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Effect of Bioptron Light Therapy on post-menopausal low back pain: A randomized controlled study

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ABSTRACT

Women's bodies undergo numerous changes throughout the post-menopausal period, many of which result in uncomfortable symptoms, including skeletal problems such as low back pain (LBP). The aim of this study was to evaluate the impact of Bioptron Light Therapy (BLT) on post-menopausal LBP in women. This study employed a pretest-posttest randomized experimental trial design. Forty post-menopausal women with LBP, aged 50 to 60 years, were randomized into two groups (study and control group). The control group (Group A, n=20) received abdominal and back isometric exercises only, whereas the study group (Group B, n=20) received BLT in addition to the same isometric exercises, three sessions per week for six weeks. Pain severity using the Visual Analogue Scale (VAS), Pain Pressure Threshold (PPT) using a pressure algometer, and functional disability using the Modified Oswestry Disability Questionnaire (MODQ) were measured for all patients in both groups before and after the treatment program. The Statistical Package of Social Sciences (SPSS) (version 19) was used for data analysis. Based on the results of our study, PPT significantly increased in both groups after treatment ($p = 0.0001$), with the study group showing a greater increase than the control group ($p = 0.001$). Pain intensity decreased significantly in both groups ($p = 0.0001$), with a statistically significant difference favoring the study group ($p = 0.0001$).

MODQ scores also significantly decreased in both groups (p = 0.0001), again favoring the study group (p = 0.0001). BLT can be included as a valuable, effective, and non-invasive method for decreasing pain and improving function for women with post-menopausal LBP.

KEYWORDS

Bioptron Light Therapy; Postmenopause; Low Back Pain; Abdominal Exercises; Back Isometric Exercises

1. INTRODUCTION

Women's bodies undergo numerous changes throughout the post-menopausal period, the majority of which result in uncomfortable symptoms include skeletal problems including back pain, osteoporosis, in addition to joint and muscle pain (Pinheiro et al., 2015).

Among the most common health complaints across post-menopausal women is low back pain (LBP). According to the literature, concerning women suffering menopausal symptoms, symptoms of musculoskeletal problems, LBP, are more common than those of hot flushes (Dugan et al., 2016).

After menopause, LBP can make it difficult for women to perform daily tasks physically because they are afraid of being hurt (Ahn & Song, 2019). Treatment for LBP includes appropriate posture, mild mobilization, stabilization exercises, a core exercise program, chiropractic and osteopathic manipulations, various electrotherapy modalities, and the use of a pelvic support belt (Silva, 2014).

Bioptron light therapy (BLT) has been utilized as a non-invasive treatment for wound healing, skin ulcers, and various musculoskeletal conditions. It involves the use of a low-level laser as a coherent light source (Nobuta et al., 2018). Valentina et al. (2020) demonstrated BLT's efficacy as either a monotherapy or an adjunct treatment for pain management in several indications, including orthopedic physical therapy (OA, RA, chronic arthritis), rheumatology (osteoarthritis, rheumatoid arthritis), and conditions such as LBP, shoulder and neck pain syndrome, and issues related to scar and muscle tissues.

The direct impact of BLT on nerve terminals and the entire neurological system, stimulating neurotransmitters and increasing secretion of endorphins, was thought to be responsible for its analgesic properties (Colic, 2012). In addition to its analgesic effects, the peripheral vasodilation caused by this treatment enhances the delivery of oxygen as well as nutrients to injured soft tissues, accelerates their recovery, and decreases pain (Medenica & Lens, 2003).

Based on our current knowledge, the literature has not identified any studies that investigate the effects of BLT on post-menopausal LBP. Therefore, the aim of this randomized controlled trial is to assess the influence of BLT on post-menopausal LBP.

2. METHODS

2.1. Study design and participants

This study employed a pretest-posttest randomized experimental trial design, conducted from May 2021 to May 2022. Prior to enrollment, each patient received a detailed explanation of the study methodology. Participation was contingent upon signing an informed consent form approved by the Ethics Committee of the Faculty of Physical Therapy at Cairo University (P.T.REC/012/003219).

Forty post-menopausal women diagnosed by Orthopedic Surgeons as post-menopausal women with LBP participated in this study. They were recruited from the Outpatient Clinic of Al Zahraa University Hospital in Cairo, Al Azhar University, and their ages ranged from 50 to 60 years. All women had experienced menopause at least three years prior to the study. Their BMI ranged from 25 to 35 kg/m². Exclusion criteria included: pelvic surgery, breast cancer or infection, internal fixation in the back or pelvis, malignancy, X-ray therapy, lumbar disc prolapse, and lumbar spondylolisthesis. The women were randomized into two groups: the control group A (n=20) and the study group B (n=20) using the coin toss method.

2.2. Tools and equipment

2.2.1. Tools and equipment for evaluation

- **Weight and Height Scale:** was utilized to evaluate the weight and height of all patients before starting the assessment to determine BMI.
- **Visual Analogue Scale (VAS)**: Utilized to assess pain intensity. It consists of a 100 mm horizontal line with "no pain" at one end and "pain as severe as it could be" at the other (Unal et al., 2017).
- **Pressure Algometer**: Used to measure pain pressure threshold (PPT) between 0 and 1,300 kilopascals (kPa). The device has a 1 cm² round rubber tip with a linear response to force application.
- **Modified Oswestry Disability Questionnaire (MODQ):** Used for evaluating patients functional disability. It consists of 10 items, each scored from 0 to 5. It is a widely used condition-specific outcome measure designed to quantify disability in patients with lumbar pathologies.

2.2.2. Tools and equipment for treatment

- **Bioptron Light Therapy (BLT):** Group B patients were treated with a light device that had the following specifications: a wavelength of 480-3400 nm, a level of polarisation of >95%, a diameter of 5 cm, with a halogen power of 20 W, a power density of 40 mW/cm2, a light intensity of 10,000 lux, a light energy of 2.4 J/cm2, a total light energy of 24 J/cm2, and the duration of session about 15 minutes.

2.3. Procedures

2.3.1. Evaluation procedures

- **Measurement of Body Mass Index (BMI):** Weight and height were measured for each woman in both groups before treatment. BMI was calculated using the formula: BMI = Weight (Kg) / Height (m^2).
- **Measurement of Pain Intensity:** A Visual Analogue Scale (VAS) was used to assess pain intensity. Each woman indicated on a scale ranging from "no pain" to "pain as severe as it could be" the point that best represented her pain level.
- **Measurement of Pain Threshold:** The examiner, trained at a pressure rate of approximately 50 kPa/s prior to the study, assessed pain threshold. The capacity to reach 250 kPa in 5 s continuously was considered clinically relevant for assessing patients (Knapstad et al., 2018). The patient was asked to lie prone with her arms at her sides, and her clothes were lifted to uncover her skin in the lumbosacral and paraspinal musculature (PSIS) areas on both sides. In order to measure PPT, the examiner placed the circular probe of the algometer at a right angle to the skin and pressed on it; the subject was instructed to say "stop" whenever the pressure or discomfort became a definite pain feeling. The PPT was measured four times at each site, with each measurement separated by 30 seconds of rest. Every patient's PPT data was averaged over all trigger locations, with the first PPT measurement for each site being thrown out and the mean of the next three PPT measurements being used.
- **Measurements of Functional Disabilities:** Functional disability was measured using MODQ; each patient was asked to answer all items of the questionnaire, then the sum of the scores was multiplied by 2 to calculate the total score, producing a score between 0 and 100; a higher score indicates a greater degree of disability (Smeets et al., 2011).

2.3.2. Treatment procedures

Isometric exercises for the abdominals and back were given to patients in the study and control groups (McGill et al., 1999). Specifically, the patient was told to assume the crock laying position. Then, for the next 15 seconds, she had to hold her pain threshold contractions of the abdominals and trunk flexions within her pain tolerance. The therapist next had the patient perform the same movement with the extension trunk by clenching her lower back muscles and pressing her lumbar spine down. Five sets are completed in total, with a minute of rest among each set.

The study group also received BLT 3 sessions weekly for a total of six weeks. The patient was positioned in a position that would maximise his or her comfort (prone position). Prior to the radiation therapy session, the lower back area was cleansed with local antibacterial, betadine, and alcohol wipes to eliminate any debris that would interfere with the laser's path. To maximize penetration, the BLT device was used at a perpendicular angle to the treatment area and a distance of 10 cm from the surface of skin. The machine was then activated for 15 minutes.

2.4. Data analysis

Descriptive analyses were conducted for all variables, presenting means and standard deviations. A t-test was employed to compare subject characteristics between the two groups. The Shapiro-Wilk test assessed normality of data distribution. Within-group comparisons before and after treatment used paired t-tests, while between-group comparisons utilized unpaired t-tests for each parameter. Statistical significance was set at $p < 0.05$ for all analyses. IBM SPSS version 19 for Windows was used for statistical computations (IBM SPSS, Chicago, IL, USA).

3. RESULTS

3.1. Participant characteristics

There was no statistically significant difference in age, weight, height, as well as BMI among the two groups, as indicated in Table 1 ($p > 0.05$).

Table 1. Comparison of the mean age, weight, height, and BMI between both groups (A and B)

	Group A	**Group B**	**MD**	**t- value**	**p-value**
	$\overline{X}$ **±SD**	$\overline{X}$ **±SD**			
Age (years)	55.2 ± 3.03	55 ± 2.91	0.2	0.21	0.83
Weight (kg)	80.25 ± 8.41	78.15 ± 7.45	2.1	0.83	0.41
Height (cm)	160.35 ± 3.08	159.55 ± 3.56	0.8	0.76	0.45

BMI (kg/m²)	31.05 ± 2.37	30.5 ± 2.54	0.55	0.71	0.48

Note: x̄=mean; SD= Standard Deviation; MD=Mean Difference; t value=Unpaired t value; p value= Probability value

3.2. Pain intensity within and between groups

Table 2 demonstrates that there was no statistically significant difference in baseline pain intensity between the two groups (p = 0.19). Pain intensity significantly decreased in both groups after treatment compared to baseline (p = 0.0001), with a notable difference favoring group B (study group) (p = 0.0001).

Table 2. Mean VAS scores pre- and post-treatment in both groups

VAS	**Group A**	**Group B**	**MD**	**t- value**	**p-value**	**Sig**
	$\bar{X}$ **±SD**	$\bar{X}$ **±SD**				
Pre-treatment	8.9 ± 0.96	8.5 ± 0.94	0.4	1.32	0.19	**NS**
Post-treatment	6.1 ± 1.07	3.25 ± 1.01	2.85	8.61	0.0001	**S**
MD	2.8	5.25				
% of change	31.46	61.76				
t- value	12.45	21				
p-value	0.0001	0.0001				
Sig	**S**	**S**				

Note: x̄=mean; SD= Standard Deviation; MD=Mean Difference; t value=Unpaired t value; p value= Probability value; S=Significant; NS= Non significant

3.3. Pain threshold of lower back within and between groups

As shown in Table 3, there is no significant difference in lower back PPT between both groups before treatment (p = 0.93). PPT significantly increased in both groups after treatment compared to before treatment (p = 0.0001), with Group (B) significantly higher than Group (A) after treatment (p = 0.001).

Table 3. Mean PPT of lower back pre- and post-treatment of both group

PPT (kg)	**Group A**	**Group B**	**MD**	**t- value**	**p-value**	**Sig**
	$\bar{X}$ **±SD**	$\bar{X}$ **±SD**				
Pre treatment	0.98 ± 0.32	0.97 ± 0.41	0.01	0.08	0.93	**NS**
Post treatment	1.69 ± 0.43	2.23 ± 0.49	-0.54	-3.66	0.001	**S**
MD	-0.71	-1.26				
% of change	72.45	129.9				
t- value	-11.42	-20.03				
p-value	0.0001	0.0001				
Sig	**S**	**S**				

Note: x̄=mean; SD= Standard Deviation; MD=Mean Difference; t value=Unpaired t value; p value= Probability value; S=Significant; NS= Non significant

3.4. MODQ results within and between groups

Table 4 shows that before treatment, there was no statistically significant difference in MODQ scores between the two groups (p = 0.74). After treatment, MODQ scores significantly decreased in both groups compared to before treatment (p = 0.0001), with a significant difference favoring group B (p = 0.0001).

Table 4. Mean MODQ scores pre and post-treatment in both groups

MODQ	Group A	Group B	MD	t- value	p-value	Sig
	$\bar{X}$ ±SD	$\bar{X}$ ±SD				
Pre-treatment	56.45 ± 6.25	57.1 ± 6.13	-0.65	-0.33	0.74	**NS**
Post-treatment	43.3 ± 5.23	28.3 ± 5.02	15	9.24	0.0001	**S**
MD	13.15	28.8				
% of change	23.29	50.44				
t- value	11.84	27.68				
p-value	0.0001	0.0001				
Sig	**S**	**S**				

Note: $\bar{x}$=mean; SD= Standard Deviation; MD=Mean Difference; t value=Unpaired t value; p value= Probability value; S=Significant; NS= Non significant

4. DISCUSSION

Based on our results, PPT significantly increased in both groups after treatment compared to before treatment (p = 0.0001), with Group B (study group) showing a significantly higher increase than Group A (control group) after treatment (p = 0.001). Pain intensity significantly decreased in both groups after treatment compared to baseline (p = 0.0001), with a significant difference favoring the study group (p = 0.0001). After treatment, MODQ scores significantly decreased in both groups compared to before treatment (p = 0.0001), with a significant difference favoring the study group (p = 0.0001). Increases in PPT, decreases in pain intensity, and lower MODQ scores indicate that patients in the BLT group experienced greater improvements in pain and functional disability compared to those in the control group, who only performed abdomen and back isometric exercises.

According Monstrey et al. (2012), the analgesic effects of BLT can be attributed to the stimulation of neurotransmitters and an increase in the release of endorphins, which act directly on nerve terminals. When a small part of the body is subjected to light, it has a powerful anti-inflammatory action. When this is done, the concentration of anti-inflammatory factors rises and the plasma levels of pro-inflammatory cytokines rapidly return to normal. These alterations are the end result of light-induced modifications to a

small volume of blood that are rapidly distributed throughout the entire blood supply via transcutaneous photo modification (Zhevago & Samoilova, 2016).

Limansky et al. (2010), observed that exposing a mouse to polarized light at its analgesic acupuncture points for just 10 minutes significantly raised the animal's pain threshold. The findings of this study are consistent with those of Stasinopoulos (2015), who examined the utilization of BLT for the treatment of tennis elbow and discovered that it significantly reduced pain and improved function for those who suffered from it.

The infrared radiation contained in the polarised light released by the Bioptron device warms the skin. Thermoreceptors perceive this exogenous light as irritating, activating the reflex, and the resulting local reactions enhance the microcirculation and nourishment of exposed tissues and also have anti-inflammatory effects. Intensifying tactile sensitivity and decreasing pain sensitivity, light alters the skin's sensations (Valentina et al., 2020).

Stasinopoulos et al. (2017) confirmed our findings, reporting that patients suffering from acute ankle sprains who had cryotherapy along with BLT therapy for five days experienced statistically significant reductions in pain intensity, edema, as well as ankle range of motion. Moreover, the results of the present study corroborated those of Mihaylova et al. (2017), who stated that physiotherapy with polarized polychromatic non-coherent low-energy light can alleviate pain, increase mobility in the lower back, and enhance the quality of life of patients with LBP.

Polarized light in the red as well as near-infrared rays may provide a feeling of warmth in the treated region. A direct mechanism on the free nerve endings or nerve trunk which supplies the affected area triggers the production of histamine and prostaglandins, which in turn increase vasodilation, adjust enzyme activity as well as metabolic rate, and increase pain threshold (Shiryan et al., 2022).

5. CONCLUSIONS

The significant increases in PPT, decreases in pain intensity, and lower MODQ scores collectively suggest that patients in the BLT group experienced greater overall improvements in managing pain and reducing functional disability compared to those in the control group. This highlights the potential of BLT as a beneficial therapeutic intervention for post-menopausal women suffering from LBP. Furthermore, BLT is a safe and effective treatment method for improving pain and functional ability in post-menopausal women with LBP.

6. RECOMMENDATIONS

- **Implementation of BLT in Clinical Practice:** Healthcare providers should consider incorporating BLT as a standard treatment option for post-menopausal women with low back pain, given its demonstrated efficacy in increasing pain thresholds and improving functional abilities.
- **Combination Therapy:** For optimal results, combining BLT with other therapeutic exercises, such as isometric abdomen and back exercises, may provide comprehensive benefits in pain management and functional improvement.
- **Patient Education:** Educate patients about the benefits of BLT and how it works, ensuring they understand the potential for improved pain management and functional outcomes. This can enhance patient compliance and satisfaction with the treatment.
- **Training for Practitioners:** Ensure that healthcare professionals are adequately trained in the application of BLT to maximize its effectiveness and safety. Regular training sessions and workshops can help maintain high standards of care.
- **Long-Term Monitoring:** Implement long-term monitoring and follow-up for patients undergoing BLT to assess the durability of the treatment benefits and to make any necessary adjustments to the therapy plan.
- **Further Research:** Encourage further research to explore the long-term effects of BLT on post-menopausal LBP and to identify any additional benefits or potential side effects. Comparative studies with other treatment modalities could provide deeper insights into the relative efficacy of BLT.

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All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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