High Intensity Laser Versus low Intensity Laser Therapy in Management of Postmenopausal Osteoporosis

Ali Abdel Monsif Thabet*, Mohamed Salaheldien Mohamed**, Mohamed Mohamed Ibrahim Ali*** and Omar Farouk Helal****

*Department of Physical Therapy for Obstetrics and Gynecology, Faculty of Physical Therapy, Cairo University.

**Department of Basic Science for Physical Therapy, Faculty of Physical Therapy, Cairo University.

***Department of Physical Therapy for Musculoskeletal Disorders, Faculty of Physical Therapy, Cairo University.

Department of Physical Therapy, Faculty of Applied Medical Sciences, Umm Al-Qura University.

****Department of Physical Therapy, Faculty of Applied Medical Sciences, Umm Al-Qura University.

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 parameters 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) with 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 this study. They were randomly divided in to two groups. Group (I) consists of 15 women received HLLT, Group (II) consists of 15 women received LLLT. Both groups were treated three sessions per week for six successive weeks. Bone mineral density of lumbar spine $(L_{1,-5})$ was measured by Dual X-ray absorptiometry (DXA). Evaluation of lumbar BMD was performed before and after the end of six weeks of treatment. Results: Comparing mean value of bone mineral density showed that high intensity laser group (Group I) was statistically higher significant (P < 0.05) compared with the low level laser group (II) at the end of the treatment course. Conclusion: Laser is an effective method can be used for management of osteoporosis to improve bone mineral density in postmenopausal women, with recommendation from this study to use HILT than LLLT.

Key words: High Intensity Laser Therapy, Low Level Laser Therapy, Bone mineral density, Postmenopausal osteoporosis.

INTRODUCTION

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^{17,22}. Osteoporosis falls and related fragility fractures 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 worldwide¹².

There are two types of osteoporosis, type I due to a decrease in cumulating estrogen which affects trabecular bone (especially vertebral bone) and affects females more than males in a ratio of 1:6 and Type II, senile osteoporosis, which is age related and occurs in cortical and trabecular bone. It affects females and males in a ratio of 2:1.²⁴ One in three women over age of 50 years will develop the disease during their lifetime where there is a loss of 20% bone mass in 5 to 7 years following the menopause²¹.

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 bone resorption and net bone loss²⁵.

The mechanism by which estrogen protects bone mass appears to be an indirect one, since there are no known estrogen receptors in bone. Most likely, at an earlier age estrogen controls the rate of bone absorption by its effect on parathyroid hormone; once estrogen levels are diminished, resorption occurs at a much faster rate¹⁹.

Low bone mass can only be diagnosed by measuring bone mineral density (BMD) by various techniques, of which the gold standard is Dual energy X-ray Absorptiometry (DEXA). BMD assessment confirms diagnosis, detects disease in asymptomatic state, predicts chances of future fractures, and is also useful for monitoring response to therapy. Low bone density has been used to predict risk for fractures as well as to diagnose osteoporosis^{6,11}.

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 \leq -2.5). For every 1 standard deviation below the mean, the fracture risk roughly doubles^{26,33}.

The acronym 'laser' stands for 'light amplification by stimulated emission of radiation. Laser 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 laser³¹. Low level laser therapy (LLLT) takes place at low radiation intensities with an output up to 500 milliwat (mW) which have been reported to stimulatory, have anti-inflammatory and analgesic effects^{1,4}.

Laser alters the cellular functions by altering intercellular communication in a manner that is dependent on the parameters of the light itself eg. wavelength, coherence. light affects the mitochondrial Laser respiratory chain by increasing the activity of certain enzymes such as cytochrome oxidase and adenosine triphosphatase $(ATP)^2$. It also increases deoxyribonucleic acid (DNA) collagen pro-collagen synthesis, and and may increase the cell production, proliferation alter locomotory or characteristics of cells¹⁶.

Low energy laser irradiation has positive effects on bone fracture healing. The mechanisms by which low-energy laser irradiations affect on bone healing still not clear^{7,16}. Helium–neon (He-Ne) laser accelerated the deposition of bone matrix and increases vascularization, altered the osteoblast and osteoclast cell population, enhanced fracture healing in Studies on animals¹⁰ and improved the bone regeneration¹³. Also, it was found that LLLT can accelerate bone formation by increasing activity³⁰, osteoblastic vascularization³, organization of collagen fibers, and ATP levels⁸.

High Intensity Laser Therapy (HILT) was introduces to the field of physical therapy is relatively recent and this technology is in constant evolution and approved by FDA in 2004. High power pulsed neodymium-doped yttrium aluminum garnet (Nd:YAG) laser work with high peak powers and able to reach and stimulate organs that are difficult to reach for classical lasers, such as the large and/or deep joints³⁴. Now the use of pulsed Nd:YAG Laser has been spreading in the therapy of pain with excellent results²⁷. Studies exist which the anti-inflammatory, describe antioedemigenic and antalgic effects of Nd: YAG Laser, thus justifying its use in the therapy of pain^{29,32}.

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

SUBJECTS, MATERIALS AND METHODS

Subjects

Thirty consecutive 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.

Their age ranged between 51 to 60 years old (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 of any medications associated with accelerated bone loss (steroids) or any medications affected bone metabolism (estrogen, calcium, vitamin D). Body mass index not exceeding 30 Kg/m^2 , non smoker, parity from 1-3 times and led sedentary life style without participation at any exercise training during this study, and, 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.

Subjects were randomly assigned into two groups: Group (I) consists of 15 subjects with BMD in lumbar vertebrae below normal level. Each subject with osteoporosis received HILT. Group (II) consists of 15 subjects with BMD in lumbar vertebrae below normal level. Each subject with osteoporosis received LLLT. Randomization was performed simply by asking the patient to choose a piece of paper which (A) or (B) letter was written. (A) considered a group (I) which received high intensity laser, while (B) considered a group II which received a low intensity laser.

Instrumentation

(l) Dual x-ray Absorptiometry (DXA); 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. 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 by measuring BMD.

Intensity (2)High Laser Therapy (HILTERAPIA) (ASA Italy): was used to deliver high intensity laser therapy. It has been recognized and approved by the FDA (Food and Drug Administration, USA) in 2004. The apparatus provided the following options: (Nd:YAG), with pulsed emission (1064 nm), Very high peak powers (1-3 KW), Elevated energy content (150 - 350 mJ), High levels energy density ($810-1780 \text{ mJ} \text{ cm}^2$), Brief duration (120-150 µs), Low frequency (10-40 Hz), Duty Cycle of about 0.1%.

(3) Low Level Laser Therapy (LEVELASER M300D); The lasers used for treatment was continuous red and pulsed infrared laser light with wavelengths of (632.8 - 904 nm) and energy density of 4 J/cm2. LEVELASER M300D is IR diode lasers deliver powers of 1000 mW CW to 3000 mW CW. The apparatus provided the following options: He-Ne laser 632.8 nm, minimum power 12 mW, He-Ne and infra red (IR) laser 904 nm, minimum power 22/35 mW, He-Ne and IR2 laser 780-870 nm, minimum power 1W.

Procedures

A. Evaluation: Initially a screening test including careful history taking and gynecological examination were conducted for each subject before entry in this study. After that BMD of lumbar spine ($L_{1.-5}$) was measured by DXA densitometry. Evaluation of lumbar BMD was performed before and after the end of six weeks of treatment.

B. Treatment: All subjects in this study received 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 must be protected by goggles at all times and that the laser ray must never be directed at eyes. Laser was irradiated to the lumbar vertebrae (L_{1-5}) using the following laser parameters. For (group I): received HILT (Nd:YAG), with pulsed emission (1064 nm). Very high peak powers (1-3 KW), Elevated energy content (150 - 350 mJ), High levels of fluence (energy density) (810-1780 mJ $/cm^2$), Brief duration (120-150 µs), Low frequency (10-40 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 initial phase, three sub-phases of fast manual scan (every10 cm scanned in about 1.5 second) was performed to lumbar region with increasing fluences (710 -910 -1530 mJ/cm²) and decreasing frequencies (30-20-15 Hz) with total energy of 2000 joules reached lumbar region. In Final phase: 3 sub-phases of slow scanning (every 10 cm scanned in about three second) with increasing fluences (710-910-1530 mJ/cm²) and decreasing frequencies (30-20-15 Hz) with total energy of 2000 joules reached lumbar region. Scans can be longitudinal and transversal to the anatomical structure to be treated, ideally following a straight lines path²⁸.

For (group II): LLLT was irradiated to the lumbar vertebrae (L1-5) using the low level laser therapy. The characteristics of laser beam included: He-Ne and IR laser with wave length 904 nm; frequency of 3000 Hz; power output 25 mW; 904 nm, Beam Diameter 1.5 mm. The delivery technique for this group was automatic scanning with energy density of 4 J/cm^2 . 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 is servo-controlled by two motors and can be turned vertically within a range of 110°. The laser emission is vertical starting from the lower part of the head; laser beam is a punctiform and can perform horizontal or vertical scanning within a 30° range ($\pm 15^{\circ}$). The laser unit automatically calculates the therapy time based on the area to be treated and the density of energy 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.

Data Analysis

The data were analyzed using paired ttest to compare between pre and post test values. Unpaired t-test was used to compare between both groups at pre-test and post test. The level of significance was set at 0.05 for all tests.

RESULTS

The pre treatment the mean value of BMD in the group (I) was (3.2 ± 0.254) mg/cm² while, the mean value of BMD post treatment was (-0.53 ± 1.17) mg/cm². There was highly significant (P<0.0001) increase in the bone mineral density in response to HILT. While in the group (II), it was founded that the pre treatment the mean value of BMD was (-3.13± -0.23) while the mean value of BMD was (-3.13± -0.23) while the mean value of BMD was (-2± 1.95) mg/cm². There was significant (P<0.05) increase in the bone mineral density in response to LLLT as observed in table (1) and figure (1).

 Table (1): Mean values of pre and post treatment and mean difference of the BMD of both groups (I) and (II).

		Pre-treatment	Post- treatment	Mean Difference	t-value	P-value	Significance
Group (I)	Mean	-3.200	-0.533	-2.667	-8.270	< 0.0001	Highly
	SD	0.254	1.172	-2.007			significant
Group (II)	Mean	-3.133	-2.000	-1.333	-2.200	0.045	Significant
	SD	0.229	1.946	-1.555			

SD: Standard Deviation



Fig. (1): Mean values of pre & post treatment of BMD between both groups (I) and (II).

Comparison between the mean value of the pre treatment BMD for group (I) and group (II) revealed no statistical significant differences (P>0.05) while comparing mean value of bone mineral density showed that Group (I) was statistically significant (P<0.05) when compared to the group (II) post treatment.

Table (2): The comparison between pre and post mean values of the bone density between both groups (I and II).

		Group (I)	Group (II)	Mean Difference	t- value	P-value	Significance		
Pre treatment	Mean	-3.200	-3.133	-0.07	0.122	-0.807	Non		
	SD	0.254	0.229				Significant		
Dest treatment	Mean	-0.533	-2.000	-1.467	2.837	0.038	Significant		
Post treatment	SD	1.172	1.946						

SD: Standard Deviation



Fig. (2): The comparison between pre and post mean values of the bone density between both groups (I and II).

DISCUSSION

Osteoporosis is a silent epidemic that has become a major health hazard in recent years, afflicting over 2000 million people worldwide¹². One in three women over age of 50 years will develop the disease during their lifetime. Loss of 20% bone mass in 5 to 7 years following menopause is seen²¹.

The results of the present study showed that there was significant different between the pre-post treatment mean value of BMD using LLLT. It has been suggested that LLLT may influence the healing process by affecting various tissue responses such as blood flow, lymphatic flow, inflammation, cellular proliferation and differentiation³.

The result of the present study was agreed with Ninomiya et al.²³ who mentioned that low energy laser irradiation has positive effects on bone fracture healing. It was found that LLLT effect is the reduction of the healing time following the implant placement and to improve the bone regeneration which is a very complex physiological process and is influenced by a series of biomechanical,

biochemical, hormonal, pathologic reactions and by skeletal cells¹³.

Researchers studied bone healing after laser irradiation using histological, histochemical and radiographic measures. These studies have demonstrated mixed results where some observed an acceleration of fracture healing⁹, while others reported delayed fracture healing after low-level laser irradiation⁵. In the recent years, the studies performed by Kandra et al.,15 demonstrated that the low level laser therapy stimulates the bone implant interaction. The histomorphomeric analysis of the treated groups demonstrated a higher bone to implant contact than the control groups^{13,15}. Renno et al.,²⁸ investigate the effects of LLLT (infrared. 830 nm) on the bone properties and bone strength of rat femora after ovariectomy. Laser irradiation was initiated 1 day after the operation and was performed three times a week, for 2 months. The results indicated that LLLT was able to prevent bone loss in rats 28 . Khandra et al.,¹⁴ demonstrated that LLLT has the ability to stimulate the attachment and proliferation of the human osteoblasts like cells cultured on titanium implant material

indicating that LLLT can modulate the activity of cells surrounding implant material¹⁴. Márquezet et al.,¹⁸ assessed histologically the effect of Laser photobiomodulation on the repair of surgical defects on the femur of rats filled with lyophilized bovine bone. The result showed that there was histological evidence of improved collagen fiber deposition at early stages of the healing; increased amount of well-organized bone trabeculae at the end of experimental the period on irradiated animals¹⁸

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 of many the treatment 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 alters the mechanics of cell micro-environment, thus acting on the cells as a mechanical stress 20 .

The results of the present study showed that there was significant different between the pre-post treatment mean value of bone mineral density for high intensity laser therapy group and there was significant different between the mean value of BMD post treatment between the two groups in favor to HILT. These could be due to the radiation of HILT which involves HILT with light absorption by chromophores which increase the mitochondrial oxidative reaction and ATP, ribonucleic acid (RNA), or DNA production (photochemistry effects) and resulting in the phenomenon of tissue stimulation (photobiology effects)³⁴.

Conclusion

Laser is an effective method used for management of osteoporosis to improve BMD in postmenopausal women with recommendation from this study to use HILT than LLLT.

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الملخص العربى

الليزر المتقطع عالي الشدة مقابل الليزر المنخفض الشدة في علاج هشاشة العظام لدى السيدة بعد انقطاع الطمث

أجريت هذه الدراسة لتحديد كفاءة الليزر المتقطع عالي الشدة مقابل الليزر المنخفض الشدة في علاج هشاشة العظام لدى السيدة بعد انقطاع الطمث. وقد شاركت ثلاثون سيدة في هذه الدراسة ، وقد تم تقسيمهن إلى مجموعتين (أ ' ب) . المجموعة (أ) تم علاجهن الليزر المتقطع عالي الشدة ، والمجموعة (ب) تم علاجهن بالليزر منخفض الشدة . وتم علاجهن لمدة 6 أسابيع بواقع ثلاث جلسات أسبوعياً . وقد استخدمت القياسات التالية : تم تقييم الحالات قبل وبعد العلاج عن طريق الاشعة السينيه الموذوجة (ديكسا). وقد اكث خلسات أسبوعياً . وقد استخدمت العلاج بالليزر المتقطع العالي و المنخفض الشدة على خليف الاشعة السينيه الموذدوجة (ديكسا). وقد اكدت نتائج هذة الدراسة على كفاءة العلاج بالليزر المتقطع العالي و المنخفض الشدة على زيادة كثافة العظام في المنطقة القطنية لدى السيدات بعد إنقطاع المثل. وقد أوضحت النتائج أن هناك انخفاض ذو دلالة إحصائية عالية زيادة كثافة العظام في المجموعة (أ) بالمقارنة بالمجموعة (ب) . وهذا يمكن أن نستخلص أن الليزر المتقطع العالي و المنخفض الشدة على زيادة كثافة العظام في المجموعة (أ) بالمقارنة بالمجموعة (ب) . وهذا يمكن أن نستخلص النتائج أن هناك انخفاض دو للهذ إحصائية عالية زيادة كثافة العظام في المجموعة (أ) بالمقارنة بالمجموعة (ب) . وهذا يمكن أن نستخلص أن الليزر المتقطع عالي الشدة كان أكثر تأثيراً وفاعلية بالمقارنة بالليزر المنخفض الشدة .

الكلمات الدالة : الليزر المتقطع عالى الشدة - الليزر منخفض الشدة – كثافة العظام – هشاشة العظام - أنقطاع الطمث .