



Original Article

Efficacy of high intensity laser therapy in the treatment of male with osteopenia or osteoporosis: a randomized placebo-controlled trial

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Abstract. [Purpose] To investigate the effect of high intensity laser therapy, alone or combined with exercise on pain, health related quality of life and fall risk in male with osteopenia or osteoporosis. [Subjects and Methods] 100 male patients with osteopenia or osteoporosis participated in the study. They had T-scores ≤ -1.5 . Patients were randomly assigned into four groups and treated with laser plus exercise, placebo laser plus exercise, laser alone and placebo laser in groups I, II, III, and IV respectively. Laser was applied to the lower back and hip regions. Exercises included aerobic exercises, weight-bearing, flexibility, and strengthening and balance exercises. Treatment were performed 3 times/week for 12 weeks. The measured outcomes were pain, health related quality of life and fall risk. [Results] All measured outcomes were significantly decreased post-treatment in all treatment groups. Laser plus exercises showed a higher significant effect than exercises with a least significant effect in the laser group in reduction of pain and quality of life. [Conclusion] High intensity laser is an effective modality for male patients with osteopenia or osteoporosis. Laser combined with exercise is more effective than exercises or laser alone in decreasing pain, fall risk an increasing quality of life after 12 weeks of treatment.

Key words: Exercises, High intensity laser therapy, Osteoporosis

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INTRODUCTION

Osteoporosis has been defined as a systemic bone disease characterised by compromised bone strength with a significant deterioration of bone micro architecture and decrease in bone mass, leading to enhanced bone fragility and a high risk to fracture¹. Osteoporosis is more prevalent in women, although about 15–30% of the estimated osteoporotic fractures occurred in 2,000 were in men². Men are less likely to receive therapy with higher mortality rates after hip fractures as compared to women³.

In the Saudi Arabian male population, the prevalence of osteopenia was 46.3%, and osteoporosis was 30.7% with an incidence of vertebral fractures between 20–24%^{4,5}. Therefore, the prevention of osteoporosis in males has an important role in improving the health related life quality of middle aged and older adults⁶.

A number pf previous researches investigated the physical therapy modalities in the treatment of osteoporosis such as exercises⁷, whole-body vibration training⁸, pulsed electromagnetic field⁹, and low level laser therapy (LLLT)^{10, 11}. Laser is able to accelerate bone tissue healing through increase osteoblast DNA and RNA synthesis in vitro studies¹².

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For the available literature there is a lack of evidence to the effect laser on osteoporosis with no study has yet investigated its effect on humans. The limitation of low power production and relatively limited penetration of the low power laser interfere with its use in human to stimulate bone tissues. The recent developed pulsed Nd:YAG, infra-red laser (1,064 nm) provide high power (3KW) and high intensity laser therapy (HILT) that can penetrate deep and is therefore able to stimulate the large and deep areas^{13, 14}. HILT used for the treatment of many musculoskeletal diseases and proved as a pain relieving modality for patients with knee osteoarthritis^{14, 15}, chronic low back pain¹³, and chronic neck pain¹⁶.

The effect of LLLT was administrated on animals or in vitro studies with no study investigated the efficacy of HILT in male patients with osteoporosis. Therefore, there is a need to investigate the effect of HILT alone or combined with exercise in the treatment of men with osteopenia or osteoporosis. Hence, the aim of the study has been to investigate the efficacy of HILT alone or combined with exercises on pain, health related quality of life and fall risk in male with osteopenia or osteoporosis.

SUBJECTS AND METHODS

The study design was a single blinded randomised placebo-control trial. This study was approved by the Ethics Review Committee at Umm Al-Qura University, Saudi Arabia with a local approval number (13-745-10). Sample size was estimated by the G-power program for Windows with an estimated power=0.95, $\alpha=0.05$, the effect size was 0.20 and it used F tests ANOVA for four groups and two measurement intervals. The recommended sample size should be a minimum of 92 patients in all treatment groups (23 patients in each group). The number of recruited patients was increased (25 in each group) for a possible drop out.

A total of 100 males older than 50 years of age volunteered to participate in the study. Careful history was taken from each patient before participating in this study. All the patients were diagnosed with osteopenia or osteoporosis (T-scores ≤ -1.5) measured by Dual-energy X-ray absorptiometry (DEXA) were included in this study. After baseline examination, a full explanation was given to all patients about study aims, while a consent form was assigned from every patient providing agreement for participation and publication of the results.

Patients were excluded from the study if they had cardiac, liver, respiratory or any advanced musculoskeletal problems (advanced osteoarthritis, bilateral hip replacement or ankylosing spondylitis). Patients were also excluded if they were alcoholic, under steroid therapy or any form of drug treatment with possible effect on bone metabolism. Furthermore, patients with a body mass index below 18.5 and above 30 kg/m² were excluded from the study.

Randomization was performed by a random number generator. Both the external evaluator and the therapists were blinded from the randomisation process. The Group I received HILT and exercises (HILT+EX), group II received placebo laser and exercises (PL+EX), group III were treated by HILT alone (HILT) and group IV received placebo laser (PL) and served as the active control group.

Pain intensity was measured using a visual analog scale (VAS) at pre and post-treatment. Patients were asked to report the level of pain in their low back area over the past few days, using 10-cm VAS. Patients choose the severity of pain by placing a mark on a line, with 0 (no pain) and 10 (the worst imaginable pain) marking the ends of the VAS line¹⁷.

Health related quality of life (HRQoL) was evaluated for all patients by a self-administered ECOS-16 questionnaire. ECOS-16 is proved to have good psychometric properties and considered as a useful tool to evaluate HRQoL to elderly with osteoporosis in research as well as in clinical practice¹⁸. ECOS-16 questionnaire includes four dimensions dealing with physical function, pain, fear of illness and psychosocial function. The score for each item ranges from 1 (best HRQoL) to 5 (worst HRQoL).

Fall risk measurement was done by a Biodex balance system (Biodex, New York, USA). Fall risk test protocol is an available test measuring the balance of the subjects over 50 who have different abilities of balance and allows identification of potential fall¹⁹. The patients stand on the platform and concentrate to fix the center of gravity within the center of the base of support while the platform was moving. The platform stability ranges from 1–12, with 1 representing the greatest instability. The lower the resistance level, the less stable the platform. Test duration was 20 seconds; the level was eight, bilateral stance type with eyes open. The patient performed three trial repetitions with 30 seconds rest period between sets. The result was compared to the result of age matched healthy individual.

The HILT was produced by HIRO 3 device (ASA, Vicenza, Italy). The HILT machine provides the following: a pulsed Nd, a YAG laser with peak powers 3 KW, average power 10.5 W, a wavelength of 1,064 nm, fluency levels (510–1,780 mJ/cm²), a brief duration (120–150 μ s), low frequency (10–30 Hz), a 0.1% duty cycle, a probe diameter of 0.5 cm and a spot size of 0.2 cm². HILT was calibrated for constant output throughout the study by the manufacturer.

All the patients received 3 sessions per week for 12 weeks. The therapist scanned longitudinally and transversely the lower back, anterolateral, lateral and posterolateral surfaces of the proximal thigh with 3,000 Joules delivered in the two phases of treatment. The average treated area was about 200 cm² with an average fluency of 15 J/cm². In the initial phase fast manual scanning was applied with gradual increased the level of fluency to 510, 610 and 710 mJ/cm² in three successive sub-phases and 500 joules in each sub-phase with a total 1,500 Joules. The final phase was the same as the initial phase, except that the scanning was slow. The same parameters were applied to the proximal thigh. The average area for the upper thigh was 300 cm² with an average fluency of 10 J/cm² and the application time for each area was approximately 18 minutes.

For placebo laser treatment, the patients in the group IV received PL only with a regular walking at home and considering

Table 1. Basic characteristics of participants in the four treatment groups

	Group I	Group II	Group III	Group IV
Age (years)	54.2 ± 3.1	53.8 ± 2.6	53.2 ± 2.8	54.0 ± 3.1
Weight (kg)	80.6 ± 7.8	81.8 ± 7.9	80.4 ± 7.8	79.4 ± 5.9
Height (cm)	1.8 ± 4.4	1.7 ± 5.2	1.7 ± 4.9	1.8 ± 6.2
BMI (kg/cm ²)	26.2 ± 2.2	26.9 ± 2.2	26.8 ± 2.6	25.5 ± 2.4
Number of patients	25	25	25	25
Number of osteopenic spine (%)	22 (88%)	23 (92%)	22 (88%)	22 (88%)
-1.1 < T < -2.4				
Number of osteoporotic lumbar spine (%) T-score ≤ -2.5	3 (12%)	2 (8%)	3 (12%)	3 (12%)
Number of osteopenic hip (%)	24 (96%)	23 (92%)	24 (96%)	24 (96%)
-1.1 < T < -2.4				
Number of normal hip (%)	1 (4%)	2 (8%)	1 (4%)	1 (4%)
T-score > -1.1				

HILT: high intensity laser therapy; EX: exercises; PL: placebo laser; BMI: body mass index; p: probability value

Table 2. Changes in pain, HRQoL, and fall risk among treatment groups

	HILT + EX		PL + EX		HILT		PL	
	Pre	12 W	Pre	12 W	Pre	12 W	Pre	12 W
Pain level (VAS)*	5.6 ± 1.2	0.7 ± 0.5**	5.3 ± 1.0	1.8 ± 0.7**	5.1 ± 1.0	1.1 ± 0.7**	5.2 ± 1.2	3.6 ± 0.9**
HRQoL*	47.8 ± 5.2	22.5 ± 4.6**	46.2 ± 4.6	28.4 ± 5.5**	45.3 ± 4.4	35.2 ± 5.6**	44.6 ± 5.3	42.4 ± 3.7**
Fall risk*	3.2 ± 0.6	2.2 ± 0.5	2.9 ± 0.9	2.5 ± 0.8	3.2 ± 0.8	3.1 ± 0.7	3.0 ± 0.9	2.9 ± 0.9**

HILT: high intensity laser therapy; EX: exercises; PL: placebo laser; 12 W: 12 weeks, VAS: visual analogue scale, HRQoL: health related quality of life

Data are expressed as mean ± standard deviation.

*Significant difference in the post treatment measurement among treatment groups.

**Significant difference in each treatment group in post treatment as compared to baseline values.

an active control group. The placebo laser was just a light of the laser equipment without laser radiation. For the PL+EX group, the patients received PL before applying the exercises. For HILT+EX group, patients received HILT and then preformed the exercise-training program.

The exercise-training program included aerobic exercises, weight-bearing, flexibility, strengthening and balance exercises. The program of exercises was performed three times per week for three months. 20 minutes walking on the treadmill in a relative speed adjusted according to the patient's tolerance with warm up phase for 5 minutes, 10 minutes of stimulus phase with intensity 40% to 60% of the maximal heart rate and 5 minutes as cool down phase. Strengthening exercises for abdominal, back, hip muscles and back stretching exercises was performed. These exercises were repeated for three sets of 10 repetitions in each set. Hip strengthening exercises were applied in a weight bearing position in front of the wall bar and in non-weight bearing positions using a Thera-band and sand bag with variable weights, according to patient tolerance in three sets of each exercise with 10 repetition maximum (3 × 10 RM). Closed kinematic chain exercises in the form of leg press exercise was applied using a Total Gym device. Static and dynamic balance training included stance activities, transitional activities and gait Activities following a schedule of training for 12 weeks. Patients in the HILT+EX and PL+EX groups were instructed to do the same program of exercises at home once daily. Patients in all the treatment groups were advised to do half an hour of daily walking. A booklet for exercise description was given to them and a report of exercise compliance was obtained. Any three successive absences from the exercise sessions would lead to the exclusion of patients from the study.

Patient demographic data as age, weight, height and BMI were analysed by one-way analysis of variance (ANOVA) using SPSS program for Windows, version 16. Comparison between groups were carried out by ANOVA with post hoc Bonferoni test. Comparison between the baselines and after 12 weeks of treatments each group was performed by either t test or Wilcoxon sign ranked test. The level of significance was set at p<0.05 for all tests.

RESULTS

A total number of 100 male patients participated in this study. The patients were randomly assigned into four groups with their mean age (53.78 ± 2.89) years, mean weight (80.56 ± 7.34) kg, mean height (1.75 ± 5.30) m and BMI (26.34 ± 2.39) kg/m². The results showed that there were no significant differences in the mean age, weight, height or BMI among treatment groups as shown in the Table 1. There were no significant differences between the four treatment groups in baseline mean values of VAS, HRQOL and fall risk scores. There were significant decreases in post-treatment results compared with baseline mean values in all treatment groups. Comparing post treatment variables among treatment groups revealed significant decreases in VAS and HRQOL scores with more significant effect on HILT+EX group more than the PL+EX group and the

HILT group with the least effect was PL group. For fall risk scores, there was no significant difference between HILT+EX and PL+EX groups and both are significant more than HILT and PL groups as shown in the [Table 2](#).

DISCUSSION

The main findings in the present study were that HILT combined with exercise has a significant effect more than PL+EX or HILT alone in decreasing pain, HEQoL or the same effect as PL+EX in decreasing the fall risk after 12 weeks of treatment.

Studies reported that HILT is effective in reducing the musculoskeletal pain^{13, 14, 16)} without any adverse effects or histological risk. The high power (3KW) of HILT with a 1,064 nm wavelength is able to penetrate the deeper layer (up to 5 cm) leading to a diffusion of laser energy more than the LLLT (1–3 cm). The low frequency (30 Hz), high power emissions with very short pulse duration of HILT is postulated to have a more penetrating effect¹³⁾.

In this study, exercises were effective in decreasing pain and fall risk after 12 weeks of treatment. The results of exercises of the present study were consistent with the results of some of the previous clinical trials^{20–23)}. Balancing exercises improve the static balance and dynamic balance^{24, 25)} as well as reduced concerns about falling and improved gait in older adults with osteoporosis²⁰⁾. Moreover, balance-training program improved the fall-related self-efficacy, gait speed, balance score and physical function in older adults with osteoporosis²¹⁾.

In the present study, exercises applied alone or with HILT were effective in Improving HRQoL after 12 weeks of treatment. Exercise training improves muscle strength²⁶⁾, static and dynamic balance²³⁾, physical function²⁷⁾, ADL²⁷⁾, the quality of life^{28, 29)} and reduce the risk of falls, therefore reducing the fracture risk³⁰⁾. Furthermore, resistance exercises reduce pain and improve fitness level, psychological status and cognitive function²⁷⁾.

The present study shows a more significant effect of HILT when combined with exercises more than the effects of exercises or HILT when applied alone. One explanation of the increased efficacy is that HILT decreased the pain induced by exercises and it relieved the secondary problems as the back pain and muscle spasm that accompanied with exercises. Moreover, HILT may be responsible for increasing the muscle efficiency during exercise and the recovery of muscle from fatigue induced by exercises³¹⁾.

HILT is an effective physical therapy modality for male patients with osteopenia or osteoporosis. Combined with exercise, HILT is more effective than PL+EX or HILT alone in decreasing pain, fall risk an increasing HEQoL after 12 weeks of treatment. Further studies discussing the effect of HILT with exercise to back and hip muscle strength may be considered for the future. The effects of such combinations should be investigated in other areas, such as in the cervical or forearm regions, or to be applied to females with osteoporosis.

All the patients were instructed to do a home exercise program with half an hour of daily walking, while exercise compliance was obtained from all of them. Although patients did not report any shortage in home-prescribed exercise, we considered this a limiting factor in the present study.

Patients in all treatment groups performed a regular walking at home. Although no patient reported any shortage in the regular walking, it was considered as a limiting factor in this study.

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