Low-intensity Laser (660 NM) has Analgesic Effects on Sternotomy of Patients Who Underwent Coronary Artery Bypass Grafts

Abstract

Background: The aim of this study was to evaluate the efficacy of low-level laser therapy for reducing the acute pain of sternotomy in patients who underwent a coronary artery bypass graft (CABG). Methods: This study was conducted with ninety volunteers who electively submitted to CABG. The volunteers were randomly allocated into three groups of equal size (n = 30): control, placebo, and laser (λ of 660 nm and spatial average energy fluency of 1.06 J/cm²). Pain when coughing was assessed by a visual analog scale (VAS) and McGill Pain Questionnaire, according to sensory, affective, evaluative, and miscellaneous domains. The patients were followed for 1 month after the surgery. Results: The laser group had a greater decrease in pain with analogous results, as indicated by both the VAS and the McGill questionnaire (P ≤ 0.05) on sensory and affective scores, on days 6 and 8 postsurgery compared to the placebo and control groups. Conclusion: Laser seems to be effective promoting pain reduction after coronary-arterial bypass grafting.

Keywords: Low-level laser therapy, myocardial revascularization, pain, sternotomy

Introduction

While the rate of mortality from cardiovascular disease (CVD) has been decreasing over the last four decades in European and other developed countries, CVD still causes the majority of deaths in certain age groups. In developing countries, such as Brazil, the mortality rate of CVD is comparable to that in developed countries. CVD is one of the major causes of nontraumatic death and is responsible for approximately 20% of all deaths of individuals older than 30 years in Brazil. The last epidemiological study on the subject revealed that 962,931 individuals older than 30 years had died in 2009, with CVD responsible for 95,449 deaths and stroke for 97,860 deaths. Recently, clinical and public health efforts to reduce the impact of CVD have highlighted the importance of calculating the short-term death risk by examining trends in the predicted 10-year risk for CVD with algorithms derived from the Framingham Heart Study. Furthermore, in many cases, the disease severity may lead patients to coronary artery bypass grafting (CABG).

The surgical procedure is complex, and most interventions need a sternal longitudinal incision, which can cause moderate to severe pain postsurgery, as well as nonnegligible incidence of chronic pain, which can persist for more than 1 year. Pain intensity around the incision has been described as higher on the 7th day postsurgery compared to 1 month after hospital discharge, and it has significant repercussions on functionality. Adequate analgesia after a sternotomy reduces postoperative adverse events and improves patient satisfaction and clinical outcomes.

The analgesic effects of low-level laser therapy (LLLT) have been validated both in vitro and in vivo. Possible mechanisms of action include endorphin secretion stimulation, reduction of interstitial fluid at the site of inflammation with a marked increase in vasodilatation, and improvement in local circulation. LLLT also can stimulate immediate analgesia to control neuropathic pain by releasing local neurotransmitters such as serotonin, promoting the release of endorphins, or increasing mitochondrial ATP production, or through anti-inflammatory effects. Although many studies have been performed to help understand the analgesic and tissue repair mechanisms of LLLT,

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additional clinical studies are necessary to better understand those effects.

The aim of this study was to evaluate the efficacy of LLLT for reducing acute pain from sternotomy in patients who underwent CABG.

Methods

All of the individuals provided written, informed consent, and their rights were protected. The protocol for this study was approved by the Local Research Ethics Committee, CAAE 0127.0.043.000-11, and registered with the Brazilian Clinical Trial Registry and the International Clinical Trials Registry Platform of the World Health Organization under RBR-38wgx6 and Universal Trial Number U1111-1128-9666, respectively.

This was a randomized, double-blind clinical trial containing both a placebo and a control group. It was carried out at Santa Maria Hospital that performs cardiac surgery for the Brazilian public health system, in Teresina, Piauí, Brazil. All patients admitted to the hospital during the study period were invited to participate if they had indicated interest in having CABG and met the inclusion criteria. The study was conducted with ninety volunteers who were randomly allocated into three groups of equal size (n = 30): control, placebo, and laser groups.

Patients who underwent elective coronary artery bypass surgery with a longitudinal sternotomy incision and extracorporeal circulation and patients between ages 18 and 75 years and of both sexes who were hemodynamically stable and had a body mass index (BMI) of less than 29.9 kg/m² were included in the study. Exclusion criteria consisted of previous thoracic surgery, emergency or urgent coronary artery bypass surgery, respiratory or renal insufficiency after surgery, low cardiac output syndrome, clinical complications that demanded changes in analgesic protocols, and any other postsurgery complications. Patients who could not be monitored during the 1st month after the operation were also excluded from the study.

The randomization and blinding procedures consisted of simply drawing cards marked 1, 2, 3, or 4, where 1 meant the control group, 2 meant the placebo group, and 4 meant the laser group, whereas 3 meant that the individual should be part of another group irradiated with light-emitting diode (LED), as part of secondary studies carried on by research group. The drawing was performed during the patient’s hospital admission, which always occurred at least 24 h before the surgery. The researchers were separated into therapists and evaluators. The therapists were assistants responsible for conducting the therapy and registering the procedures, and the evaluators were responsible for assessing the patients and their outcomes. Each patient was identified by a code registered by one of the therapist researchers, who ensured that the evaluating researchers were blinded to the code until the final statistical analysis was performed. The patients were blinded to the study by the use of opaque goggles during the laser irradiation.

A preoperative assessment consisted of an explanation of the procedures; inclusion and exclusion criteria certification; a clinical assessment, including laboratory tests; and group drawing. The laser group was subjected to irradiation immediately after surgery and on subsequent days 2, 4, 6, and 8. The irradiation was performed at spots alongside the incision 2 cm apart, perpendicularly and in contact with the skin, for a total of eight points. A translucent film protected the probe. The equipment’s characteristics and irradiation parameters are described in Table 1. The placebo group was subjected to the laser application process but with the equipment turned off. The control group was only subjected to the assessment protocols and the follow-up. The outcome assessed was pain during the hospitalization period and after the 1st month postsurgery.

The evaluating researchers participated in a training program for intra- and inter-examiner agreement to calibrate their level of concordance. Pain was assessed using an 11-point visual analog scale (VAS) and the McGill Pain Questionnaire from day 2 to the 1st month postsurgery. Patients were stimulated to cough, and their level of pain was recorded at that moment. Coughing is important for these patients because they must be stimulated to keep their airways free from obstructions, which helps prevent respiratory complications in the postoperative period. The employed analgesic protocol was the one routinely set by the hospital, which consisted of tramadol hydrochloride and dipyrone administered intravenously on a fixed 6-h schedule. Morphine sulfate was administered on an as-needed basis. Those patients who needed morphine were excluded from the study. The patients were followed for 1 month after surgery, and their pain was also evaluated during this period.

The results were evaluated using the software STATISTICA 7.0 StatSoft® (Dell Statistica (Headquarters), Tulsa,

| Parameters | Values |
|------------|--------|
| Equipment  | Laser Hand MM Optics® |
| Energy density (J/cm²) | 6 |
| Energy (J) | 2.4 |
| Power (W) | 0.04 |
| Spot diameter (cm) | 0.5 |
| Spot size (cm²) | 0.4 |
| Time of irradiation (s) | 60 |
| Power density (W/cm²) | 0.1 |
| Treatment time per point (s) | 60 |
| Number of spots | 8 |
| SAEF | 0.24 |
| Wavelength (nm) | 660 |

SAEF = Power output × time treatment per point × point numbers/total treated area. SAEF: Spatial average energy fluency
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Results

Ninety patients were subjected to the study, and their anthropometric characteristics are described in Table 2. No significant differences in age, weight, height, or BMI were found among the groups. According to preoperative clinical registers, all participants were using antihypertensive drugs of different classes, such as thiazide diuretics, calcium channel blockers, angiotensin II receptor antagonists, and beta-blockers. Control and placebo groups have also been a part of the study carried on by the same research group, comparing the healing and analgesic effects of LED at $\lambda$ 640 ± 20 nm, previously published by de Oliveira et al.\textsuperscript{[10]}

Pain according to the visual analog scale

Figure 1 shows a significant decrease in the pain level for all groups from the 1\textsuperscript{st} to the 8\textsuperscript{th} day and a complete absence of pain perception after the 1\textsuperscript{st} month. Nevertheless, the laser group experienced less pain on days 6 and 8 postsurgery compared to the control and placebo groups, according to an intergroup Kruskal–Wallis test with multiple comparison by Dunn’s test ($P \leq 0.05$).

Pain according to the McGill Pain Questionnaire

Figure 2 shows pain perception based on the McGill Pain Score. It is possible to note a significant decrease in the pain level for all groups from the 1\textsuperscript{st} to the 8\textsuperscript{th} day, but the laser group experienced lower pain scores on days 6 and 8 postsurgery compared to the control and placebo groups ($P \leq 0.05$).

Discussion

Ninety individuals were included in the present study based on the inclusion and exclusion criteria. Table 2 shows the anthropological data of the participants. Variables such as weight, height, and BMI presented no significant differences among the groups. Regarding gender, males had 2 times greater prevalence, which corresponds to epidemiological statistics for CVD.\textsuperscript{[11]}

Cardiac surgery with sternotomy causes acute pain immediately after surgery. A number of studies have suggested

| Table 2: Anthropometric characteristics of participants (mean±standard deviation) |
|-------------------------------------------------|----------------|----------------|----------------|----------------|
|                                                | Control        | Placebo        | Laser          |               |
|                                                | n (%), Mean±SD | n (%), Mean±SD | n (%), Mean±SD |               |
| Gender                                         |                |                |                |               |
| Female                                         | 11 (36.7), 60.2±10 | 10 (33.3), 59.0±8.8 | 11 (36.7), 60±8 |               |
| Male                                           | 19 (63.3), 64.6±10 | 20 (66.7), 63.3±8.9 | 19 (63.3), 65.3±10.00 |               |
| Age                                            |                |                |                |               |
| Weight                                         | 1.6±0.1        | 1.6±0.1        | 1.6±0.1        |               |
| Height                                         | 25.42±2.5      | 25.2±3         | 25.5±3.94      |               |
| BMI: Body mass index                           |                |                |                |               |

Figure 1: Pain according to visual analog scale (mean ± standard error)

Figure 2: Pain according to McGill score

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that cardiac surgery patients have significant pain after surgery in both the Intensive Care Unit and after their transfer to the floor. This pain is believed to be caused by peripheral mechanoreceptors that are stimulated during surgical procedures with sternal retraction. Most of the pain after a sternotomy is caused by damage to the skin and subcutaneous tissues, bone, and sternal cartilage. The principal thoracic nerves providing sternum sensitivity are T2–T6. Intercostal nerves arising from the thoracic nerve roots innervate the sternum, ribs, and surrounding subcutaneous tissue. The pericardium is innervated with pain fibers that ascend from the phrenic nerve, vagus nerve, and sympathetic trunks.

After CABG, patients experience considerable pain during the critical postoperative period. Cardiac postsurgery pain can cause complications such as atelectasis, pneumonia, and deep vein thrombosis because pain can limit a patient’s ability to cough and mobilize efficiently. Moreover, persistent postoperative pain can have a negative psychological effect and delay postoperative recovery. In this study, pain was assessed by the VAS and the McGill questionnaire for the first time on the 2nd day after surgery. At this time, patients were conscious, extubated, breathing spontaneously, and, consequently, able to cooperate. The patients were stimulated to cough, and their pain level was recorded. The assessment was repeated every 2 days until the 1st day after hospital discharge, on the 8th day postsurgery, and again at the 1-month postsurgery follow-up. Yorde et al. studied 104 patients’ perceptions of pain after cardiac surgery and reported that 46.1% of patients experienced pain with coughing, 26.5% with physical therapy, 32.4% with self-moving, and 27.4% with movement assisted by nurses. Lahtinen et al. also testified that cough was the main trigger for sternotomy pain after CABG. In their study with 113 patients, 78% mentioned pain when coughing as severe.

The VAS has been proven to be one of the most reliable scales for the evaluation of pain intensity. Although the VAS is a subjective method of pain assessment, it is one of the best available options for pain studies. In Figure 1, we can see that all groups experienced a pain decrease from the 2nd day to the end of the 1st month postsurgery, when patients recorded a pain level of zero. On the 2nd to 4th days, all groups had similar pain perception. Nevertheless, on the 6th day to 1st day after hospital discharge (the 8th day postsurgery), we noticed that the pain reduction was statistically greater in the laser group than in the placebo or control groups (P ≤ 0.05) when coughing.

Figure 2 shows a graph with pain perception according to the McGill Pain Questionnaire. This questionnaire was developed by Melzack to assess the sensory, affective, and evaluative dimensions of pain and has been translated into Brazilian Portuguese and used to complement the VAS. This instrument has also been used to evaluate pain after cardiac surgery. According to the sensory dimension, the laser group experienced a lower pain level on days 6 and 8 postsurgery as compared to the control and placebo groups. When assessed by the affective dimension, the analgesic effect was observed on the 6th day. Evaluative and miscellaneous dimensions did not present any significant difference among the groups in pain perception. Sensory scores are comparable with those on the VAS assessment [Figure 1], revealing an analgesic effect on the 6th and 8th days. However, the other dimensions were not capable of detecting this effect, which could be explained by the fact that sensory words are easier for patients who just underwent surgery to express. Yorde et al. mentioned that sensory expressions had been used to describe surgical pain, including words such as sharp, stabbing, aching, and dull, and are expressed more easily by patients. Pimenta and Teixeira also mentioned that the sensory dimension had a higher impact on the McGill questionnaire on pain assessment. This idea was reinforced by Gauthier et al. when validating the McGill Pain Questionnaire to assess pain in younger and older people with cancer.

Similarly, postoperative cardiac surgical patients related strong emotional components of pain, which could explain why that dimension could be considered more effective for reevaluating postsurgical pain. This fact has important clinical implications. Patients are expected to ambulate and participate in a physiotherapy regimen beginning the day after surgery. When pain is not properly managed, patients may experience difficulties in reaching the planned goals of care. Khoeiry et al. reported that at baseline and 1 month postoperative, 98% of patients had some level of anxiety. Those findings were also reported by Lima et al. and Karlekar et al. and could support the higher influence of affective aspects on the McGill scores when applied to postoperative cardiac patients.

A number of studies revealed that LLLT could affect pain in multiple ways. de Jesus et al. showed that in rats with partially injured Achilles tendons, LLLT probably modulated the pro-inflammatory agents by reducing the interleukin-1β (IL-1β) and cyclooxygenase-2 (COX-2) messenger RNA (mRNA) expressions and, consequently, reducing the PGE2 levels, and also by reducing cell migration and the quantity of neutrophils, mast cells, and macrophages in the injured tissue. Furthermore, comparable results were found by Prianti et al. who studied the COX-2 mRNA expression in both subplantar and total brain tissues in a model of peripheral inflammation induced by the administration of carrageenan. Souza et al. reported that LLLT could reduce oxidative stress because it is associated with a mechanism involving the upregulation of histone deacetylase activity and the inhibition of lipopolysaccharide/H2O2-induced tumor necrosis factor and IL-8 secretion, which also results in pain control.

**Limitations**

As “adequate pain relief” was not defined, most of the patients remained with pain scores more than 5, up to day 6. This is a gross limitation, which we did not overcome.
In this study, we investigated the efficiency of a therapy protocol using LLLT (with 6 J/cm²) for analgesic purposes in patients who underwent CABG. With the present therapy parameters, it may be assumed from our data that LLLT was effective in controlling pain mainly after the 6th day postsurgery. Further study is needed to clarify the influence of different protocols and doses and their effects on mediators and cell types in inflammatory models and clinical trials.

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Conflicts of interest

There are no conflicts of interest.

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