High Intensity Pulsed Nd:YAG Laser in painful knee osteoarthritis: the biostimulating protocol.

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ABSTRACT

Laser therapy is a widely used instrumental methodology in the physiotherapy treatment of osteoarthritis pain. High Intensity Laser Therapy (HILT, Nd:YAG laser) in last years proved to be effective in painful Knee Osteoarthritis (KO), due to its high intensity and to the
depth reached by the laser ray. Several HILT protocols are available to treat this condition, in relation to the phase of the disease and to the clinical data of the patient.

Aim of this study was to analyze the clinical efficacy and the safety of HILT, using a biostimulating protocol in patients with symptomatic KO.

34 out-patients with symptomatic KO (II-III Kellgren-Lowrence Scale stage) were enrolled and randomized to treatment (16 patients, Group A) or to waiting list (18 patients, Group B). The study is an open-label, before and after study. The treatment consisted in HILT biostimulating treatment (10 sessions, three time a week) for Group A and no treatment for Group B. The patients were assessed by WOMAC Scale, before treatment (t0), after treatment (t1) and after 4 months (t2). At the same time intervals were assessed the patients in the waiting list.

HILT-treated patients showed a highly statistically significant improvement between t0 and t1 in WOMAC scale, and the improvement was maintained at follow-up (t2), while the patients in the waiting list showed a worsening tendency. No side effect was found in the treated group.

The HILT treated patients showed good clinical results, in pain and functional items. We conclude that this HILT protocol seems a good medical instrument for pain control in KO and for improvement of patient's quality of life.

INTRODUCTION

High Intensity Laser Therapy (HILT) is a powerful laser-therapy, which showed interesting results in osteoarthritis pain treatment [1,2,3,4]. Knee OA pathogenesis is characterized by the combination of flogistic and degenerative aspects, which clinically presents as phases of acute and intense pain over a chronic degenerative background [5,6].

The prevalence of knee pain and of symptomatic knee OA is increasing [7]. The longitudinal, population-based US study (Johnston County Osteoarthritis Project, 2008) conducted on 3.068 participants found that nearly half of the adult's sample will develop symptomatic knee OA, in at last one knee by age 85 years, suggesting similar risks in the general US population. Knee OA is the most frequent form of lower extremity OA and it has a profound clinical and public health burden [8,9]. Disability and functional impairment is mostly determined by pain [10], and pain reduction, together with the control of the disease progression are the two main targets of the therapeutic approach. Among physiotherapy treatments, Low Level Laser Therapy (LLLT) is widely proposed as an effective alternative treatment for arthritis and especially knee osteoarthritis, though there is weak evidence to support EBM recommendation of low level laser therapy for short term treatment of OA [11]. The effects of laser therapy are due to its photo-chemical, photothermal and photo-mechanical actions, and the therapeutic efficacy are related to its antiflogistic, antalgic, antioedema and biostimulating effects [12,13].

In particular the laser's biostimulating effect is due to the facilitation of tissues repair, by increasing the cells metabolic activity and microcirculation activation.

In last ten years high powerful therapeutic lasers were developed. In particular some studies [14,15] indicate that High Intensity Laser Therapy (HILT), a Nd:YAG laser application modality, can be very effective in pain and flogosis control, due to its intense and deep effects [16,17]. HILT Hero 3 is a powerful laser instrument with a pulsed beam and high frequency (wavelength 1064 nm) which reaches very high peak power (1-3 kW).

HILT can provide an homogeneous distribution of the ray into the deep tissue, such as the intraarticular space, and the light intensity is able to activate the main biologic mechanisms involved in antalgic therapy, and likely, in repearing and regenerative therapy. Beyond the photo-thermal effect, which is one of the most important effects in laser-therapy, more complex biological and cellular reactions must be considered [18]. A distinguishing characteristic of HILT is its capability to produce photomechanical effects on the treated tissues, due to the very short duration and the very high intensity of the impulse. This phenomenon can produce important therapeutical effects, because such stimulation can trigger biological signals to promote repair and tissue regeneration, together with vascular and lymphatic system activation: previous researches [18,19,20] showed that Nd:Yag laser radiation leads to cellular cytoskeleton reorganization in endothelial, mesenchimal and connective cells, and to their stimulation to extra-cellular matrix production, similarly to mechanical stimulus. Nd:YAG laser stimulation favours extra-cellular matrix production and its assembly, it induces connective cells differentiation and endothelial layers formation, thus promoting tissue repair processes ("regenerative effect").

In knee painful OA more than one treatment protocol are available with this kind of high intensity laser. It is possible to treat pain, using a specific sequential protocol, applied on the joint, on the surrounding tissue and over the muscle tender-trigger points. This treatment showed interesting results, in knee OA and in other joints problems. [2,3,4,14,15]

AIM OF THE STUDY

The present study was an open-label, before-after clinical trial. The aim was to evaluate the clinical and functional efficacy of the HILT treatment, using a biostimulating protocol, in patients affected by symptomatic knee osteoarthritis.

MATERIAL AND METHODS

Patients. Patients suffering for symptomatic KO were recruited for this trial from outpatients of the Recovery and Rehabilitation Agency (AOU Careggi, Firenze). Patients with symptomatic KO, aged were included. Informed consensus was obtained. Inclusion criteria required the presence of symptomatic KO (following ACR criteria [21]), II-III stade of Kellgren-Lawrence Scale [22] on the radiological evaluation. Exclusion criteria were: therapy with oral anticoagulants, non compliant patients (cognitive impairment or psychiatric disorder), neoplastic pathology, and presence of deep vein thrombosis. The patients' evaluation included history and clinical examination.

Initial assessment (t0), before treatment, included WOMAC Scale [23] The patients were randomized in two groups, following the method of random number table.

Treatment. After randomization the patients underwent two different treatments: Group A was treated with High Intensity Laser Therapy (ten sessions, on alternate days), see Table I, whilst Group B was in the waiting list for the treatment. The treated patients were reassessed at the end of the treatment (t1) and after 4 months (t2). The untreated patients were assessed at the same intervals. HILT technique was performed by manual scansion and contact grip, which is used to treat deep organs. We used linear scansion, according to the knee specific access areas (optical windows). Each session provides maximal fluencies and frequencies (fluency 1430-1780 mJ/cm2; frequency 25-30 Hz), with slow scansion in six optical windows, 500 J/window, 3000 J/session. Data analysis. Data of patients were compared by Student t-Test.

RESULTS

Thirty-four patients, for a total of 41 knees, were included in the analysis. 16 and 18 patients respectively were treated with HILT treatment (Group A) or waiting list (Group B). All the patient but two (one in Group A, and one in Group B) finished the study. Baseline data of the two Groups are explained in table II. Mean age was 65.5 years (range: 46-78) and 67, 2 years (range: 45-80) for Group A and Group B respectively, while the proportion of male (M) and female (F) patient was 6 M, 10 F and 6 M, 12 F respectively. WOMAC Scale values at t0 were 41.4 ±9 (Group A) and 40.5 ±5 (Group B).

At t1 the treated group showed greatly different results in the scales points: Group A changed WOMAC values from 41.4 ± 9 to 17.5 ± 5 ($p < 0.001$), whilst Group B WOMAC values were not varied from 40.5 ±5 to 38 ± 2 (p = n.s.), see Table III. At follow-up (4 months) Group A substantially maintained the improvement, with a slight regression: WOMAC scale showed little but statistically significant variations at t2: 24.8 ± 7, while Group B showed a worsening score (t2 = 43.5 ± 1). WOMAC sub items related with pain, stiffness and function were analysed too, see Table IIIa.

These items showed the same tendency of total WOMAC scale scores (see Table IIIa and Table IIIb). At t2 this results showed a regression, which resulted statistically significant (t2 vs. t1 $p<0.005$), but the improvement between t0 and t2 remained highly significant (see Figure 1). In figure 2 is shown the different course of sintomathology in the treated vs. the untreated patients 99, 8% of the Group A patients were improved and 1 patient (0, 2%) was not varied. At follow-up the clinical effects were maintained in 75% of the subjects, while in 25% there was a regression. No HILT-treated patient showed side effects.

HILT treatment protocol (GroupA): pulsed high power laser, Nd:YAG, λ1064nm, (HIRO 3 ASAlaser), for 10 sessions, on alternate days, biostimulating program. This program is articulated in one phase, with low manual scansion and contact grip. Linear scansion was used, according to specific access areas (optical windows). Each session provides maximal fluencies and frequencies (fluency 1430-1780 mJ/cm2; frequency 25-30 Hz), in six optical windows, 500 J/window, 3000 J/session.

Table I: HILTerapia Treatment protocol

DISCUSSION

The data about HILT efficacy in osteo-articular diseases are increasing [1,14,15, 24, 25, 26]. Our study tested the clinical efficacy of the biostimulating laser protocol. Previous studies demonstrated the significant effects using antalgic protocol, which is technically different, as it uses different manual scansion and doses [1,2,3,4].

Our study showed a relevant short-term efficacy of this technique on knee pain reduction and on stiffness and function improvement. The effect was especially evident at the end of the treatment, where it pertains 99, 8% of the pts., and it is maintained by 75% of the subjects after 4 months.

This intense and powerful treatment, achieved a rapid pain control, in almost all the patients. In respect of previous researches [3,4] this antalgic effect was even more likely and evident.

Nevertheless a percentage of the treated subject (25%) showed a certain regression at follow-up. This data was not predictable in relation to the rationale of the study. A merely speculative explanation could be that photomechanical effect is the main responsible of the antalgic response, but that our treatment duration was not till

	Pats. number	Mean age	sex	WOMAC Scale
GROUP A	16 (21 knees)	65.5±1	10 F, 6 M	41.4 ±9
GROUP B	18(20 knees)	67.2± 3	12 F, 6 M	40.5 ±5

Table II: Groups baseline characteristics

	WOMAC Scale - t0	WOMAC Scale - t1	WOMAC Scale - t2
GROUP A	41.4 ± 9	17.5 ± 5	24.8 ± 7
GROUP B	40.5 ±5	38.6 ±2	43.5±1

Table III:
WOMAC Scales Values at t0, t1 and at the follow-up (t2) of the two Groups

WOMAC	t0	t1	p-value
Total (0-96)	41,4 ± 9	17,5 ± 5	p<0.001
Pain	6,8	3,1	p<0.005
Stiffness	3,9	1,2	p<0.001
Function	30,8	13,8	p<0.001

Table III A:
WOMAC Scale Values (total and sub-items) before treatment (t0), at the end of treatment (t1) in the HILT treated group

WOMAC	t0	t1	p-value
Total	17,5 ± 5	24,8 ± 7	p<0.005
Pain	3,1	4,5	p.n.s.
Stiffness	1,2	2,4	p.n.s.
Function	13,8	16,1	p.n.s.

Table III B:
WOMAC scale Values (total and sub-items) at the end of treatment (t1) and at follow-up (four months)(t2) in the HILT treated Group

WOMAC	t0	t1	p-value
Total	41,4 ± 9	24,8 ± 7	p<0.001
Pain	6,8	4,5	p<0.005
Stiffness	3,9	2,4	p<0.005
Function	30,8	16,1	p<0.001

Table III C:
WOMAC scale Values (total and sub-items) before treatment (t0) and at follow-up (t2) four months) in the HILT treated group

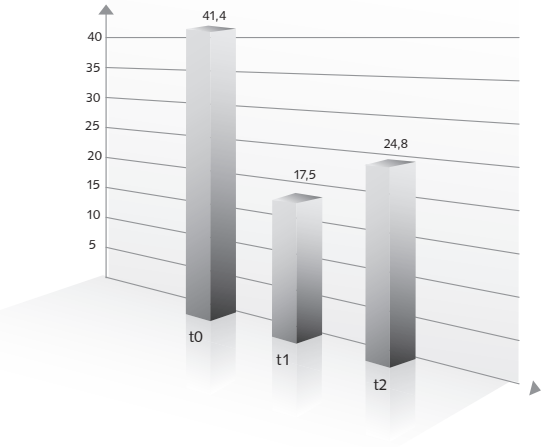

Figure 1: Results of the HILT- treated patients

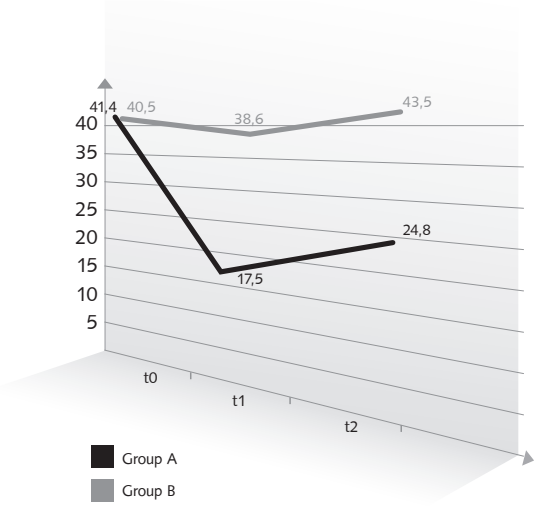

Figure 2: Course of sintomathology in the treated vs. the untreated patients, according to WOMAC scale (Group A: Hilterapia, Group B: no treatment): the untreated group did not improve, rather it got worse.

sufficient to stimulate more permanent cellular reactions, eventually more than ten sessions are needed to reach this result. We are aware that this study has got some limits. Firstly we do not have the prove of the molecular intra-articular effects: we cannot demonstrate the stimulation of the connective cells, but only clinical effects. Secondly it has small numbers of patients and there is not a control group of differently treated patients (i.e. placebo laser therapy).
So the work must go on: as several researches found HILT efficacy, we need to increase the patients population and to find standard therapy programmes regarding the dose and duration of the laser therapy to optimize the treatment.
Different HILT regimes were applied in painful Knee OA, with different doses and duration [1,2,3,4] and it seems that these various HILT therapy regimes were all safe and effective methods in the treatment of knee OA.

CONCLUSIONS

In conclusion, this study revealed that a short-period application of HILT biostimulating protocol is more effective in pain reduction and in functional ability improvement than no treatment in patients with symptomatic knee OA. Thus, HILT can be an important instrument in pain control contributing to the long-term management of chronic painful knee. The study confirms the safety of the technique.

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