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High Intensity Laser Versus Low Intensity Laser Therapy in Management of Postmenopausal Osteoporosis.

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ABSTRACT

Background:
It is estimated that 30%-50% of women will suffer an osteoporotic fracture in their lifetime. Laser therapy has a positive effect on bone regeneration and healing that is dependent on the characteristics of the light itself (eg, intensity and wavelength).

Objective:
The aim of the present study was to compare the possible effect of High Intensity Laser Therapy (HILT) versus Low Level Laser Therapy (LLLT) on bone mineral density (BMD) of lumbar vertebrae in postmenopausal women with osteoporosis.

Methods:
Thirty postmenopausal osteoporotic women participated in the study and were randomly divided in two groups. Group I consisted of 15 women receiving HILT, Group II consisted of 15 women receiving LLLT. Both groups have been exposed to three sessions of treatment per week for six successive weeks. Bone Mineral Density (BMD) of lumbar spine (L1.-5) was measured by Dual X-ray absorptiometry (DXA). Evaluation of lumbar BMD was performed before and after the end of the six weeks of treatment.

Results:
Comparing mean values before and after treatment, the BMD measures showed that both groups had a statistically significant improvement after laser therapy. Comparing the two groups, the improvement showed by BMD was higher in Group I (HILT) than in Group II (LLLT). The difference between the two groups was statistically significant (P > 0.05)

Conclusion:
Laser can be an effective method for the management of osteoporosis and improvement of BMD in postmenopausal women. On the basis of the findings of this study, HILT results more effective than LLLT.

INTRODUCTION

Osteoporosis has been defined as a systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk [1,2].

Osteoporosis and fractures related to bone fragility represent a serious and global public health problem. Currently, it is estimated that 30%-50% of women and 15%-30% of men will suffer an osteoporotic fracture in their lifetime. It is a silent "epidemic" that has become a major health hazard in recent years, afflicting over 2000 million people worldwide [3].

There are two types of osteoporosis: type I, due to a decrease in cumulating estrogens, which affects trabecular bone (especially vertebral bone) and affects females more than males, in a ratio of 6:1; type II, senile osteoporosis, which is age related and occurs in cortical and trabecular bone, affects females and males in a ratio of 2:1 [4]. One in three women over the age of 50 years will develop the disease during their lifetime, with a loss of 20% bone mass in 5 to 7 years following the menopause [5].

A sharp decrease in ovarian estrogen production is the predominant cause of rapid, hormone-related bone loss during the first decade after menopause, as a result of higher bone turnover, an imbalance between bone formation and resorption with net bone loss [6].

The mechanism by which estrogens protect bone mass appears to be an indirect one, since there are no known estrogen receptors in bone. Most likely, at an earlier age estrogens control the rate of bone absorption by the effect on parathyroid hormone; once estrogen levels are diminished, resorption occurs at a much faster rate [7].

Low bone mass can only be diagnosed by measuring bone mineral density (BMD) by various techniques, of which the gold standard is DEXA (Dual energy X-ray Absorptiometry). BMD assessment confirms diagnosis, detects disease in asymptomatic state, predicts chances of future fractures, and is also useful for monitoring response to therapy [8, 9].

A World Health Organization working group proposed that osteoporosis should be diagnosed in epidemiologic studies when bone mineral density is 2.5 standard deviations (SDs) or more below the mean for healthy young adult women at the spine, hip, or wrist (corresponding to a T-score of ≤ -2.5). For every 1 standard deviation below the mean, the fracture risk roughly doubles [10, 11].

The acronym 'laser' means 'light amplification by stimulated emis¬sion of radiation'. Lasers are electromagnetic wave amplifiers which can produce pencil-like beams of electromagnetic waves with special properties. The earliest medical lasers, developed in the 1960s and 1970s, were relatively high powered and utilized the concentration of energy in a tiny, pencil-like beam for tissue destruction and coagulation. Some beneficial effects were noted in sites adjacent to the coagulated tissue, at which low energy had been applied. This led to the therapeutic use of low-energy lasers [12]. Low level laser therapy (LLLT) takes place at low radiation intensities, with an output up to 500 mw, which have been reported to have stimulatory, anti-inflammatory and analgesic effects [13-14].

Laser alters the cellular functions and affects the mitochondrial respiratory chain by increasing the activity of certain enzymes such as cytochrome oxidase and adenosine triphosphatase [15]. It also increases DNA synthesis, collagen and pro-collagen production, and may increase the cell proliferation or alter locomotory characteristics of cells [16].

Low energy laser irradiation has positive effects on bone fracture healing. The mechanisms by which low-energy laser irradiations affect bone healing is still not clear [16-17]. In studies on animals, He-Ne laser accelerated the deposition of bone matrix and increased vascularization, altered the osteoblast and osteoclast cell populations, enhanced fracture healing [18] and improved bone regeneration [19]. Also, it was found that LLLT can accelerate bone formation by increasing osteoblastic activity [20], vascularization [21], organization of collagen fibers, and ATP levels [22].

The introduction of High Intensity Laser Therapy (HILT) in the field of physical therapy is relatively recent. High power pulsed Nd:YAG laser works with high peak power and is able to reach deep tissues, such as deep joints, that are difficult to reach for classical lasers [23] . The use of pulsed Nd:YAG laser has spread for pain therapy with excellent results [24]. Studies exist which describe the anti-inflammatory, anti-oedeme and antalgic effects of Nd:YAG laser, thus justifying its use in the therapy of pain [25, 26].

To our knowledge, no studies up to date have been conducted on possible effects of HILT on BMD of lumbar vertebrae in postmenopausal women with osteoporosis. The aim of the present study was to compare the possible effect of HILT and LLLT on BMD of lumbar vertebrae in postmenopausal women with osteoporosis.

MATERIALS AND METHODS

Patients:

Thirty postmenopausal women were recruited from Kaser El-aini Hospital and Ain Shams Hospital, Cairo –Egypt. DEXA was used to diagnose osteoporosis in lumbar vertebrae with no evidence of vertebral compression fractures.

We enrolled in the study patients with age ranging from 51 to 60 years (to avoid inclusion of older patients with multiple medical problems) with no history of cancer, renal disease, gastrectomy, metabolic bone disease or any condition (such as a neurogenic, myopathic or connective tissue disorder) that could cause secondary osteoporosis. The women did not intake any drug associated with accelerated bone loss (steroids) or any drug affecting bone metabolism (estrogen, calcium, vitamin D). The body mass index did not exceed 30 Kg/m2. The patients did not smok and led sedentary life style without participation at any exercise training during this study. They had natural menopause at least 1 year before entry into the study with no history of ovariectomy. All women were given a full explanation of the treatment protocol and a written informed consent form giving agreement to participation and publication of results was signed by the patients and the study was approved by the Departmental Council and the

Ethics Committee of the Faculty of Physical Therapy, Cairo University.

Subjects were randomly assigned to two groups: Group (I) consisted of 15 subjects with BMD in lumbar vertebrae below normal level (osteoporosis); they were treated with HILT. Also Group (II) consisted of 15 subjects with BMD in lumbar vertebrae below normal level (osteoporosis), but they were exposed to LLLT. Randomization was performed simply by asking the patients to choose a piece of paper on which A or B letter was written. (A) Corresponded to Group I (HILT) while (B) corresponded to Group II, which received LLLT.

INSTRUMENTATION:

(I) Dual Energy x-ray Absorptiometry (DEXA)

(Model QDR-1000W, Hologic, Inc., Waltham, MA) was used for the qualitative assessment of BMD in the vertebral bodies of the lumbar spine for both groups. DEXA performs an imaging test that measures bone density (the amount of bone mineral contained in a certain volume of bone) by passing x-rays with two different energy levels through the bone. It is used to diagnose osteoporosis (decrease in bone mass and density). It is also called bone mineral density scan (BMD scan).

(2) High Intensity Laser Therapy (HILT):

An Hilterapia system HIRO 3.0 (ASA, Vicenza, Italy) was used to deliver high intensity laser therapy. The source was a Nd:YAG laser with pulsed emission (1064 nm), very high peak power (up to 3 KW), high energy content (up to 350 mJ per pulse), high levels of fluence (energy density) (360-1780 mJ\ cm2), short pulse duration (< 120 µs), low frequency (10-30 Hz), duty cycle of about 0.1%. It has been recognized and approved by the FDA (Food and Drug Administration, USA) in 2004.

(3) Low Level Laser Therapy (LLLT):

Was performed with a LEVELASER M300D equipped with the optional version made of an He-Ne and IR laser, minimum power 22/35 mW. So, the emissions used for the treatment were continuous red and pulsed infrared light with wavelengths of 632.8 and 904 nm, respectively.

PROCEDURES:

A. Evaluation:

A screening test including careful history taking and gynecological examination was conducted for each subject before entry in this study. After that, BMD of lumbar spine (L1.-5) was measured by DEXA densitometry. Evaluation of lumbar BMD was performed before and after the end of six weeks of treatment.

B) Treatment:

All subjects in this study were exposed to three sessions per week for six successive weeks. The treatment procedure was explained to all subjects. Skin was cleaned with alcohol. During the irradiation, the position of the subjects was the same for both groups (prone lying position with a pillow under her abdomen). The eyes of both patient and operator were protected by goggles at all times so that laser ray could never reach eyes. Laser was irradiated to the lumbar vertebrae (L1-5) using the following laser parameters:

Group I - patients received HILT (Nd:YAG), with pulsed emission (1064 nm), very high peak power (up to 3 kW), elevated energy content (up to 350 mJ), high levels of fluence (energy density) (360-1780 mJ /cm2), brief duration (< 120 µs), low frequency (10-30 Hz), Duty Cycle of about 0.1%. The delivery technique for this group was scanning with total energy of 4000 joule.

HILT was delivered in two different phases: initial phase and terminal phase. In the initial phase, three sub-phases of fast manual scan (10 cm scanned in about 1.5 seconds) were performed to lumbar region with increasing fluences (710 -910 -1530 mJ/cm2) and decreasing frequencies (30-20-15 Hz), a total energy of 2000 joules reached the lumbar region. The final phase consisted of 3 sub-phases of slow scanning (10 cm scanned in about 3 seconds) with increasing fluences (710-910-1530 mJ/cm2) and decreasing frequencies (30-20-15 Hz), a total energy of 2000 joules reached the lumbar region. Scans were longitudinal or transversal to the anatomical structure to be treated, ideally following a straight lines path [27].

Group II – patients were irradiated by LLLT to the lumbar vertebrae (L1-5). The characteristics of the laser beam included: He-Ne and IR lasers with wavelengths 632.8 and 904 nm, respectively; frequency of 3000 Hz; power output 25 mW; beam diameter 1.5 mm. The delivery technique for this group was automatic scanning with energy density of 4 J/cm2. Laser scan over the lumbar region by adjusting the laser scanned area with amplitude-frequency adjustments of horizontal and vertical scanning. The laser-head position was servo-controlled by two motors and could be turned vertically within a range of 110°. The laser emission was vertical starting from the lower part of the head; laser beam was punctiform and could perform horizontal or vertical scanning within a 30° range (±15°). The laser unit automatically calculated the duration of the therapy on the basis of the treated area and the energy density to be transferred.

OUTCOME MEASURE

BMD was collected at lumbar spine using DEXA for both groups pre-treatment and at the end of treatment after six weeks.

Groups	Pre treatment		Post treatment		t value	P value
	mean	SD	mean creams	SD		
HILT group I	-3.2	0.25355	-1.0667	0.67788	11.117	< 0.0001[a]
LLLT group II	-3.1333	0.22887	-2.5667	0.49522	3.697	< 0.002[a]
Mean Difference	-0.06667		1.5			
t value	-0.756		6.92			
P value	0.456[b]		< 0.0001[a]			

SD: Standard Deviation a: Significant b: Non significant

Table I - BMD Mean values pre and post treatment and mean differences in both the groups under study.

DATA ANALYSIS

The data were analyzed using paired t-test to compare the values found pre and post treatment into each group. Independent t-test was used to compare between the two groups at pre and post treatment. The level of significance was set at 0.05 for all tests.

RESULTS

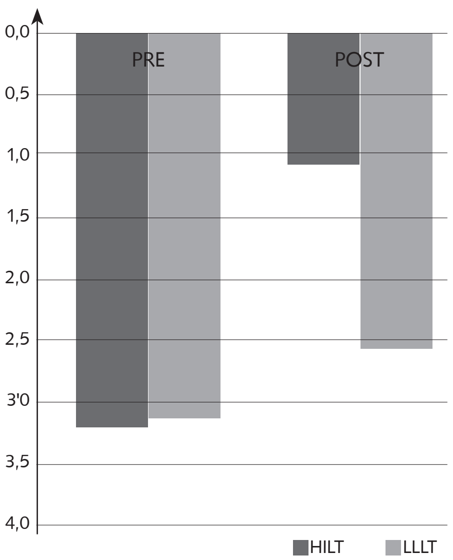

Figure 1:
Comparison between pre and post treatment BMD mean values in both the study groups

As shown in table I and figure 1, before treatment the mean value found analyzing the measures of BMD performed on patients belonging to the Group I (HILT) was – 3.2 ± 0.25, while in the Group II (LLLT) the mean value of BMD was – 3.1333 ± 0.22. By comparing Group I and Group II, the statistical analysis did not reveal any significant difference, indicating that patients enrolled in the study were homogeneously distributed in the two groups. Immediately after the end of the treatment, the mean value of BMD found in patients belonging to the Group I (HILT) was – 1.06 ± 0.6. Compared to the pretreatment value, it revealed a highly significant (P>0.0001) improvement in BMD in response to HILT

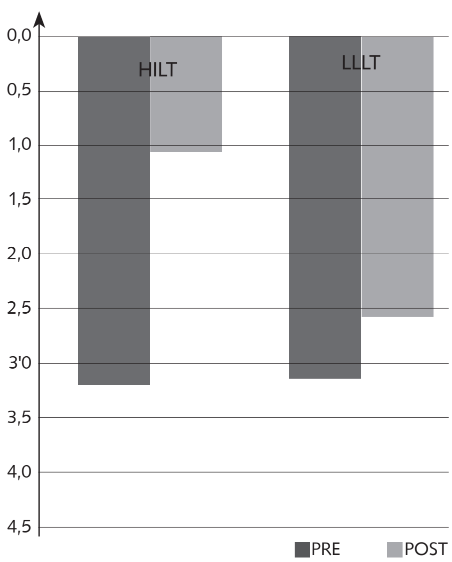

Figure 2:
Comparison between both HILT and LLLT groups in pre & post treatment of BMD.

(table I, figure 2). Also group II showed a statistically significant increase in BMD after LLLT, with a mean value of – 2.5 ± 0.4 (table I, figure 2).

The comparison between the two groups as regards the extent of improvement in BMD observed after the laser therapies clearly pointed out that the increase in BMD induced by HILT was significantly higher than that produced by LLLT (t value: 6.92 and p <0.0001; see table I and figure).

DISCUSSION

The study we have described in this paper had a dual purpose: to evaluate the effectiveness of laser therapy in the treatment of osteoporosis and to compare the effects obtained with two different laser therapies, the former performed with a low level laser emission (LLLT), the latter performed with a pulsed high intensity Nd:YAG laser (HILT).

It has been suggested that LLLT may influence the healing process by affecting various physiological functions and processes such as blood flow, lymphatic flow, inflammation, cellular proliferation and differentiation [21].

Our study show that there was a significant difference between the pre and post treatment mean values of BMD

in patients treated with LLLT. These results are in accordance with the data of Ninomiya et al. [28], who reported that low energy laser irradiation has positive effects on bone fracture healing and therefore may stimulate bone formation. It was found that LLLT reduced the healing time following implant placement and improved bone regeneration, which is a very complex physiological process influenced by a series of biomechanical, biochemical and hormonal factors [19].
Researchers studied bone healing after laser irradiation using histological, histochemical and radiographic measures. These studies have shown conflicting results, because some observed an acceleration of fracture healing [29] while others reported delayed fracture healing after low-level laser irradiation [30]. In recent years, the studies performed by Kandra et al. [31] demonstrated that LLLT stimulates the bone implant interaction.

The histomorphomeric analysis of the treated groups demonstrated a higher bone to implant contact than the control groups [19, 31]. Renno et al. [27] investigated the effects of LLLT (infrared, 830 nm) on the bone properties and bone strength of rat femur after ovariectomy. Laser irradiation was initiated 1 day after the operation and was performed three times a week, for 2 months. Femora were submitted to a biomechanical test and physical properties evaluation.

The results indicated that LLLT was able to prevent bone loss in rats [27]. Khandra et al., [32] demonstrated that LLLT has the ability to stimulate the attachment and proliferation of human osteoblasts like cells cultured on titanium implant material indicating that LLLT could modulate the activity of cells surrounding implant material [32]. Márquezet et al., [33] assessed with histological analysis the effect of laser modulation on the repair of surgical defects on the femur of rats filled with lyophilized bovine bone. The results showed that there was histological evidence of improved collagen fiber deposition at early stages of the healing and increased amount of well-organized bone trabeculae at the end of the experimental period on irradiated animals [33].

The application of high power lasers in physiotherapy is quite recent. It is due to the development of instruments which allow the control of photothermal and photomechanical processes to obtain therapeutic effects without tissue damage. In particular, pulsed Nd: YAG laser has proved its versatility and efficacy in the treatment of many different musculoskeletal diseases and it is believed to have anti-inflammatory, anti-edema, analgesic and also reparative effects. The interaction between tissue and laser radiation can alter the mechanics of cell micro-environment, thus acting on the cells as a mechanical stress [34].
The results of the present study show that there was a very significant difference between the mean values of BMD pre- and post-treatment in patients exposed to HILT.

Moreover, although an improvement in BMD has been observed both in Group I (HILT) and in Group II (LLLT), the improvement induced by HILT was significantly higher than that induced by LLLT. This could be due to the characteristics of the source used in the HILT, which emits very short pulses that can reach deeper tissue during the treatment.

In conclusion the results indicate that laser therapy is an effective method for the management of osteoporosis in postmenopausal women and HILT is more effective than LLLT in improving BMD.

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