Key words: Knee osteoarthritis, viscosupplementation, laser therapy, HILT, Hilterapia®

Effects of Hilterapia® vs. Viscosupplementation in knee osteoarthritis patients: a randomized controlled clinical trial.

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ABSTRACT

Therapeutic approach in Knee Osteoarthritis (KO), a long lasting disease with both epidemiological and social implications, may consider local interventions which are useful along the course of the pathology. Viscosupplementation has got efficacy with little side effects. Lasertherapy (Low Level Laser Therapy-LLLT-) is widely used but we don't still have sure demonstrations on its efficacy. High Intensity Laser Therapy (HILT, Hilterapia®) seems to be more effective than LLLT, due to its higher intensity and to the depth reached by the laser ray.

The aim of this study was to compare the efficacy of Hilterapia® to viscosupplementation in patients with symptomatic KO.

41 out-patients with symptomatic KO (II-III Kellgren-Lowrence Scale stage) were enrolled and evaluated by WOMAC and Lequesne Scales, before treatment (t0), after treatment (t1) and after 4 months (t2). After randomization, the treatment consisted in viscosupplementation (4 Hyaluronic acid infiltrations 1/week) for Group A, or Hilterapia® (antalgic treatment, 10 sessions, three time a week) for Group B.

Both the groups (A and B) showed a highly statistically significant improvement between t0 and t1 in WOMAC and Lequesne Scales. The improvement was maintained at follow-up (t2) either by Group A or Group B. No side effect was found, neither in Group A nor in Group B.

Hilterapia® showed analogous results to viscosupplementation. We conclude that Hilterapia® seems a good medical instrument for pain control and for improvement of patient's quality of life.

INTRODUCTION

Although underestimated, knee osteoarthritis (KO) is an important pathology, with both epidemiological and clinical implications [1, 2]. KO is a complex disease whose pathogenesis includes the contribution of biomechanical and metabolic factors [3, 4] which gradually lead to articular joint tissues destruction. As the disease progresses, clinical features include joint pain, limitation of movement, tenderness, and episodic inflammation. Especially among the elderly, chronic pain and disability can develop [5, 6]. Disability is directly correlated with pain level. Pain control, together with the control of the disease progression are the two main targets of the therapeutic approach.

EULAR recommendations for the management of osteoarthritis include pharmacological and non-pharmacological treatment modalities [7]. Considering the frequent side effects of long-term systemic pharmacotherapy [8], local treatments may be useful, such as instrumental physiotherapy or intra-articular injections. Viscosupplementation with hyaluronic acid (HA) represents one of the possible local treatments [9, 10, 11, 12]. Among physiotherapic treatments, Low Level Laser Therapy (LLLT) has been often proposed for pain and flogosis control in osteoarthritis, although no conclusions could be drawn on the optimal dose, the wavelength and the duration of treatment [13].

Some preliminary studies [14, 15, 16] indicate that High Intensity Laser Therapy (HILT, Hilterapia®), a more recent laser application modality, can be more effective than LLLT in pain and flogosis control, due to its more intense and deeper effects.

The present study was a prospectic, open-label, randomized clinical trial.

The aim was to evaluate the clinical and functional efficacy of Hilterapia®, compared with viscosupplementation, in patients affected by symptomatic knee osteoarthritis.

MATERIALS AND METHODS

Patients. Patients suffering for symptomatic KO were recruited for this trial from outpatients of the Recovery and Rehabilitation Agency (AOU Careggi, Firenze). Forty-one patients with symptomatic KO, aged 50-85 years, were included. Informed consensus was obtained. Inclusion criteria required the presence of symptomatic KO (following ACR criteria [17]), II-III and IV stade of Kellgren-Lawrence Scale [18] on the radiological evaluation. Exclusion criteria were: therapy with oral anticoagulants, non compliant patients (cognitive impairment or psychiatric disorder), neoplastic pathology, presence of deep vein thrombosis. The patients' evaluation included history and clinical examination. Initial assessment (t0), before treatment, included WOMAC Scale [19] and Lequesne Scale [20].

The patients were randomized for treatment in two groups, following the method of random number table.

Treatment. After randomization the patients underwent two different treatment

protocols: Group A was treated with hyaluronic acid intraarticular infiltrations (4 infiltrations, 1 session/week, mw 500-1000 kD), whilst Group B was treated with Hilterapia® by pulsed Nd:YAG laser (HIRO 3 ASA S.r.l., Vicenza, Italy): ten sessions on alternate day, see Table I.

Hyaluronic acid infiltrations protocol (Group A): 4 sessions of Hyaluronic acid infiltrations, molecular weight 500 -1000 kD, once a week. Infiltration is performed by anterior access with supine patient and flexed knee.

Hilterapia® protocol (Group B): pulsed high power laser, Nd:YAG, ◘1064nm, 10 sessions, on alternate days, analgesic program, in manual scansion. This program is articulated in three phases (initial, intermediate and final phase). Every phase is articulated in sub-phases in which increasing fluency (510-710 J/ cm 2) and decreasing frequency (15-10 Hz) are administered, total energy 2000-3000 J. The total session duration is 15-20 minutes.

Table I: Treatment protocol of the two groups

The patients were reassessed at the end of the treatment (t1) and after 4 months (t2).
Data analysis. Data of patients were compared by Mann-Whitney and Wilcoxon tests.

RESULTS

Forty-one patients were included in the analysis. 22 and 19 patients respectively were randomized to hyaluronic acid treatment (Group A) and Hilterapia® (Group B). All the patient but one (Group A) finished the study. Baseline data of the two Groups are explained in table II.
Although this was a randomized comparative study, the small number of patients did not guarantee against differences between treatment groups' baseline characteristics. The experimental groups resulted not exactly balanced for all the variables collected at baseline. Nevertheless the two groups resulted comparable and the resultant variables were not related to the initial differences. Median age was 74.4 years (range:53-84) and 70.2 years (range:54-81) for Group A and Group B respectively, while the proportion of male (M) and female(F) patient was 2 M, 17 F and 5 M, 17 F respectively. WOMAC Scale values at t0 were 51.7 ±11 (Group A) and 46.3 ± 3 (Group B); Lequesne Scale values at t0 were 12.3 ± 4 (Group A) and 14.4 ± 3 (Group B), see Table II.

	Pats. number	Median age	sex	WOMAC Scale	Lequesne Scale
GROUP A	22	74.4 yrs. (53-84)	2 M, 17 F	51.7 ±11	12.3 ± 4
GROUP B	19	70.2 yrs (54-81)	5 M, 17 F	46.3 ± 3	14.4 ± 3

Table II: Groups baseline characteristics

	WOMAC Scale t0	WOMAC Scale t1	WOMAC Scale t2
GROUP A	51.7 ± 11	35.5 ± 13 (p< 0.001)	31.4 ± 18
GROUP B	46.3 ± 3	26.7 ± 7 (p<0.001)	28.2 ± 13 (p:ns)

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

	Lequesne Scale t0	Lequesne Scale t1	Lequesne t2
GROUP A	12.3 ± 4	9.1 ± 3 p< 0.001	9.7 ± 5 (p:ns)
GROUP B	14.4 ± 3	9.2 ± 4 p<0.002	9.6 ± 4 (p:ns)

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

At t1 the two groups showed improvement in the scale points: Group A changed WOMAC values from 51.7 ± 11 to 35.5 ± 13 (p< 0.001). WOMAC values of Group B varied from 46.3 ± 3 to 26.7 ± 7 (p<0.001), see Table III and Figure 1. t1 Lequesne values were 9.1 ± 3 (Group A) and 9.2 ± 4 (Group B), and these results were statistically significant versus t0: p< 0.001 and p<0.002 respectively, see Table IV and Figure 2. At follow-up (4 months) both the two groups maintained the improvement: t2 Lequesne values were 9.7 ± 5 for Group A, and 9.6 ± 4 for Group B. WOMAC scale also showed little variations at t2: 31.4 ± 18 for Group A and 28.2 ± 13 for Group B. At 4 months follow-up there was a little tendency towards improvement in Group A, whilst a little worsening was seen in Group B, but WOMAC and Lequesne values at t2 showed little variations, reaching no statistical differences, neither in Group A nor in Group B versus t1 values. WOMAC sub item related with pain was analysed too, see Figure 3. This item showed the same tendency of total WOMAC scale scores (see Figure 3).
No patient, in Group A neither in Group B,

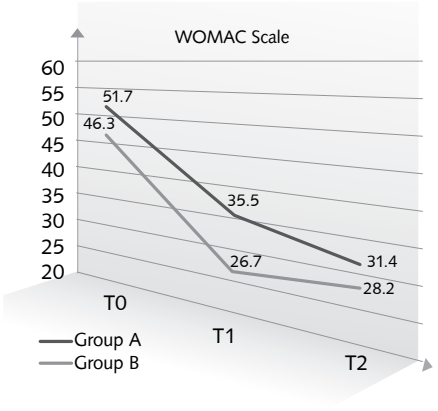

Figure 1: WOMAC Values before treatment (t0), at the end of treatment (t1) and after 4 months.

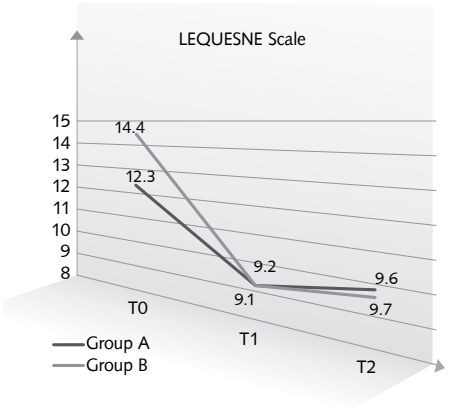

Figure 2: Lequesne Values before treatment (t0), at the end of treatment (t1) and after 4 months.

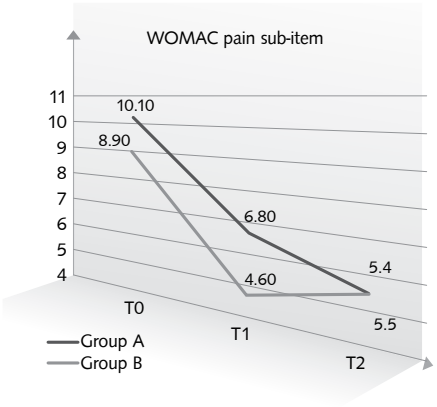

Figure 3: WOMAC pain sub-item values before treatment (t0), at the end of treatment (t1) and after 4 months.

showed side effects.

DISCUSSION

WOMAC and Lequesne Scales are functional measurements, as they both investigate domains as pain, gait, and knee related ADL [19, 20, 21].

Scientific literature shows that knee pain and age are important determinants of functional impairment in elderly subjects [22, 23, 24]. Knee pain is central to daily living, and experiencing mobility limitations devalues self-worth [25, 26]. Pain control represents one of the principal tasks in KO, especially in order to get over acute phases. Viscosupplementation [27, 28] is a well known and accepted modality to improve pain and perhaps the osteoarthritis evolution too. It has reached evidence based demonstrations, reported through recent reviews [13, 28].

Among instrumental physical therapy the effectiveness of low level lasertherapy has been often investigated with variable results. Despite a widespread use of this technique, a recent Cochrane review [13] didn't succeed in demonstrating a sure effect of lasertherapy, mainly due to methodological causes of the studies (differences in number of cases, doses and wavelength of laser, etc.). Traditional lasertherapy, which is a low level laser therapy, has got some limits, especially related both to a poor penetration and to a low intensity of the light radiation [29]. Experimental data [30] seem to enhance the hypothesis that high intensity laser therapy may overcome these difficulties, and the first clinical studies confirm its efficacy [14, 15, 16]. Our study aimed to investigate the clinical efficacy of Hilterapia® in KO, compared with viscosupplementation, which is nowadays a good reviewed medical treatment, and it is accepted following EBM criteria too.

In relation to hyaluronic acid effects, our results agree with precedent literature findings, as the patients treated with intra-articular injections improved significantly, at the end of the treatment and at follow-up. The evolution of the improvement indicates a long-acting effect, as the results are maintained, and perhaps improved, at follow-up. In our study, Hilterapia® (antalgic program) showed a great efficacy too, comparable with viscosupplementation, achieving a rapid pain control and its maintenance till 4 months. Local clinical experiences strengthen the Hilterapia® efficacy, but, till today, sufficient proven data are very few. Our study gets into these first clinical researches, as a preliminary work. We don't still know which is the optimal sessions timing for the best results in KO patients. In our study we found a good clinical efficacy using a treatment protocol of 10 sessions on alternate days, but in this initial experience it seemed to us that patient's improvement begins rapidly during the first sessions, reaching a plateau.

To verify this hypothesis we are now using a shorter protocol, which provides the same laser program, 5 sessions on alternate days. The short term effects seem equally very good, but we don't still have the definitive and the follow-up data.

CONCLUSIONS

Viscosupplementation confirms its efficacy in KO, and Hilterapia® showed analogous results to hyaluronate acid treatment, at least in the medium term. From our data Hilterapia® appears to be a good medical instrument for pain control in KO, with consequent improvement in patient's quality of life. It has a rapid and long lasting effect, it is a non invasive technique and no side effects were reported. Our preliminary results suggest that Hilterapia® may be a useful resource in the management of knee osteoarthritis.

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