Class IV versus class IIIb laser therapy on median sternotomy incision healing after coronary artery bypass graft: A Randomize Control Trail

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Abstract

The aim of this study was to investigate the effects of class IV high-level laser therapy (HLLT) versus class IIIb low level laser therapy (LLLT) on sternotomy healing following coronary artery bypass grafting (CABG) surgery. Forty- five patients male patients who had CABG surgery in the age range of 45–65 years were divided randomly into three equal groups ($n = 15$). The group HLLT laser received HLLT plus traditional wound management, while the group LLLT laser received LLLT plus traditional wound management. The control group only received a traditional wound management in form of saline irrigation, dressing, and topical bivatracin spray according to hospital protocol. All groups were offered 10 sessions over 4 weeks. Wound dehiscence and pain score were evaluated pre- and post-treatment, Statistical significance was set at $P < 0.05$. There was a significant decrease among the laser group (A and B) in PUSH score and pain test, while control groups showed a non-significant decrease. HLLT and LLLT were found to be the most effective methods for sternotomy healing post-CABG surgery, with HLLT offering superior performance in the case of the high deep penetration and significance less time needed to deliver the same joules/ cm compared to LLLT used for the wound site.

Key words: *Coronary arteries bypass grafting .high level laser therapy, Low-level laser therapy. Median sternotomy healing.*

INTRODUCTION

Coronary heart disease affects about half of all men and nearly a third of all women over 40 (1). Most patients undergoing CABG surgery as a first procedure require median sternotomy, with a few patients undergoing heart transplantations (2). Infective complications of surgical site in cardiac surgery, i.e Sternal wound healing complications vary from superficial skin infections to sternal instability; represent a severe complication with enormous impact on morbidity and mortality (SI) and mediastinitis (3). Poorly controlled post-operative pain is associated with sympathetic nervous system activation and an increased hormonal stress response (4). Better pain control was associated with lower rates of cardiovascular complications, pneumonia, and postoperative hypercoagulability (5). Slow healing of the sternum usually results in severe problems in terms of deep sternal wound infection (6). Moreover, psychological aspect of pain can also influence healing of chronic dehiscent wounds. Psychological symptoms [e.g., depression, anxiety, and ways of being (decreased functional ability, perceived locus of control, and self-efficacy)] affect the perception and experience of pain. Psychological factors related to pain in palliative care of chronic wounds can become an influential factor for healing by secondary or primary intention. (7) The top biological effects of laser are Pain Reduction, Anti-Inflammation, Accelerated Tissue Repair and Cell Growth, Improved Vascular Activity and Improved Nerve Function/ Healing as laser therapy by influencing mitochondrial metabolism and enhancing ATP production (8). Specifically, it helps stimulate vasodilation and improve temperature modulation while enhancing lymphocyte responses in the injured area (9)., increases fibroblast proliferation, keratinocyte proliferation, and early epithelialization (10), increasing the amount of free NO in the area which causes vasodilatation and enhances oxygenation but it also aides in the formation of new capillaries via Neovascularization (11), blocking the depolarization of A delta and C-Fiber afferent nerves which slows the afferent signal transmission from peripheral nociceptors (12). Prolonged relief from photo bio modulation can be explained by normalizing resting membrane potentials in nerve cells (13), Laser treatment has shown to increase the resting potential closer to the norm of ~70Mv via increased axonal sprouting and nerve cell regeneration (14). High level laser therapy HLLT is considered an effective safe modality for wound healing, laser therapy also can improve local blood circulation, blood vessel permeability, and cell metabolism (15). The 630–700 nm wavelengths are used to improve the blood supply, stimulate the metabolism of skin cells, and accelerate wound healing; and the 800–1,200 nm wavelength is used to accelerate wound healing and support the treatment of ulcerations (16).

Patients and methods

All of the patients signed a written declaration of informed consent relating to participation and the publication of results. The protocol for this study was approved by the local research ethics committee (NO: P.T.REC/012/003308) and was registered on ClinicalTrials.gov with ID: NCT05853237, the study was carried from March to November 2022. This study was carried out on CABG surgery patients at cardiothoracic surgery department Al Kasr Al Aini teching hospital. All patients admitted to Kasr Al Aini university hospital for CABG during the study period were invited to participate if they met the inclusion criteria. The study was conducted with 45 patients who were randomized into HLLT laser, LLLT laser and control groups; the three groups were of equal size (n = 15 in each group). Measurements were obtained before and after the intervention period, which was4 weeks. All of the patients were able to receive the same medical and physical rehabilitation programme during the hospitalization period.

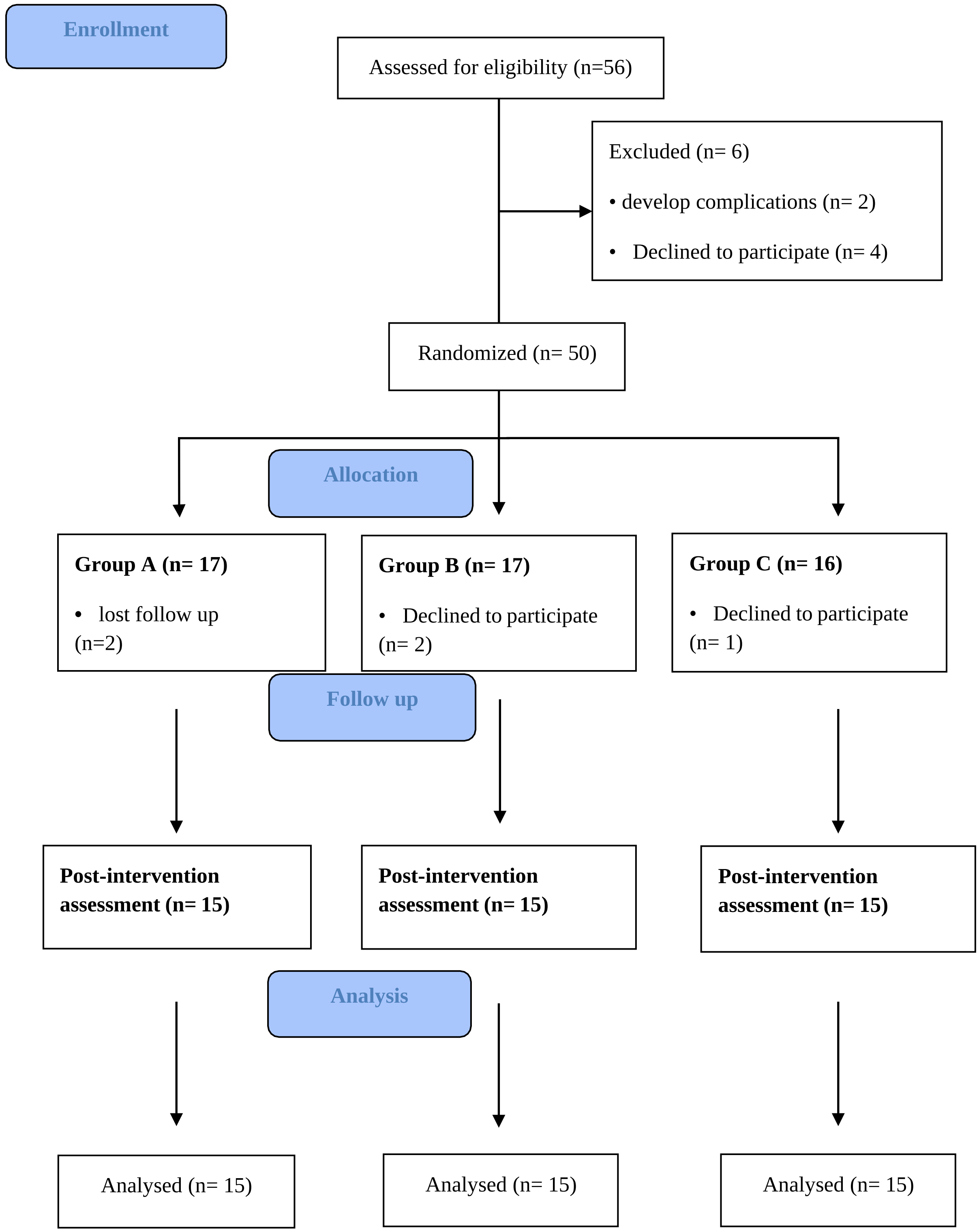
All patients in the study had undergone elective CABG surgery involving median sternotomy incision and extracorporeal circulation (through a heart-lung machine). The inclusion criteria were as follows: aged between 45 and 65 years; male gender; haemodynamic stability; body mass index

(BMI) from 18.5 to 29.9 kg/m2; Non-infected sternotomy site; Normal ejection fraction to ensure normal vascularity. The exclusion criteria included previous thoracic surgery; emergency or urgent coronary artery bypass surgery; respiratory insufficiency after surgery, manifesting hypoxemia with partial oxygen pressure in arterial blood < 60 mmHg; Ejection fraction < 50%; Paramedian sternotomy which may cut wire causing sternal mobilization which is the start of deep wound infection; Bilateral mammary harvesting which decrease blood flow to sternum (18); low cardiac output syndrome with ST segment elevation in multiple electrocardiogram leads, cardiac arrhythmias or hypotension, according to the American College of Cardiology Foundation and American Heart Association (19); other medical conditions, such as diabetes, uncontrolled hypertension and obesity.

Power analysis

Sample size was determined a priori using G*Power (version 3. 1. 9. 2). the calculation was based on the F-test and the type-I error rate was set at 5% (alpha level: 0.05). Meanwhile, the effect size of 0.427976 of the main outcome variable (sternal separation, non-infected wound) was obtained from a pilot study performed on three patients from each group, while the type-II error rate was set at 80% power. Considering a 15% dropout rate, the appropriate minimum sample size for this study was 45 patients.

Figure 1. CONSORT chart



Assessment of eligibility

Fifty-two male patients were recruited to participate in the study. During assessment for eligibility, eleven patients were excluded because they refused to participate in the study and the other three had post-operative sternotomy healing complications as shown in CONSORT chart (Fig. 1). Allocation was concealed using sealed opaque envelopes.

Outcome measures

Wound Dehiscence

The PUSH Tool monitors three parameters: surface area of the wound, wound exudate and type of wound tissue.

• Length x Width: Using a centimeter ruler, measure the greatest length (head to toe) and greatest width (side to side). Multiply these two measurements (length x width) to get a surface area estimate in square centimeters. (cm2).

• Exudate Amount: Assess the amount of drainage present after removing the dressing. Exudate should be estimated as none, light, moderate, or heavy.

• Tissue type: refers to the various types of tissue found in the wound (ulcer):

Grade	Description
4	Necrotic tissue (Eschar): Black, brown or tan tissue that adheres firmly to the wound bed or ulcer edges and may be either firmer or softer than surrounding skin
3	Slough: Yellow or white tissue that adheres to the ulcer bed in strings or thick clumps, or is mucinous
2	Granulation tissue: Pink or beefy red tissue with a shiny, moist, granular appearance
1	Epithelial tissue: For superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface
0	Closed/Resurfaced: Wound completely covered with epithelium (new skin)
The total score ranges from 0 to 17 (0 = healed). A comparison of total scores measured over time provides an indication of the improvement or deterioration in wound healing. **(20)**	

Pain assessment

Pain was measured during task performance using a 100-mm visual analogue scale (VAS) ranging from 0 (no pain at all) to 10 (maximal pain). The tasks performed by the patients included: rotating the trunk, swinging the arms when walking, sitting to standing, supine to sitting, suddenly losing footing, coughing, and reaching above shoulder height (21). A higher score on the VAS meant higher pain intensity.

Intervention

Group (A): High level laser therapy (HLLT)

Summus, platinum P4, class IV high power therapy Diode laser 4 wavelengths (980, 915, 810, and 650), continuous wave peak power up to 24 watts & frequency up to 20 KHZ. start from day one surgery for 4 successive weeks, the goal in the phase I (1st 10 days after surgery) is decontamination, improve circulation, pain reduction &wound healing acceleration The goal of phase II (next10 days till complete healing) is improve osteo-integration, pain reduction & enhance superficial collagen production to decrease scarring. The parameters are: Power > 500 mW; fluence 20 joule/ cm2 with (980, 915, 810 nm) and 5 joules/ cm2 by 650 nm; mode (continuous); hand piece radius = 2.5 cm; spot size (Area) = 5 cm; application by scanning not spotting to avoid thermal effect and time of session is 5- 10 minutes

Group (B): Low level laser therapy (LLLT)

Use the same protocol as in HLLT with the same wave lengths but with low power Power = 200- 300 mW; fluence 20 joule/ cm2 with

(980, 915, 810 nm) and 5 joules/ cm2 by 650 nm; mode (continuous); hand piece radius = 2.5 cm; spot size (Area) = 5 cm; application by spotting and time of session was 25- 30 minutes.

Group (C): Traditional wound care

According to the hospital protocol Irrigation of the wound by normal saline, betadine application, bivatracin spray and Change dressing daily to protect the wound from infection

Statistical analysis

Data analysis

ANOVA test was conducted for comparison of subject characteristics between groups. Chi-squared test was conducted for comparison of sex distribution between groups. As the data was not normally distributed, Kruskal-Wallis test was conducted for comparison of the median values of PUSH score and VAS between groups and was followed by Mann–Whitney test to identify the significance difference between each two groups. Wilcoxon Signed Ranks Test was conducted for comparison of pre and post treatment in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

Results

- Subject characteristics:

Table (1) shows the subject characteristics of group A, B and C. There was no significant difference between groups in age, BMI and sex distribution ($p > 0.05$).

Table 1. Basic characteristics of participants.

	Group A	Group B	Group C	F-value	p-value
	mean ± SD	mean ± SD	mean ± SD		
Age (years)	49.66 ± 7.54	48.06 ± 6.61	48.46 ± 7.18	0.21	0.81
BMI (kg/m²)	24.07 ± 3.17	24.26 ± 4.07	23.93 ± 3.17	0.03	0.96

SD, standard deviation; χ2, Chi-squared value; p-value, level of significance

Figure 1. Mean age of group A, B and C.

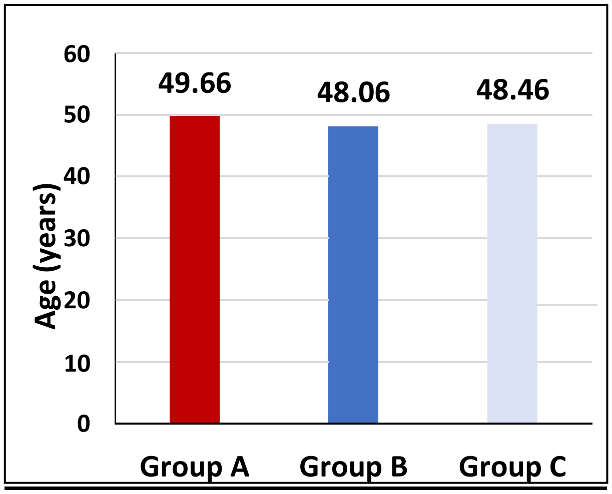
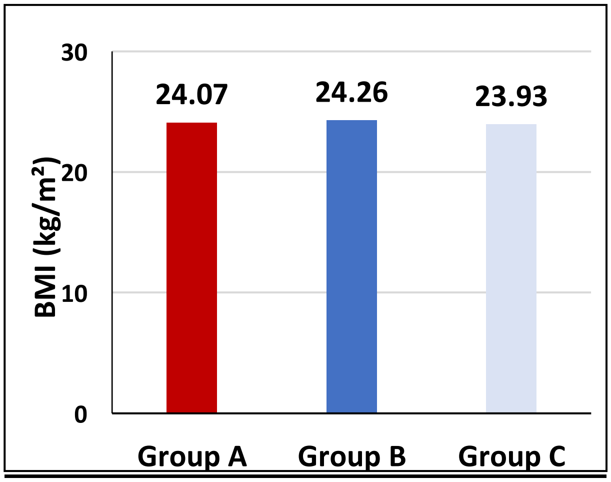


Figure 2. Mean BMI of group A, B and C.



Effect of treatment on PUSH score and VAS:

Within group comparison

There was a significant decrease in PUSH score and VAS of group A ($p <$ and group B post treatment compared with that pretreatment ($p < 0.001$). There was no significant change in PUSH score and VAS of group C ($p > 0.05$). (Table 2).

Between group comparison

There was a significant decrease in PUSH score and VAS of group A compared with that of group B and group C post treatment ($p < 0.001$). There was a significant decrease in PUSH score and VAS of group B compared with group C post treatment ($p < 0.001$). (Table 2).

Table 2. Median values of PUSH score and VAS pre and post treatment of group A, B and C:

	Group A	Group B	Group C	p-value		
	Median (IQR)	Median (IQR)	Median (IQR)	A vs B	A vs C	B vs C
PUSH score						
Pre treatment	14 (16, 10)	13 (14, 10)	13 (15, 11)	0.33	0.81	0.25
Post treatment	0 (1, 0)	3 (3, 2)	12 (15, 11)	0.001	0.001	0.001
Z- value	-3.41	-3.41	-1.60			
p-value	***p = 0.001***	***p = 0.001***	***p = 0.11***			
VAS				0.48	0.58	0.91
Pre treatment	10 (10, 9)	10 (10, 9)	10 (10, 9)	0.001	0.001	0.001
Post treatment	0 (0, 0)	2 (4, 1)	10 (10, 8)			
Z- value	-3.47	-3.41	-1.63			
p-value	***p = 0.001***	***p = 0.001***	***p = 0.10***			

IQR, Interquartile range; Z- value: Wilcoxon signed ranks test value; p-value, Level of significance.

Figure 3. Median values of PUSH score pre and post treatment of group A, B and C.

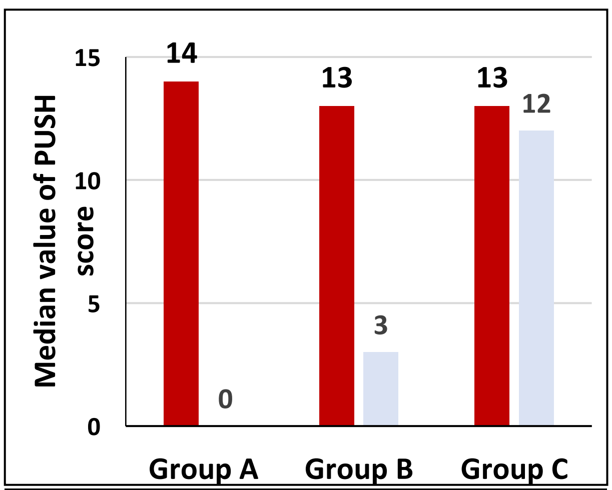
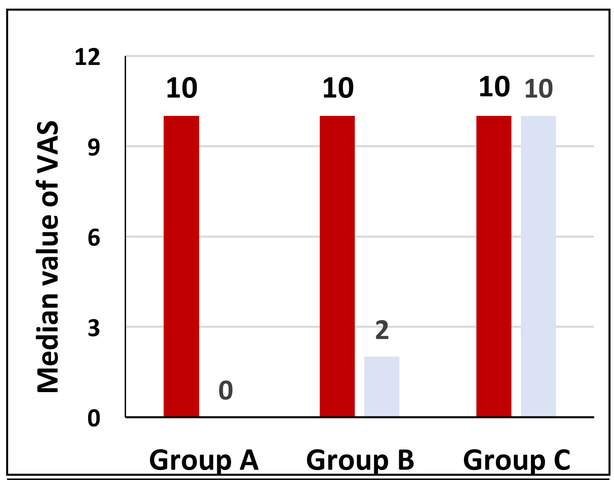


Figure 4. Median values of VAS pre and post treatment of group A, B and C.



Discussion

This randomized controlled trial is the first trial to investigate the effect of class IV high-level laser therapy (HLLT) versus class IIIb low level laser therapy (LLLT) on sternotomy healing following coronary artery bypass grafting (CABG) surgery. The results of the present study showed improvements in all LASER groups (A and B). There was a significant decrease among the laser group (A and B) in PUSH score and pain test, while control groups showed a non-significant decrease. HLLT and LLLT were found to be the most effective methods for sternotomy healing post-CABG surgery, with HLLT offering superior performance in the case of the high deep penetration and significance less time needed to deliver the same joules/ cm compared to LLLT used for the wound site.

Sternal dehiscence after the operation is a recognized complication occurring in 1% to 25% of cases. (22) The likelihood of postoperative sternal wound problems in CABG is increased by the interaction of primary and secondary risk factors. In this study, we identified several key risk variables for dehiscence, including prolonged cardiopulmonary bypass operation duration and higher blood loss throughout the procedure. Also, some people smoke and take poor care of their wound hygiene. The issue had become more problematic due to secondary risk factors such an elevated prothrombin time (25 s), which may have enhanced the risk of morbidity throughout the healing phase and led to dehiscence.

Laser therapy involves triggering particular cytokines and growth factors that control the various stages of wound healing in order to address delayed wound healing. This quickens the process of wound resurfacing (re-epithelialization) and fills the space around the wound with granulation tissue. (23) By increasing the activity of the mitochondrial respiratory chain, which results in an increase in the generation of cytochrome oxidase and ATP, LASER has a significant impact on altering cellular functioning. (24)

Moreover, they efficiently promote local angiogenesis, which speeds up bone growth and modifies collagen fiber configurations. The mechanics of the cell microenvironment are altered by LASER therapy and tissue contact, resulting in increased activity. (25)

Khoo et al. (2014), who concluded that LLLT after CABG surgery could decrease cardiac cell damage and accelerate cardiac tissue repair, recommended laser therapy as a promising intervention for improving prognosis after CABG surgery. (26)

Application of laser therapy at the fracture site accelerates the bone repair process, especially the early stages of bone remodelling, by increasing callus volume and BMD. LLLT also increases new bone formation in osteopaenic rats and augments bone strength, calcium content and BMD. (27)

The results of this study are in line with those reported by Baptista and colleagues (2009), who examined the effect of LASER therapy on the prevention of sternotomy dehiscence in 40 patients. Their results indicated that patients in the LLLTirradiated group had a 500% better sternotomy healing status than in the placebo group. This outcome calls for the application of LLLT immediately following surgery during the initial inflammatory phase so as to be an effective prophylactic therapy. (28)

A systematic review by Peplow, et al., the authors posit LLLT irradiation to regulate the formation of nitric oxide synthase leading to increased production of nitric oxide – which is known for its anti-inflammatory, antithrombotic effects in wound healing. We found that LLLT application also produced analgesia for the bilateral shoulders, as is also claimed by Peplow et al., in a review. A possible mechanism for it could be increased blood flow after irradiation leading to resolution of inflammatory response in the shoulder joints. (29)

In a single-case study, Dixit S, Maiya A, (2013) discover that the Laser therapy induces biomodulation of dehiscence sternal wound following median sternotomy in CABG. Laser therapy may be heralded as a potential new method for noninvasive, effective, and safe wound care in postoperative dehiscent wound. Analgesic effect of laser therapy may be incorporated for early rehabilitation for painful shoulders following mechanical failure of sternum postoperatively in CABG. This can contribute to early functional rehabilitation of an individual thereby promoting improved quality of life in individuals postoperatively. (30)

The results of our study are also consistent with those of Fernandes et al. (2016), who reported the efficacy of LLLT (λ = 660 nm) with regard to sternotomy healing in patients

who had undergone CABG surgery. The measured outcomes were hyperaemia and wound closure scores. The patients who received LLLT showed a significant improvement in hyperaemia and wound closure scores, while their sternotomy incisions demonstrated less hyperaemia, incisional bleeding and dehiscence. (31)

Conclusion

LASER therapy is potent physiotherapy modalities, providing better sternotomy healing for patients who have undergone CABG surgery, compared with traditional wound care management alone. HLLT and LLLT were found to be the most effective methods for sternotomy healing post-CABG surgery, with HLLT offering superior performance in the case of the high deep penetration and significance less time needed to deliver the same joules/ cm compared to LLLT used for the wound site.

Compliance with ethical standards

Conflicts of interest: the authors declare that they have no conflicts of interest.

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