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Osteopathic manipulative treatment in obese patients with chronic low back pain: A pilot study

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ABSTRACT

Background: Obesity is frequently associated with various musculoskeletal disorders including chronic low back pain (cLBP). Osteopathy is a discipline emphasizing the conservative treatment of the disease in an olistic vision. We designed a randomized controlled study to investigate whether Osteopathic Manipulative Treatment (OMT) combined with specific exercises (SE) is more effective than SE alone in obese patients with cLBP.
Methods: nineteen obese females with cLBP, randomized into 2 groups: SE + OMT and SE were studied during the forward flexion of the spine using an optoelectronic system. A biomechanical model was developed in order to analyse kinematics and define angles of clinical interest.
Outcome measures: kinematic of the thoracic and lumbar spine and pelvis during forward flexion, pain according to a visual analogue scale (VAS), Roland Morris Disability Questionnaire and Oswestry Low Back Pain Disability Questionnaire.
Results: significant effects on kinematics were reported only for OMT + SE with an improvement in thoracic range of motion of nearly 20%. All scores of the clinical scales used improved significantly. The greatest improvements occurred in the OMT + SE group.
Conclusions: combined rehabilitation treatment including Osteopathic Manipulative Treatment (OMT + SE) showed to be effective in improving biomechanical parameters of the thoracic spine in obese patients with cLBP. Such results are to be attributed to OMT, since they were not evident in the SE group. We also observed a reduction of disability and pain. The clinical results should be considered preliminary due to the small sample size.

1. Background

Chronic low back pain (cLBP) is a common condition which represents a major economic burden worldwide and an important cause of absence from work and healthcare consultation (Frank and De Souza, 2001; Webb et al., 2003; Dunn and Croft, 2004; Ogden et al., 2006). In the USA, it is estimated that 40%–85% of the population with cLBP have consulted healthcare professionals in regard to their pain (Deyo and Tsui-Wu, 1987; Carey et al., 1996).

Obesity contributes to the development of a number of conditions, including impairment of the spine (Kostova and Koleva, 2001; Fanuele, 2002), and it has been recognised as being a risk factor for cLBP. A body mass index (BMI) association with pain has been observed (Barofsky et al., 1998; Fontaine et al., 1999), and weight reduction is expected to reduce musculoskeletal pain (Fontaine et al., 1996; Martin et al., 2001).

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Many individuals with cLBP seek care from general practitioners, but chiropractors (Deyo and Tsui-Wu, 1987) and osteopaths (Licciardone, 2008) are also consulted. Manual therapies have rapidly become some of the most fashionable and diffuse approaches to cLBP (Moffett, 1999). The guidelines consider spinal manipulation a valid treatment for pain, and function so as to be used together with rehabilitative approaches in chronic cLBP ranging from low to high levels of disability (Negrini et al., 2006; McCarthy, 2007). These are considered to be particularly effective in the acute and sub-acute phase (Licciardone, 2004; Fritz et al., 2007).

According to the literature, manipulation alone cannot treat complex conditions in which the physical, psychological and social elements are deeply interconnected (Andersson et al., 1999; Assendelft et al., 2003; Licciardone, 2004; Licciardone et al., 2005; Santilli et al., 2006).

Searching with the keywords "manual therapy" or "manipulative treatment," we can usually find together osteopathy and chiropractic together (Negrini et al., 2006; McCarthy et al., 2007). Osteopathic Manipulative Treatment (OMT), a conservative treatment using only manipulative techniques, is commonly used by osteopaths to integrate more conventional rehabilitation treatment for LBP. As for the effectiveness of specific exercises (SE) in cLBP, a solid body of literature is available (Deyo et al., 1987; Moffett et al., 1999; Heymans et al., 2004; Negrini et al., 2006; Fritz et al., 2007; Hough et al., 2007; McCarthy et al., 2007). No specific protocol has been developed to treat obese patients with cLBP: Many protocols have been shown to be effective, but several of those studies have been lacking in terms of quality (Hayden et al., 2005; van Middelkoop et al., 2010; Negrini et al., 2010). Obese patients with cLBP can be considered a specific LBP subgroup having particular features which may require a customised approach. In a previous study on the biomechanical characteristics of the spine in obese females with cLBP, we showed that the thoracic range of motion (ROM) is significantly reduced in the obese female subject with and without cLBP as compared to the normal-weight controls (Vismara et al., 2010). The thoracic ROM limitation may play a role in the onset or maintenance of cLBP (Gilleard and Smith, 2007; Vismara et al., 2010). The thoracic spine function has a relevant impact on the functioning of the lower (lumbar) and upper (cervical) traits (Cleland et al., 2005). Thoracic spinal manipulation has been shown to be effective in reducing neck pain (Cleland et al., 2005; Lau et al., 2011), thus supporting the mechanical connection between cervical and thoracic spine (Cleland et al., 2005). In a previous study, we reported increased thoracic stiffness in obese female patients with LBP (Vismara et al., 2010). The improvement of thoracic ROM of obese cLBP patients could therefore represent a main goal in rehabilitation and prevention of LBP. To verify this hypothesis, we designed a randomised controlled study to compare the biomechanical results of two rehabilitative interventions, OMT combined to SE vs. SE alone, in obese patients affected by cLBP.

2. Methods

2.1. Participants

Twenty-one obese females (BMI > 30 kg/m^2) complaining of cLBP with symptoms lasting for more than six months and the absence of medical treatment were included in the study. The exclusion criteria were secondary LBP, osteoporosis, osteoarthritis or neurological conditions precluding physical exercise, cardiovascular (diagnosed after treadmill stress tests), respiratory conditions and psychiatric disorders.

2.2. Study design

Patients were randomized into 2 groups: Specific Exercises + OMT (SE + OMT; 10 women, Age: 42.59 $\pm$ 12.01 years; BMI: 42.98 $\pm$ 4.75 kg/m^2) and Specific Exercises (SE; 11 women, Age: 44.73 $\pm$ 8.43 years; BMI: 42.38 $\pm$ 5.99 kg/m^2). The assignments were generated by a computer and presented in sealed, sequentially numbered envelopes. At the baseline, an osteopath evaluated each of the patients in order to confirm the correct indication for osteopathic treatment.

The study was approved by the Ethical Committee of the "Istituto Auxologico Italiano," and each of the participants provided a signed informed consent.

All the patients were evaluated before (pre-) and after (post-) treatment with clinical scales and 3-D motion analysis of trunk kinematics. Of these patients, 2 were excluded because of missing data in POST treatment.

2.3. Treatments

As for the SE group (only specific exercises) the protocol consisted of a combined back school (Heymans et al., 2004) and cognitive behavioural approach (Henschke et al., 2010) aimed at reinforcing and stretching the abdominal and back muscles, mobilising the spine, and providing the patients with correct ergonomic knowledge for the safe use of the spine. All patients underwent ten 45-min SE sessions, which included:

1) An introductory talk intended to educate the patient about the changes in spinal physiology, pain and posture as related to obesity and other risk factors. The patients received practical information about the duration and aims of their rehabilitative programs.
2) Active exercises, with four levels of consideration:
   - 1st level: Active exercises in supine posture, specific breathing techniques for warm-up and muscle relaxation.
   - 2nd level: Exercises in supine posture, focussing on posture, proprioception and motor control.
   - 3rd level: Exercises in the supine, prone, sitting and standing positions to increase the mobility of the pelvis and spine.
   - 4th level: Progressive trunk extensor muscle strengthening, stretching and spinal mobilisation.
3) Education: Three meetings were held to teach patients the ergonomics of movement during the activities of daily living in order to enhance effectiveness of the rehabilitative program and prevent future relapses of LBP.

As for OMT + SE group, in addition to specific exercises previously described, patients underwent an additional 45-min individual session provided by an experienced skilled osteopath (with at least three years of work experience after graduation). The OMT was targeted to the patient's clinical picture. The techniques used were high-velocity, low-amplitude thrust in thoracic spine (Downie et al., 2010); cranial techniques (Sutherland, 1939; Magoun, 1966; Kostopoulos et al., 1992); and myofascial release (Fryer et al., 2009). The application of such techniques was based on the methodological and conceptual theory of osteopathic dysfunction, i.e., "damaged or altered function of the somatic components: skeletal structure, joint, myofascial in relation to the vascular system, lymphatic and nervous" (ICD-9-CM International Classification of Diseases, 2009).

2.4. Measures

The primary outcome measures were related to kinematics. We used a six-camera optoelectronic motion analysis system (Vicon

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460, Vicon Motion Systems, Oxford, U.K.) operating at a sampling rate of 100 Hz with passive markers placed at specific landmarks by an experienced operator, in a manner consistent with the literature (Peharec et al., 2007; Menegoni et al., 2008; Vismara et al., 2010). Specifically, two were placed on the thoracic (T1 and T6), two on the lumbar vertebrae (L1 and L3), one on the sacrum (S1), four on the pelvis (left/right anterior and left/right posterior superior iliac spines), and two on the acromion of the left and right shoulders (Fig. 1).

After preparation, each of the participants was instructed to comfortably flex her trunk forward at her own preferred speed with the feet apart at shoulder width.

The secondary outcome measures were clinical scales for LBP: Visual Analogue Scale (VAS 0–100) for measuring pain (Huskisson, 1974), the Roland and Morris Disability Questionnaire (RM) (Roland and Morris, 1983) and the Oswestry Low Back Pain Disability Questionnaire (OQ) (Fairbank et al., 1980) for the assessment of disability.

2.5. Data analysis

Three-dimensional data from the optoelectronic system were processed using the multipurpose biomechanical software SMART Analyzer (BTS, Milan, Italy). The following angles were identified and calculated (Fig. 2) in order to characterise trunk mobility in the sagittal plane: forward trunk inclination (αFTI), anterior pelvic tilt (α1), lumbar movement (α2), and thoracic movement (α3) (Cleland et al., 2005; Gilleard and Smith, 2007; Peharec et al., 2007; Menegoni et al., 2008; Fryer et al., 2009; Gonzalez-Iglesias et al., 2009; Vismara et al., 2010; Lau et al., 2011).

The above-mentioned angles were evaluated at the initial standing position (START) and ROM was calculated as the difference between the maximum value and the START value.

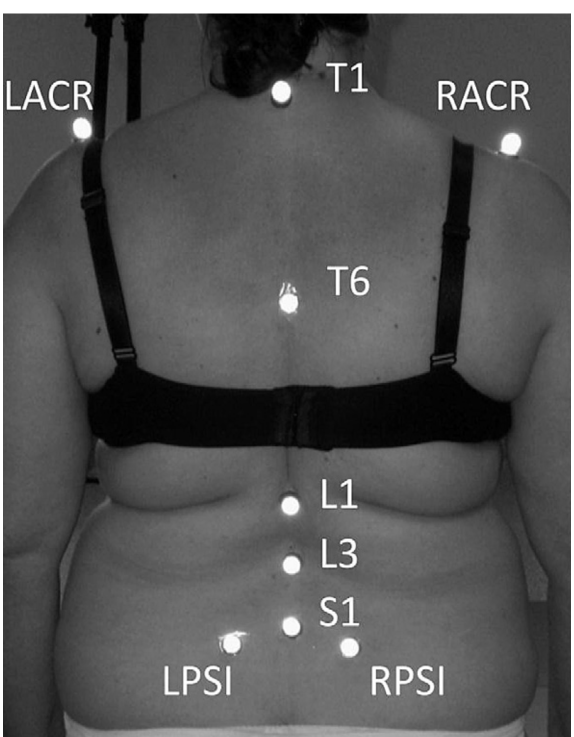

Fig. 1. Marker setup. Markers were placed on superior posterior iliac spines (LPSI, RPSI), on superior anterior iliac spines (LASI, RASI not visible), on spine spinous processes (S1, L3, L1, T6, T1) and on acromions (LACR, RACR).

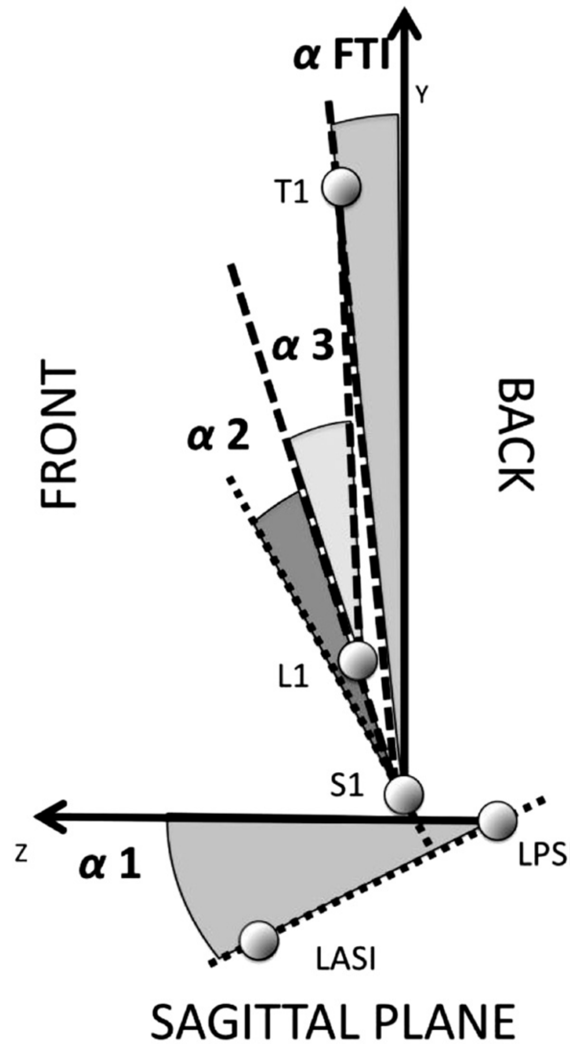

Fig. 2. Representation of markers and angles in the sagittal plane during forward flexion: αFTI, α1, α2 and α3.

2.6. Statistical analysis

All the previously defined parameters were computed for each participant, and subsequently the mean values and standard deviations of all indexes were calculated for each group.

The Kolomogorov–Smirnov test was used to verify whether the parameters were normally distributed. However, the parameters were not normally distributed, so we used the Mann Whitney *U* test to assess the differences among groups at the PRE stage, and the Wilcoxon paired test between the pre- and post-sessions in order to determine whether a specific treatment introduced statistically significant changes. *P*-values less than 0.05 were considered significant.

Furthermore, the differences between PRE and POST in SE + OMT and SE groups were estimated using the Cohen effect size (d') (Cohen, 1988). Responsiveness is considered to be "trivial" for $d' < 0.20$, "small" for $0.20 < d' < 0.50$, "moderate" for $0.50 < d' < 0.80$ and "large" for $d' > 0.80$.

3. Results

All patients included in the study showed a good compliance and successfully completed the treatment protocols; 2 patients of the group OMT + SE could not be assessed with instrumental measures in POST session and so the group SE + OMT was composed by 8 women (Age: 42.00 ± 11.41 years; BMI: 43.04 ± 5.09 kg/m^2). In Table 1, the mean values and standard deviation of forward flexion angles and clinical scales for the two groups (SE + OMT, and SE) at PRE and POST are listed.

At PRE, no statistical difference was present between SE + OMT and SE in terms of the biomechanical parameters and clinical scales ($p > 0.05$). While SE showed no change in the biomechanical parameters at POST, SE + OMT displayed a significant improvement of nearly 20% in the thoracic ROM (ROM $\alpha 3$).

As for the clinical scores, all the clinical scales improved significantly in both groups, but the improvement was significantly higher in SE + OMT than in SE (VAS: −74% vs. −46%; RM: −67% vs. −24%; OQ: −64% vs. −29%, respectively) ($p < 0.05$).

All the results were confirmed using the exact probabilities for small samples. Moreover, all the significant parameters in the PRE-POST comparison in both groups presented a large effect (Cohen $d' > 0.80$).

4. Discussion

The main goal of this study was to investigate the biomechanical changes in the spine after a program based on Specific Exercises (SE) integrated with OMT (SE + OMT) as compared to a program based only on SE in obese patients with cLBP. The two groups were homogeneous, with similar initial scores on the clinical scales used and trunk position. The parameters of trunk kinematics improved at POST, particularly at the thoracic level, but only in SE + OMT. Both groups improved significantly in terms of clinical outcomes, but SE + OMT showed the greatest degree of improvement. These results suggest the effectiveness of OMT + SE in improving spinal function, (increased thoracic ROM on the sagittal plane). Bautmans et al. (2010) have reported the effectiveness of thoracic mobilisation in improving thoracic kyphosis in osteoporotic women. In a previous study we found an increased stiffness of the thoracic spine of obese females as compared to lean counterparts (Vismara et al., 2010). Thus we hypothesised that such stiffness could be related to the onset and/or maintenance of LBP in obese subjects. Our present findings support this hypothesis. From a clinical standpoint, definitive conclusions cannot be drawn from our small preliminary study, so further data should confirm our clinical findings. Furthermore, a direct correlation between trunk stiffness and disability cannot be evicted from our data. However, to our knowledge these are the first biomechanical data documenting the effect of spinal manipulation on the thoracic spine. Previous studies have documented the efficacy of spinal thoracic thrust in improving function, pain and disability in subjects complaining of neck pain (Cleland et al., 2005; Gonzalez-Iglesias et al., 2009; Lau et al., 2011), but no biomechanical data was collected.

According to the Italian clinical guidelines (Negrini et al., 2006), a reduction of disability should be the main goal for the LBP patient. Our study shows that, in obese patients, a combined passive (OMT) and an active approach (SE) can be successfully combined to improve the LBP-related disability. Special Exercises alone appear to reduce pain significantly but do not affect trunk kinematics.

The strength of this paper is the methodology applied in the analysis of trunk movement. To our knowledge, no other study has assessed the combined effect of SE and OMT with optoelectronic equipment. Previous studies (Menegoni et al., 2008; Vismara et al., 2010) have shown the usefulness of the kinematic approach in providing functional data of the spine. This approach, however, is costly and time-consuming, so that the sample size of a study is limited. Consequently, the external validity of our findings is reduced, and larger studies will need to confirm our results. Other strengths are the randomisation of treatment, being aimed at the prevention of selection bias, and the blinded evaluation of the trunk movement.

A possible confounding factor of this study is the interaction between patients and operators. It is well known that the interaction between the operator and the patient is, per se, responsible for a placebo effect. This was not relevant in our protocol, since both groups related with at least one operator. A third, untreated group would possibly improve the statistical power of the study. However, in our opinion the human interaction would eventually influence pain and disability but would be very unlikely to change spinal mobility, as assessed in our protocol.

As for the external validity of our findings, the highly selected population studied can be considered a subgroup of cLBP patients. Our findings can be applied to the population of obese cLBP women but not to the general cLBP population. Previous studies have suggested the presence of trunk stiffness in patients with recurrent LBP (Hodges et al., 2009; Jones et al., 2012), but the systems of measurement have differed among studies and the data on muscular co-contraction as a reaction to stability perturbation has not been homogeneous. Muscular function was not investigated as part of our study, so we cannot ascertain whether stiffness originates from muscular activation or the retraction of ligaments. Further high-quality studies, possibly as randomised controlled trials, are necessary in order to understand the extent to which

Table 1
Mean (standard deviation) of forward flexion angles and clinical scales for the two groups considered in the pre- and post-sessions (PRE and POST). Trunk, pelvis, lumbar and thoracic positive values were indicative of forward flexion of the segment considered, while negative values indicated otherwise. * = $p < 0.05$, PRE vs. POST session.

		Group SE + OMT		Cohen's d'	Group SE		Cohen's d'
		PRE	POST		PRE	POST	
Biomechanical parameters							
αFTI [°]	START	7.21 (3.54)	6.39 (4.37)	0.20	6.32 (4.55)	4.76 (3.11)	0.41
	ROM	101.74 (14.48)	104.69 (11.98)	0.22	92.02 (12.58)	92.14 (10.37)	0.01
α1 [°]	START	21.33 (3.72)	20.30 (4.76)	0.24	22.19 (6.21)	23.85 (6.49)	0.26
	ROM	52.11 (12.74)	55.23 (9.73)	0.28	48.03 (11.44)	49.17 (11.58)	0.09
α2 [°]	START	−8.53 (7.77)	−6.65 (9.39)	0.23	−13.96 (13.34)	−16.75 (10.41)	0.24
	ROM	27.86 (4.43)	24.80 (7.16)	0.52	23.44 (9.74)	22.68 (8.74)	0.08
α3 [°]	START	−6.35 (7.79)	−10.45 (9.76)	0.46	−2.29 (13.96)	−3.43 (13.22)	0.08
	ROM	30.24 (5.88)	35.99 (7.76)*	0.84	29.25 (10.85)	28.99 (8.39)	0.03
Clinical scales							
VAS		55.00 (6.46)	14.12 (11.52)*	4.55	54.36 (8.02)	29.64 (8.13)*	3.06
RM		9.38 (2.13)	3.13 (2.85)*	2.51	9.64 (2.54)	7.27 (2.19)*	0.99
OQ		9.63 (2.45)	3.5 (1.69)*	2.96	13.00 (4.47)	9.18 (3.34)*	0.97

Abbreviations SE: Specific Exercises; OMT: Osteopathic Manipulative Treatment; RM: Roland Morris Disability Questionnaire; OQ: Oswestry Low Back Pain Disability Questionnaire.

spinal manipulation can be effective in the chronic phase. Long-term follow-up studies are also needed for the confirmation of our results.

5. Conclusions

An approach combining specific exercises and OMT is effective in reducing pain and disability in cLBP obese patients, similarly to SE alone, but unlike SE alone it has also been associated with a significant improvement in kinematics of the thoracic spine flexion. ROM improvements seem to be specifically due to OMT, since the group treated with SE alone did not report the same results. OMT seems to provide an additional benefit when integrated within a multidisciplinary approach which includes active specific exercises.

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