

A randomized control trial on the effectiveness of osteopathic manipulative treatment in reducing pain and improving the quality of life in elderly patients affected by osteoporosis

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Summary

Introduction. In the elderly population, a decrease in bone mineral density (osteoporosis) is often associated with a decrease in quality of life and an increase in self reported body pain. This pain originates from the musculoskeletal system and can potentially affect different areas of the body.

Aim. The aim of this study was to investigate the effect of osteopathic manipulative treatment (OMT) on self reported pain and quality of life in an elderly population.

Design. Randomized placebo controlled trial.

Methods. Patients were recruited from the Geriatric Department, Bassini Hospital (Milan, Italy). Patients were randomly assigned to either 6 sessions of OMT (n = 37 patients) or an equivalent number of sham manipulative treatment (SMT) (n = 35 patients). The main outcome variables were QOL measured by QUALEFFO -41 and overall bodily pain measured using a visual analog scale (VAS). Data were analyzed using a two factor ANOVA (treatment x time) for repeated measurements with an α level set at $p \leq 0.05$.

Results. Main result of this study was that OMT compared to SMT showed a significant decreased of disability. This effect was demonstrated by a significant interaction in the overall disability score ($p = 0.001$) and the Mental wellbeing ($p = 0.058$), Health perception ($p = 0.005$) and Pain ($p = 0.003$) QUALEFFO -41 subscales, while no significant difference (no interaction) for pain as measured by VAS and for the Daily activities, Walking, Household cleaning and Leisure time activities QUALEFFO -41 subscales ($p > 0.05$) was found. No adverse effects were recorded during the study.

Discussion. This study demonstrated that, in a group of el-

derly subjects affected by osteoporosis OMT was able to increase self reported QOL while the effect on body pain perception is unclear. This overall improvement in QOL appears to be caused by an improvement in psychological factors (i.e. Mental wellbeing and Health perception) rather than physical factors. In fact, all QUALEFFO -41 subscales related to physical function demonstrated no significant interaction. The effect of OMT on Pain perception is less clear. In fact, there was no effect on pain as assessed by VAS while a significant improvement was observed when the QUALEFFO -41 subscale was used. This could be due to the metric properties of the two pain measurement methods; an alternative explanation could be that VAS measures mainly pain quantity while QUALEFFO -41 subscales measures mainly pain quality. The lack of effect of OMT on physical function needs to be confirmed by more direct measurements of this variable.

KEY WORDS: osteoporosis; osteopathic treatment; quality of life; pain.

Introduction

The definition of the disease osteoporosis is based mainly on pathologic criteria that give special characteristics of skeletal fragility that make the bone susceptible to fracture even from modest trauma. In the fourth decade of life there is already a progressive loss of bone mass and a processes of transformation that can cause bone deformities of the same bone architecture and an increased susceptibility to fractures (1-4).

Several studies have demonstrated the relationship between bone mineral density (BMD) and deterioration of some aspects of quality of life (5-11).

The cost to the National Health Service (NHS) for 79 known drugs (12) used for osteoporosis is around 500 to 600 pounds per year per patient (13-17), if one calculates that the incidence of osteoporosis in the elderly in Italy, is around 18% to 25% in men and in women (24) and that the benefits of the new Note 79 extend to 1.2 million patients (14-17), it is easy to deduce that the incidence of osteoporosis on health spending is considerable.

In addition the cost of social work and hospital admissions for the loss of autonomy implies that inability to perform certain activities without the help of other people (nurses, carers) or to collaborate with family workers (care for grandchildren, tidy up the house, grocery shopping).

Functional limitations and pain affecting people with osteoporosis and who disrupt the quality of life, leading to these social costs of disease are attributable to the musculoskeletal system and therefore can be treated through osteopathic therapy. Osteopathic treatment acts on neuro-musculo-skeletal system, on the basis of the relationship between structure and function, in order to stimulate the body's inherent self-regulatory process (to achieve this objective techniques will be performed on any body part considers that the osteopath to be correlated with the pain and functional limitation of the patient).

Using methods of treatment aimed at improving proprioception and posture (18) you can change conditions predisposing to complications of the disease such as decreased balance and increased risk of falls due to hyperkiphosis and reduced muscle strength (19-21).

The osteopathic approach uses a wide range of techniques: the presence of bone demineralization and degree must be taken into consideration when performing the treatment as a contraindication to the application of certain maneuvers (22).

In order to improve joint mobility and improve muscle responses in the course of osteoporosis, the therapeutic approach uses functional osteopathic techniques (23) and soft tissue techniques (24) designed to increase the ability to accept change of length and tension more easily and thereby improve the ability of structures to adapt to movements with plausible decrease in pain and functional limitations (25) and increased autonomy (self-sufficiency and independence) of the subjects.

This study aimed at assessing the usefulness of osteopathic treatment in addition to the usual treatment of approaching a highly debilitating disease such as osteoporosis, which results in significant consequences "personal" and "social" in an attempt to improve the quality of life of patients.

Subjects and methods

Subjects

The recruitment of subjects took place after visiting medical specialist at the Geriatric Unit of the "Bassini" Hospital located in Cinisello Balsamo (Milan, Italy). The main inclusion criteria were the following ones: 1) age of subjects between 60 and 90 years and 2) both sexes with the presence of osteopenia or osteoporosis. The exclusion criteria were the following ones: 1) excessive bone loss (T-score well -7), and 2) presence of fracture in place. Local ethics committee approval and written informed consent from all subjects were obtained before study initiation.

Design

A randomized, controlled single-blind parallel-group was applied. At time of patient inclusion in the study, the patients were randomized through a computer-generated sequence to osteopathic manipulative treatment group (OMTG) or to serve as a sham manipulative treatment group (SMTG).

Treatments

Patients assigned to the osteopathic treatment were subjected to the usual therapy, established as a result of medical specialist visits, and 6 weekly sessions of osteopathic treatment. The osteopathic treatment, lasting 30 min, was structured in its case-type (black box), while meeting the following general criteria: 1) respect for the patient and his pain, 2) execution of postural objective investigation of the subject, which aimed at discovering the cause of pain and functional limitations, and 3) use of different types of techniques, chosen on the basis of the results of the examination posture, while respecting the characteristics of each individual. To achieve this objective techniques were performed on any body part that the osteopath found to be correlated with the disorder and the patient's functional limitation. It paid particular attention to the restrictions of mobility at all levels: articulation, myofascial, visceral and head in accordance with the principle that the restriction of mobility is a predisposing factor for the onset of pain, functional impotence and instability (25).

Patients included in the SMTG were subjected to the usual therapy, established as a result of medical specialist visits, and 6 weekly sessions of osteopathic treatment placebo. The osteopathic treatment, placebo 30 minutes, consists of postural examination and palpation of nonspecific different parts of the body in different positions supine.

Variables

The patient's bodily pain was evaluated before the treatment cycle using a VAS scale. Patients were instructed to assess pain in various parts of the body and give it a value on a visual scale from

1 to 10. The pain is therefore assessed to be considered a general non-specific pain caused by the disease and not necessarily in place.

At the beginning of the first and last session patients were requested to complete the questionnaire on quality of life with the support of QUALEFFO -41 requires an investigator blinded to group assignment (11, 26-28). The questionnaire provides an overall assessment QUALEFFO -41 quality of life of the patient using a scale from 41 to 205, the overall score is in turn divided into subscales ("pain", "perception of health", "mental health", "daily activities", "housework", "leisure" and "path") with scores ranging from 0-3, 0-4, 0-5.

Statistical analysis

A non parametric 2-sample t tests were used to compare age and sex between two groups of patients. The extrapolated numerical variables were analyzed with an analysis of variance (two-way ANOVA [treatment x time]) for repeated measures with groups as independent variables. All data were reported as mean and standard deviation. Furthermore, in all tests the level of significance was set at $p < 0.05$. The SPSS software version 13.0 running on Windows was used.

Results

Ninety -six patients belonging to the inclusion and exclusion criteria were enrolled; twenty-four of them did not complete the study for reasons not dependent on the current study, complications of underlying conditions for 4 and 6 for difficulty in reaching the venue of the study. The remaining 72 patients completed the study. Table 1 summarizes their main demographic characteristics at study entry.

There was no statistically significant difference in age and sex between two groups of patients.

In Figure 1 the results of the VAS for pain are shown. There was no significant difference ($p = 0.4$) between the two groups of patients studied for this variable measured before 6 treatment sessions (OMTG1 = 4.4 ± 2.6 , OMTG6 = 4.1 ± 1.9 , SMTG1 = 4.8 ± 2.5 , SMTG6 = 4.6 ± 2.7).

Regarding the results of the questionnaire of quality of life there was significant difference ($p = 0.001$) between OMTG and SMTG in the total score of the questionnaire to -41 QUALEFFO first and sixth treatment session (OMTG1 = 107 ± 25 , OMTG6 = 91 ± 29 , SMTG1 = 112 ± 27 , SMTG6 = 110 ± 31) (Figure 2).

The analysis consists of the subscales from which the questionnaire showed a significant difference between the two groups in the fields of investigation "pain" ($p = 0.003$) (Figure 3), "perception of health" ($p = 0.005$) (Figure 4), finally, a trend toward significance was found in the subgroup "path" of the questionnaire ($p = 0.049$) (Figure 5). No significant difference was found in the fields of investigation "mental well-being" ($p = 0.06$), "daily activities" ($p = 0.2$), "housework" ($p = 0.3$), "leisure activities" ($p = 0.1$).

Table 1 - The main demographic characteristics of the patients that completed the study.

	OMTG	SMTG	P value
Number of subjects	37	35	
Mean age (SD)	77.2 (5.3)	76.8 (8.2)	0.1*
Sex M/F	11/26	10/25	0.9**

Abbreviation: OMTG, osteopathic manipulative treatment group; SMTG, sham manipulative treatment group; SD, standard deviation; M, male; F, female.

* Non parametric Wilcoxon test; ** Non parametric Chi-square test.

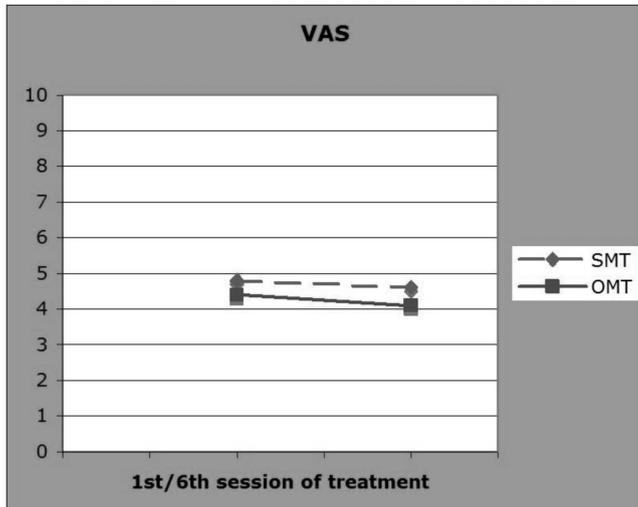


Figure 1 - Visual Analogic Scale (VAS) scores values recorded at the first visit and the sixth visit in Osteopathic Manipulative Treatment (OMT) group (solid line with squares) and Sham Manipulative Treatment (SMT) group (dashed line with rhombuses).

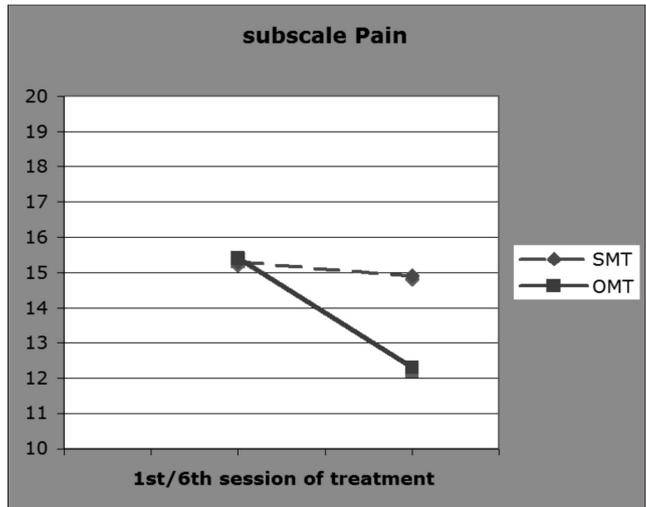


Figure 3 - Values subscale of "pain" of the questionnaire QUALEFFO -41 recorded at the first visit and the sixth visit in the Osteopathic Manipulative Treatment (OMT) group (solid line with squares) and Sham Manipulative Treatment (SMT) group (dashed line with rhombuses).

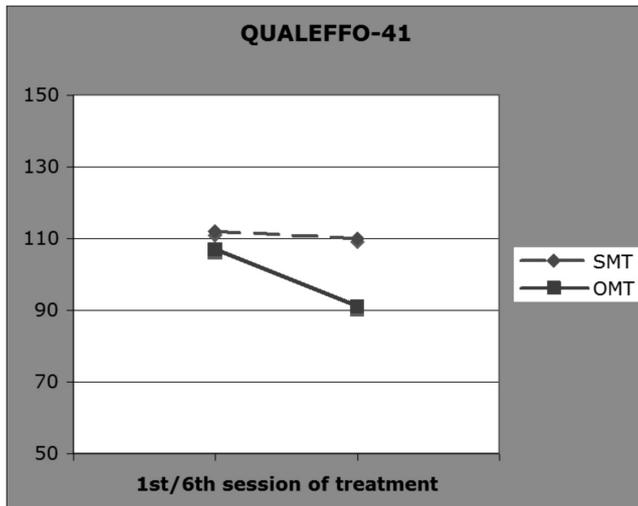


Figure 2 - Values of questionnaire of quality of life QUALEFFO -41 recorded at the first visit and the sixth visit in the Osteopathic Manipulative Treatment (OMT) group (solid line with squares) and Sham Manipulative Treatment (SMT) group (dashed line with rhombuses).

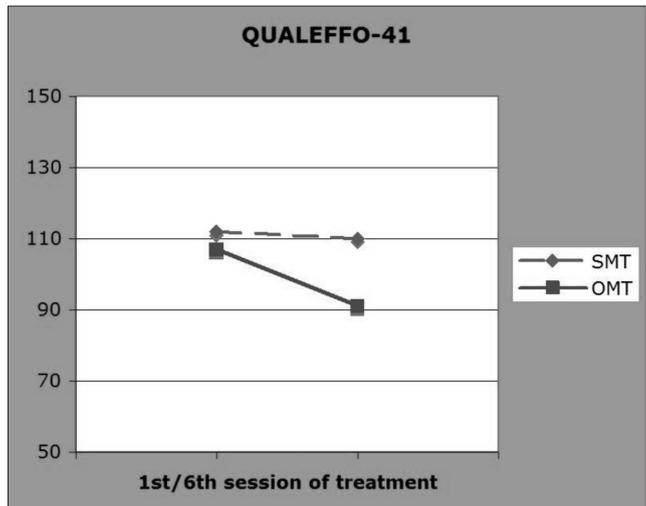


Figure 4 - Values subscale of "pain" of the questionnaire QUALEFFO -41 recorded at the first visit and the sixth visit in the Osteopathic Manipulative Treatment (OMT) group (solid line with squares) and Sham Manipulative Treatment (SMT) group (dashed line with rhombuses).

Discussion

The results of this study demonstrate the effectiveness of osteopathic treatment in the short term to improve the quality of life measured by QUALEFFO -41 in a group of geriatric patients suffering from osteoporosis. In contrast, the change in the level of pain measured by VAS scale reported by the patients showed no difference between the two study groups.

Improving the overall quality of life appears to be linked to an improvement of mental well-being linked to the perception of health status and, at least in this questionnaire, the decrease in pain. The reasons for the difference between the two pain scales (VAS and pain items of QUALEFFO -41) will be discussed later.

The improvement of the perception of health shows a figure that appears to confirm the results of Licciardone et al. in patients with musculoskeletal pain underwent osteopathic manipulative treatment administered in both the outpatient hospital (29-32).

Improving the quality of life found in this study refers to the per-

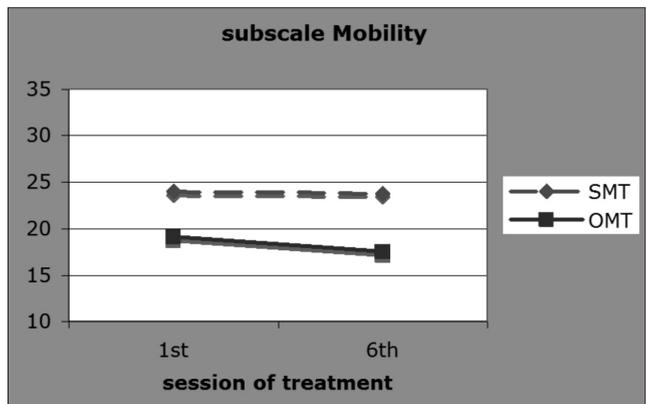


Figure 5 - Values subscale of "Path/Mobility" of the questionnaire QUALEFFO -41 recorded at the first visit and the sixth visit in the Osteopathic Manipulative Treatment (OMT) group (solid line with squares) and Sham Manipulative Treatment (SMT) group (dashed line with rhombuses).

ception of the patient immediately after the end of the treatment period and is therefore considered a short-term effect. It is not possible, according to data from this study whether the effects shown can be maintained over time and therefore this study is limited by the fact that there is no follow-up evaluation. The choice not to make this measurement is related to the fact that this trial, among the first of its kind in Italy, was conducted to test the feasibility of an osteopathic treatment in a geriatric ward. Future studies will test the effect of long-term of osteopathic treatment.

A bias in which we incurred for the measurement of the T-score of the participants in the study because it appears to be overestimated because of an error in the measurement phase, this figure does not affect the validity of the study because the subjects included are full-blown osteoporosis by earlier analysis. As for the pain data reported the results are conflicting: the VAS does not show a significant difference between the two groups, despite a difference between the averages between the 1st and 6th meeting is for the benefit of the treated group, while the specific subscale of the QUALEFFO -41 shows a high significance for the reduction of pain in the treated group.

This trend can be traced to the discordant assessment methodology: the VAS provides a certain amount of pain perception, while the -41 QUALEFFO asks characterization qualifying pain, in particular related to the spine.

Patients enrolled in the present with features starting polyarthralgias and various functional changes related to pain (5, 6, 7, 8, 9, 10, 11): the VAS was administered with the intent of an overall assessment of pain and not specific to individual districts algic presented by each patient, this methodological choice may have limited verification by VAS pain state. In addition, there has been a difficulty in getting patients to understand the compilation of the visual-analogue scale, mainly related to age and socio-cultural draw. The results demonstrated by the subscale of the questionnaire show that osteopathic manipulative treatment is effective in reducing the perception of pain depends on the quality of life of the patient: this is particularly associated with the localization of spinal pain and therefore in line with the results we had in several studies clinical efficacy of osteopathic treatment in nonspecific chronic low back pain (32).

The questionnaire presented the subscales related to age-related functional limitations and the osteoporotic process: the differences in these two groups were not significant, however, the trend shows an improvement in mean differences in particular with regard to the subscale "path". The possibility of introducing a standardized assessment more objective could highlight functional improvements cannot be assessed through the questionnaire and not influenced by the perception of the individual patient.

In conclusion, this study demonstrates the effectiveness of osteopathic treatment in the short term to improve the quality of life in a group of geriatric patients suffering from osteoporosis. The effects on pain are less easy to be interpreted and they require further studies which should also include medium- and long-term evaluations and objective measures of physical function.

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