significantly reduced at 1, 4, 8, 12, 16, and 24 h after surgery [29].

Another study evaluates the LLLT (5 J/cm^2) on pain and perineal healing after episiotomy [16]. Fifty-four postpartum women who had a spontaneous birth with a right mediolateral episiotomy were subjected to three sessions of irradiation. No significant difference was observed between the groups regarding perineal healing and pain scores after LLLT [16]. Similar results from a previous study indicated that after LLLT irradiation, no difference was seen between the scores of episiotomy healing and perineal pain up to 2 h, 20–24 h, and 15–20 days after normal birth [16, 37]. These results indicate that the anatomical area and the type of surgery could influence pain and healing.

Reduction of pain should have interfered positively in improving the health status among the treatment of episiotomies [38]. Our study showed similar effects. LLLT has a positive acceptance by patients for promoting physical improvement and emotional well-being after surgical procedures [38].

In this study, it is clear that pain not showed significant difference between groups in baseline, but p value is close to 0.05. Therefore, one proof that this does not interfere is the significant intragroup and post-experiment intergroup effect and also by the effect measure (Cohen's d) that reveals clinical impact effects between interventions. This study had certain limitations, wherein, the population losses occurred throughout the study, despite all the exclusions had being considered to intention to treat analysis; moreover, the reduced period for pain assessment, which was limited to the discharge from hospital. The thermal measurement was not quantified or calibrated in this study, and future investigations should consider this for more accurate LLLT effects [39]. The LLLT can easily be routinely applied in postpartum patients with an aim to reduce pain and to help restore functionality.

Conclusion

This study suggests that LLLT was effective in relieving surgical wound pain after cesarean section. Laser therapy seems to be a good nonpharmacological resource for pain improvement after cesarean section; however, different protocols and long-lasting effects need to be investigated in future trials.

Authors' contributions AMPHA: conceptualization, planning, data collection, and writing of the manuscript. KRRS: data collection and planning. EMSF: writing of the manuscript, supporting data analysis, and proofreading. RP: conceptualization, planning, data analysis, and writing of the manuscript. MTABCM: conceptualization, planning, data analysis, and writing of the manuscript. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interests The authors declare that they have no conflict of interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (include name of committee + reference number) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the local institutional ethics committee from Federal University of Rio Grande do Norte (number: 1.998.386). The study was registered in the REBEC platform (Identifier: RBR-6B8HCC).

Informed consent Informed consent was obtained from all individual participants included in the study.

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