



**Prevalence and recovery rate of  
low back pain and leg pain in osteopathic practice**

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A project submitted in partial fulfillment of the requirements for the degree of Master  
of Osteopathy

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# DECLARATION

*Name of candidate: Nataliya Chemeris*

This dissertation is submitted in partial fulfillment for the requirements for the Unitec degree of Master of Osteopathy. The regulations for this degree are set out in the Master of Osteopathy Programme Schedule and are elaborated in the course handbook.

## *Candidate's declaration*

I confirm that:

- This research project represents my own work;
- The contribution of any supervisors and others to the research project was consistent with the Unitec Code of Supervision.
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee. Research Ethics Committee Approval Number: 2006.574

Candidate  
(*Nataliya Chemeris*)

Date:

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## **Abbreviations**

DNA – did not arrive

MRI – magnetic resonance imaging

LBP – low back pain

ACC – Accident Compensation Corporation

NZ – New Zealand

LB – low back pain group

UL – low back pain and/or referred upper leg pain group

LL – low back pain and/or referred lower leg pain group

SLR – straight leg raise test

VAS – visual analog scale pain measurement

## **Section 1: Review of Literature**

## **INTRODUCTION**

Low back pain (LBP) is one of the most extensively researched topics in modern medical science. A literature search was conducted to obtain the best available evidence for the sources, progression and treatment effects for patients with LBP focusing special attention on referred leg pain and sciatica in the general population. Studies were identified through searches in MEDLINE, EMBASE and OSTMED databases, as well as tracking down cited research in the individual papers. Keywords used were low back pain, sciatica, prevalence, etiology, natural history, treatment, manual therapy, osteopathy. Articles were restricted to English language and publishing date up to November 2006.

## **LOW BACK AND LEG PAIN**

### **Sources of LBP and leg pain**

Low back pain is one of the most frequent complaints that osteopaths and other manipulative professions encounter in clinical practice. Despite numerous studies and copious published information, many aspects regarding the source of pain, incidence of LBP and effectiveness of treatment interventions for LBP remain unclear.

Experimental studies have shown that back pain can arise from noxious stimulation of nearly all anatomical tissues of the spine, including muscles, ligaments, dura mater, facet and sacro-iliac joints, vertebral endplate and even intervertebral discs (Adams et al., 2002). Some studies have demonstrated that stimulation of deep spinal structures, such as periosteum and deep spinal ligaments, can give rise to referred pain in a distant area of the back or limb (Kellgren, 1977; Sinclair et al., 1948). The referred pain in these studies was dull in character and vague in distribution. For the majority of low back pain with or without referred symptoms the anatomical source of pain can not be established on clinical grounds alone (Grieve, 1994). Low back pain that is not related to obvious spinal pathology is regarded at present by orthodox medical science as non-specific mechanical back pain. Deyo and Weinstein (2001) estimate that 70% of all low back complaints fall into the category of non specific low back pain with a further 10% attributable to degenerative spine disease.

With regards to degenerative changes in the spine, an association between disc degeneration and low back pain was found in one cross-sectional study (Luoma et al., 2000), but no predictive value or only weak association was found for disc degeneration and low back pain in prospective studies (Borenstein et al., 2001; Elfering et al., 2000; Savage et al., 1997). A systematic review of observational studies that explored correlations between X-ray signs of degenerative spine disease and low back pain (van Tudler et al., 1997) reported weak to moderate association between degenerative changes (disc space narrowing, osteophyte formation and sclerosis) on the radiographs and low back pain, however, no firm evidence of causal relationship was found.

Many clinicians and researchers (BenDebba et al., 2002; Grotle et al., 2005; Jenner & Barry, 1994; Speed 2004) regard low back pain and sciatica as one clinical entity. In contrast, since ancient times sciatic pain was considered a separate syndrome that has a different character and distribution of pain needing a different treatment approach (Karampelas et al., 2004). Modern studies (Ido and Urushidani, 2001; Kuslich et al., 1994; Lindahl, 1966) have demonstrated that true sciatic pain that spreads down the leg could only be reproduced in locally anaesthetized patients by applying an external stimulus to a nerve root. Furthermore, the typical familiar sciatic pain was reproducible only on stimulation of the compressed nerve root, not on stimulation of a normal nerve root, annulus fibrosus or any other tissue around the vertebral segment (Kuslich et al., 1994).

Over the last few decades the main cause of nerve root compression has usually been attributed to an intervertebral disc herniation. Recent studies have identified that nerve root compression might not be caused by disc herniation for at least some of the patients with sciatica. An orthopaedic study found that intradiscal injections of a contrast solution reproduced sciatic pain in 60-70% of patients with different degrees of disc disruption even without disc herniation (Ohnmeiss et al., 1997). With the technological advances in modern imaging, especially MRI, it is now evident that not all disc herniations are accompanied by sciatica or low back pain. Around 20% of asymptomatic subjects before 60 years of age were found to have at least one herniated disc (Boden et al., 1990). Further studies have found that, except for severe nerve compression and disc extrusions, the degree of disc herniation or nerve root compression on MRI scans did not correlate with the patients' subjective sciatic symptoms (Karppinen, 2001; Beattie et al., 2000). Again, as with non-specific low back pain, it is often difficult to attribute the source of sciatica to an anatomical structure on the basis of the clinical data alone or even with the aid of imaging methods, such as MRI and X-ray scans.

All of the studies mentioned above were based on a pain generation model that relies heavily on mechanical nociception in which low back pain is supposedly produced by simple mechanical pressure or stretch on, or within, the soft tissue, facet joint, intervertebral disc or by a herniated disc on a nerve root. While testing this theory, researchers have used provocations that do not naturally occur in the human body, such as hypertonic solutions, electrical irritation or pressure with a metal object (e.g. a blunt forceps probe). Both the mechanical theory and the logic of experiments could be misleading or of limited relevance to clinical practice and real patients. For example, the pain generation mechanism can be related to processes other than mechanical pressure, including central nociceptive mechanisms. The results of experiments with unnatural pain provocation may not be extrapolated to physiological and pathophysiological conditions.

An alternative hypothesis advocates an inflammatory mechanism of ‘mechanical’ spinal pain (Jayson, 1986), where mechanical irritation gives rise to local aseptic inflammation. Recently this hypothesis has attracted a new wave of scientific interest with new research on tumor necrosis factor as one potential candidate that may partially explain neuropathic pain (Mulleman et al., 2006). Other mechanical lesions have been described, and identified as causing referred sciatic pain, such as piriformis syndrome (Durrani and Winnie, 1991) or sacro-iliac joint (Frieberg and Winke, 1974).

### **Prevalence of LBP and leg pain**

The life time prevalence of low back pain has been estimated at 60-70% internationally (Adams et al., 2002). A telephone survey conducted in New Zealand found the annual incidence of back pain at 63.7% and “total” prevalence at 79% (Laslett et al., 1991). Around 14% of low back pain sufferers experienced pain below the knee.

It is difficult to estimate the prevalence of true sciatica in the general population without proper clinical examination that would include comprehensive neurological and orthopaedic tests. Survey data indicates that the life time prevalence of sciatic pain is between 10 and 30 % and is dependent on occupation (Hofman et al., 2002; Riihimaki et al., 1994). The life time prevalence of true sciatica is estimated to be between 2% and 5% (Adams et al., 2002). Reported risk factors for sciatic pain include male gender, younger age, height above 180 cm, obesity, prolonged driving and pregnancy (Cowan et al., 1992; Heliovaara, 1989).

## Natural course

The scientific understanding of the natural history of low back pain has been changing in recent years. Previously, a high remission rate in acute non-specific LBP was reported, with approximately 90% resolving within 6 weeks (Carey et al., 1995; Coste et al., 1994). Later studies have focused on longer follow up periods and found 23% to 35% of patients still suffered from back pain after 12 weeks from onset (Grotle et al., 2005; van den Hoogen et al., 1998) and after one year follow up period 12 % to 45% still complained of back pain (Schjøttz-Christensen et al., 1999; van den Hoogen et al., 1998), with one study reporting only 25% full recovery after 12 months (Croft et al., 1998). Some of the studies (Grotle et al., 2005; Schjøttz-Christensen et al., 1999) included patients with referred leg pain below the gluteal fold into the cohort which might also contribute to the differences in findings comparing to the earlier studies.

A recent systematic review with meta-analysis of the prognosis of acute low back pain found strong evidence of improvement of symptoms within 1 month, however, as many as 73% of the patients reported at least one recurrence of pain within the following 12 month period (Pengel et al., 2003). The data on the natural course of low back pain were pooled from control groups in the studies of interventions for low back pain. A fluctuating nature of low back pain has been proposed, but some researchers found four (Dunn et al., 2006) or even eight (Barker, 1977) subgroups in patients with low back pain and sciatica who had different characteristics and prognosis.

The data on recovery rate from sciatica is conflicting. There are no published randomized controlled studies that report progress of a group of patients with sciatica or leg pain without treatment intervention, either at all, or with sham treatment. Most studies compared different treatment approaches, like surgical versus conservative, or analysed a mixed cohort, in which patients received a variety of uncontrolled interventions and management strategies. In one study, most sciatic symptoms and signs had improved within the first three months of treatment, however, 71% still experienced some level of pain after one year (Balague et al., 1999), whereas in a cohort study more than 50% of patients still complained of leg pain at two and four years after initial examination and conservative treatment (Tubach et al., 2004). In the Balague et al. (1999) study the cohort consisted of patients in heavy physical occupations, but the authors found other factors, in particular

anthropometric and psychological factors, also influenced the severity (pain and disability level, quality of life) and persistent nature of symptoms.

Treatment outcomes of low back pain and sciatica have been researched in a cross sectional prospective study (BenDebba et al., 2004), which included a group of patients with persistent low back and/or sciatica who weren't prescribed any treatment. The difference in pain scores between this group and a group receiving conservative treatment were minimal at the initial consultation and improved almost in parallel over a 24 month period, but the conservative group recorded better progress on the disability score. The study focused on patients with chronic intermittent pain and did not specify outcomes for low back pain and sciatic pain separately, which makes it difficult to generalize the findings to all sciatic pain sufferers. The results may indicate that chronic low back pain and sciatica patients, who are not severe enough to undergo surgical treatment, improve gradually over time with or without treatment.

Surgical studies report that patients with sciatic symptoms due to disc lesions have favourable outcomes with conservative treatment in the long term, providing the pain and disability weren't severe enough to warrant surgical treatment (Atlas et al., 2001; Postacchini., 1996). Cowan et al (1992) found radiological evidence of decreasing disc herniation size in 76% of patients at one year follow up. In several high quality prospective studies short term outcomes for patients with sciatica and disc herniation was significantly better for patients who underwent surgery, but at 10 years follow up pain and disability scores between conservative and surgical interventions were not significantly different (Saal, 1996; Weber, 1983).

In relation to disc herniation, no statistically significant correlations were found between the outcome of conservative treatment and MRI parameters at the time of admission (Carragee & Kim, 1997). A small, but more recent study by Masui et al. (2005) confirmed these findings using a longer follow up period. The study followed 21 patients with degenerative disc disease over 7 years and found that in all of them, radiological evidence of degenerative process progressed over time. There was no correlation found between the clinical course and the degree of degeneration or the size of disc herniation visible on MRI scans. Although the findings have limited power due to a high drop-out rate (19 out of 40 subjects), it is noteworthy that the majority of those who didn't have a follow-up MRI scan were reported as clinically asymptomatic at the time of follow up.

Other studies found heavy physical labor (Beija et al., 2004), occupations involving driving and height above 180 cm (Leclerc et al., 2003) to be associated with poor clinical outcome (pain reduction and return to work), whereas short duration of sciatica (less than 6 months) and younger age were associated with better outcomes (Carragee & Kim, 1997). Longer durations of pain have been statistically correlated with poor clinical outcomes in some studies (Balague et al., 1999; Vucetic et al., 1999) but not in others (Beija et al., 2004; Komori et al., 2002). The difference could most likely be explained by different methodology of the studies, i.e. in the first two trials (Vucetic et al., 1999; Balague et al., 1999) the outcome measure was return to work, whereas in the last two it was the self-reported improvement by the patients.

It is worth noting that conservative treatment protocols in all of the above studies consisted of mostly medical treatment modalities, such as pharmaceuticals, epidural injections, traction and sometimes physiotherapy with exercises. Manipulative and manual treatment groups were not included.

In summary, the natural course and prognosis of sciatica and leg pain is less clear than for low back pain, but seems to be favorable in the longer term. The severity of the condition decreases quickly, however, a large proportion of patients continue to experience some degree of pain and disability after one or more years.

## MANUAL TREATMENT

### Low back pain

Manipulative treatment, including soft tissue and massage like techniques, joint mobilization and manipulation have been the mainstream treatment modality of several professions including chiropractic, osteopathy, manipulative physiotherapy and other forms of manual medicine. These methods seem to have attracted more scientific investigation regarding their effectiveness than any of the health interventions for other health problems.

The modern evidence-based approach in medical science is based on the evidence hierarchy pyramid. The lower level of the pyramid is allocated to expert opinions with higher levels of the pyramid allocated to case controlled studies with randomized controlled studies and systematic reviews at the top of the pyramid. Accordingly, the grade of evidence is rated from the bottom of the pyramid as level D to the top as level A. The highest level of evidence at present is allocated to systematic reviews and meta-analysis studies (Phillips et al., 1998). A number of systematic reviews of manipulative treatment of low back pain have been published with mixed or inconclusive results. Even a *systematic review of systematic reviews* of manipulative treatment has been attempted very recently by Ernst and Canter (2006). Ernst and Canter concluded that the data failed to demonstrate that spinal manipulation was effective for “any condition”. Specifically for low back pain, Ernst and Canter concluded that manipulation is superior to sham treatment, but not to any other treatments. Several published critiques (Breen et al., 2006; Bronfort et al., 2006) of Ernst and Canters systematic review have raised serious questions about the methods employed in the study and have therefore questioned its credibility. First, only systematic reviews from the last 5 years were included, thus omitting several reviews published before 2000. Exclusion criteria cut off some of the large high quality studies, like UK BEAM trial (UK BEAM Team, 2004). The included reviews were extremely heterogeneous with regards to the condition and age. All age groups from infants to elderly have been included in the Ernst and Canter review as well as studies of spinal manipulation for “any condition”. The providers of manipulative treatments in the review were from several different professions. Last, three of 16 reviews analysed were written by one of the current authors (Ernst) which raises the potential for personal bias. One of those previous reviews (Ernst and Harkness, 2001) had also included a trial of low statistical power designed as a preliminary study (Hawk et al., 1999), but was analysed as a randomised controlled trial. The pre-defined selection

criteria in that particular review were also narrowed to spinal manipulation defined as high velocity low amplitude thrust techniques excluding mobilization or soft tissue techniques that are a very important part of many manual treatments, especially the approach commonly utilized by osteopaths.

Another critical analysis of systematic reviews of any conservative treatment for chronic low back pain, including manual treatments found 36 reviews of “satisfactory” quality (Furlan et al., 2001). The evidence from nine of them that investigated the effectiveness of manipulative treatment was conflicting. Two reviews came to positive conclusions about spinal manipulative treatment, one did not find evidence of its effectiveness and the rest came to ambiguous conclusions.

In a systematic review by Assendelft et al (2004) the authors mentioned 13 other systematic reviews, eight of which reported positive evidence for the effectiveness of manipulative treatment and the rest (n=five) found no evidence for its effectiveness. This was a very thorough systematic review of randomized controlled studies undertaken for the Cochrane Collaboration which found manipulative treatment to be no more effective for low back pain than non-manipulative care provided by general practitioners or other health providers. The review, again, investigated spinal manipulation provided by different health care professionals, including physiotherapists, chiropractors and osteopaths. The inclusion criteria were narrow enough to make a homogenous group of patients of similar age (adult patients), having similar syndromes of low back pain, receiving manipulation and/or mobilization against control groups of either other conventional treatments or sham treatment. The trials from a sufficiently long period, 1966 to 2000, were pooled and patients with referred symptoms were included. The inclusion of patients with referred pain may have challenged the homogeneity of the groups and affected the final analyses, for instance, patients with referred pain could have been represented differently in different studies affecting the response to manipulative treatment. The authors, however, used leg pain as an ‘effect modifier’ for their data analysis and found it made ‘little difference’ to the final results. The conclusion from the review was that manipulative treatment remains one of the options for low back pain sufferers, albeit that it is no more effective than any other treatment modality.

Not only the quality of the systematic reviews varied considerably, but sometimes the conclusions made in them were also confusing. In one review with meta-analysis (Ferreira et al., 2002) the authors pooled together the data on pain reduction after spinal manipulation and found a decrease in

pain intensity of seven millimeters (mm) on VAS (100mm VAS). In a different study group the same authors pooled data from three other trials and the average reduction of pain on VAS was 14 mm. A two-fold difference in pain reduction between two groups after supposedly similar intervention requires further explanation. What could explain this difference in different trials? It could be because of different manipulative approaches between trials, different population groups and different assessment and measurement methods. Differences could also be due to poor reliability of the methods used to record pain intensity. Such inconsistencies in reported results of using VAS as a pain measurement tool may compromise the results both of primary trials and the subsequent systematic reviews.

A recent large scale pragmatic trial ‘Back Pain Exercise And Manipulation’ (BEAM) attempted to overcome some of the design faults of previous studies by developing a universal manual treatment package to be used in the study and by utilizing a rigorous research design . A spinal manipulation package was agreed between United Kingdom registered osteopaths, chiropractors and physiotherapists (Harvey et al., 2003). Inclusion criteria did not allow patients with anything else but non-specific mechanical low back pain, although referred pain not below the knee was allowed. The trial randomized patients into 4 groups and used various outcome measures. The study found small but significant superiority of manipulative treatment over “best GP care” at three months and one year (UK BEAM Trial Team, 2004). Some criticism has been expressed in the literature over the validity of the “best care” GP group, as opposed to usual GP care (Vogel et al., 2005) and the possibility of a large statistical improvement if applied to a subgroup was voiced.

Overall, despite a large number of trials, systematic reviews and their latest critical analysis, the evidence on the effectiveness of manipulative treatment for low back pain remains controversial. There is some evidence that manipulation is no less effective for non-specific low back pain than other treatment regimes and may be more effective for certain subgroups of patients. These subgroups are yet to be definitively identified through carefully designed and executed research.

### **Leg pain and sciatica**

Very few well designed studies have examined the effectiveness of manipulative treatment for sciatic pain separately from the treatment of low back pain. Probably for that reason, no systematic

reviews of manual treatment for isolated leg pain (arising from spinal structures) or sciatica have been published to date. The only systematic review that has investigated conservative treatment for sciatica (Vroomen et al., 2000) published controversial results. It included only trials of traction and exercise for sciatica for patients with herniated intervertebral discs. An attempt at literature review of manipulative treatment for sciatica, mainly due to disc herniation (Haldeman & Hooper, 1999), also found conflicting evidence. It concluded that manipulation was a “reasonable option” for conservative management of conditions with sciatica.

According to some textbooks, a practitioner needs to be cautious about manipulating patients with sciatic symptoms. Cyriax (1979) recommended avoiding manipulation for sciatica with neurological signs or even without such signs if sciatica symptoms are subsiding. Some authors even list acute disc herniation and syndromes of radicular compression as contraindications to high velocity manipulations (Schneider et al., 1988).

Rather than the more robust double blinded designs, most of the authors of earlier studies of manipulative treatment for sciatica have used single blinded or non-blinded designs. One of the earlier studies (Chrisman et al., 1964) found significant benefit of manipulation for decreasing the intensity and distribution of leg pain and improving the range of straight leg raising. The effect was more evident in patients with a normal myelogram, in other words, without evidence of nerve root compression. The authors utilized spinal manipulation under general anesthesia in the treatment group. Applying manipulative treatment under anaesthetic decreases the generalisability and external validity of this study because most manipulative professions (chiropractors, osteopaths, physiotherapists) do not use anaesthesia in their practice. It is not possible to attribute the effect of treatment to manipulation itself or to general anaesthesia. In addition, the control group was significantly smaller than the treatment group making statistical analysis less than valid.

Physiotherapy in the form of spinal manipulation has been investigated by Coxhead et al. (1981) and found to be beneficial in treating sciatic pain in the short term, but no statistical difference with a control group receiving traction, exercise or corset, was found at four and sixteen months follow up. The quality of the trial was low not only because of absence of blinding, but also because of poorly designed interventions in the treatment group and the control group. The intervention group received not only manipulation, but also the same types of treatment as the control group, although in a random order. A more recent randomized controlled study of mobilization and manipulation by

physiotherapists (Hofstee, 2002) found manipulative treatment to be no more effective for sciatic pain than simple continuation of routine daily activities. There was potential for selection bias in the Hofstee (2002) study as the patients were referred by their general practitioners. Another criticism is that this study investigated physiotherapeutic manipulation and hydrotherapy. Such treatment approach can not be easily generalized to the osteopathic approach, because osteopathic manipulative treatment as a system differs from physiotherapeutic in the paradigm and practical application of manipulative techniques and hydrotherapy is not commonly practiced by osteopathic practitioners.

A study by Mathews et al. (1987) of four treatment methods for low back pain and sciatica found marked pain relief after spinal manipulation, especially in patients with pre-treatment findings of limited straight leg raise tests. In contrast, a hospital based trial found limitation of the straight leg raise test to be negatively associated with treatment outcome (Berthelot et al., 1999). The latter study did not include manipulation, but concentrated on bed rest and steroid injections. An earlier study by O'Donaghue (1983) found no differences in how patients with low back pain or sciatica responded to manipulative treatment. There were no differences between four groups receiving four different treatment routines; traction, manipulation, exercises or corsets. There was no control group who received no treatment or sham treatment so it is not possible to conclude whether the patients in all groups improved due to the natural course of the condition or due to the treatment. Another study of three non-surgical interventions for sciatica found significant improvement in all three groups receiving either medical care, chiropractic manipulation or spinal epidural injection (Bronfort et al., 2000). However, due to small group sizes in this study direct comparisons between groups was not reported. The aim of the study was to test a design for a future larger trial rather than comparing the treatment interventions.

Several chiropractic studies investigating manipulation for low back pain with leg pain have been published. One study of chiropractic manipulation found 90% improvement in subjective symptoms in patients with sciatic pain (Stern, Cote & Cassidy, 1995). These results should be viewed cautiously in light of weaknesses in the study design, which was not blinded, used a small number of patients (n=71) and failed to employ appropriate randomization. An observational study by Cassidy et al. (1983) compared treatment outcomes after spinal manipulation for four different groups of patients: 'posterior joint syndrome', 'sacro-iliac syndrome', 'nerve root entrapment syndrome' and 'central spinal stenosis syndrome'. The authors concluded that patients with 'no leg pain' or with

‘proximal leg pain’ responded better than patients with distal leg pain. In the distal leg pain group, patients with referred pain responded better than patients with nerve compression syndromes. Unfortunately, the clinical syndromes used by the authors to create four study groups are not widely recognizable in the clinical or scientific literature or across manipulative specialities, which makes it difficult to interpret and generalize their findings. Another study analyzed statistical data on chiropractic management and clinical outcome of patients with low back and leg pain (Cox & Shreiner, 1984). The average number of days to attain maximum improvement was 43 and the number of visits 19. A later study found the average number of visits to a chiropractor for acute low back pain with or without leg pain to be 13.2 (Carey et al., 1995). Although these numbers are quite different, they may provide a point of comparison with similar data for osteopathic treatment.

## **SAFETY**

A separate issue is the safety of spinal manipulation for patients with low back pain and intervertebral disc herniation. A systematic review by Oliphant (2004) estimated the risk of complications of disc herniation after spinal manipulation to be significantly lower in comparison to the risks of complications after conventional therapies such as taking non-steroidal anti-inflammatory medication or spinal surgery. The review included studies of manipulative treatment regardless of different professions, whereas specific rates of complications may differ by professional group. No reliable data exist, but based on this review, manipulation might be considered safe in cases of low back pain and disc lesions.

## **OSTEOPATHIC APPROACH**

The success of osteopathic manipulative treatment for back pain and sciatica has been claimed since the earliest osteopathic literature was published (Hazard, 1899). As knowledge about the mechanisms of sciatica improved, osteopaths became more cautious: Stoddard (1969) considered manipulation acceptable in cases of prolapsed disc and radicular syndromes only if the patient’s symptoms were not improving. Modern osteopathic textbooks advocate osteopathic manipulation as “a primary treatment for radiculopathy due to functional causes” (Kuchera, 1997).

The latest (Licciardone et al., 2005) systematic review and meta-analysis of osteopathic randomized controlled trials which wasn't included in the later Ernst & Canter's meta-analysis (2006) states that osteopathic manipulative treatment significantly reduces chronic low back pain with the effect lasting for at least three months. Licciardone et al., (2005) used rigorous statistical methodology, but suffered some weaknesses due to low number and heterogeneity of the trials included. Only randomized controlled trials were included and only those conducted in ambulatory clinics, thus minimizing selection bias of studies focused on industrial or hospitalized population. The authors performed a meta-analysis of all possible variants and came to the conclusion that osteopathic treatment provided a higher degree of pain relief than placebo, although the size of the effect was small (Cohen's  $d=0.30$ ). The authors noted that pain reduction was consistent regardless of the type of osteopathic treatment used, specifically American model which includes general medical care or British, which utilizes manipulative treatment only.

The Licciardone et al (2005) meta-analysis would have been a fundamental review if it wasn't for the poor quality of the individual trials it analysed. Six of the studies were very different and most of them had significant weaknesses. Two studies (Hoehler, Tobis & Buerger, 1981; Cleary & Fox, 1994) specified a narrow treatment protocol, which was limited to the use of high velocity low amplitude techniques in the first and to low force techniques in the second trial. The rest of the studies allowed a "variety of techniques, individualized to patient". Licciardone et al. (2005) appropriately argued that osteopathic treatment is not just a type of the technique used, but also includes a holistic approach to the patient and this is how it should be utilized in the research setting. Unfortunately, the approaches in the other four trials were too different.

One of the trials was conducted by Andersson et al. (1999) in the US osteopathic setting and suffered numerous methodological pitfalls and biases. Patients were selected by a practitioner who confirmed a 'suitable lesion' thus creating major selection bias. Treatment protocols were poorly defined and both groups used 'conventional treatment', which was poorly defined and consisted of NSAIDs, muscle relaxants and even injections in a non-controlled fashion. Osteopathic approach was described as an adjunct to the 'usual care' without precise descriptions of the type of technique used. At the end of the treatment of both groups there was no significant difference in the treatment outcome as measured by pain and disability questionnaires.

Burton, Tillotson & Cleary, 2000) conducted a single-blinded randomized controlled trial of chemonucleolysis (chemical injection into an intervertebral disc) versus spinal manipulation. The authors found osteopathic manipulative treatment to be equally effective in treating symptomatic disc herniation, however, chemonucleolysis as a method of treatment for intervertebral disc herniation has not been properly researched and certainly is not considered as a gold standard in treating sciatic pain (Legge, 2002). Furthermore, chemopapain which was used in the trial has been withdrawn from the market in some countries in the late 1970s due to its side-effects (Wood, 1979). So the study results have doubtful external validity.

Licciardone, one of the authors of the systematic review, was the main researcher in the third trial (Licciardone et al., 2003). The osteopathic treatment approach employed was fairly common for the majority of osteopaths around the world: the treatment was aimed at somatic dysfunctions using soft tissue techniques, a variety of functional techniques, high velocity thrusts and cranio-sacral treatment. Two other groups received either sham manipulative therapy or no manual therapy at all. Both real and sham treatment groups reported improvements in pain and function on 3 and 6 months follow up significantly greater than the no treatment group. Understandably, patients in these two groups used fewer co-treatments than the no treatment group. The lack of greater improvement in the treatment manipulative group could be related to insufficient experience of the practitioners administering the treatment – all of them were undergraduate students. The statistical power of the study was quite weak with only 91 patients enrolled in the study.

Furthermore, all the individual trials in the Licciardone's (2005) systematic review suffered certain degrees of selection bias and significant drop-out rates, while earlier trials failed to use validated outcome measures like Roland-Morris Disability Questionnaires or even visual analog pain scales.

Some researchers have attempted to conduct pragmatic randomized controlled studies without blinded assessment or treatment. The Randomized Osteopathic Manipulation Study (ROMANS) trial (Williams et al., 2003) found a short term effectiveness of the osteopathic treatment in addition to “usual care” within the first two months and greater psychological satisfaction in that group after 6 months. As in the previous studies, the “usual care” was an uncontrolled mixture of interventions and some patients in the osteopathic intervention group also received corticosteroid injection into tender ligaments or peripheral joints. Such loose treatment protocols make it difficult to attribute the

improvement in the intervention group to osteopathic treatment alone and the use of injections once again limits the generalisability of the study.

## **SUMMARY**

The data from the published research to date indicates that low back pain with or without referred leg pain is a very common health condition the exact source of the majority of which can not be easily determined on the basis of the history, clinical examination or even with the aid of most modern investigation methods. The natural course of LBP is generally benign, but recurrences are very common. There is some evidence that manipulative treatment, including osteopathic, is at least as effective as conventional medical treatment.

Sciatica with the typical neurogenic pain below the knee can be reproduced by stimulating an already compressed sciatic nerve directly or by injecting intervertebral discs. Compression of the nerve by the herniated nuclear material, except in very severe cases, does not correlate with the clinical picture. The natural course of sciatica is less clear, but also appears to be benign with a large number of patients remaining symptomatic 1 year and later after the onset of the condition. There is no robust evidence for the efficacy of manipulative treatment in sciatica.

No controlled or observational studies have been published on osteopathic treatment of leg pain and sciatica separately from low back pain or as a subgroup. This research is aimed at separating leg pain syndromes from low back pain syndromes and comparing the groups as seen in a clinical setting.

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## **Section 2: Manuscript**

This manuscript has been prepared in accordance with the Instructions for Authors of the *International Journal of Osteopathic Medicine*.

**Prevalence and recovery rate of  
low back pain and leg pain in osteopathic practice**

## **Prevalence and recovery rate of low back pain and leg pain in osteopathic practice**

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## ABSTRACT

### **Prevalence and recovery rate of low back pain and leg pain in osteopathic practice**

*Background and Objectives:* Low back pain (LBP) with or without referred pain down the leg is one of the most common spinal complaints. The aim of the study was to investigate the prevalence of referred leg pain in osteopathic practice and to compare characteristics and recovery rate for LBP patients versus leg pain patients.

*Design:* A retrospective survey of all new patients with low back pain and/or leg pain treated in a provincial multi-practitioner osteopathic practice over five year period (2000-2004).

*Setting:* The Osteopathic Clinic, a multi-practitioner practice in a rural community in Tauranga, New Zealand.

*Subjects:* Clinical notes of all consecutive new patients to the practice with low back and/or referred leg pain.

*Methods:* 1801 patients' records were selected for the study. Data on age, gender, occupation, pain duration, treatment response and duration, as well as past history of back trouble, insurance contribution and treating practitioner were manually searched for in the patients' paper notes and recorded into a computer database. A comparative analysis was performed for low back pain and referred leg pain groups.

*Results:* The prevalence of mechanical LBP was 38.13% of all new patients, lower leg pain 10.38% of patients with LBP and 3.96% of all new patients during 5 years. Significant differences were found in the mean age, pain duration, SLR test, recovery rate and outcomes between the groups. Compared to back pain without leg pain patients with referred leg pain had older mean age (47 vs.42), higher frequency of positive SLR test (2.5% vs. 15% of documented tests), less favourable outcome (39% vs. 20.9% completely recovered) and longer duration of treatment in the acute stage (58% needing less than 3 sessions as opposed to 42.8%). For chronic patients the differences were not significant. No difference in ACC insurance co-payments, history of previous episode or occupation was observed between the groups. The majority of patients reported improvement or recovery during the osteopathic treatment, the mean number of visits was lower than in reported chiropractic surveys.

*Conclusion:* Referred leg pain is a complicating factor for mechanical low back pain. The prevalence of leg pain confirmed the data published in New Zealand for the general population, but was lower than in published osteopathic literature in the UK. Both LBP and leg pain groups improved during osteopathic care, but more patients with leg pain had less favourable outcome and required longer treatments. The difference wasn't significant for chronic LBP and leg pain groups.

*Key Words:* low back pain, sciatica, prevalence, osteopathy, manipulative treatment.

## **AIMS AND OBJECTIVES**

This research was aimed at establishing the prevalence of referred leg pain in osteopathic practice and analyzing two subgroups of patients (with and without referred leg pain) that reacted differently to osteopathic treatment resulting in different requirements for the numbers of treatment sessions and duration of treatment. Other variables between two groups such as gender distribution, age and occupation were included into comparing the profiles. In addition, the relationship between the number of treatments and Accident Compensation Corporation (ACC) insurance co-payments, variations of treatment duration between several osteopathic practitioners were investigated.

## INTRODUCTION

Much attention has been devoted to low back pain in scientific medical literature. Referred leg pain and sciatica are frequently investigated as part of mechanical low back pain<sup>1-5</sup>. Clinical and anecdotal experience suggests that patients with referred leg pain and especially sciatic pain, have more complicated history of the complaint and react differently to osteopathic manipulative treatment than patients with uncomplicated low back pain. Patients with referred leg pain seem to respond less favourably to treatment with poorer outcomes and requiring longer treatments.

While low back pain is recognized as being highly prevalent<sup>6</sup>, the exact incidence and prevalence of leg pain has not been established. For sciatic pain life time prevalence is estimated to be between 10% and 30%<sup>2,7</sup> and 'true' sciatica life time prevalence between 2% and 5%<sup>6</sup>. The natural course of uncomplicated low back pain without leg pain appears to be benign with the majority of patients recovering within the first 6 weeks of onset<sup>5,8,9,10</sup>, but recurrences and residual symptoms are frequent<sup>10,11,12</sup>. Natural course of sciatic pain is less clear. It was reported to be benign, but residual symptoms were reported in up to 50-70% of patients on a follow up of 1 year and longer<sup>13,14</sup>.

It is accepted in the scientific literature that the majority of low back pain can be classified as 'non-specific mechanical' low back pain<sup>15</sup> for which no pathological source could be found. The origin of 'true' sciatic pain has been linked to sensitized sciatic nerve or structures within intervertebral disc<sup>16,17,18,19</sup>. Modern investigational studies using MRI scans failed to find correlations between the disc degeneration or herniations and clinical picture of low back pain with sciatica, except for in severe cases of nerve compressions by disc extrusions<sup>20,21</sup>. No predictive value or only weak association was found for disc degeneration and low back pain in prospective studies<sup>22,23,24</sup>.

Recently some studies attempted to summarise and critically assess systematic reviews and meta-analysis trials that have been published on the subject of manual and manipulative treatment. For the effectiveness of manipulative treatment in cases of mechanical low back pain conclusions were contradictory<sup>1,25,26</sup>. A meta-analysis of randomized controlled trials of osteopathic treatment for low back pain<sup>25</sup> found osteopathic manipulative approach significantly more effective than placebo, although the magnitude of the effect was small.

Manipulative treatment of leg pain and sciatica has not been a subject of rigorous scientific scrutiny and most of the available data published are in observational or pragmatic trials with significant methodological weaknesses in most of them. Positive effect of manipulation was found in several studies<sup>28-32</sup>. Some studies, including one randomized controlled study<sup>33,34</sup> found no differences between manipulation and usual care or continuation of daily activities.

In summary, for the majority of low back pain with or without referred symptoms the anatomical source of pain can not be established on the clinical grounds alone<sup>35</sup>. It appears, that low back pain and referred leg pain have to be approached and treated on the symptomatic, as well as functional, rather than etio-pathogenic grounds. This study attempted to investigate two groups of patients that osteopaths treat most commonly in their practice, those with low back pain and referred leg pain. Prevalence and recovery rate was the main focus of the study.

## METHODS

*Design:* A retrospective survey was designed to analyse a cohort of all new patients at a multi-practitioner osteopathic clinic over a period of five years, from 2000 to 2004 inclusive.

*Inclusion criteria:* Patients between 20 and 69 years suffering from low back pain with or without pain radiation down the leg, who had never attended the clinic before. Previous osteopathic or other manipulative treatment elsewhere was accepted.

*Exclusion criteria:* Non-referred leg pain (e.g. peripheral articular or soft tissue pain), an established diagnosis or signs of systemic pathology, signs of current psychological disturbance, patients who were short term visitors to the area whose outcome could not be followed up.

*Setting:* The Osteopathic Clinic in Tauranga (NZ) was selected as a suitable practice in which to undertake the research. It serves a mixed population of city residents and a rural community. The practice has been established for over 20 years with five full time practitioners working five days a week, practicing mainly structural osteopathy, which is based on soft tissue and manipulative techniques.

*Intervention:* All patients in the research group received individualized osteopathic treatment based on soft tissue techniques, joint mobilization and manipulation. As a part of treatment they were also given explanation of their condition in accordance with the current evidence-based recommendations to remain as active as possible, use over-the-counter pain relief medication if necessary and were allowed to use non-prescription ointments or creams. In cases of intractable pain patients were advised to visit their general practitioner to obtain NSAIDs and sick leave, if too uncomfortable to work. The majority of patients were also recommended simple mobilizing exercises for lumbar spine and hips.

*Data collection:*

Paper based patients' notes were manually searched and data on eligible patients was recorded into a database table created using Microsoft Access software. The parameters documented were age (full years at the moment of the initial consultation); gender (male or female); pain duration (full number

of weeks at the time of the initial consultation); outcome (*Resolved, Improved, No change, Worse, did not arrive – DNA*). The outcome classification was based on how patients perceived their progress with regards to symptoms and disability at the end of treatment.

Occupation was classified as *Sedentary* (mostly office work), *Physical* (mostly manual labour), *Mixed* (combination of sitting and manual work), *Not working*.

If the patients suffered an episode of low back pain in the past history, not directly related to the current complaint, i.e. with pain free period of at least 12 weeks after the last attack, it was recorded in the section *Previous episode*.

Straight leg raise test was recorded in two categories – leg raising restricted by pain or muscle guarding at less than 45 degrees (<45°) and leg could be elevated higher than 45 degrees (>45°).

Treatment duration was recorded separately for the number of sessions and for the duration in weeks after the initial session. Treatment for the current episode was considered completed if a patient did not return to the clinic during 12 weeks after his last session.

Recurrence was recorded as “Yes” if a patient returned to the clinic within 12 months after the last sessions with a similar problem, otherwise “No” was recorded.

Some patients were eligible for a partial subsidy for their treatment by Accident Compensation Corporation (ACC). This was recorded as “Yes” or “No” in the ACC section.

Treating practitioners were differentiated by the style of hand writing and were given a numerical code, each which was also included into the database.

Special attention was paid to carefully classify patients according to the area of pain. Three areas of pain were differentiated:

- pain limited to low back – LB (between the area of 12 thoracic vertebra and gluteal fold);
- low back and/or upper leg pain – UL (referred pain into groin, front or upper thigh, but not below the knee);
- low back and/or referred pain below the knee - LL.

If the data were missing from the clinical notes, *Not recorded* group was included into the appropriate category.

The study was approved by the Unitec Research Ethics Committee, Auckland.

### *Statistical analysis*

SPSS for Windows version 14.0 was used for all statistical analyses. A total of 1801 patients were included into the study. In the initial analysis all the patients were divided into three groups (LB, UL and LL) for detailed analysis (Table 1). Mean age, male to female ratio, distribution by occupation type, distribution by outcome, treatment duration with the mean number of sessions, percentage of patients with previous episode of pain, ACC contribution and recurrence were calculated for each group. Pain duration was classified and calculated for each group as acute (less than 6 weeks), subacute (longer than 6 weeks, but less than 12 weeks) and chronic (longer than 12 weeks).

Next the total group was divided into 2 sub categories, according to the pain duration – acute patients with pain duration of less than 12 weeks and chronic, with pain duration of equal or longer than 12 weeks. Such grouping was aimed at further homogenizing the patients as to the duration of the condition.

To test the difference between the three groups various statistical methods were used. Normal distribution of data appeared only in the age distribution between the groups. A one-way ANOVA was used in this instance. In cases of skewed data, as in the results for duration of pain, treatment duration and treating practitioner, non-parametric Kruskal-Wallis rank test was used. For categorical data (gender distribution, occupation, previous episode, ACC contribution, SLR test and recurrence) Chi-square test was used. For all the tests  $p < 0.05$  was considered statistically significant and a Bonferroni adjustment was applied in cases of multiple mean comparisons.

Finally, the data on the prevalence and recovery rate in the current study was compared to the published data for osteopathic and other manipulative professions. Descriptive statistics were used to draw the comparisons and make general observations.

## **RESULTS**

### **General statistics**

During the 5-year period (2000-2004), 4723 new patients attended the clinic. Of those, 1801 were eligible to be included in the study (38.13%). Patients with low back pain only, without referred pain below the buttock into the leg, represented 63.2% of the group (1139), patients with referred pain into the leg, but not below the knee represented 26.4% (475) and patients with referred pain below the knee 10.4 % (187). The characteristics of the three patient groups are represented in Table 1.

Table 1. Characteristics of patients with Low Back Pain (LB), low back pain and/or Upper Leg referred pain (UL), low back pain and/or referred Lower Leg pain (LL).

		<i>PAIN SITE</i>		
		<b>LB (1139)</b>	<b>UL (475)</b>	<b>LL (187)</b>
<b>AGE</b>	<i>Mean, years(SD)</i>	42.13 (12.6)	44.20 (11.9)	47.03 (11.4)
<b>GENDER</b>	<i>M</i>	600 (52.7%)	220 (46.3%)	88 (47.1%)
	<i>F</i>	539 (47.3%)	255 (53.7%)	99 (52.9%)
<b>OCCUPATION</b>	<i>PHYSICAL</i>	339 (29.8%)	154 (32.4%)	55 (29.47%)
	<i>SEDENTARY</i>	378 (33.2%)	143 (30.1%)	56 (29.9%)
	<i>MIXED</i>	234 (20.5%)	104 (21.9%)	36 (19.3%)
	<i>NOT WORKING</i>	155 (13.6%)	61 (12.8%)	32 (17.1%)
	<i>Not recorded</i>	33 (2.9%)	13 (2.7%)	8 (4.3%)
<b>PREVIOUS EPISODE</b>	<i>Yes</i>	713 (62.6%)	295 (62.1%)	118 (63.1%)
	<i>No</i>	260 (22.8%)	95 (20.0%)	42 (22.5%)
	<i>Not recorded</i>	166 (14.6%)	85 (17.9%)	27 (14.4%)
<b>PAIN DURATION</b>	<i>Acute (&lt;6 wks)</i>	890 (78.1%)	347 (73%)	117 (62.6%)
	<i>Subacute and chronic (≥6 weeks)</i>	249 (21.9%)	128 (27%)	70 (37.4%)
	<i>Acute and subacute (&lt;12wks)</i>	972 (85.3%)	393 (82.7%)	137 (73.3%)
	<i>Chronic (≥12 wks)</i>	167 (14.7%)	82 (17.3%)	50 (26.7%)
<b>SLR</b>	<i>&gt;45 degrees</i>	594 (52.2%)	262 (55.2%)	119 (63.6%)
	<i>&lt;45 degrees</i>	29 (2.5%)	32 (6.7%)	28 (15.0%)
	<i>Not recorded</i>	516 (45.3%)	181 (38.1%)	40 (21.4%)
<b>ACC co-payments</b>	<i>Yes</i>	776 (68.1%)	338 (71.2%)	134 (71.7%)
	<i>No</i>	363 (31.9%)	137 (28.8%)	53 (28.3%)
<b>TREATMENT DURATION</b>	<i>Mean, weeks</i>	5.01	5.79	6.28
<b>N of SESSIONS</b>	<i>Mean</i>	4.12	4.67	5.38
<b>OUTCOME</b>	<i>RECOVERY</i>	444 (39.0%)	155 (32.6%)	39 (20.9%)
	<i>IMPROVED</i>	540 (47.4%)	236 (49.7%)	108 (57.8%)
	<i>NO CHANGE</i>	59 (5.2%)	40 (8.4%)	22 (11.8%)
	<i>WORSE</i>	3 (0.3%)	4 (0.8%)	7 (3.7%)
	<i>DNA</i>	93 (8.2%)	40 (8.4%)	11 (5.9%)
<b>RECURRENCE</b>	<i>No</i>	908 (79.7%)	376 (79.2%)	163 (87.2%)
	<i>Yes</i>	231 (20.3%)	99 (20.8%)	24 (12.8%)

## Age

In all three groups the highest number of patients was in the 40-50 years age interval (Figure 1). There was a statistically significant difference in the mean age between the groups which increased from 42 in the low back pain group to 47 years in the group with referred pain to the lower leg ( $P < 0.001$ ). Further two sample two tailed t-test confirmed significant difference for mean age between LB/UL ( $P = 0.002$ ) and UL/LL groups ( $P = 0.006$ ).

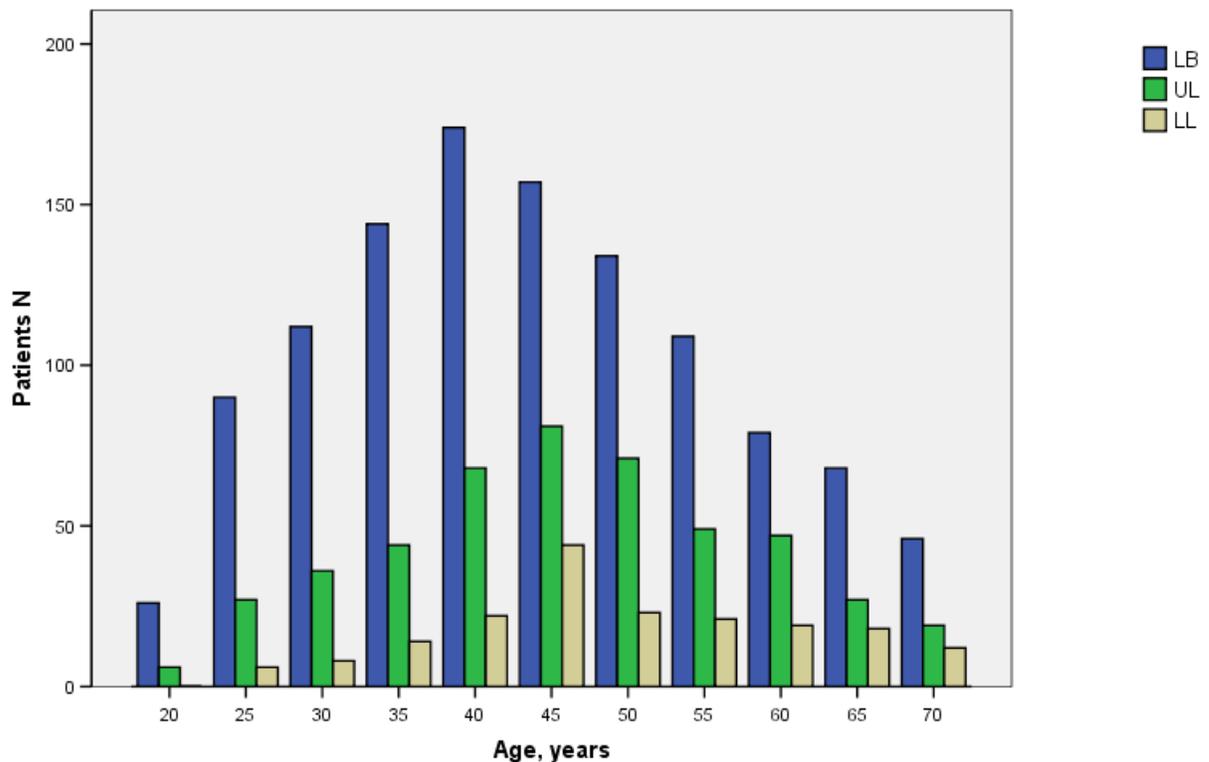


Figure 1. Age distribution in the LB, UL and LL groups, age intervals - 5 years.

## Gender distribution

There was a significant association between the pain site and gender in the low back pain group (LB) and upper leg (UL) referred pain group ( $\chi^2_{LBUL}(1) = 5.428$ ,  $P = 0.041$ ), with more females than males experiencing referred pain to the upper leg and opposite for low back pain, but the size of the effect was very small (odds ratio = 1.29). For two other comparisons no significant association between the site of pain and gender was found ( $\chi^2_{LBLL}(1) = 0.30$ ,  $P = 0.863$ ;  $\chi^2_{ULLL} = 2.031$ ,  $P = 0.154$ ).

### *Occupation, previous episodes and ACC co-payments*

There was no difference in the three groups in relation to the occupational profile selected for this study ( $\chi^2(8) = 5.657$ ,  $P = 0.686$ ).

Reported previous episodes of low back problems were not significantly different between any of the three groups (For all frequencies:  $\chi^2(4) = 3.785$ ,  $P = 0.436$ ; for separate groups:  $\chi^2(1)_{LBUL} = 0.807$ ,  $P = 0.369$ ;  $\chi^2(1)_{LBLL} = 0.016$ ,  $P = 0.901$ ;  $\chi^2(1)_{ULLL} = 0.217$ ,  $P = 0.641$ ). There was a substantial number of patients' notes (15.4%) without a specific indication on whether the patient reported any previous episodes of back or leg pain. The relative number was about the same in all three groups.

There was also no significant association between ACC insurance co-payments and the pain site groups (For all frequencies:  $\chi^2(2) = 1.992$ ,  $P = 0.369$ ; for separate groups:  $\chi^2(1)_{LBUL} = 1.437$ ,  $P = 0.231$ ;  $\chi^2(1)_{LBLL} = 0.929$ ,  $P = 0.335$ ;  $\chi^2(1)_{ULLL} = 0.016$ ,  $P = 0.898$ ).

### *Straight leg raise test*

The straight leg raise test was considered positive if there was pain radiation in the leg at 45 degrees or less. Almost half (45%) of patients with low back pain without referred pain did not have their SLR test results recorded in the notes. It is likely that in most of these cases a practitioner did not perform the test as there were no clinical indications to suspect nerve root involvement. In contrast, almost 80% of patients with lower leg referred pain had the results of SLR test documented in their notes. From the recorded data 15% of patient in the LL group had the test positive at less than 45 degrees, as opposed to 2.5% of patients in the LB group or 6.7% in the UL group. The difference was significant at  $P < 0.001$ ,  $\chi^2(2) = 35.508$ .

### *Pain duration*

It is common to classify pain that lasted less than 12 weeks as acute and pain for longer than 12 weeks as chronic. Overall, 1550 patients (86.06%) came with acute pain and 251 (13.94%) with chronic. There was a significant difference in the pain duration between the groups, with the mean

pain duration in the low back pain group of 7.91, upper leg 8.97 and lower leg 12.79 weeks ( $P < 0.001$ ,  $\chi^2(2) = 34.858$ ). The distribution was positively skewed in all three groups, so grouping analysis was performed.

The ratio of chronic patients increased from 14.66% in LB group to 17.26% in UL group and to 26.74% in LL group ( $\chi^2(2) = 22.439$ ,  $P < 0.001$ ). Longer pain duration before presenting is likely to be related to less optimistic natural history of the conditions with referred leg pain and poor response to previous treatments. Unfortunately, the data on treatment interventions before coming for osteopathic treatment was not collected and further analysis could not be made.

### *Treatment outcome*

Patients in all groups reported subjective improvement or complete recovery during the course of osteopathic treatment: in LB group 86.4% of patients recovered or improved, in UL - 82.3% and in LL - 78.7%. Patients with referred leg pain progressed less favourably during the treatment. Almost 20% less patients with lower leg referred pain reported complete recovery at the end of their treatment comparing to patients with low back pain only. Less than 1% of patients with low back pain reported deterioration during the treatment, whereas in patients with lower leg pain 3.7% got worse. For statistical analysis patients who got worse were added to those who reported no change after treatment. The difference between three groups in the treatment outcome was highly significant ( $\chi^2(6) = 45.4556$ ,  $P < 0.001$ ). Patients who got worse or did not feel any change in their condition had between 1 and 19 treatment sessions and were included into analysis of treatment duration.

### *Recurrence*

A total of 19.7% came back to the clinic with recurrence of the spinal pain within one year after the last treatment session. In LB and UL group there was no difference in the proportion of the returned patients, whereas in LL group comparing to LB group significantly less patients (12.83% vs 20.29%) came back to the clinic with spinal pain with or without referred pain ( $\chi^2(2) = 6.215$ ,  $P = 0.045$ ).

### *Treating practitioner*

A total of 11 practitioners worked at The Osteopathic Clinic over the studied period. There was a significant difference in the proportion of patients from the three groups seen by different practitioners ( $\chi^2(20) = 44.668$ ,  $P=0.001$ ). There was also a significant association between the number of sessions and the treating practitioner ( $\chi^2(10) = 52.284$ ,  $P < 0.001$ ). These associations could be related, for instance, as practitioners who treated more LL patients had longer treatment duration and larger number of sessions, and alternatively, the style of practice of a practitioner could have influenced how long that practitioner felt it necessary to continue the treatment.

Because of the large number of practitioners and relatively small numbers of patients treated by some of them it was not feasible to perform any further statistical analysis.

### *Treatment duration and number of sessions*

The mean treatment duration/mean number of sessions increased from 5.01wks/4.12 in LB group to 6.28wks/5.67 in the LL group (Treatment duration:  $\chi^2(2) = 12.895$ ,  $P=0.002$ ; number of sessions:  $\chi^2(2) = 23.293$ ,  $P < 0.001$ ). Because the data were positively skewed, the mean figure for treatment duration and for the number of sessions was not a good indicator of the frequency distribution.

### *Treatment duration, cluster analysis*

Table 2 illustrates the treatment duration and number of sessions for LB, UL and LL groups. More patients in the LB group required one week or less for their treatment comparing to UL or LL group ( $\chi^2(2) = 11.432$ ,  $P=0.003$ ), but there was no significant difference between the three groups in the proportion of patients who required 6 weeks of treatment or less ( $\chi^2(2) = 4.698$ ,  $P=0.095$ ). There was also no difference between the groups in the proportion of patients who had more than 12 weeks of treatment ( $\chi^2(2) = 4.591$ ,  $P=0.101$ ).

Table 2. Treatment duration and number of sessions in proportional intervals for LB, UL and LL groups

		<i>LB</i>	<i>UL</i>	<i>LL</i>
Treatment duration, weeks	≤ 1	484 (42.5%)	191 (40.2%)	55 (29.4%)
	≤6	916 (80.4%)	367 (77.3%)	139 (74.3%)
	≤12	1040 (91.3%)	420 (88.4%)	164 (87.7%)
	>12	99 (8.7%)	55 (11.7%)	23 (12.3%)
Number of sessions	1-3	669 (58.7%)	255 (53.7%)	80 (42.8%)
	4-6	305 (26.7%)	124 (26.1%)	52 (27.8%)
	7-12	131 (11.5%)	71 (14.9%)	40 (21.4%)
	>12	34 (2.9%)	25 (5.3%)	15 (8.0%)

For the number of sessions (Figs. 2,3,4), there was a tendency for an increase in the proportion of patients who received a higher number of treatment sessions from LB group through to LL groups. In the LB group 87.7% of patients required 6 treatment sessions or less, whereas in UL group it was 83.7% and in the LL group 75%. In the LL group three times as many patients received more than 12 sessions as those in LB group. The difference was highly significant ( $\chi^2(6) = 32.772$ ,  $P < 0.001$ ).

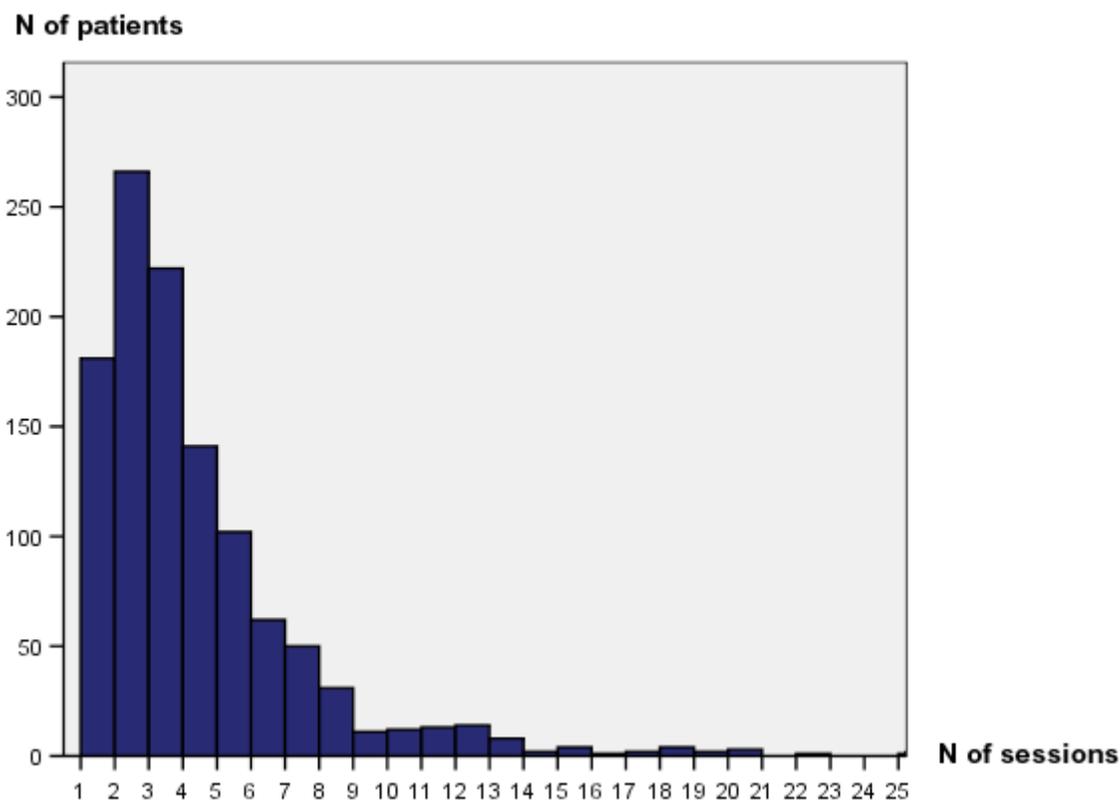


Figure 2. Number of treatment sessions in LB group. There were 12 ‘outliers’ who received 25 sessions or more, they are not included into the histogram.

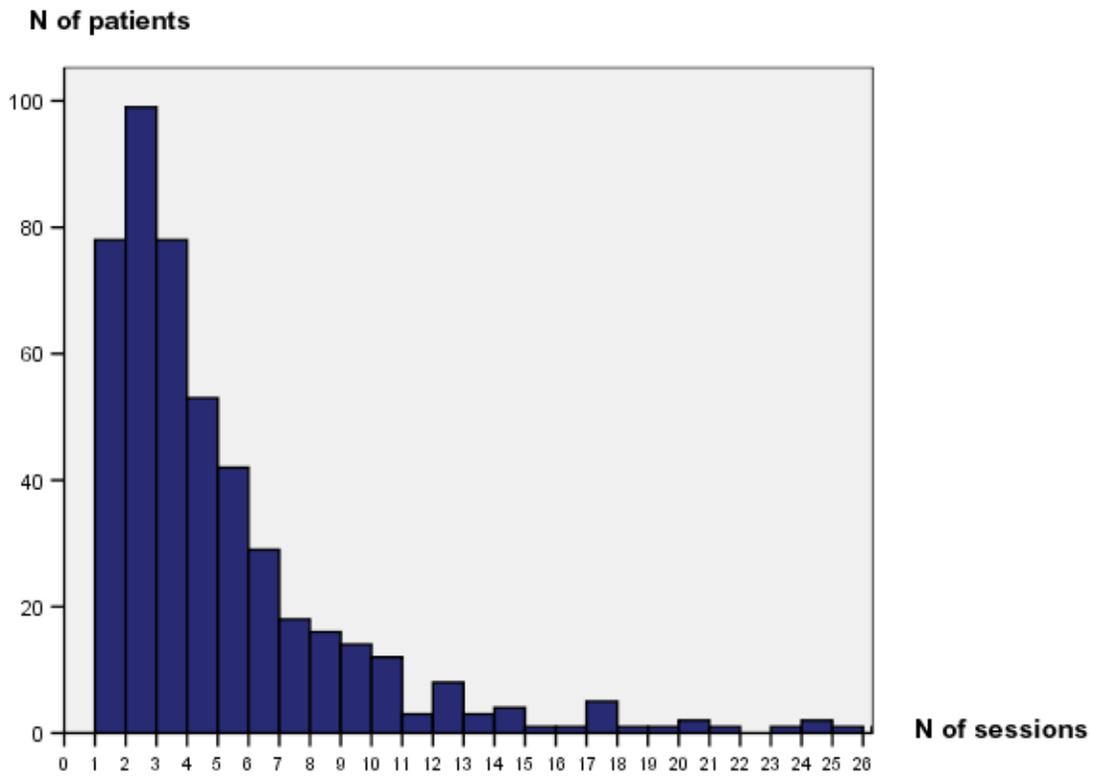


Figure 3. Number of treatment sessions in UL group.

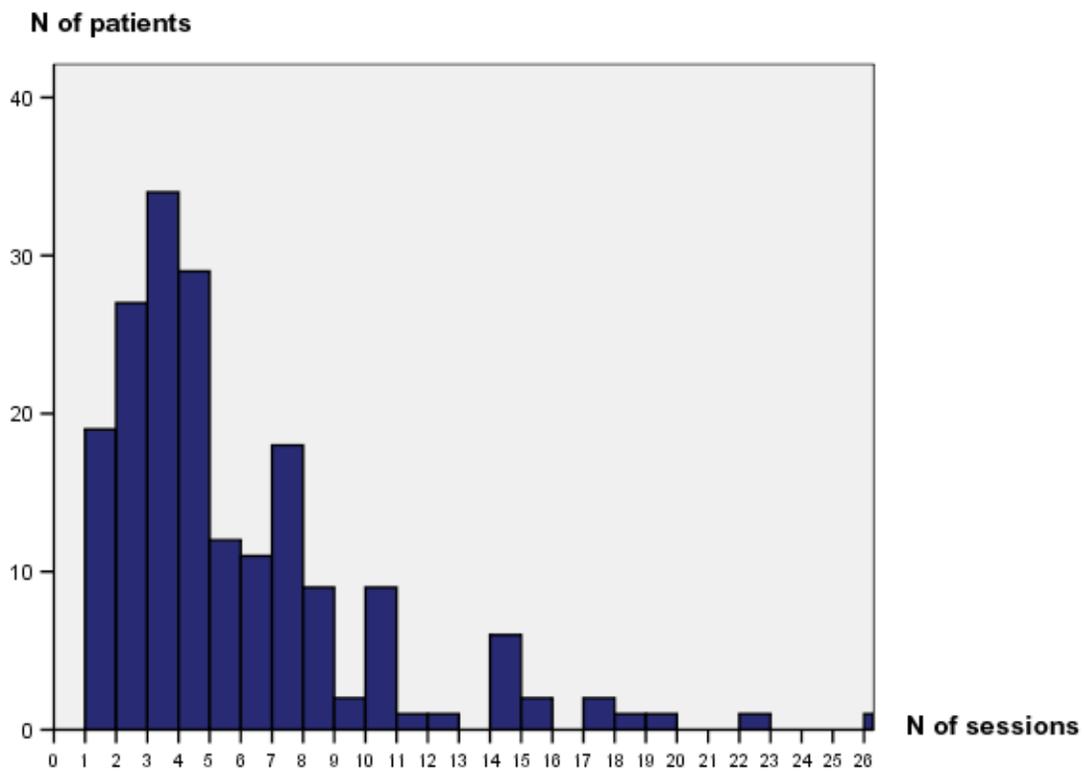


Figure 4. Number of treatment session in LL group.

## Acute pain, duration up to 12 weeks

Because a larger proportion of the LL group had a chronic history of the problem, it was decided to undertake a separate analysis of patients' profiles and treatment duration of acute conditions in all three groups, as chronic pain sufferers may have different prognosis and associated features. A total of 1550 patients had their pain duration 12 weeks or less. Table 3 summarises age, gender, treatment duration and outcome for the acute patients.

Table 3. Characteristics of acute patients in LB, UL and LL group.

		PAIN SITE		
		LB (998)	UL (404)	LL (148)
<b>AGE</b>	<i>Mean, years (SD)</i>	42.27 (12.5)	43.7 (11.7)	47.43 (11.4)
<b>GENDER</b>	<i>M</i>	541 (54.21%)	192 (47.52%)	70 (47.30%)
	<i>F</i>	457 (45.79%)	212 (52.48%)	78 (52.70%)
<b>TREATMENT DURATION</b>	<i>Mean, weeks</i>	4.072	4.4721	5.0743
<b>N of SESSIONS</b>	<i>Mean</i>	3.7194	4.3441	4.9932
<b>OUTCOME</b>	<i>RECOVERY</i>	410 (41.1%)	142 (35.1%)	32 (21.6%)
	<i>IMPROVED</i>	458 (45.9%)	193 (47.8%)	84 (56.8%)
	<i>NO CHANGE</i>	48 (4.8%)	28 (6.9%)	16 (10.8%)
	<i>WORSE</i>	2 (0.2%)	4 (1.0%)	5 (3.4%)
	<i>DNA</i>	80 (8%)	37 (9.2%)	11 (7.4%)

### Age

Significant difference was found between the mean age of three groups ( $P < 0.001$ ). This time, however, the t-test difference of age between LB and UL group was not statistically significant ( $P = 0.049$ ), but was still highly significant between LB and LL groups ( $P < 0.001$ ) and between UL and LL groups ( $P = 0.001$ ).

### Gender

There was a significant association between gender distribution and the pain syndrome ( $\chi^2(2) = 6.478$ ,  $P = 0.039$ ). Again, there were more males in the LB group than in UL or LL group.

### *Treatment outcome*

Treatment outcome showed very similar distribution to the total group with more favourable outcome in the LB group compared to UL group and, especially, LL group ( $\chi^2(6) = 35.375$ ,  $P < 0.001$ ).

### *Treatment duration and number of sessions*

The general tendency in the treatment duration and the number of sessions was the same as previously in that treatment duration and the number of sessions increased from LB group to UL and LL groups. Comparing to the previous results for the total group, more patients recovered earlier and less patients required more than 12 treatment sessions across all three groups (Table 4).

Table 4. Treatment duration and number of sessions in proportional intervals for acute LB, UL and LL groups

		<i>LB</i>	<i>UL</i>	<i>LL</i>
Treatment duration, weeks	$\leq 1$	446 (44.7%)	174 (43.1%)	51 (34.5%)
	$\leq 6$	828 (83%)	328 (81.1%)	118 (79.8%)
	$\leq 12$	930 (93.2%)	371 (91.7%)	133 (89.9%)
	$> 12$	68 (6.8%)	33 (8.2%)	15 (10.1%)
Number of sessions	1-3	608 (60.9%)	227 (56.2%)	70 (47.3%)
	4-6	267 (26.8%)	111 (27.5%)	41 (27.7%)
	7-12	104 (10.4%)	48 (11.9%)	27 (18.2%)
	$> 12$	19 (1.9%)	18 (4.5%)	10 (6.8%)

In acute patients there was no difference in the treatment duration between three groups in the proportion of patients who required one week for their treatment or less ( $\chi^2(2) = 5.505$ ,  $P=0.064$ ), in the proportion of patients who required less than 6 weeks of treatment ( $\chi^2(2) = 1.300$ ,  $P=0.522$ ) or in the proportion of patients who had more than 12 weeks of treatment ( $\chi^2(2) = 2.423$ ,  $P=0.298$ ).

For the number of sessions, however, there was a statistically significant difference associated with higher number of sessions in the LL group comparing to UL and, especially, LB group ( $\chi^2(6) = 25.175$ ,  $P < 0.001$ ).

## Chronic pain, longer than 12 weeks

The number of patients with pain duration more than 12 weeks was relatively small in the three groups and did not provide adequate statistical power to draw meaningful conclusions. Table 5 summarises age, gender, treatment duration and outcome for the chronic patients.

Table 5. Characteristics of chronic patients in LB, UL and LL groups.

		<i>PAIN SITE</i>		
		<b>LB (141)</b>	<b>UL (71)</b>	<b>LL (39)</b>
<b>AGE</b>	<i>Mean, years (SD)</i>	41.14 (12.9)	47.07 (12.4)	45.51 (11.5)
<b>GENDER</b>	<i>M</i>	59 (41.8%)	28 (39.4%)	18 (46.2%)
	<i>F</i>	82 (58.2%)	43 (60.6%)	21 (53.8%)
<b>TREATMENT DURATION</b>	<i>Mean, weeks</i>	11.48	11.49	10.84
<b>N of SESSIONS</b>	<i>Mean</i>	6.93	6.49	6.85
<b>OUTCOME</b>	<i>RECOVERY</i>	34 (24.1%)	13 (18.3%)	7 (18%)
	<i>IMPROVED</i>	82 (58.1%)	43 (60.6%)	24 (61.5%)
	<i>NO CHANGE</i>	11 (7.8%)	12 (16.9%)	6 (15.4%)
	<i>WORSE</i>	1 (0.7%)	0	2 (5.1%)
	<i>DNA</i>	13 (9.2%)	3 (4.2%)	0

### *Age*

A significant difference between the mean age in three chronic groups was demonstrated between the mean age of patients in three groups ( $P=0.004$ ). As opposed to the acute group, the t-test difference of age between LB and UL group was statistically significant ( $P=0.002$ ) and was not significant between LB and LL groups ( $P=0.059$ ).

### *Gender*

In the chronic group there was no significant association in gender distribution between three groups ( $\chi^2(2) = 0.467, P= 0.792$ ).

### *Treatment outcome*

Treatment outcome in the chronic group was quite different from the acute group or total group. There was no statistical difference in the treatment outcome between the three groups ( $\chi^2(8) = 16.032$ ,  $P < 0.042$ , but 40% of cell count less than 5). Nevertheless, only 1 of 141 patients in LB group (0.7%) got worse during the course of treatment as opposed to 2 out of 39 (5.1%) in LL group. The size of the groups might have been too small to establish statistical significance of this difference.

### *Treatment duration and number of sessions*

The treatment duration and number of treatment sessions in the chronic group did not differ as much as in the previous two analyses. In all three groups a larger proportion of patients required more than 12 weeks and more than 12 treatment sessions. The difference between the three groups was not significant ( $\chi^2(2) = 2.440$ ,  $P = 0.295$ ).

In chronic conditions there was no significant difference in the number of sessions required by patients in the three groups ( $\chi^2(6) = 8.819$ ,  $P = 0.184$ ).

Table 6. Treatment duration and number of sessions in proportional intervals for chronic LB, UL and LL groups

		<i>LB</i>	<i>UL</i>	<i>LL</i>
Treatment duration, weeks	$\leq 1$	38 (27%)	17 (24%)	4 (10%)
	$\leq 6$	88 (62%)	39 (55%)	21 (54%)
	$\leq 12$	110 (78%)	49 (69%)	31 (79%)
	$> 12$	31 (22%)	22 (31%)	8 (21%)
Number of sessions	1-3	61 (43%)	28 (39.5%)	10 (26%)
	4-6	38 (27%)	13 (18%)	11 (28%)
	7-12	27 (19%)	23 (32.5%)	7 (33%)
	$> 12$	15 (11%)	7 (10%)	5 (13%)

## **DISCUSSION**

The aim of the research was to establish the prevalence for low back pain and leg pain separately in osteopathic practice with further analysis of these two subgroups of patients for such variables as age, gender distribution, occupation history of previous pain, ACC insurance contribution, SLR test, treatment outcome and treatment duration. To the authors knowledge this is the first study undertaken in the New Zealand setting that attempts to compare the characteristics and response to treatment of two groups of patients that represent the most frequent syndromes in manipulative medicine - those with low back pain and leg pain.

### **Prevalence**

In a large survey of 43 osteopathic practices in the UK the prevalence of associated leg pain was “some 50%”<sup>36</sup>. In a chiropractic study in the US the prevalence of referred leg pain was reported at 63.4%<sup>3</sup>. In this current survey the prevalence of referred leg pain was much lower (36.75%) than in other similar studies and could be reflecting the differences in population profile or self-selection of patients. The leg pain in this survey was defined as pain below the buttock, whereas in the quoted research it wasn’t stated and buttock pain might have been classified as referred leg pain.

The percentage of low back pain patients who also had pain below the knee in this study (10.4%) was close to the prevalence reported for the urban New Zealand population, which was 14.3%<sup>37</sup> for prevalence. Thus this study cohort which serves a mixture of urban and rural population appears to have similar prevalence of low back and referred leg pain.

### **Age**

Previous studies found the peak incidence of low back pain with or without sciatica in the age group between 40 and 50 in both general and osteopathic practice<sup>14,36,38-44</sup>. The Mini-Finland Survey<sup>4</sup> found the peak incidence of sciatica to be in the younger age (45-54 years), comparing to the ‘unspecified low back pain’ (55-64 years) in the same survey group.

The findings from this study support those of Miranda et al<sup>45</sup> who found more patients with sciatica in the 45-54 age group, rather than 35-44. Miranda and colleagues suggest that older age and associated degenerative changes and higher incidence of disc herniation were thought to be the reason for developing sciatic pain in the older age group.

## **Gender**

Some studies have reported a higher proportion of women reporting leg pain and sciatica than men<sup>36,38,39</sup> whereas others found the opposite with more males having sciatica<sup>14,46,47</sup>. Although there was a statistical difference in male:female ratio between the groups in the current study, the difference was so small that it is unlikely to have any clinical implications. Unlike in the previous studies, the male:female ratio was approximately the same.

## **Occupation, previous episodes and ACC insurance contribution**

Previous studies have reported dose related relationships between heavy physical work and low back pain<sup>48</sup>. In this current study the occupational distribution of the participants did not differ between the groups. Most probably, more detailed analysis of occupational load factors and duration of the exposure to them are necessary to demonstrate any association between the type of job and presence of referred leg pain. The absence of differences between the groups in the occupational profile, reported previous episodes and ACC contribution makes the baseline characteristics of the studied groups very similar. This similarity of the groups justifies a conclusion that any differences in outcome, treatment response and recurrence are unlikely to be related to financial or occupational factors.

The large number of patients' notes without a specific indication on whether the patient reported any previous episodes of back or leg pain probably indicates the practitioners' omission to clarify the information from the patient's history or failure to document a negative finding.

## **Straight leg raise test**

In an earlier study, pain below the knee and positive SLR demonstrated good clinical agreement with radiological evidence of disc herniation<sup>14</sup>. It is possible that the majority of patients in LL group with positive SLR had some degree of intervertebral disc lesion. In addition, patients with internal disc disruption, but without bulging or herniation may also have leg pain similar to those with annulus deformity and nerve root compromise<sup>20</sup>. However, obvious disc lesions on MRI may not be well correlated with clinical symptoms, so the data on positive SLR test could not be easily interpreted as evidence of disc lesion.

It is not possible to conclude how many patients in the LL group in fact had a disc lesion, especially since the proportion of patients with positive SLR was relatively small and the results of clinical neurological examination not recorded in the data extracted for this study.

## **Pain duration**

Chronicity of low back pain is an established risk factor for continuation of low back pain trouble<sup>49</sup>. Chronic pain patients respond less favourably to manipulative treatment<sup>50</sup>. This current study found a higher percentage of patients with referred leg pain reported pain for longer than 12 weeks and a higher proportion of patients with leg pain continued to receive treatment after 12 weeks compared to patients with low back pain alone. Therefore, it is suggested that the presence of pain down the leg, especially below the knee, can be considered a risk factor for the presence of a pain problem that exceeds 12 weeks duration.

## **Outcome**

Rapid improvement of acute low back pain has been well documented in the research<sup>5,8-12,51</sup>. Several studies have reported favourable outcomes for sciatic patients as well. Seferlis et al.<sup>52</sup> reported that all sciatic patients improved in 1 month regardless of type of conservative treatment. After 6 months of conservative treatment good outcome and recovery was reported in 76.5% of patients<sup>39</sup> or even 95%<sup>5</sup>. In the manipulative professions, O'Donaghue<sup>34</sup> reported similar results for physiotherapy

treatment of a mixed cohort of patients with low back pain and some with leg pain; 7.5% of them got worse and 20.4% remained the same after 4 months of treatment. A comparison of GP and chiropractic care revealed good outcomes in both groups within the first 3 months of treatment with the recovery rate being slightly faster in the chiropractic care group<sup>41</sup>. Similar to low back pain, there is emerging evidence that sciatic pain may not resolve completely or tends to recur with the majority of patients suffering incomplete recovery subjectively and objectively<sup>11</sup>. Sciatic pain may have a similar intermittent course as uncomplicated low back pain.

The current study shows that the majority of patients in all three groups improved within 3 months of treatment, but patients with leg pain had a less favourable outcome with a higher proportion of negative outcomes and fewer patients with full recovery. The recovery in this study represents the patients' subjective report of improvement in their symptoms of pain and disability. It is possible that more objective pain and disability questionnaires together with blind assessments could have produced different results, but unfortunately these outcome measures are not widely used in clinical practice. In addition, a prospective trial, rather than the retrospective survey, would strengthen the validity of the research.

## **Recurrence**

The percentage of patients who returned to the clinic within 1 year after completing the treatment (about 20%) is not a good indicator of relapse of the initial problem, as very often the new episode was related to another physical injury such as lifting or falling. Moreover, the number of patients with a possible relapse of the same problem might have sought care from other treatment providers or decided not to seek help at all. Considering less favourable outcome of treatment in the LL group, patients may be more likely to try a different health provider in case of the relapse. Indeed, noticeably fewer patients with lower leg pain (13% vs. 20 % in the LB and UL groups) came back to the clinic with a recurrence of the same pain ( $\chi^2(2) = 6.215$ ,  $P=0.045$ ).

## **Treatment duration**

It has been found that longer pain duration is associated with poorer response to spinal manipulative treatment<sup>53,54</sup>. The longer pain duration in patients with referred leg pain could be one of the factors

related to poorer response of leg pain sufferers to treatment in this current study. Less favourable response to treatment and, as a result, more treatment sessions and longer duration of treatment is likely to be related to more complicated mechanisms of pain in cases of referred leg pain, which was postulated to include hyperexcitability and central sensitization phenomena<sup>55,56</sup>. Those mechanisms are probably related to the neurological network of lower lumbar spinal segments, including segmental nerve roots, recurrent nerves von Lushka and, possibly, central pathways of the nociceptive system. At least some of the anatomical causes could be attributed to the presence of intervertebral disc lesions, but the favourable outcome for the majority of patients within a relatively short period of time suggests functional, rather than anatomical causes of the conditions with referred leg pain.

Comparing to the data from published research for low back pain conditions<sup>57</sup> (lumbar sprains lumbago, somatic dysfunctions), the mean number of visits claimed from the insurance companies by physiotherapists (20.63, median 10) and chiropractors (31.16, median 14) was notably higher than in the current study. The studies conducted by chiropractic practitioners in the clinical settings found noticeably smaller figures, from 10.4 visits<sup>58</sup> to 18.6<sup>3</sup>. No published data on the number of treatment for sciatic pain by manipulative practitioners was located.

### **Chronic groups**

Patients in all three chronic groups reported improvement in the level of pain and disability during osteopathic treatment, confirming the results of a previous study<sup>43</sup>. There was no significant difference between the low back pain group and referred leg pain groups in the treatment outcome and the duration of treatment. The duration of treatment was significantly longer for all three groups and the outcome less favourable than in the acute groups. It is now established that the strongest risk factors for development of chronicity in cases of spinal pain are mainly related to psycho-social factors<sup>59</sup>. Similarities between all three chronic groups confirm that factors other than pain distribution may be important determinants of outcome and treatment duration in their case.

## **Limitations of the study**

The major limitations of this study lie in the quality of the original data. Being based on the clinical notes from a practice, the reliability and validity of the results might be compromised. While the data on age, gender, ACC insurance co-payments and the duration of osteopathic care are based on simple and strict documentation protocols, several parameters on the clinical history and examination are less reliable. The outcome measures were not quantifiable or standardized and were subject to practitioner's bias, occupational profiles were not well detailed, and some records in the notes were missing. Some diagnostic tests and treatment protocols like SLR and osteopathic techniques used were not standardized between several practitioners, however, the research suggests good inter-observer reliability for SLR within 10 degrees of mistake<sup>60</sup> and with a cut off angle of 45 degrees the positive test results analysed in this study appear reliable.

## **Final note**

Using a triage approach, most LB patients may be classified as having 'mechanical back pain' or 'non-specific back pain'. It is apparent that in the acute stage referred pain down the leg and, especially, to the lower leg is a more complicated syndrome with different clinical features, prognosis and response to manipulative treatment. Researchers should take care to separate patients with referred leg pain from simple non-complicated low back pain, because patients with leg pain have different clinical characteristics and respond differently to manipulative treatment comparing to patients with low back pain only.

## CONCLUSIONS

- The prevalence of lower leg pain in osteopathic practice is in accord with other New Zealand data from physiotherapy survey, but slightly less than UK surveys.
- Referred leg pain, especially below the knee, constitutes a separate subgroup of patients with mechanical spinal conditions. This subgroup is characterized by older mean age, more chronic course and less favourable response to manipulative treatment.
- Referred leg pain is a risk factor for the development of chronicity and for less favourable responses to manipulative treatment, in particular those patients with referred leg pain may expect less successful treatment outcomes and longer duration of treatment than those patients without referred leg pain.
- The majority in all three groups of low back pain, upper leg referred pain and lower leg referred pain improved within the first 12 weeks of osteopathic treatment.
- The number of consultations and the treatment duration was much lower in this study than in reported data for chiropractic.
- Referred leg pain tends to occur later in life, tends to have a more chronic course and is likely to require longer treatment with less optimistic outcome in the acute stage
- Patients with chronic low back, with or without referred leg pain, show no difference in how they respond to osteopathic treatment, requiring longer treatment than the acute group

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### **Section 3: Appendices**