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CASE BASED REVIEW

Osteopathy for musculoskeletal pain patients: a systematic review of randomized controlled trials

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Abstract The objective of this systematic review was to assess the effectiveness of osteopathy as a treatment option for musculoskeletal pain. Six databases were searched from their inception to August 2010. Only randomized clinical trials (RCTs) were considered if they tested osteopathic manipulation/mobilization against any control intervention or no therapy in human with any musculoskeletal pain in any anatomical location, and if they assessed pain as an outcome measure. The selection of studies, data extraction, and validation were performed independently by two reviewers. Studies of chiropractic manipulations were excluded. Sixteen RCTs met the inclusion criteria. Their methodological quality ranged between 1 and 4 on the Jadad scale (max=5). Five RCTs suggested that osteopathy compared to various control interventions leads to a significantly stronger reduction of musculoskeletal pain. Eleven RCTs indicated that osteopathy compared to controls generates no change in musculoskeletal pain. Collectively, these data fail to produce compelling evidence for the effectiveness of osteopathy as a treatment of musculoskeletal pain.

Keywords Musculoskeletal pain · Osteopathy · Systematic review

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Background

Musculoskeletal pain (MSP) is a major health problem, accounting for approximately one-quarter of general practice (GP) consultations in the United Kingdom (UK) [1–3]. There are considerable variations in terms of definitions, causes, localizations, and treatment strategies of MSP pain [4, 5]. MSP pain can be continuous, recurrent or chronic. It often affects well-being, the level of function and quality of life [6]. It can be located within a variety of anatomical regions such as neck, shoulder, higher back, elbow, wrist/hand, lower back, hip, knee, ankle, foot. Several risk factors have been identified, e.g., occupational exposure, educational status, psychosocial characteristics such as stress, anxiety, emotions, cognitive functioning and maladaptive behaviors such as avoidance or smoking [4] and gender and age [5].

Osteopathy is the branch of medicine that was founded by Andrew Taylor Still in the mid to late nineteenth century in the USA [7]. Osteopathic physicians use techniques collectively referred to as osteopathic manipulative treatment (OMT) that is aimed at restoring the body's balance and releasing pain. To date no definitive conclusions about the effectiveness of osteopathy in the management of MSP has been drawn, and the usefulness of OMT in treating MSP is unclear. Therefore, the aim of this paper is to critically review the evidence for or against the effectiveness of osteopathy in MSP patients.

Method

Literature searches were performed in August 2010 to identify all controlled clinical trials of osteopathic manipulation/mobilization for MSP patients (Table 1). The follow-

Table 1 Controlled clinical studies of osteopathy for the treatment of musculoskeletal pain

First author Year [ref]	Study design (Jadad score)	Characteristics of participants (*n*)	Experimental intervention (details see Table 3)	Control intervention	Primary outcome measure	Main result
[17]	3	41 chronic neck pain patients	Sham ultrasound + OMT	Sham ultrasound only	10-point NRS	Significant inter-group difference of longitudinal changes (P=0.02)
[15]	2	58 acute neck pain patients	OMT	Drugs-30 mg of ketorolac tromethamine	11-point NRS	No difference between the groups at 1 hour posttreatment (P=0.10)
[14]	3	60 postsurgery patients	OMT + standard care	Sham treatment + SC	Functional Independence Measure (FIM), daily analgesic use; length of stay; Medical Outcomes Study Short Form-36	No differences between groups
[16]	2	53 patients with epicondylopathia humeri radialis	OMT	Chiropractic techniques, antiphlogistics, and cortison injections	Pressure pain test, Thomsen test, middlefinger extension test, and test for strength	No differences between groups
[24]	2	109 LBP patients	OMT	Short-wave diathermy (SWD) and a placebo (detuned SWD)	VAS 100 mm	No differences between the groups
[21]	4	201 patients with neck or back pain	OMT	SC	Extended Aberdeen Spine Pain Scale (EASPS)	Significant difference in favor of osteopathy at 2 months [95% CI, 0.7–9.8]
[9]	3	178 LBP patients	OMT	SC	RMDQ and Oswestry questionnaire, VAS.	No difference between groups
[10]	2	55 patients with acute ankle injuries	OMT	SC	Edema, range of motion, and pain (VAS)	A significant (F=5.92, P=0.02) improvement in edema and pain following in favor of osteopathy
[22]	4	40 patients with sciatica	OMT	Chemonucleolysis	Leg pain, back pain and self-reported disability	No significant difference between groups at 12 months
[13]	4	91 LBP patients	OMT	Sham manipulation, and no-intervention	SF-36, a 10-cm VAS for overall back pain, RMDQ, lost work or school days because of back pain, and satisfaction care	No difference between groups
[12]	1	29 elderly patients with shoulder pain	OMT	Placebo treatment	ROM and pain	No difference between groups
[11]	1	24 female fibromialgia patients	(1) OMT, (2) OMT and teaching group	(3) moist heat group, and (4) current medication	Dolorimeter measurements, the Chronic Pain Experience Inventory, and the Present Pain Intensity Rating Scale	Pain threshold, perceived pain attitude toward treatment, activities of daily living, and chronic pain attributes favored OMT
[18]	2	25 patients with temporomandibular disorders	OMT	Conventional conservative therapy	VAS	No difference between groups
[23]	4	239 LBP patients	OMT	Exercises or manipulative physiotherapy	Oswestry Disability Index (ODI), EuroQol-5D, and subjective responses to pain and treatment.	No difference between groups
[19]	2	41 healthy volunteers	OMT	No treatment	ROM	No difference between groups
[20]	3	70 patients with neck pain	OMT (HVLA thrust)	Manual mobilization	ROM and pain	Improvements in neck pain at rest and mobility favored OMT

ing databases were searched (since January 1980 until August 2010): Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL, AMED, PsycINFO using the search osteopathy, osteopathic manipulative medicine, OMT, Spencer Technique, Jones Technique, Strain-Counter Strain, Positional Release Techniques, Visceral Manipulation, Cranial Osteopathy, Cranio-Sacral Technique, Myofascial and soft tissue release, muscle energy technique, High Amplitude Low Velocity Thrust (HVLA), musculoskeletal, pain, fibromyalgia, osteoarthritis (OA), rheumatoid arthritis (RA), orthopaedic, trauma, sprain, strain, soreness, epicondylopathy, tennis elbow, golfers elbow, carpal tunnel syndrome, bones, limbs, extremities, joints, muscles, tendons, fascias, ligaments, cartilages, trigger points, trigger point therapy, tender points, myofascial to identify all relevant published articles on the subject. Experts were also contacted and asked for any unpublished data. The reference lists of all located articles were scanned for further relevant literature. Additionally, relevant published book chapters were hand-searched for further articles. No language barriers were imposed. Exclusion criteria were trials by osteopaths not using osteopathic manipulation/mobilization.

All retrieved data including uncontrolled trials, case studies, pre-clinical and observational studies were reviewed for safety information. However, only randomized controlled clinical trials (RCTs) testing osteopathy in MSP patients of age 18 and above, any sex were included.

Two authors extracted data independently using a custom made data extraction form. For each study, trial design, randomization, blinding, dropout rate, inclusion and exclusion criteria, details of treatment method and control groups, main outcomes measures, and main results were extracted. Quality of studies was assessed using the five-point Jadad scale [8] (Table 2). Points were awarded as follows: study described as randomized, 1 point; additional point for appropriate randomization method, 1 point; inappropriate randomization method, deduct 1 point; patient blinded to intervention (patient blinding was assumed where the control intervention was indistinguishable from the treatment group); 1 point; evaluator blinded to intervention, 1 point; description of withdrawals and dropouts, 1 point. Clinical trials with 4 or 5 points were considered high quality. Two independent reviewers (EE, PP) validated data using a predefined standardized form. Any differences were resolved through discussion.

Results

Study description

The search strategy generated a total of 128 references, of which 61 were considered to be potentially relevant. We did not locate any unpublished trials. A total of 27 clinical trials were retrieved for further evaluation of which 16 involving 1,314 patients were eligible for inclusion (Fig. 1).

The studies originated the US [9–15] Germany [16, 17], Italy [18], Australia [19], Spain [20] and the UK [21–24]. Patient populations were heterogeneous ranging from neck pain patients [15, 17], LBP patients; [9, 13, 22–24] neck or back pain patients; [21] postsurgery patients; [14] elderly shoulder pain patients; [12] tennis elbow patients; [16] fibromyalgia patients; [11] patients with temporomandibular disorders; [18] acute ankle injuries [10] or healthy volunteers [19]. Control groups received sham ultrasound [17], or placebo sham manipulation [12], or no-intervention [13] [19], drugs [15], moist heat [11], chemonucleolysis [22], sham treatment + standard care [14], chiropractic techniques, antiphlogistics and cortison injections [16], exercises or manipulative physiotherapy [23], manual mobilization [20], short-wave diathermy (SWD) and a placebo (detuned SWD) [24], or standard care [9, 10, 18, 21].

Study quality

The quality of the RCTs varied from 1 to 4 points on the Jadad scale. In the RCT of [22] allocation concealment and exclusion criteria were appropriately executed and described. In addition two tailed Student's *t*-tests, chi-squared tests and multiple regression seem strong enough. Nevertheless, this study lacks intention to treat analysis, inclusion criteria, and power calculations and the sample is relatively small.

In the study of [23] sample calculations, clearly described exclusion criteria, and strong statistical methods strengthen methodological design. However, no inclusion criteria, concealed allocation to groups, and lack of intention to treat analysis altogether increase the risk of bias.

In the study of [11] there is also not concealed allocation. Too, neither inclusion nor exclusion criteria are mentioned. The study also lacks intention to treat analysis and power calculations. However, statistical analysis is supposed to has adequate power to detect effects measured.

In the study of [12] appropriately described allocation concealment, inclusion and exclusion criteria, and intention to treat analysis seems to be lacking. Power calculations and one-way ANOVA used minimize the risk of bias.

In the study of [15] inclusion and exclusion criteria are both well defined and there a power calculation was done prior to their study. No intention to treat analysis is described. Spearman rank-order correlation test and subjective outcome measures used lower the methodological quality of this study.

In the RCT of [14] there is unclear whether allocation concealment was adequately performed. Power calculations and chi squared and t-tests seem appropriate. Exclusion criteria do not exist in their study and inclusion criteria seem to be ill-defined. Furthermore, the sample size is small.

Table 2 Quality assessment of the included studies

Study	Domain					Sum
	Random sequence generation	Appropriate randomization	Blinding of participants or personnel	Blinding of outcome assessors	Withdrawals and dropouts	
[22]	1	1	0	1	1	4
[23]	1	1	0	1	1	4
[12]	1	0	0	0	0	1
[15]	1	1	0	0	0	2
[14]	1	0	0	1	1	3
[13]	1	1	0	0	1	3
[18]	1	0	0	1	0	2
[10]	1	0	0	0	0	1
[19]	1	0	1	1	0	3
[20]	1	1	0	1	0	3
[11]	1	0	0	0	0	1
[21]	1	1	0	0	1	3
[9]	1	0	0	1	1	3
[24]	1	0	0	0	1	2
[16]	1	1	0	0	0	2
[17]	1	1	0	0	1	3

In the study of [13] the risk of bias was lower in terms of allocation concealment, power calculations, and clearly defined eligibility criteria. Lack of intention to treat analysis, unsupported claims regarding generalizibility, may limit the worth of this study.

In the study of [18] there was no allocation to group concealment. Study also lacks power calculations and intention to treat analysis. Relatively strong statistics used (ANOVA) and well defined exclusion criteria strengthen the methodological robustness.

In the study of [10] intention to treat analysis was performed. Also, exclusion and inclusion criteria are relatively well defined and statistical analysis used minimize the risk of biases.

In the study of [19] intention to treat analysis and power calculations lack appropriate description. There are insufficiently described inclusion and exclusion criteria. However, ANOVA and robust outcome measures decrease the risk of bias.

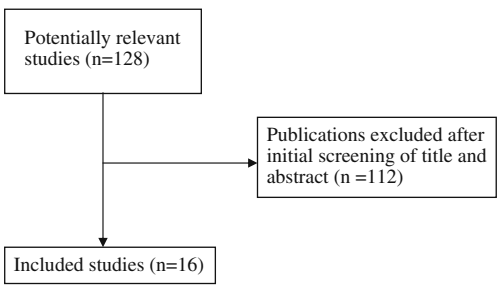

Fig. 1 Flow chart diagram

In the study of [20] inclusion and exclusion criteria were clearly described; and strong statistics used reduce the risk of methodological flaws. However, there was no intention to treat analysis described.

In the study of [21] exclusion criteria are broadly described. Intention to treat analysis and power calculations are all included. Nevertheless this study has limitations such lack of allocation concealment, relatively wide confidence intervals and lack of appropriately described intervention, i.e. spinal manipulation.

In the study of [9] eligibility criteria and allocation concealed were explicitly described, but it lacks of clearly defined inclusion criteria. Power calculations and intention to treat analysis seem to be missing.

In the study of [24] high risk of bias was related to inappropriate randomization and allocation concealment, lack of blinding, intention to treat analysis. Clearly described exclusion criteria, drop outs, strong statistical tests and the use of placebos may compensate for possible biases. This study was scored as 2.

In the study of [16] inclusion criteria, intention to treat analysis, are not described adequately. However, appropriate statistical methods used may compensate for possible biases.

In the study of [17] exclusion and inclusion criteria has clearly been described. Nevertheless, it lacks appropriate handing of incomplete data and sampling methods.

Discussion and conclusions

Our review essentially shows that the effectiveness of osteopathy for MSP is not well-documented (Table 3). This contradicts a review of [7]. However, this review and meta-analysis is burdened with high risk of bias for several reasons. Firstly, in this review and meta-analysis, four out of six included studies actually showed no difference between OMT and controls [9, 13, 22, 24]. Secondly, it lacks a critical assessment of the methodology and validity of the included primary studies [25].

In order to maintain conceptual clarity in our review, we aimed to distinguish between chiropractic and osteopathic treatments and the former were excluded from this review. Five out of 16 trials that met our eligibility criteria suggested that OMT is effective for MSP [10, 11, 17, 20, 21]. Eleven RCTs shown that there is no difference between OMT and controls [9, 12–16, 18, 19, 22–24]. The evidence from RCTs of OMT for treating MSP is thus far from conclusive (Table 4).

Osteopathic manipulative treatment differed across studies ranging from soft tissue stretching, passive "joint play" (JP), and HVLA [22] Spencer Technique [12]

Table 3 Osteopathic treatments applied in the included studies (direct quotes from primary studies)

Study	Intervention (direct quote)
[22]	"...soft tissue stretching of the lumbar and buttock musculature, low-amplitude passive articulatory manoeuvres of the lumbar spine and judicious use of high-velocity thrusts to one or more lumbar articulations"
[23]	"...each therapist did not necessarily use all of the interventions listed under each subgroup heading; rather, they chose which modalities they deemed most appropriate from that list". [this list included: soft tissue massage, soft tissue inhibition, soft tissue stretch muscle energy, articulation, HVLA, functional, exercise advice, education, discussion of psychological issues, nutrition/dietary advice
[12]	"seven-step Spencer shoulder technique: Step 1—extension with elbow flexed; step 2—flexion with elbow extended; step 3—compression circumduction; step 4—circumduction ith traction with elbow flexed; step 5—adduction with external rotation with elbow flexed; step 6—internal rotation; step 7—stretching tissues and pumping fluids with the arm extended."
[15]	"...a combination of HVLA thrust, muscle energy, and soft tissue techniques."
[14]	"...one or a combination of the following techniques: myofascial release; strain/counterstrain; muscle energy; soft tissue; high-velocity low-amplitude (not at the surgical site); or craniosacral manipulation."
[13]	"… one or a combination of the following techniques: myofascial release, strain-counterstrain, muscle energy, soft tissue; high-velocity low-amplitude thrusts and cranial-sacral."
[18]	"...gentle techniques such as myofascial release, balanced membranous tension, muscle energy, myofascial release, joint articulation, high-velocity, low-amplitude thrust and cranial-sacral therapy…"
[10]	"...a combination of the soft-tissue techniques…" [soft tissue and fascial techniques, muscle energy and strain and counterstrain techniques, lymphatic drainage techniques]
[19]	"...a single, short-lever, HVLA distractive (caudal) thrust directed at the talocrural joint […] with the patient in the supine position."
[20]	"Gentle ipsilateral side flexion and contralateral rotation were introduced from the restricted side until slight tension was palpated in the tissues at the contact point. An HVLA thrust was directed upward and medially in the direction of the patient's contralateral eye."
[21]	"...osteopathic spinal manipulation, but also advice about keeping active, exercising regularly and avoiding excessive rest. Occasionally, if symptoms persisted despite osteopathy, tender ligaments or peripheral joints were injected with corticosteroid and local anaesthetic."
[9]	"A variety of techniques were used, including thrust, muscle energy, counterstrain, articulation, and myofascial release. The treating physician chose the techniques used."
[24]	"...soft-tissue manipulation, passive articulation of stiff spinal segments, and manipulation of the vertebral facet of sacroiliac joints using minimal rotation."
[17]	"… direct techniques (high-velocity, muscle energy, myofascial release), indirect techniques (functional techniques, balanced ligamentous tension), visceral and/or cranial techniques."
[16]	"muscle-energy/mobilization techniques for the extremities, the spine and inner organs (4 sessions a 50 min)"
[11]	"…a combination of Jones strain/counterstrain techniques and other osteopathic modalities applied to those TPs [tender points] the patient identified as most troublesome. Other modalities […] included myofascial release, muscle energy, soft tissue treatment, and craniosacral manipulation."

Table 4 Adverse effects as reported in RCTs

Study	Adverse effects
[22]	Not reported
[23]	Not reported
[12]	Not reported
[15]	Mild adverse effects in 8 patients in the control group and one in treatment group
[14]	Not reported
[13]	Not reported
[18]	Not reported
[10]	Not reported
[19]	Not reported
[20]	Not reported
[21]	No adverse events were reported in either treatment group
[9]	Not reported
[24]	Not reported
[17]	No serious AE reported. Occasionally, patients reported tiredness on the day of treatment
[14]	No AEs were noted
[11]	Not reported

combination of HVLA, muscle energy technique (MET), soft tissue techniques (STT) [15], myofascial release (MR), balanced membranous tension, MET, JP, cranio-sacral technique (CST) and HVLA [18], HVLA only [19, 20], osteopathic spinal manipulation, advice and corticosteroid injection and local anesthetic [21], soft tissue manipulation, JP, and HVLA [24], HVLA, MET, MR, functional technique, balanced ligamentous tension visceral manipulation and/or CST [17], to combination of one or more techniques such as HVLA thrust, MET, strain-counterstrain (SCS), JP, MR [9], SST and fascial techniques, MET, SCS, or lymphatic drainage [10], MR, SCS, MET, STT, HVLA, and CST [13, 14], soft tissue massage, inhibition, or stretch, JP, HVLA, functional, exercise, dietary or psychological advice [23]. Patient populations were heterogeneous ranging from neck pain patients [15, 17, 20], LBP patients [9, 13, 22–24], both neck and back pain patients [21], postsurgery patients [14], elderly shoulder pain patients [12], tennis elbow patients [16], to fibromialgia patients [11], patients with temporomandibular disorders [18] acute ankle injuries [10], or healthy volunteers [19]. Control groups were heterogeneous too. These included sham ultrasound [17], or placebo sham manipulation [12], and no-intervention [13] [19], drugs [15], moist heat [11], chemonucleolysis [22], sham treatment + standard care [14], chiropractic techniques, antiphlogistics, and cortison injections [16], exercises or manipulative physiotherapy [23], manual mobilization [20], short-wave diathermy (SWD) and a placebo (detuned SWD) [24], or standard care [9, 10, 18, 21]. Primary outcome measures (POM) also differed ranging from NRS [15, 17], VAS [9, 10, 13, 18, 24], life quality [13, 14, 23], range of motion and pain [12, 20], ROM [19], among others. In four cases the methodological quality of the studies was high [13, 21–23]. Location of pain varied too ranging from shoulder pain [9, 12], LBP [13, 22–24], neck pain [15, 17, 20, 21], tendon pain [16], ankle [10], or temporo-mandibular joint [18]. In four trials only adverse effects were reported [15–17, 21]. Given the fact that 12 trials did not report adverse reactions at all safety of OMT remains unclear. In most cases, the methodological quality of the trials was low, with only four RCTs scoring "3" and nine RCTs scoring less than "3" out of 5 possible points for methodological quality.

Only one trial (out of 4) of a high quality reported significantly greater improvement in POM [21]. Three trials (75%) that were of high quality reported no between groups differences [13, 22, 23]. Four trials (of 12) that were of low quality claimed that OMT is superior to control groups [10, 11, 17, 20]. Eight trials that were of low quality reported no differences between OMT and controls [9, 12, 14–16, 18, 19, 24].

Eleven trials were conducted by osteopaths [10–17, 19–21]. Five of them reported significant improvements in terms EASPS [21] and pain [10, 11, 17, 20]. Six reported no differences in terms of pain [13, 16] and ROM [12, 14, 15, 19].

The total number of patients that benefited from OMT was 291 and the number of patients that OMT was equally effective as control intervention was 923. The only one trial of high quality conducted by osteopath that showed significant improvements in favor of OMT used unusual outcome measures [21].

Essential elements in convincingly generalizing evidence are independent replications. Such studies of OMT in the treatment of MSP are lacking. Different research groups should undertake RCTs in patients with same clinical conditions utilizing same treatment protocols. Lack of equivalence or non-inferiority trials which compare OMT with equally effective therapies are missing.

Our review has several limitations. Firstly, the potential incompleteness of the reviewed evidence we may have limited the validity of the results. Secondly, publication and location biases that are well known phenomena may also influence the results of this systematic review. Thirdly, difficulties with operationalization and conceptualization of MSP and its variability may affect the findings of this review. Lastly the total number of trials included in our review and analysis and the total sample size are too small to allow definitive judgments.

Future studies of OMT should be in line with accepted standards of trial design and reporting (CONSORT). In particular, studies should be of adequate sample size, use validated outcome measures, control for non-specific effects

and minimize other sources of bias. Reporting of these studies should be such that results can be independently replicated.

In conclusion, the notion that OMT alleviates MSP is currently not based on the evidence from independently replicated high quality clinical trials.

Disclosures None

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