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Osteopathic manipulative treatment results in sustained relief from spinal pain in older patients: A pilot crossover study.

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ABSTRACT

Osteopathic Manipulative Treatment is commonly used to complement conventional treatment of back pain. The present study verified whether OMT, associated with training program, reduces spinal pain in older. A pilot randomized, double-blind crossover study was conducted at Sport Association of Milan, Italy. We recruited 19 subjects above 60 years old, with presence of SP for more than 3 weeks and with intensity score higher than 3 (NRS score). All patients underwent a multi-component group exercise program for older adults and were randomized in two groups: in the study group (SG) OMT was added, while the control group (CG) continued with the exercise only. After 6 weeks a crossover was applied to the 2 groups and OMT was added to CG, while SG continued with the exercise only. Self-reported measures: the Numeric Rating Scale (NRS) was used at each time to evaluate treatment outcomes. At pre-crossover, SG had a significant improvement in pain perception ($p<0.05$), while CG had a not significate improvement in pain perception ($p=0.33$).At post-crossover, the SG remains relatively stable ($p=0.37$), while CG after OMT addition have a significant benefit on pain perception ($p=0.001$). At follow-up, pain improvement is sustained ($p=0.32$). OMT associated to exercise reduce spinal pain in older patients. Our study suggests that OMT associated to exercise leads to significant improvement on pain relief in patients with chronic SP in a short term and the exercise allows to maintain these improvements for several months.

Keywords: Osteopathic manipulative treatment; spinal pain; exercise; back pain; musculoskeletal pain; older pain.

INTRODUCTION

Persistent pain is one of the most common and compelling reasons for seeking treatment [1;2] and represents a common symptom and a significant problem for older adults [3;4]. Prevalence ranges from 41% for back pain to 12% for chest and facial pain [5].

Spinal pain (SP) refers to pain felt in the region of the spine, which might originate from the spine itself (intervertebral discs, facet joints), or from nearby structures, including ligaments, fascia, muscles and nerve root dura [6;7] and has a prevalence of 27% in the elderly [8]: the most frequent manifestations include low back pain (LBP) and neck pain (NP).

Musculoskeletal structures, including arthrodial joints and myofascial elements, and related vascular, lymphatic, and neural structures all contribute to the somatic system. An alteration of the homeostatic equilibrium that regulated this system, referred to as "somatic dysfunction" in osteopathic medicine [9], might contribute to the generation of SP.
The pathophysiology of SP remains poorly understood [10] and the long-term pain management is difficult [11]. The aim of interventions for SP is to relieve pain and improve function through coping strategies. The main treatments are physical therapy, back exercise, pharmacological treatment (Non steroid inflammatory drugs, NSAIDs and opioids), epidural corticosteroid injection and lumbar supports. Other strategies include the use of acupuncture, heat therapy and transcutaneous electrical nerve stimulation [12]. The efficacy of these treatments is however somehow limited. Opioids have important side effects including dizziness, drowsiness and potential

addiction. NSAIDs have been clearly implicated in gastric ulceration and bleeding, have important kidney toxicity and might contribute to atherothrombosis [13].

Non pharmacological treatments for SP focuses on providing patients with education, advice and information that promote self-management, including suggestions on increasing the level of physical activity and encouragement to remain always physically active [14].

Osteopathic manipulative treatment (OMT) is commonly used to complement conventional treatment of musculoskeletal disorders, including those that cause LBP. American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment for Patients With Low Back Pain states that OMT is sometimes effective at reducing pain [15], including that in the lumbar and sacrum/pelvis region which has been shown to be directly associated with back-specific disability and inversely associated with the general patient health status [9]. We have recently observed that OMT significantly enhances the efficacy of the pharmacological treatment of chronic pain associated to injury of the spinal cord [16].The aim of present study was to verify whether OMT, associated with training program, is effective to reduce SP in older people and whether the benefit is maintained after treatment discontinuation.

MATERIALS AND METHODS

Study. A pilot randomized, double-blind crossover study has been performed between January 2010 and September 2010. Patients underwent a simple long-term physical activity training program for older adults aimed at increasing aerobic, muscle-strengthening, flexibility and balance activity based on the classification of recommendations and level of evidence are expressed in American College of Cardiology/American Heart Association (ACC/AHA) format [17]. Patients were randomized, from a computer-generated list using block randomization, in two groups: in the study group (SG, 9 subjects) OMT was added, while the control group (CG 10 subjects) continued with the exercise training program only. The two groups were matched for age (9 vs 10) and sex. After 6 weeks (T1) a crossover was applied to the 2 groups and OMT was added to the control group (CG), while the study group (SG) continued with the exercise training program only. At T0 we obtained from all patients: demographic and clinical characteristics, pain localization, pain onset, use of drugs for pain control. All patients were evaluated, from examiner, three times, i.e. after six (T1-crossover) and twelve (T2) weeks from the beginning of the study and at the follow-up after five weeks from the end of the protocol treatments (OMT and exercise) (Fig. 1).

Ethic. The authors declare no conflict of interest and no commercial or other source of funding was received. This study was conducted in accordance with the Helsinki Declaration, written informed consent was obtained from the patients and was specifically approved by Local Ethic Committee related to the institution in which it was performed.

Subject. Patients were unrolled by a physical of sport, that worked at Arciuisp Sport Association of Sesto San Giovanni, Milan, Italy, through flier advertisements. 19 subjects with non-specific chronic SP were recruited and they attended the gym lessons at least 10 years. Inclusion criteria were age above 60 years, the presence of clinical diagnosis of SP, performed by general practitioner, for more than 3 weeks, with intensity score higher than 3 measured with the Numeric Rating Scale (NRS), for pain iintensity. Exclusion criteria were spinal fracture, spinal osteomyelitis, herniated disk, ankylosing spondylitis, cauda equine syndrome, musculoskeletal injury, radicular pain, traumatic injury, visceral pain and cancer.

Outcome measurements. Numeric Rating Scale (NRS), that is a validated scale to measure the intensity of pain, with numbers between 0 and 10, with 0 representing absence of pain and 10 the worst possible pain experienced by the patient.

Osteopathic manipulative treatment. The OMT protocol based on osteopathic principles of body unit, structure-function relationship and homeostasis [15], was designed for each patient on the basis of the results of the osteopathic examination and included myofascial release, strain–counter strain, muscle energy, soft tissue, cranial sacral and visceral approach.

The manipulation techniques of the OMT protocol were administered in the following sequence: dorsal e lumbar soft tissue, rib raising, back and abdominal myofascial release, cervical spine soft tissue, suboccipital decompression, sacro-iliac myofascial release [15]. Soft tissue technique consists of massage, stretching, kneading, and direct inhibitory pressure to relax the musculature. Rib raising articulates each rib for the purpose of improving rib cage motion and theoretically stimulates the sympathetic chain ganglia. Myofascial release is a method for reducing tissue tension. Back and abdominal myofascial release techniques are used to improve back movement and

internal abdominal pressure. Suboccipital decompression involves traction at the base of the skull, which is considered to release restrictions around the vagus nerves, theoretically improving nerve function. Sacro-iliac myofascial release are used to improve sacro-iliac joint movement and for reducing ligament tension. Strain-counterstrain and muscle energy technique are used for reducing the presence of trigger points and their pain intensity.

OMT was repeated once every fortnight during 6 weeks for each group, for a total of 3 treatments. Each treatment was administered by an osteopathic physician and lasted 45 minutes.

Exercise protocol. An assigned professional health specialist carried out the exercise protocol, that was developed based on and the Methodology Manual for ACC/ AHA Guideline Writing Committees. The progressive exercise intensity was depending on each person and the clinical objective was to reduce the risk of chronic back pain and functional limitations. The frequency of session gym was two days each week. The sessions were organized followed this methodology: aerobic, muscle-strengthening and flexibility activity. Aerobic activity based on moderate-intensity aerobic physical activity for 20 min, that involves a moderate level of effort relative to an individual's aerobic fitness. This activity was in addition to routine activities of daily living of light-intensity or moderate-intensity activities lasting less than 10 min in duration. Muscle-strengthening activity was performed on 8–10 exercises using the major muscle groups. To maximize strength development, a resistance was used that allows 10–15 repetitions for each exercise. The level of effort for muscle-strengthening activities started moderate to become high. Muscle-strengthening activities included a progressive-weight training program and similar resistance exercises that use the major muscle groups.

Flexibility activity, necessary for regular physical activity and daily life, was performed activities that maintained or increased flexibility for 10 min. The regular sessions that lasted 60 minutes twice a week.

Statistics. All analyses were calculated by using an intention-to-treat approach with parametric test, because the data were normally distributed. Continuous data and categorial data were analyzed by t-test and Fisher exact test. Differences in NRS scores between SG and CG at T0-T1, T1-T2 and T2-follow-up time were investigated by repeated measures ANOVA, including the "pain" (NRS scores) as dependent variable, "time" (T0,T1,T2 and follow-up) as the repeated-measures factor, "groups" (study and control) as between-subjects factors and onset and duration of physical activity as covariate. Both main effects, effects of interaction between factors were considered. The evaluation of the relation between onset and duration of exercise and OMT effect and exercise effect alone was calculated with Pearson's correlation. To estimate OMT effect and exercise alone it was used delta NRS scores between T0-T1 (Δ T0-T1), T1-T2 (Δ T1-T2), T2-follow-up (Δ T2-follow-up). The significance level (α) was considered at .05. The Statistical Package for Windows (SPSS Inc. Chicago) was used for statistical analyses.

RESULTS

Demographic characteristics of participants are presented in Table 1.

At T0 patients were randomized in two groups, 9 in the study group (SG) and 10 in the control group (CG). Both groups were homogenous for age, sex, weight, height, SP duration and pain duration (Table 1) and for NRS scores (p=0.40) (Table 2).

Repeated-measures ANOVA analysis within-subjects reveals a statistically significant interaction between time and groups (F=10.23; p=0.006). Between-subjects analysis shows a significant difference between groups (F=5.05; p=0.04). Patients within the SG had a significant improvement in pain perception six weeks after addition of OMT (T1: 3.90±0.72 vs 6.14±0.68, p=0.33) (Table 2). The covariate analysis (onset and training duration) reveals a significant effect of training duration on pain relief in the CG only (F= 6.51, p=0.038). In fact, a significant positive correlation in this group exists between Δ T0-T1 and training duration (r=0.70, p=0.023), indicating that OMT is required for the beneficial effect of exercise on SP.

Six weeks after crossover (T2), the repeated-measures ANOVA analysis within-subjects shows a significant interaction between time and groups (F=19.24; p=0.001). In addition, the t-test analysis for independent sample at T2 highlights that CG and SG have similar NRS values (3.16±3.1 vs 2.70±2.00; t=0.37, p=0.70): pain perception within the SG remains relatively stable six weeks after OMT discontinuation (t=-0.94, p=0.37). Conversely patients within the CG after OMT addition have a significant benefit on pain perception, as assessed by their NRS scores (t=9.00, p=0.001) (Table 3). ΔT1-T2 and treatment duration do not correlate after addition of OMT into CG (r=0.32;p=0.37). Repeated-measures ANOVA analysis within-subjects carried out at follow-up indicate that pain improvement is sustained (F=1.04; p=0.32), without interaction between time and group (F=0.002; p=0.96) (Fig. 2).

Between-subjects analysis does not show significant differences between groups (2.67±2.74 vs 2.15±2.01; F=0.24; p=0.63) (Table 4).

DISCUSSION

The aim of present study was to verify if OMT, associated to a regular training program, is effective at reducing SP in older adults in the short and long term. Indeed we found that the treatment is effective, with prompt and significant improvement of pain perception in both groups of subjects at the pre and post-crossover ($p<0.05$) and that the pain relief is sustained for several weeks (up to five months) even after OMT discontinuation.

In contrast, we did not observe a significant pain relief in older adults undergoing the training program *per se*. A significant pain improvement correlated with training duration (p=0.038). At least two reasons could be involved in this apparent discrepancy. On the one hand we have studied a relatively small patients cohort and as such only relatively important differences can be identified. On the other hand, recruited subjects had already been trained according to the guidelines of the American College of Sport Medicine for a substantial time span (11.53±9.35 years, Table 1). Indeed, most previous studies exploring the benefit of a regular training program have focused on overall unselected elderly populations, including a relatively important fraction of sedentary subjects [18;19;20]

There are many studies, in literature, that report the efficacy of exercise [21;22] and OMT [23;24] in pain management, with improvement of LBP and NP. Of importance, the reliefassociated to OMT and exercise *per se* is in these studies relatively short-lasting. Previous studies in particular report the efficacy of OMT in LBP and NP management [23;24]. Our study thus had been not designed to confirm this information, but to verify whether we could overcome the major limitation, *i.e.* the relatively short duration of the relief. Indeed the combination of OMT with a relatively simple training program results in greater short-term pain reduction than exercise only and in more sustained benefits across multiple outcomes in comparison to only OMT.

It is not clear which are the mechanisms underlying the results we have obtained. Both exercise and OMT might have an effect on the endocannabinoid system and on the inflammatory axis [25;26], thus favoringhypoalgesia [27]. Moreover, exercise programs of sufficient intensity and duration result in the release of peripheral and central beta-endorphins, which have been associated with changes in pain sensitivity [28]. An interaction between pain modulation and the cardiovascular system might also be involved [29]. In fact, pain regulation and blood pressure control involve the same brain stem-nuclei, neurotransmitters (*e.g.* monoamines) and neuropeptides [30]. Additionally, blood pressure and heart rate increase during aerobic and isometric exercise, and these changes have been associated with alteration in the sensitivity to painful stimuli.

OMT is supposed to influence the function of related components of the somatic system that establish complex feedback mechanisms between the brain, spinal cord, peripheral nerves and musculoskeletal structures [15], reducing the pain caused from central sensitization mechanisms and cytokine release [31;32;33;26;34]. In a recent study in particular a reduction in the concentration of the prototypic inflammatory cytokine TNF-α has been reported after 12 weeks of OMT and the change was associated with the extent of the clinical benefit [26]. Further study are necessary to verify whether this variation is indeed responsible of the pain relief and OMT and exercise may serve to effectively reduce cytokines concentration and thereby alleviate pain in patients with chronic SP or just represents an epiphenomenon. The epidural administration of the TNF-α inhibitor, etanercept leads to significant improvement of sciatica [35;36], even if the effect appears smaller than that of corticosteroids and in some cases of placebo [37;38].

Our study has limitations. The sample size is relatively small and might not be representative of the overall elderly population. Moreover we used selection criteria in a patient population largely composed of persons in fair physical condition, used to regular physical training and with relatively little secondary gain. We have excluded patients with significant coexisting co-morbidities, which are likely to cause a lower response rates. As such, we have studied a relatively homogenous group of older adults. Therefore, further studies are warranted to verify whether the response rates we have observed are representative of those we could observe in the unselected population of older patients, including previously untrained sedentary subjects, and whether this approach can be safely translated to the clinical practice even for patients aged 80 and over.

In conclusion, our study suggests that OMT associated to regular exercise leads to significant and early improvement of pain in patients with chronic SP and that exercise allows to maintain these improvement for several months. This could be explained by the effect that both treatments have on of the expression of inflammatory signals correlated to SP, but it is not clear thus far which are the mechanisms underlying this effect. Further study is necessary to dissect the events underlying the augmentation effect of exercise on OMT into SP management.

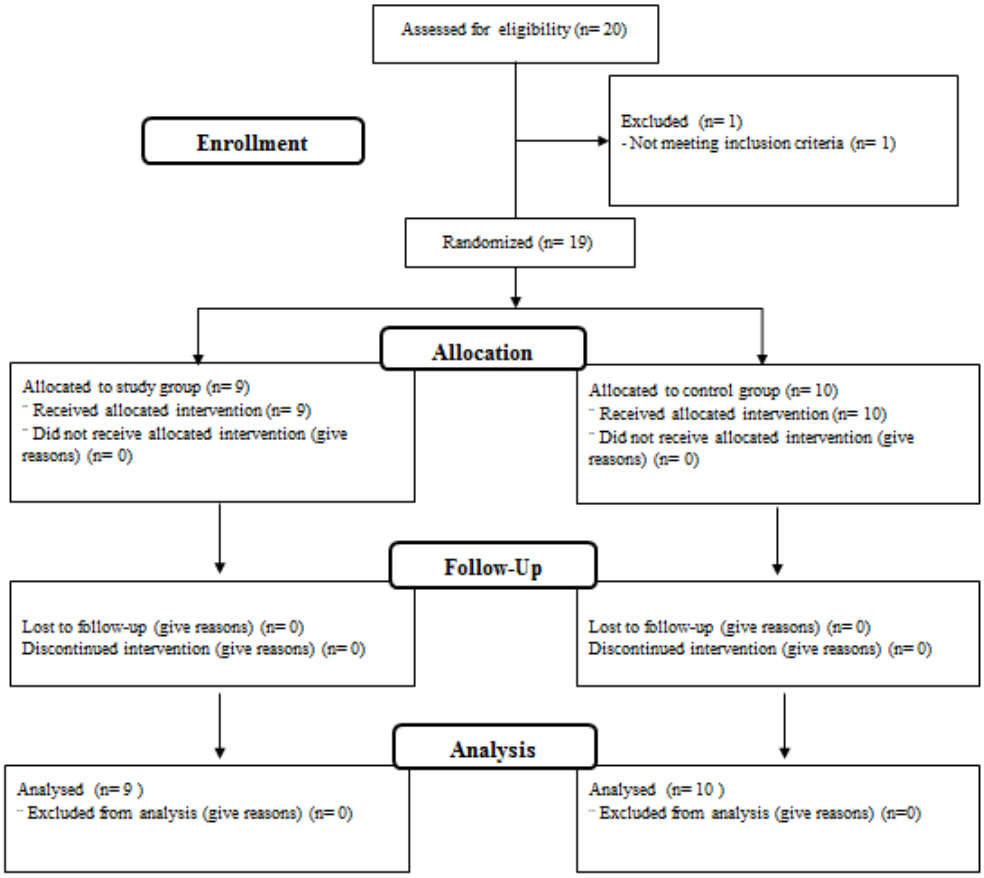

Figure 1: **flowchart of study design.**

The flowchart of the study design that reports: how many patients were recruited with inclusion and exclusion criteria, evaluation times, crossover time and treatment for each groups.

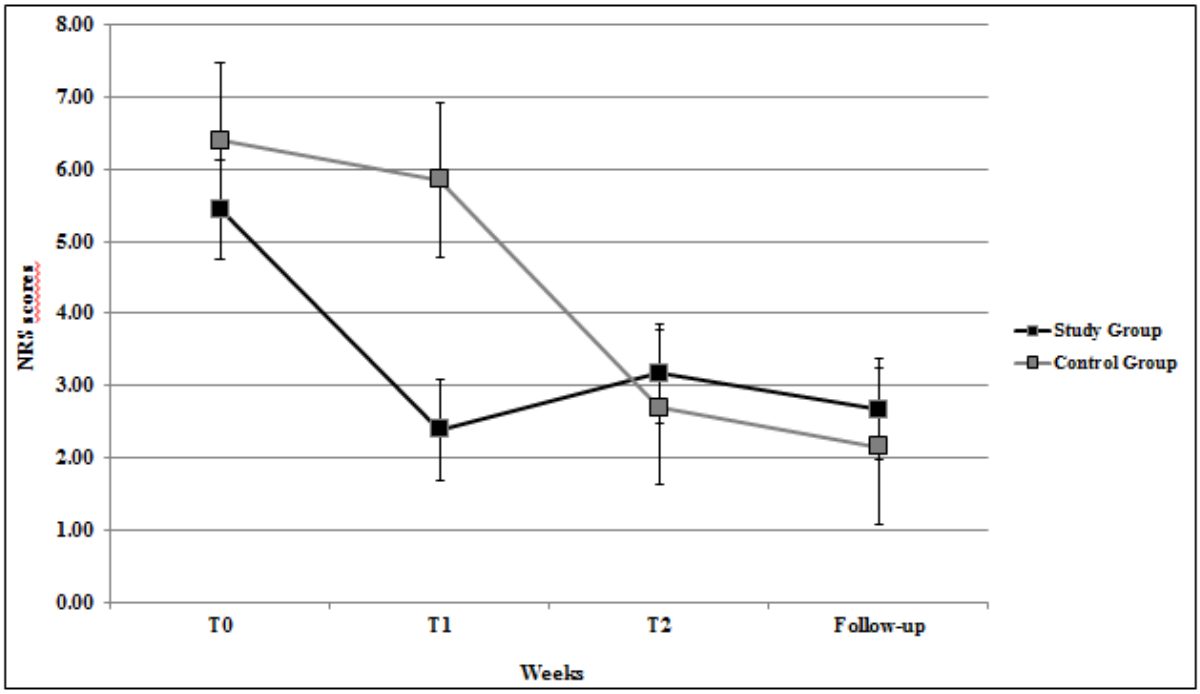

Figure 2: **pain perception from T0 to follow-up.**

Pain trend in study and control groups pre and post crossover (T1) at various treatments time points (between T0 and follow-up). Pain perception was evaluated by VNS evaluation (mean, y axis) in patients that underwent osteopathic manipulative treatment and a regular exercise program (SG) or the regular exercise program only (CG) pre and post-crossover (T1) at various time points T0→follow-up (weeks, x axis).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Characteristics	Study (9)	Control (10)	p
Age (years)	68.9±6.60	69.8±6.86	0.77*
Sex (F:M)	8F:1M	9F:1M	0.74**
Weight	71.00±12.64	67.70±11.58	00.56
Height	162.00±7.61	157.10±10.46	00.26
Pain duration (years)	11.66±12.94	15.00±11.72	0.56*
Training duration pre-OMT (years)	12.66±9.69	10.50±9.43	0,04306
Drugs use (answer yes)	5	2	0.13**
Other sports	5	4	0.41**
**Independent samples T-test*			
***Fisher exact test*			

Table 2.NRS scores at time T0-T1

Groups	T0	T1 (cross-over)	p*
Study	5.44±1.94	3.90±0.72	**<0.05**
Control	6.40±2.80	6.14±0.68	0.33
Δp	0.40	**<0.05**	
**ANOVA repeated measures α<0.05 significant level*			

Table3. NRS scores at time T1-T2

VNS	T1 (cross-over)	T2	p*
Gr. Studio	3.90±0.72	2.70±2.00	0.37
Gr. Controllo	6.14±0.68	3.16±3.1	**<0.05**
*Δp**	**<0.05**	0.70	
**ANOVA repeated measures α<0.05 significant level*			

Table 4.NRS scores at time T2-Follow-up

Groups	T2	Follow-up	p*
Study	2.70±2.00	2.67±2.74	0.54
Control	3.16±3.1	2.15±2.01	0.44
Δp	0.70	0.63	
**ANOVA repeated measures α<0.05 significant level*			

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