

What evidence is there for osteopathy? (May 2013)

• Key messages

This summary of osteopathic research should be treated as a very basic snapshot of past and current activity:

- Osteopathy is delivered in a variety of settings
- Patients report high satisfaction with treatment
- There is good quality evidence supporting the beneficial effects of manipulation for back pain
- The government recommends osteopathy for sub-acute and chronic low back pain
- The risk of experiencing serious adverse reaction to osteopathic treatment is very small; reports of serious adverse events are rare.
- Around half of patients may experience mild short lived resolving treatment reactions

Further information concerning osteopathic research can be found on the NCOR website www.ncor.org.uk

Introduction

There is increasing interest in the provision of osteopathy from the public at large, from the NHS and from government^{1,2}. This type of treatment is currently used by some 13% of the population in the United Kingdom³.

Professional regulation

Osteopathy is a profession that has been regulated by statute since the passing of The Osteopath's Act (1993)⁴. A new regulatory body, the General Osteopathic Council (GOsC), was formed in 2000. Osteopaths practise throughout the UK and overseas; most osteopaths work in private practice but a growing number work within the

National Health Service (NHS). Registration with the GOSc is renewed annually subject to certain requirements e.g. the retention of professional indemnity insurance, meeting mandatory continual professional development requirements, and the maintenance of high standards of professional practice.

Training

Osteopaths undergo four years training resulting in the award of BSc (Hons) Ost or BSc(Hons) Ost Med. Osteopaths who qualified before 1990 hold the award of Diploma in Osteopathy (DO). There are now eleven osteopathic training establishments in the UK which have met RQ status. Many of the osteopathic educational institutions (OElS) have recently begun an extended training programme resulting in the award of Master of Osteopathy (MOst). An increasing number of osteopaths are also undergoing postgraduate training for MSc, MRes and PhD awards.

Research within OElS is continually being undertaken to ensure high standards of competence for students, and ongoing assessment of teaching practices^{5,6,7,8}.

Osteopathic practice

Osteopathic care contains over 100 different techniques or procedures^{9,10,11,12,13}. The most commonly used structural approaches are broadly grouped into seven major types:

- High velocity low amplitude (also called thrust or manipulation techniques). This involves a quick movement within a joint's normal range of movement and does not exceed the anatomic barrier of the joint. Movement can be targeted to specific spinal segments and, with appropriate positioning of the patient, requires very little force. The goal of the technique is to restore joint play^{14,15}. The technique is frequently characterised by a clicking sound whose source has been investigated by a number of researchers^{16,17}. This technique most closely resembles chiropractic manipulation and is subject to most contraindications.
- Soft tissue/massage techniques¹⁸
- Articulation involving gentle repetitive movement of a joint to try and increase the range of movement¹⁹.
- Muscle energy. This involves repeated isometric contractions with passive joint movement to increase joint mobilisation and lengthen contracted muscles^{10,11}.
- Counterstrain. This involves the symptomatic joint being placed in a position of least discomfort while at the same time monitoring the degree of tenderness at a nearby tender point until the tenderness reduces^{10,11,20}. The only contraindication is patient unwillingness or inability to cooperate.

- Myofascial release techniques. These techniques are similar to deep massage techniques and are designed to stretch muscle and reduce tension¹¹.
- Lymphatic pump techniques. These techniques attempt to mechanically assist lymphatic drainage. There are a small number of contraindications to this technique²¹.

The wide range of techniques ensures that care of the patient is tailored to their general health and wellbeing, their age, presenting symptoms and any comorbidities they currently possess. A wide range of symptoms are treated in clinical practise; low back pain is the most common but pain to the cervical spine, shoulder joint, and knee joints are also very commonly presented.

Access to treatment

Access to osteopathic treatment is through a variety of locations: private practices, NHS hospital outpatient departments, General Practices (GPs) and clinics attached to osteopathic education institutions^{22,23,24,25}. In some areas neck and back pain services are commissioned and patients can get referred to these via their GP and patients are treated free at the point of delivery of care, these osteopaths are contracted via the NHS through the 'Any qualified provider' commissioning of services. The vast majority of patients access treatment through private practices. Traditionally, musculoskeletal disorders, particularly low back pain, have been the commonest reasons for a patient to visit an osteopath. The limited survey work that has been done suggests that back pain accounts for approximately fifty percent of an osteopath's workload and that musculoskeletal-type presentations make up the majority of the rest of the case load²⁶. However, these data have to be treated with some caution as they are either dated²⁷, based on teaching clinics²⁸, single practices^{29,26} or single day surveys with poor response rates^{30,31}. A new initiative began in 2007 with the development of a standardised data collection (SDC) tool for the osteopathic profession to collect data on patient profiles, their route to treatment, the interventions delivered, and outcomes of care. Data collection using the SDC tool took place for a three month period in 2009. The findings of this study are contained in a full report that can be found at http://www.ncor.org.uk/wp-content/uploads/2012/10/SDC_final_report_2011.pdf

An executive summary can be found at http://www.ncor.org.uk/wp-content/uploads/2012/10/SDC_Executive_Summary.pdf

Initial screening takes place at first consultation and referrals are made where patients are not suitable for osteopathic treatment. Education relating to a patient's condition is also emphasised as part of their management to produce suitable coping strategies and prevent the recurrence of injury where possible.

Clinical governance

The introduction of clinical governance into the healthcare arena has affected not only NHS practitioners but those in complementary health care professions such as osteopathy^{32,33}. Clinical governance has modified the focus from quality assurance to encompass standards on record keeping, monitoring outcomes, clinical audit, patient satisfaction measures, patient safety and the implementation of evidence³⁴. These demands reflect some of the requirements outlined in the recent “Fitness to Practice” guidelines issued by the General Osteopathic Council³⁵.

Patient satisfaction constitutes one aspect of clinical governance and studies of this nature have been undertaken in a range of different settings. These settings have included osteopathic clinics attached to osteopathic educational institutions (OEI), and osteopathic services provided on GP premises. The study within the OEI was a descriptive and exploratory investigation of patient satisfaction and perceptions of treatment. The majority of patients expressed satisfaction with treatment, the explanations they received and their perceived health outcomes³⁶. Chronic low back patients reported their satisfaction with the treatment they received for back pain from GPs and osteopaths practising within the same surgery. Although levels of satisfaction were high for all treatments, patients reported significantly higher scores for satisfaction with the osteopathic treatment³⁷.

Evidence and practice

Research within the osteopathic profession has taken place over a number of years; capacity in terms of research active osteopaths is steadily growing. Research activity relating to many of the osteopaths who are based in OEIs can be found in the NCOR Annual Reports³⁸. The National Council for Osteopathic Research (NCOR) was formed in 2003 and until May 2012 was based at the University of Brighton under the direction of Professor Ann Moore, Professor of Physiotherapy at the University of Brighton. Professor Moore was succeeded in this role on 1st May, 2012 by Dr Dawn Carnes from Barts and The London School of Medicine and Dentistry, which is where NCOR is now based. NCOR is involved in a number of initiatives, some of which appear on the NCOR website www.ncor.org.uk.

Clinical guidelines

Osteopathy increasingly features in clinical recommendations, notably for back pain^{39,40}. The Clinical Standards Advisory Group (CSAG) produced clinical guidelines for the management of acute low back pain in 1994 which produced guidance on diagnostic triage, and principal recommendations for treatment based on evidence in this area³⁹.

Manipulation was recommended “within the first six weeks of the occurrence of symptoms for patients who need additional help with pain relief or who are failing to return to normal activities”.

The European back pain guidelines (www.backpaineurope.org) have examined both acute and chronic back pain and have made recommendations accordingly. The acute low back pain guidelines suggest "consideration of referral for spinal manipulation for patients with acute low back pain who are failing to return to normal activities"⁴¹. The guidelines for chronic low back pain recommend that "short courses of manipulation/mobilisation can also be considered for chronic low back pain patients"⁴².

This work was followed by the Musculoskeletal Services Framework which provides advice concerning the use of osteopathic care/spinal manipulation⁴³. Most recently the National Institute for Health and Clinical Excellence (NICE) has reviewed the evidence looking at the acute management of chronic non-specific low back pain; this looks specifically at back pain that has lasted longer than six weeks but not more than thirteen months⁴⁴. The consultative process began in 2008 and guidelines were produced in May 2009. The guidelines have produced information concerning a variety of different treatments and approaches for patients with non-specific low back pain. This includes up to 9 sessions of manual therapy treatment which includes osteopathy.

Low back pain – clinical trials.

Low back pain is the symptom for which the highest numbers of patients consult osteopaths³¹. Commentators have recorded the view that for acute, uncomplicated low back pain “osteopathy and chiropractic were rated as effective by most experts”⁴⁵.

Acute low back pain

Gurry et al. (2004) looked at a multidisciplinary setting within Plymouth Primary Care Trust (PCT)⁴⁶. It found that the return to work time was quicker using this service which included osteopaths than GP and physiotherapy services alone. An audit of the service revealed that 84% of patients with low back pain can be managed without the need for hospital referral; this represents a considerable saving for the PCT. Hoehler et al. (1981) and Andersson et al. (1999) studied both acute and chronic back pain patients in their clinical trials^{47,48}.

Chronic low back pain

In 2004, funding was awarded by the Medical Research Council for the United Kingdom Back Pain, Exercise and Manipulation (UK BEAM) randomised trial⁴⁹. This looked at how a package of care involving one or a combination of treatment approaches could improve low back pain in patients. The study's authors concluded that the combination of spinal manipulation and exercise was more beneficial than when the treatments were used in isolation, and when compared to "best care" offered through general practice. An economic evaluation was made for this study and this concluded that adding spinal manipulation to "best care" was a cost effective way to manage back pain in general practice⁵⁰. Further analysis of the BEAM trial data has recently been undertaken looking specifically at the number needed to treat NNT⁵¹. This work, undertaken by Froud et al. (2009), found that, in contrast to the small mean differences originally reported in the BEAM trial data, NNTs were small and could be attractive to clinicians, patients, and purchasers. Further analysis of the BEAM trial data has attempted to identify characteristics of randomised controlled trial participants which predict greater benefits from physical treatments for low back pain: in turn this would allow more appropriate selection of patients for different treatments⁵². The analysis of this data found that baseline participant characteristics did not predict response to the UK BEAM treatment packages, and in particular, this analysis suggests that the distinction between sub-acute and chronic low back pain may not be useful when considering treatment choices.

Williams et al. (2003) undertook a pragmatic trial for spinal pain in primary care for patients experiencing back pain from between 2 and 12 weeks⁵³. The study's authors concluded that a primary care osteopathy clinic improved short-term physical and longer term psychological outcomes, at little extra cost to normal GP care. Rigorous multicentre studies are now needed to assess the generalisability of this approach. A cost-utility analysis has also been undertaken for this study concluding that a primary care osteopathy clinic may be a cost-effective addition to usual general practice (GP) care⁵⁴. A relative improvement in the mean quality-adjusted life-years (QALYs) for the osteopathy treatment group versus usual GP practice care was noted. This was associated with a small increase in mean health service costs. However, this conclusion was subject to considerable random error and a larger scale study will be required to further investigate the economic benefits. Work has also been undertaken by osteopaths in the United States examining the cost effectiveness of OMT as an intervention⁵⁵.

A number of studies have investigated the use of Osteopathic Manipulative Treatment (OMT) in the treatment of chronic low back pain^{56,57,58,59}. The work by Gibson et al. (1985) investigated both sub-acute and chronic low back pain patients⁵⁶. These studies

were among a number included by Licciardone et al. as part of their systematic review and meta-analysis⁶⁰. The authors concluded from this meta-analysis that OMT significantly reduces low back pain. The level of pain reduction is greater than expected from placebo effects alone and persists for at least three months. Additional research is warranted to elucidate mechanistically how OMT exerts its effects, to determine if OMT's benefits are long lasting, and to assess the cost-effectiveness of OMT as a complementary treatment for low back pain. A number of other studies have been conducted examining the management of chronic back pain using spinal manipulation but they failed to meet the inclusion criteria for this systematic review either on methodological grounds, or because they involved chiropractic manipulation⁶¹.

Chown et al. (2008) have more recently attempted to investigate the difference in outcome between patients being treated with group exercise, physiotherapy or osteopathy in a hospital setting⁶². The interventions offered in this prospective study were group exercises led by a physiotherapist, a one-to-one session with a (predominantly manipulative) physiotherapist, and a one-to-one session with an osteopath. Outcome data was collected at baseline, 6 weeks and 12 months post discharge using the Oswestry Disability Index (ODI) the EuroQol EQ-5D (including a simple health status visual analogue scale), a shuttle walk test (SWT), and questions relating to life satisfaction and satisfaction with the intervention. Attendance levels were greatest for osteopathy (80%). The mean change in ODI score for osteopathy participants exceeded that of physiotherapy participants by 0.84 (95% CI -0.35 to 5.2). The drop-out rate at this stage of the study was found to be less among the osteopathy group; a number of reasons have been suggested for this including more flexible appointment schedule, patients' preference for hands-on treatment, personal characteristics, or past experience within private practice.

Licciardone et al recently published a study of the efficacy of osteopathic manual treatment (OMT) and ultrasound therapy (UST) for non-specific, chronic low back pain⁶³. They conducted a randomised, double-blind, sham controlled trial to study the short-term effect of these interventions. UST was not found to be effective. Back-specific functioning, general health, work disability specific to low back pain, safety outcomes and treatment adherence did not differ between the OMT and sham OMT groups. However, the authors found that OMT met or exceeded the Cochrane Back Review Group criterion for a medium effect size in relieving chronic low back pain and patients in the OMT group used prescription drugs for low back pain less frequently than the sham OMT group during the 12 weeks of the study. In addition, patients in the OMT group were more likely to be very satisfied with their back care throughout the study.

Back pain and pregnancy

The occurrence of low back pain during pregnancy has been well documented by a number of authors including osteopaths^{64,65}. Licciardone et al. (2009) undertook a randomised controlled trial of back pain and related symptoms during the third trimester of pregnancy⁶⁶. The authors concluded that osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.

Psychological factors and low back pain

Considerable work has been undertaken looking at the role of psychological factors and their effect on patients' recovery from low back pain. Early work was undertaken by osteopath Professor Kim Burton and colleagues which has stressed the need for awareness of psychological factors and their impact on outcomes of care^{67,68,69,70}. This has more been followed by work undertaken by Williams et al. (2007) looking specifically at the psychological outcomes associated with spinal manipulation⁷¹. The most important risk factors for neck and back pain are psychosocial but systematic reviews in this area have focussed exclusively on pain and spine-related disability. Williams' systematic review has shown that there was some evidence that spinal manipulation improved psychological outcomes compared with verbal interventions.

Osteopathy and safety

A number of studies are currently being undertaken to investigate the incidence of adverse events related to osteopathy. Episodes of soreness after treatment are short lived (24 hours) and are commonly found in many other therapies using a "hands-on" approach⁷². Anecdotally the profession has enjoyed an extremely safe reputation since it uses less high velocity manipulation than other professions. The use of such high velocity manipulation techniques to the cervical spine has contributed to incidents of adverse events which have been reported by other manual therapy professions. The GOsC recently commissioned four research projects to investigate adverse events associated with osteopathic practice. They were undertaken as collaborative projects between osteopathic educational institutions and experienced researchers from Barts and The London, the University of Warwick and the University of Brighton. One of the studies looked at adverse events associated with physical interventions in osteopathy and other manual therapies. This published work attempted to gain a consensus on what specifically defines an adverse event in manual therapy⁷³. The findings of the systematic review examining adverse events in manual therapies have been published

also⁷⁴. The review reports that nearly half of patients after manual therapy experience adverse events that are short-lived and minor; most will occur within 24 hours and resolve within 72 hours. The risk of major adverse events is very low, lower than that from taking medication. The authors suggest that risk is inherent in all health interventions and should be weighed against patient-perceived benefit and alternative available treatments. Further work has been undertaken at the European School of Osteopathy teaching clinic looking at adverse events occurring within patients^{75,76}. Gibbons and Tehan (2006), and Leach (2006) have also made contributions in this area^{77,78}.

The three additional studies, funded by the General Osteopathic Council, have been concluded and their final reports are available on the GOSc website^{79,80,81}.

Adverse events arising from lumbar spine manipulation in the presence of disc injuries have also been reviewed. Oliphant (2004), Lisi et al. (2005) and Snelling (2006) have each undertaken reviews of the evidence in this area^{82,83,84}. Oliphant concluded that an estimate of the risk of spinal manipulation causing a clinically worsened disc herniation in a patient presenting with a lumbar disc herniation is calculated from published data to be less than 1 in 3.7 million. He suggested that the apparent safety of spinal manipulation, especially when compared with other interventions, should stimulate its use in conservative treatment plans. This work pre-dates that of Lisi and Snelling who are more cautious in their conclusions; they conclude that the evidence indicates there is some suggestion of an early benefit of spinal manipulation in patients with disc herniation, but there were insufficient good-quality trials to reach definitive conclusions.

Educational interventions

Osteopaths recognise the importance of education in the management of low back pain. Evans et al. (2005) investigated the use of initiatives designed to assist practitioner and patient decisions about appropriate information for low back pain included in printed evidence-based clinical guidelines⁸⁵. Wheller et al. (2006), and Howard and Gosling (2008) investigated patients' attitudes to prescription of exercise, and factors affecting compliance with interventions to aid patient outcome^{86,87}. These studies build on the earlier work of Professor Kim Burton, who has been involved in the development of several evidence-based information packages for both practitioners and patients concerning the management of low back pain^{88,89,90}.

Physiological assessment of low back pain

Laboratory-based studies attempting to understand the underlying effects of osteopathic treatment are continually ongoing. Studies have been undertaken to try and assess the effect of osteopathic manipulation treatment (OMT) on blood flow^{91,92}. The effects of OMT on pain markers in the blood have been studied by Degenhardt et al. (2007)⁹³; the role of OMT and its effect on the endocannabinoid system has been investigated by McPartland (2008)⁹⁴.

The mechanisms of action for OMT have been theorised by Brownhill (2007) and Lucas (2005) and the effects of trunk and limb muscle activity has been investigated by Blaich et al. (2006)^{95,96,97}. Work has been undertaken by Clark et al. (2009) to examine whether MRI-derived T2 or side-to-side differences in T2 (asymmetries) differ in low back muscles between subjects with acute low back pain (LBP) compared to asymptomatic controls, and to determine if a single osteopathic manipulative treatment (OMT) session alters these T2 properties immediately and 48-hours after treatment⁹⁸.

Potter et al. (2006) used both dynamic and static procedures to try and measure intra-examiner reliability when identifying a dysfunctional segment in the thoracic and lumbar spine⁹⁹. The diagnosis of a biomechanical joint dysfunction is fundamental to classification of musculoskeletal disease, and a reliable biomechanical diagnosis is necessary to justify the use of spinal manipulation to correct it. Although diagnosis of joint dysfunction is considered an important prerequisite to spinal manipulation, little assessment has been made of the clinician's ability to reliably identify a joint that is exhibiting signs of biomechanical dysfunction; there are very few reliability studies reported in the literature and this work has attempted to increase knowledge in this area. Investigations into the physiological effects of osteopathic techniques are continually ongoing; more studies of this nature are produced in OEIs in the US and New Zealand.

Studies facilitating clinical competence

The ability to correctly identify areas of anatomical dysfunction and locate them for treatment is empirical to any successful therapy. Increasing number of studies are focussing on clinical competence to maintain high standards of professional care. Correct identification of anatomical landmarks has been studied by Kmita et al. (2008)¹⁰⁰. The use of spinal assessment tests has been investigated by an increasing number of researchers. Esteves et al. (2008) has examined the use of multisensory integration in an osteopathic clinical examination setting¹⁰¹. The findings of the study

suggest that during the development of expertise in osteopathic practice, the integration of visuotactile information may become central to the diagnosis of somatic dysfunction thus contributing to increased diagnostic reliability. A variety of examination techniques have been investigated to improve diagnostic accuracy. These include palpation of the sacroiliac joints, assessment of lumbar curves, assessment of leg length measurement and its effect on the lumbar spine, and techniques to assess the spine and sacroiliac joints^{102,103,104,105,106}. Increasing knowledge in this area will increase diagnostic accuracy and selection of appropriate treatment techniques thereby contributing to improving the outcomes of care.

Current work within the osteopathic profession

All osteopaths recognise that further research into clinical practice is required to examine practice for the ultimate benefit of patients. The creation of an infrastructure for osteopathic research in 2003 will contribute to this. The lack of provision of funding to undertake more research remains a significant obstacle for osteopathy. The General Osteopathic Council, fulfilling its remit of acting in the best interests of patients, is currently funding work investigating patients' expectations of osteopathic care. This work has been undertaken by Dr Janine Leach, Senior Research Fellow at the University of Brighton in collaboration with Professor Ann Moore, Dr Ann Mandy, Dr Vinette Cross, Mrs Laura Bottomley, Mr Adam Fiske, Carol Fawkes, and Mr Matthew Hankins. The importance of focussing on patient care is in accordance with the recommendations of the recent report by Lord Darzi, and will build on the work previously undertaken by other healthcare professionals^{107,108}. The study has now concluded and the final study report can be found on the GOsC website¹⁰⁹. Papers are currently being prepared for publication.

The role of manual interventions, including osteopathy, in the treatment of sciatic pain has been investigated as part of a systematic review being undertaken by medical osteopath, Dr Nefyn Williams. This work was undertaken as part of a Health Technology Assessment; further information about this study can be found at:

<http://www.hta.ac.uk/project/1687.asp>.

Conclusion

This summary of osteopathic research should be treated as a very basic snapshot of past and current activity. Clinical trial information has focused on studies that are osteopathic and are of higher quality; the trials and reviews cited were included within the considerations by NICE for their recent guideline development work.

Further information concerning osteopathic research can be found on the NCOR website www.ncor.org.uk. You can also contact NCOR via the website.

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