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EBM in Clinical Practice: Implementation in Osteopathic Diagnosis and Manipulative Treatment for Non-Specific Low Back Pain Patients

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1. Introduction

1.1 Non-specific low back pain in western countries

Low back pain (LBP) is an extremely common problem which most people in industrialized countries experience at some point in their lives. The prevalence of LBP in the USA ranges from 8% to 56% (Manchikanti, 2000). Estimation of the one-year incidence of a first-ever episode of LBP ranges between 6.3% and 15.4%, while estimation of the one-year incidence of any episode of LBP ranges between 1.5% and 36%. Studies have found the incidence of LBP is highest in the third decade, and overall prevalence increases with age up to the 60-65 year age group, and then gradually declines. Many environmental and personal factors influence the onset and course of LBP. In addition to age, commonly reported risk factors include low educational status, stress, anxiety, depression, professional dissatisfaction, low levels of social support in the workplace and whole-body vibration activities. LBP has an enormous impact on individuals, families, communities, governments and businesses throughout the world (Hoy et al, 2010), and associated costs are estimated at between between $20 billion and $50 billion per year (Nachemson, 1992).

Non-specific low back pain (NS-LBP) represents about 85% of LBP patients seen in primary care (Deyo and Phillips, 1996), and the vast majority of LBP patients seen by physical therapists are classified under this label. This classification process differentiates between specific spinal pathology, nerve root pain and simple or NS-LBP (Waddell, 2004). Patients suffering from NS-LBP who are not improving may benefit from referral for spinal manipulation provided by a trained spinal care specialist such as a physical therapist, chiropractor, osteopathic physician or physician who specializes in musculoskeletal medicine (NGC-7704, 2009). No evidence was found to support recommending regular manipulative treatment for the prevention of LBP (NGC-7704, 2009). High-quality evidence suggests that there is no clinically relevant difference between the efficacy of spinal manipulative therapy (SMT) and other interventions for reducing pain and improving function in patients with chronic NS-LBP. Determining cost-effectiveness of care is of high priority (Rubinstein et al, 2011). Risk of serious complications after spinal manipulation is low (estimated risk: cauda equina syndrome, less than one in one million). Current guidelines contraindicate manipulation on people with severe or progressive neurological deficit (NGC-7704, 2009).

1.2 Osteopathy and osteopathic medicine

In the USA, osteopathic physicians are licensed to practise the full scope of medicine. In Europe, Australia and New-Zealand, osteopaths are first-contact practitioners trained in private or academic institutions with Bachelors or Masters degree levels, and they are allowed to provide only osteopathic manipulative treatment (OMT) (WHO Benchmarks, 2010). OMT is one of the numerous treatment approaches within manual and manipulative therapies for the management of a variety of musculoskeletal and non-musculoskeletal conditions. A wide range of manual techniques described in the *Authorized Osteopathic Thesaurus (AOT)* (Authorized Osteopathic Thesaurus, 2009) are used for the treatment of somatic dysfunction (SD). A SD is a functional disturbance of the musculoskeletal system tissues and related vascular and neurological components (Rumney, 1975). Osteopathic care relies on four tenets: (1) the body is a unit; the person is a unit of body, mind, and spirit, (2) the body is capable of self-regulation, self-healing, and health maintenance, (3) structure and function are reciprocally interrelated and (4) rational treatment is based upon an understanding of the basic principles of body unity, self-regulation, and the interrelationship of structure and function (Rogers et al, 2002).

The distinguishing features of osteopathic care described in the scientific literature seem to be the concept of SD, the OMT and the four basic tenets of osteopathic therapeutic principles (WHO Benchmarks, 2010). Although these concepts were proposed mainly for educational purposes, they appear to be central in osteopathic practice, and are currently challenged by evidence-informed osteopathy (Fryer, 2008).

The SD is a pathological entity referenced in the International Classifications of Diseases (ICD) 10 and has a political use as a tool distinctive from other manual therapies (Zegarra-Parodi, 2010). This concept relies however on biomechanical and neurophysiological theories that are partially supported in clinical practice. It is recommended to osteopathic physicians to use OMT for NS-LBP caused by musculoskeletal conditions, i.e. to treat SD related to LBP (NGC-7504, 2009).

OMT is a distinctive therapeutic modality which significantly decreases LBP with an effect size of -0.30 (CI 95% = [-0.47;-0.13]). The level of pain reduction is greater than expected from placebo effects alone and persists for at least three months (Licciardone et al, 2005a).

1.3 Purpose

The purpose of this chapter is to describe current clinical and scientific evidence regarding the concept of somatic dysfunction associated with non-specific low back pain for osteopathic manipulative diagnosis and treatment. This clinical concept will be analyzed in the light of evidence-based medicine.

2. Methods

A systematic literature search was conducted in July 2011 to identify published papers examining osteopathic manipulative diagnosis and treatment of NS-LBP patients. The research included studies from 1975 onwards, i.e. since SD was first defined by Rumney. The databases searched were Medline, CINAHL and the Cochrane library. The search terms were as follows: key term - "somatic dysfunction", "low back pain", "osteopathic manipulative treatment" or "OMT" "osteopathic diagnosis". The key terms were searched for in the title, abstract and keywords. Studies were included if they were written in English or French. The reference lists of retrieved studies were scanned to identify additional relevant papers.

3. Results

3.1 Osteopathic diagnosis: The somatic dysfunction concept

3.1.1 Historical aspects

Littlejohn, one of the pioneers of osteopathy, developed the concept of physiological disturbance associated with mechanical strain from the bony structures in 1903. He suggested that a properly functioning nervous system was a key element to maintain health and recover from disease. Burns then began to study physiological effects following manipulations at the Kirksville College of Osteopathic Medicine (KCOM) in the early 20th century. She mapped the effects produced by osteopathic lesions - manipulable lesions described by osteopaths - at different spinal segments, and found a close correspondence in the pattern produced in experiments on animals and the clinical patterns observed in herself and her colleagues (Allan, 1986). Experimental studies suggested the involvement of the parasympathetic and the sympathetic pathways in the genesis of the osteopathic lesion through viscerosomatic reflexes (Burns, 1948). Denslow and Korr (Denslow, 1993; Korr, 1997) from KCOM led the first experimental studies on the human body to lend support to a model providing a neurological explanation for the origin and maintenance of the osteopathic lesion. They observed paraspinal muscle hyperexcitability associated with two misaligned vertebrae and alteration of sympathetic nervous system activity through sudomotricity studies. Some musculoskeletal symptoms quickly improved with manipulation: the nervous system is the only system that can operate almost instantaneously and may therefore be the mechanism behind the effects seen following manipulation. They developed the "facilitated segment" concept (Korr, 1979): an injured somatic or visceral structure produces discordant afferent impulses creating what is now described as a sensitization of the dorsal horn. The osteopathic lesion was initially described according to its characteristic features: altered range and quality of joint movement, altered tissue texture in the surrounding tissues, and sometimes apparent asymmetry of one vertebra compared to the others (Korr, 1947).

Rumney, from the KCOM, wrote the first paper describing the concept of SD (Rumney, 1975). Three major components of disease had been identified: visceral, psychic and somatic. He focused on the somatic component. He thought that the osteopathic profession had misled other health professions about what osteopathy was, by introducing the adjective "osteopathic" to terms, as in "osteopathic lesion" or "osteopathic pathology", creating difficulties communicating with other scientific groups. Inaccurate concepts used by early osteopaths for manipulations such as the "bone out of place" were then replaced by concepts focusing more on the physiopathological consequences of biomechanical impairments as scientific knowledge increased within the osteopathic profession. The SD was therefore defined as *"an area of impaired function of related components of the musculoskeletal system (muscle, bone, fascia and ligament) and its associated or related parts in the vascular, lymphatic, and nervous systems"*. Three important criteria for manual diagnosis were described: tissue changes, hyperalgesia and motion changes. This diagnosis is based on different signs in order to lead to a precise treatment, making specific adjustments. This concept was a shift from previous theories, which held that a global approach was sufficient to be effective.

In 1990 Van Buskirk, an American osteopath, came up with a model to support the SD pathogenesis (Van Buskirk, 1990). This model focused on nociceptors, as they were the only described sensory receptors which could generate muscle hypertonia, autonomic arousal, and consequent loco-regional circulatory impairments commonly associated with SD. Van Buskirk's SD model brought together three previous models based on: changes in nervous system activity, in connective tissue and in local circulation. Nervous system activity changes associated with SD corresponded to an increase of sympathetic outflow caused by localized excessive nociceptive information from visceral or somatic structures. Maintaining excessive nociceptive input would be detrimental to the normal function of the organ involved, and immune function would theoretically be diminished. These afferents would also produce reflex muscle contraction by axon reflex and sympathetic vasodilatation effects which would engorge the affected muscles and produce a restriction of motion. Over time, the muscle would become fibrotic and if stretched or strained again, nociceptors would be activated once again.

3.1.2 Physiological studies

Fryer, from Victoria University, Australia, recently revisited the SD neurophysiological theories with modern equipment (Fryer, 1999; Fryer, 2003), focusing on paraspinal tissue texture changes detected with palpation associated with electromyographic (EMG) data. A literature review has shown that the concept of reactive muscle contraction associated with intervertebral dysfunction seems plausible (Fryer et al, 2004a). The deep paraspinal muscle inhibition observed during dynamic and static activities was used as a theoretical framework for a possible relationship between dysfunctional muscle activity and tissue texture change findings with SD. However abnormal paraspinal tissues detected with palpation were associated with increased and/or decreased muscle activity (Fryer et al, 2004b). They then tried to find a possible relationship between an abnormal paraspinal muscle palpation and local sensitivity measured using an algometer. They observed that paraspinal sites identified as having abnormal tissue texture and tenderness diagnosed by palpation, had significantly lower mean pressure pain threshold than other sites immediately surrounding the abnormal region (Fryer et al, 2004c). These results tend to corroborate common palpation findings diagnosed by osteopathic practitioners. Increased motor activity might be a contributing factor to tissue changes detected with palpation (Fryer et al, 2006).

Fryer pursued his studies at the Andrew Taylor Still Research Institute (ATSRI) in Kirksville where Korr and Denslow had worked 60 years before. Principal biases, i.e. thinner intramuscular wires, proper statistical analysis and limited cohort size, were corrected. Recent studies concluded that there was no evidence of distinguishing EMG activity in the deep thoracic paraspinal musculature at sites identified as abnormal to palpation under resting conditions, compared to sites identified as normal (Fryer et al, 2010a). They suggested that other factors than muscle activity, such as tissue fluid and inflammatory mediators, could be responsible for the apparent abnormality of these tissues during palpation.

3.2 Osteopathic palpatory findings in LBP patients

The SD concept underlies the diagnosis and the treatment in osteopathic medicine in clinical guidelines. In the USA, the National Guideline Clearinghouse (NGC) recommended that OMT be utilized by osteopathic physicians to treat SD associated with NS-LBP (NGC-7504, 2009). This recommendation has a 1a level of evidence (the highest level) and is based on the results of a systematic review of randomized controlled trials (Licciardone et al, 2005a).

Fundamental requirements for a diagnostic test to be recommended to clinicians are its accuracy and its reliability (Bossuyt et al, 2003). Over recent years, evidence-based medicine has challenged osteopathic practicioners to favor proven reliable palpatory tests when diagnosing patients' conditions. Determining the accuracy and reliability of diagnostic tests used in osteopathy is therefore a high priority (Lucas and Bogduk, 2010). For that purpose, the ATSRI tried to investigate the interobserver reliability of common osteopathic palpatory tests used to evaluate the lumbar spine (Degenhardt et al, 2005). Three practitioners performed common palpatory tests for the clinical findings associated with SD: tenderness, tissue texture changes, vertebral positional asymmetry, and motion asymmetry in subjects. The procedure was repeated and the results were re-evaluated after consensus training had been completed by the examiners. This study showed that the initial evaluation of interobserver reliability for the four tests was poor to fair (kappa ranged from -0.02 to 0.34). Acceptable kappa values for clinical tests were achieved after consensus training only for tissue texture and tenderness, but the tenderness test was the only test that had a good kappa value (k=0.68).

The lack of reliable tests in manual medicine is common as there is no gold standard except for pain. Acceptable reliability in diagnosing SD could however be achieved with appropriate and regular training in clinical studies and then be recommended to clinicians. Snider et al. (2008) investigated the incidence and severity of SD of four lumbar vertebral segments (L1-L4) in subjects with chronic NS-LBP. They included 16 subjects with chronic LBP and 47 subjects without chronic LBP. Subjects' four lumbar vertebral segments (L1-L4) were evaluated. From 15 palpatory tests taught at KCOM, the four that achieved greatest inter-examiner reliability in the Degenhardt et al. study (2005) were included in a specific training protocol designed to promote consensus between examiners. The two groups showed significantly different severity of SD, determined from tissue texture changes ($p=0.006$) and static rotational asymmetry ($p=0.008$). Severity was found to be greater for the chronic LBP group than for the non-LBP group. Significant differences were observed in the incidence of vertebrae testing positive for resistance to anterior springing ($p<0.001$) and tenderness ($p=0.002$), with both occurring more frequently in the chronic LBP group than in the non-LBP group. Furthermore, the severity of SD as determined with resistance to anterior springing ($p<0.001$) and tenderness ($p=0.001$) was also significantly different between the two groups, with the chronic LBP group again showing greater severity than the non-LBP group. NS-LBP patients have more severe SD compared to asymptomatic patients and clinicians usually associate these clinical findings with symptoms to shape specific OMT for each patient. Snider et al. (2010) investigated the association of lumbar SD as assessed with palpation with bone mineral density (BMD) among LBP and healthy patients. They observed that lumbar segments with palpated rotational asymmetry had higher mean BMD T scores than lumbar segments with no asymmetry (p=0.002). Lumbar segments with anterior motion restriction had higher mean BMD T scores than lumbar segments with no motion restriction (p=0.03). LBP patients demonstrated higher regional mean lumbar BMD T scores than those without LBP (p<0.001). These results suggest an association of objective lumbar vertebral BMD variation to palpatory findings associated with SD.

Although patients describe the same symptoms, OMT is test-dependent and then specific according to SD incidence and severity, and the association made with symptoms by the practitioner. Pain provocation tests are currently described as the most reliable, and soft tissue paraspinal palpatory diagnostic tests and landmarks as not reliable. Practitioners should therefore combine their own experience with current data to select specific tests in order to achieve a precise SD diagnosis.

3.3 Osteopathic Manipulative Treatment for LBP patients

It has now been established that SD can be treated by OMT (Fryer, 1999) and several studies describe the benefits of OMT in the treatment of LBP (Licciardone et al, 2005a). However even if scientific evidence supporting the effectiveness of OMT has emerged, there is still a lack of scientific evidence to describe the psycho-physiological mechanisms underlying these treatments (Evans, 2002).

The main explanations for the effects of manual techniques are based on data from human and animal studies, and recent models rely on neurophysiology (Pickar, 2002; Skyba et al, 2003). Manipulation-induced hypoalgesia has been demonstrated in studies with human subjects (Sterling et al, 2001). Skyba et al. (2003) demonstrated in an experimental study on rats, that the antihyperalgesia produced by joint manipulation appears to involve descending inhibitory mechanisms which utilize serotonin and norepinephrine. Pickar (2002) explained that spinal manipulation impacts proprioceptive primary afferent neurons from paraspinal tissues, paraspinal tissues. He suggested that this can affect pain processing, possibly by altering the central facilitated state of the spinal cord, the motor control system, and through somato-somatic reflex and somato-visceral reflex. Several studies have shown a relationship between spinal manipulation and response of the autonomic nervous system (ANS): spinal manipulation induced a sympathetic response that was measured by the modification of skin conductance or the α-amylase-activity (Sterling et al, 2001; Henderson et al, 2010) and OMT produced vagal response (Henley et al, 2008).

Several studies (Sherman et al, 2004; Andersson et al, 1999; Licciardone et al, 2003) describe OMT's beneficial effects on symptoms of chronic pain patients. For NS-LBP patients in particular, Degenhardt et al (2007) observed a decrease in pain blood markers associated with a decreased level of stress described by patients 24 hours after receiving OMT.

3.4 Osteopathic diagnosis and Osteopathic Manipulative Treatment records in a clinical setting

Despite the SD's ICD classification (ICD-10, 2007), the SD nomenclature is not universally used: a 2010 study of the UK osteopathic profession revealed multiple terms used to describe this palpatory diagnosis of "somatic dysfunction", including "restriction", "naming by anatomical aetiology", "dysfunction", "facet lock", "motion restriction" and more than 12 other names (Fryer, 2010b). Despite the lack of uniform terminology for the SD, the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy standardized the palpatory diagnosis of SD by developing and validating the Outpatient Osteopathic Subjective Objective Assessment Plan Note Form Series (OOSNF). These data records sheets are standardized and used to objectively measure and record the diagnosis and treatment of SD during patient encounters (Sleszynski et al, 1999). Two systematic reviews (Seffinger et al, 2004; Stochkendahl et al, 2006) recommended that clinicians should not base their diagnosis on a single clinical examination such as palpation, but rather on a range of tests and findings (Brunse al, 2010). The SD diagnosis is not used in a pain and movement model as in manual medicine for example, but includes other previously described clinical findings. Its four diagnostic criteria are commonly represented in the osteopathic literature by the acronym TART: **(T)** tissue texture abnormality: effusions, laxity, stability, tone; **(A)** asymmetry: crepitation, defects, masses, misalignment; **(R)** restriction of motion: contracture and **(T)** tenderness: pain (Outpatient Osteopathic SOAP Note Form, 2002; Authorized Osteopathic Thesaurus, 2009).

The OOSNF musculoskeletal table is used to collect data on the musculoskeletal evaluation of 13 anatomic regions: head, cervical, upper thoracic (T1–T4), midthoracic (T5–T9), lower thoracic (T10–T12), lumbar, sacrum/pelvis, pelvis/innominate, lower extremities (left and right), upper extremities (left and right), and ribs. For each of the patient's anatomic regions, the osteopathic practitioner evaluates the severity of SD. The scoring criteria for levels of SD are as follows: (0 – None): no SD present or background levels of SD only, (1 – Mild): more than background levels of SD, minor TART elements present, (2 – Moderate): obvious TART elements, which may or may not be overtly symptomatic, with significant restriction of motion and/or tenderness elements present and (3 – Severe): key SD with significant symptomatology, including restriction of motion and/or tenderness elements that "stand out" with minimal search or provocation (Sleszynski et al, 1999).

Johnson and Kurtz (2003) classified OMT in three categories: (1) direct techniques which engage the restrictive barrier: articulatory, High-Velocity Low-Amplitude Thrust (HVLAT), muscle energy, soft tissue, (2) indirect techniques applied away from the restrictive barrier: counterstain, cranial, facilitated positional release, functional, fascial ligamentous release, and (3) direct-indirect techniques: myofascial/integrated neuromuscular release, lymphatic. The OMT modalities used to treat the SD evaluated in correlation with the patient chief complaint and the perception of how the SD in each region responded to OMT immediately after treatment are reported. The scoring criteria for responses after OMT are either: (R) Resolved: the SD is completely resolved without evidence of it ever having been present, (I) Improved: the SD is improved but not completely resolved, (U) Unchanged: the SD is unchanged or the same after treatment as it was before treatment, (W) Worse: the SD is worse or aggravated immediately after treatment. In the final section, the osteopathic practitioner details new medications, exercises he wishes the patient to carry out and nutritional, food or diet recommendations (Outpatient Osteopathic SOAP Note Form, 2002).

Members of the profession should consider the long-term value of this widely accessible database which will facilitate descriptive and clinical osteopathic studies (Sleszynski and Glonek, 2005). These tools, which have been used in published research are necessary for the osteopathic profession's future, as governments and paying third-parties require more evidence to justify treatment reimbursement. The profession has the opportunity to provide data to describe, explain, and support OMT's effectiveness for musculoskeletal and non-musculoskeletal conditions.

3.5 Osteopathic management of LBP patients: Patient-practitioner interaction

The emphasis in treating patients who have NS-LBP is on improving function, decreasing peripheral nociception and central facilitation, and empowering individuals to move forward in resuming their normal daily life activities (Kuchera, 2005).

A growing number of chronic pain patients are consulting complementary and alternative medicine (CAM) practitioners owing to dissatisfaction with mainstream medicine. (Kuchera, 2007) Patients appreciate having an individual answer to their symptoms, and an understandable explanation. As diagnosis in osteopathic medicine is not based only on pain, patients presenting the same symptoms may not receive the same treatment. Each osteopathic practitioner designs a specific treatment according to the patient's expectations and his/her osteopathic diagnosis, i.e. the SDs relating to the NS-LBP. The test-dependant OMT for SD may focus on various local, spinal and supra-spinal theoretical outcomes determining technique choices and goals. OMT is chosen and adapted after obtaining patients' consent, and treatment strategies depend on the patient's ability to face the treatment's homeostatic response and the main underlying pathophysiological mechanism (Kuchera, 2007).

Lifestyle and habits, including ergonomics, are crucial points to take into consideration as they may be provoking or sustaining factors for SD, and can challenge treatment results or even prevent amelioration. Patient history should therefore encompass these aspects and look carefully for possible personal or occupational biomechanical stressors. Such information could be included in a specific patient education programme in order to avoid dysfunctional strain patterns leading to recurrent symptoms.

According to Kuchera (2007), physical examination of chronic pain patients by osteopathic practitioners should not be limited to searching for pain generators, as chronic pain is often associated with anxiety, depression and a reduction in the quality of life. Chronic pain shifts pain activity from the sensory cortex to the anterior cingulate gyrus, leading patients to describe their suffering rather than the location of their pain. Osteopathic practitioners use patient communication about social, family and emotional impact of illness rather than focusing on pain (Carey et al, 2003) and provide health and diet advice (Kuchera, 2007).

An American study showed that the length of consultation was longer for osteopathic physicians compared to allopathic physicians: 20 minutes versus 15 minutes on average ($p<0.01$) (Sun et al, 2004). This feature may have a positive therapeutic influence on the perception and understanding of pain by the patient, which is described as a possible psychosocial risk factor for transition from acute to chronic pain (Penney, 2010). Quality of care and patient satisfaction with osteopathic practitioners could be attributed to communication and empathy (Pincus et al, 2000).

4. Discussion

4.1 Osteopathic diagnosis for LBP patients

The International Association for the Study of Pain (IASP) describes two main models to explain LBP's physiopathological mechanisms: the End-Organ Dysfunction Model (EODM) and the Altered Nervous System Processing Models (ANSPM) (Pain, Clinical Updates: Low Back Pain, 2010). Both models are for educational and treatment purposes; it is supposed that treatment is more effective if it targets specific physiopathological mechanisms. The EODM supports the theory that nociceptive stimuli are caused by lumbar spine pathologies such as injuries, degenerative changes or repetitive strain injuries. However LBP does not always correlate with lumbar spine pathologies diagnosed by MRI scans or pain provocation/palliation techniques. It is proposed in the ANSPM that perception of sensory information is altered. This alteration might be due to physiological changes within the nervous system with an increased susceptibility to pain due to psychological vulnerabilities, such as depression or anxiety. In daily practice, practitioners reported that patients suffering from LBP are predisposed to reporting additional chronic pain syndromes. Researchers have discovered that sensory neurons, usually silent in healthy patients, may become reorganized and generate spontaneous action potentials leading to a rewiring of the central nervous system in chronic pain conditions. However symptoms described by LBP patients cannot be explained with a single model but rather with a combination of EODM and ANSPM with variation for each patient. It is interesting to observe that the clinical concept of SD combines these two approaches, i.e. a biomechanical strain from somatic and visceral structures which is associated with altered reflexive neurological responses from the involved anatomical area to the spinal cord.

SD diagnosed among NS-LBP patients may be causative, reflexive, reactive or perpetuating, or a mix of these. Models for SD are controversial and rely on biomechanics (Triano, 2001) and neurophysiological reflexes (Van Buskirk, 1990; Pickar, 2002; Howell and Willard, 2005). Data from scientific literature about mechanical and neurophysiological modifications observed in LBP patients may also be interpreted by osteopathic practitioners using the SD concept, but this does not give a scientific validation of this concept. Here are two examples of results from EMG and ulstrasonography studies on LBP patients where the results could be "osteopathically" interpreted, i.e. focusing not only on local physiopathological changes but also looking at possible interactions with other anatomical areas according to their biomechanical and neurophysiological functions. Some of these physiopathological changes could also be associated with palpatory findings by experienced practitioners and be interpreted using the concept of SD to improve osteopathic diagnosis.

In a comparative study, Van Dieën et al. (2003) revisited conflicting evidence on the modified activity of trunk muscles in NS-LBP patients. The main theory was based on a pain-spasm-pain model where it was considered that pain was generating muscle activity which in turn caused pain. This model was supported by EMG activity found during motor tasks: increased activity of antagonist muscles, decreased activity of agonist muscles, and no increased activity in static posture. However Van Dieën et al. highlighted that previous studies demonstrated disparate results caused by methodological flaws especially in the normalization of EMG data. After improving the standardization of the EMG baseline, they measured the activities of agonist and antagonist trunk muscles during trunk motions in healthy and LBP patients. EMG ratios between lumbar and thoracic erector spinae were calculated and they observed that trunk muscle use in patients with LBP was greater than in healthy control subjects. They suggested a trunk muscle strategy aiming to increase spinal stability in LBP patients.

It has been hypothesized that the connective tissues forming the fascial planes of the back play a role in the pathogenesis of chronic LBP. In a randomized trial, Langevin et al. (2009) observed that LBP patients had, on average, 25% greater perimuscular connective tissue thickness than did subjects without LBP. According to these authors, increased thickness and disorganization of connective tissue layers due to inflammation, fatty infiltration, fibrosis and adhesions may impair the normal relative movement of connective tissue planes, increase tissue stiffness, decrease range of motion and predispose to further injury. Disorganized connective tissue layers may also cause pain due to trapping of sensory nerve fibres through the collagen matrix.

4.2 Osteopathic Manipulative Treatment for LBP patients: Implications for treatment

Licciardone, Brimhall and King from the Osteopathic Research Center (ORC) carried out a systematic review and meta-analysis of randomised clinical trials on OMT for LBP (Licciardone et al 2005a). The effects of SMT on LBP patients were already reported in the literature but no data was available to evaluate the specific OMT on that patient population. Spinal manipulations and mobilizations are effective in adults for acute, subacute LBP and for chronic LBP (Bronfort et al, 2010).

Eight OMT studies versus control treatments were included in their meta-analysis. They were conducted between 1973 and 2001 in the USA and the UK. They met good methodology quality criteria. The methodological quality of four of the OMT trials was independently confirmed in a recent systematic review which included a best evidence synthesis incorporating eight explicit quality criteria, including similarity of baseline characteristics of subjects or reporting of adjusted outcomes; concealment of treatment allocation; blinding of subjects; blinding of providers or other control for attention bias; blinded or unbiased outcomes assessment; subject dropouts being reported and accounted for in the analysis; missing data being reported and accounted for in the analysis; and intention-to-treat analysis or absence of differential co-interventions between groups in studies with full compliance.

Two out of the three authors reviewed the articles independently, and conflicting data were resolved by consensus. Effect size computed with Cohen's d statistic was used to report all trial results. Effect size is the measure of the strength of the relationship between two variables in a statistical population. The negative effect found size represented a greater decrease in pain among OMT subjects relative to control treatment subjects.

This meta-analysis included 525 subjects with LBP from the 8 eligible trials. Pain associated with OMT was very significantly reduced. Analysis was performed with a best-case and a worse-case scenario. Both supported the efficacy of OMT for LBP, and showed an improved reduction in pain with OMT in comparison with placebo control or active treatment, though the worst-case scenario was not found to be statistically significant. LBP symptoms treated with OMT were significantly reduced in the short-term (effect size, -0.28; 95% CI, -0.51 to -0.06; $p = 0.01$), medium-term (effect size, -0.33; 95% CI, -0.51 to -0.15; $p < 0.001$), and long-term (effect size, -0.40; 95% CI, -0.74 to -0.05; $p = 0.03$) follow-up periods. Overall results showed a statistically significant reduction in LBP in patients treated with OMT. Stratified meta-analyses were performed to control for moderator variables, and this showed that OMT significantly reduced low back pain versus active treatment / placebo control and versus no treatment control. OMT might act as a substitute for, or decrease the use of, medication known to carry risks of substantial side-effects. Contrary to the USA, osteopaths in the UK are not licensed physicians. Effect sizes observed in the UK study were comparable to those found in the USA studies suggesting that the results reflected accurately the effects of OMT and not other elements of low back care.

Systematic imaging prior to OMT is not part of professional guidelines, but its absence may limit the differential diagnosis process, and prohibit the use of some potentially iatrogenic OMT. The most serious adverse effects of manual techniques are vertebral artery dissections following cervical manipulations (Vogel, 2010). A systematic review of the literature on the side effects of manual therapies (Carnes et al, 2010) concluded that severe side effects were low but half of patients described post-manipulative transient mild to moderate side effects. Patients treated by final year students in a clinical center integrated in a UK osteopathic school were surveyed about the main side-effects experienced after OMT (Rajendran et al, 2009). Patients consulted primarily for LBP (33%) and neck pain (20%). Local pain (24.3%), local stiffness (18,3%), and an increase in the pain that motivated the consultation (11.8%) were the most common side-effects reported. They were felt up to two days after the consultation but 96% of these manifestations were considered by the patients as mild or moderate.

The numbers of OMT sessions for LBP patients reported varies in the literature (Licciardone et al, 2005a): treatment protocols included from 4 to 10 sessions lasting from 15 to 45 minutes over a period of one to six months. The authors did not reference or justify their choices for the protocol which were mainly based on experts' opinions. However, the format most consistent with current clinical practice would be around 6 to 8 sessions with a frequency of one session every 2 weeks over a period of 3 to 4 months.

Sloan and Walsh (2010) demonstrated how the language used by practitioners could affect patients' pain perception and outcomes among LBP patients. Mechanical explanations about patients' conditions were associated with better outcomes than degenerative ones. Placebo responses are often described pejoratively and interpreted as something administered to patients which cannot be controlled, but the patient's response is nonetheless a positive one. Nocebo responses may result from words used by practitioners while talking with their patients to describe their conditions. Practitioners should keep in mind the possible iatrogenic effects of their vocabulary, and should use simple and neutral words in order to give patients an explanation that makes sense to them. As with all other healthcare practitioners, the placebo response could therefore be enhanced, and depends mainly on how osteopathic practitioners describe their understanding of the symptoms. This affects patients' beliefs about prognosis and attitudes towards treatment and self-care (Abbey, 2011).

4.3 Osteopathic Manipulative Treatment for LBP patients: Implications for training

Palpation teaching presents specific challenges. Four main issues have been described in the scientific literature surrounding manual therapies, and should be addressed to improve palpation teaching: hand positioning, amount and direction of force and interpretation of tissue response (Degenhardt, 2009). Educators in osteopathy train students to perform techniques and to adapt them according to patient needs in a clinical context, to describe relative and absolute contraindications, and to describe expected outcomes. The typical lecturing process is to teach OMT every year from the first year, gradually teaching more complicated and refined methods to develop students' skills (Standard 2000: Standard of proficiency March 1999. General Osteopathic Council (GOsC), 2000).

Osteopathic training within universities now includes a sound background to the biomechanical and neurophysiological aspects of OMT. Theoretical models of action are currently shifting away from a classical mechanistic view to a systemic view, incorporating data from recent publications. Different models of practice in osteopathy have been described: biomechanical, neurological, respiratory/circulatory, behavioral/psychological and bioenergetic models (WHO Benchmarks, 2010). They differ regarding the application of forces and comprehension of the body's response to mechanical and psychological stresses. Palpatory findings associated with SD may vary according to the theoretical model, and this may create cognitive conflicts (Johsua and Dupin, 1993). Diversity of concepts requiring different cognitive and manual approaches may be a source of confusion for students. Some osteopathic education centres have therefore prioritized SD and OMT theoretical and practical training according to their scientific levels of evidence. Manipulation and mobilization were therefore prioritized probably because they are better supported by current evidence. This is probably because these direct OMTs are similar to techniques performed and studied by other professionals (Lederman, 2005). Direct OMTs use mainly biomechanical (Triano, 2001) and neurophysiological models (Van Buskirk, 1990; Pickar, 2002; Howell and Willard, 2005).

Clinimetrics is the practice of assessing or describing symptoms, signs and laboratory findings by means of scales, indices and other quantitative instruments (Feinstein, 1987). It is clinically important to focus on this during training in order to train future professionals to make appropriate decisions about patient management, based on the best level of evidence available. A clinical measurement instrument, such as a test, should ideally be *valid* (it should measure what it is intended to measure), be *reliable*, i.e. reproducible (the instrument score should remain stable when there has been no change in the performance), be *responsive* to change over time, and be *precise* enough to measure the minimal clinically important change (MIC), defined by Jaeschke et al (2009) as the smallest difference in score in the domain of interest which patients perceive as beneficial, and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management. These challenging aspects have been assessed for osteopathy osteopathy. As with as with other manual therapies, not having gold standards to evaluate tests with to assess their validity is a problem (Lucas and Bogduk, 2011). Studies assessing diagnostic reliability should be standardized, and under ideal conditions conditions, have certain variables controlled, the most important being that the examiners should be blinded to other examiners' findings for inter-examiner reliability studies. The application and interpretation of the test should be appropriate and there should be enough time between repeated measurements to avoid altering results.

Osteopathic educators should prioritize the contents of their training programmes according to the tests' performances. Tests should also be, as stated above, valid, responsive to change over time, such as before and after treatment, and precise enough to measure the MIC. Insufficient performance of tests in the detection of MIC may cause a type-2 error in RCTs; no difference is observed during the study when in reality there is a difference between groups (Lucas and Bogduk, 2011). Students should also be aware of such limitations of studies during critical appraisal of published literature in the manual therapies field.

4.4 Evidence-oriented osteopathy

EBM has been defined by Sackett et al. (1996) as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients". Incorporation of EBM in daily practice for clinicians is a challenging issue, especially for manual therapists therapists, owing to the lack of reliable and valid tests excepting, the pain reproduction tests. Evidence based medicine cannot however be "cookbook" medicine because each patient is a unique individual with different medical needs (ATSU, Evidence Based Medicine, 2011). For example, the main pathophysiological mechanisms underlying a patient's symptoms or injury might be evaluated through case history: sclerotomal tissue pain described as "deep, dull, or toothache-like", and myotomal pain that is difficult to localise and is described as "crampy" or "stiff" (Kuchera, 2007). Discussing the generalizability of published data also requires critical appraisal skills that are common to all other healthcare professionals, and osteopathic practitioners should ask themselves if results from research are applicable specifically to their patients. Interpretation of such studies has, however, several limitations. The main one is that osteopathy should be considered as a complex intervention (Sturmberg and Martin, 2008), and needs to be evaluated using specific methodological tools which are different for pharmacological interventions.

A scope of practice for osteopathic practitioners is about to be published in Europe (European Federation of Osteopaths (EFO), The Scope of Osteopathic Practice in Europe, 2011). Osteopaths themselves have defined the indication for OMT as the presence of SD that is clinically significant. The SD concept may however be perceived as perverted by part of the profession when used as a tool to categorize their patients, rather than a tool to diagnose and treat them (Johnson and Kurtz, 2003). This concept has caused the profession to lose part of its monistic vision (Lee, 2005), by implying a direct link between SD and symptoms and diseases, which in reality corresponds to a biomedical model (Leigh, 1994)

The concept of SD is clinically relevant, particularly in its association with LBP and its prevalence in a clinical setting (Licciardone et al, 2005b) but a clear distinction should be made between clinical evidence and scientific evidence for the concept of SD. SD is more prevalent in subjects with chronic LBP than in subjects without chronic LBP (Snider et al, 2008), and specific OMT is provided on a test-dependent basis for each patient. Patient agreement should also be obtained, and patient values and expectations for the outcome of the OMT should be acknowledged. Although OMT for the treatment of SD associated with LBP is now included in clinical guidelines in the USA, osteopathic practitioners should understand that successful clinical outcomes do not validate this concept. Data from existing clinical, descriptive and physiological studies with strong methodology could only support some of the most common assertions within the osteopathic profession.

As for all other disciplines, osteopathic curricula should rely on the best available evidence, and challenges are arising concerning some osteopathic concepts due to conflicting current evidence (Fryer, 2008). A balance between clinical findings and scientific evidence in osteopathic curricula should therefore be found. Osteopathic practitioners themselves are able to provide critical analysis of their own clinical procedures, and are able to change them according to current scientific evidence (Zegarra-Parodi and Fabre, 2009). For example, OMT training has shifted from expert opinion-based theories (Fryette, 1954) to a more scientific approach (Gibbons and Tehan, 2001; McCarthy, 2001), which includes recent biomechanical studies on spinal coupled movement (Bogduk and Mercer, 2000; Herzog, 2000). Hartmann's minimum leverage techniques concept (Hartmann, 1996) fits with current biomechanical understanding, its main educational objective relying on obtaining pre-manipulative tension with combined leverage on a specific joint and therefore reducing amplitude of the manipulation. Systematically training osteopathic students to find evidence for clinical decisions relative to individual patient needs may be relevant in order to improve their appraisal skills, and use them in a clinical setting once they become professional. This is a long term process. The osteopathic profession has moved from an empirical body of practice to a regulated profession included in different healthcare systems.

Osteopathic medicine is a relatively young profession compared to allopathic medicine, and the lack of scientific studies to support common clinical procedures is currently being addressed, especially in the USA and in the UK; countries where osteopathy was first regulated and where dedicated research institutions now exist: ATSRI and ORC in the USA and the National Council for Osteopathic Research (NCOR) in the UK. The situation is not improved by the fact that there is no regulation or official research facilities in many countries.

5. Conclusion

There is a growing body of clinical evidence to support the use of the concept of SD during osteopathic diagnosis and manipulative treatment for NS-LBP patients. Interpretation of osteopathic palpatory findings is central to the creation of a treatment plan, and the choice of OMT. The concept of SD is also fundamental for osteopathic educators to transmit their experience. This concept is however being challenged owing to the relative lack of scientific evidence, and the current demands from academic and governmental institutions. Successful outcomes in a clinical setting with the use of the SD concept do not equal a validation of this concept. It needs to be re-evaluated in the light of evidence-oriented osteopathy. The SD is currently a clinically descriptive concept rather than one with supporting scientific evidence. The published clinical and experimental data should nevertheless be presented and taught, so that osteopathic practitioners can provide OMT based on the best available levels of evidence.

6. Author contribution statement

RZP designed and planned the book chapter. All authors were involved in data collection and analysis. RZP and JDR wrote the first draft of the manuscript. All authors edited and approved the final version of the manuscript.

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