Osteopathic Manipulative Medicine (OMM) and Reduction of NSAID Use in Low Back Pain: A Pilot Study

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OSTEOPATHIC MANIPULATIVE MEDICINE (OMM) AND REDUCTION OF NSAID USE IN LOW BACK PAIN: A PILOT STUDY

A Thesis in Biomedical Sciences by Kristopher Kelly
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Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Biomedical Science
May 2014
We approve the thesis of Kristopher Kelly.

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Abstract

Osteopathic Manipulative Medicine (OMM) and Reduction of NSAID Use In Low Back Pain: A Pilot Study
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MS Biomedical Sciences, May 2014
Philadelphia College of Osteopathic Medicine
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This randomized controlled pilot study is to determine if a combination of muscle energy and soft tissue techniques can reduce the amount of daily NSAID use in patients suffering from chronic non-specific low back pain (CNSLBP). Osteopathic manipulative treatment has been shown to be useful in treating low back pain. However, its role in reducing daily NSAID use in CNSLBP patients is unclear. This study was conducted at PCOM from January 2014 to April 2014. By design, patients were to be randomized into either a treatment group consisting of OMT or a control group consisting of a sham OMT. Of the two patients who were recruited, one met the eligibility criteria (n=1). This patient was randomized into the treatment group with OMT and was allowed to continue to take NSAIDs as needed to treat low back pain. The primary outcomes included a percent reduction in daily NSAID use and a percent reduction in daily pain scores from a 11-point 10 log scale. As compared to the baseline data, the patient who received osteopathic manipulative treatment presented with an increasing trend in daily NSAID use and pain scores. The competitive soccer combined with the clear diagnosis of iliolumbar ligament strain can account for the continuous discomfort and somatic dysfunction. With only one patient, there was no comparison to sham manipulation. No conclusion can be made to address OMT reducing daily NSAID use and pain in patients suffering from CNSLBP with the limited amount of data we obtained from this study. Further assessment of the difficulty with clinical research was discussed.
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The only way to do great work is to love what you do.

—Steve Jobs
Chapter 1. Introduction

Back pain is a major concern for the developed world. It affects men and women of all ages and causes an immense economic burden on individuals, families, communities, industries, and governments (Hoy et al, 2010). Orrock (2013) described Low back pain (LBP) as a 21st century epidemic. It is currently considered a public health problem, has a high rate of disability, and is the leading cause of activity limitation and absenteeism in the workforce throughout the world. Approximately 75% of adults will experience LBP at least once in their life (Majid and Truumees, 2008). It is estimated that approximately 15% to 20% of the U.S. population experiences LBP annually, and at any given time, 2% of the population is disabled due to back problems (Licciardone et al, 2003). LBP is the most common condition cited by patients seeing a Doctor of Osteopathic Medicine (DO), accounting for approximately 11% of visits (Earley, 2010). Also, LBP symptoms are the second leading reason for office visits to primary care physicians (Early, 2010).

1.1 Epidemiological Parameters

Epidemiological studies on LBP consist of a substantial amount of heterogeneity limiting the amount of accurate data. In the most current systematic review Hoy et al (2010) found the 1-year incidence of a first-ever episode of LBP to range from 6.3% to 15.4%, while the 1-year incidence of any episode of LBP to range from 1.5% to 36%.
Additionally, Hoy et al (2010) found the point prevalence to range from 1.0% to 58.1% and 1-year prevalence from 0.8% to 82.5%.

1.2 Low Back Pain Anatomy

LBP encompasses both lumbar and sacral spinal regions. Lumbar spinal pain is defined as pain perceived anywhere in the area bordered by the last thoracic spinous process, the first sacral spinous process, and the lateral borders of the erector spinae. Sacral spinal pain is defined as pain perceived anywhere in the area bordered by the first sacral spinous process, the posterior sacroccocygeal joints, and the posterior superior iliac spines. These borders define the area of pathology, but the pain is not restricted to these sites. Many experience discomfort in their lower limb, which is known as somatic referred pain; it is due to damaged structures sharing the same nerves and innervation (Bonica’s Encyclopedia, 2010).

1.3 Low Back Pain Terminology

The length of illness is a necessary and important parameter to consider when managing LBP. Adjectives, such as acute, subacute, and chronic are used to describe the period of time LBP has been perceived. Acute pain is defined as pain of recent onset, subacute pain as lasting at least five to seven weeks but no longer than 12 weeks and, finally, chronic pain is defined as that lasting equal to or longer than three months (Bonica’s Encyclopedia, 2010). This study will be focusing on the latter.
LBP can be classified as either specific or non-specific. Specific LBP has a known cause and some types of specific LBP are spondylolysis, spondylolisthesis, sacroiliac joint syndrome, lumbar spinal stenosis, lumbar disc herniation, etc. Non-specific LBP has no known cause and will be the focus of this study.

1.4 Sources of Low Back Pain

A majority of LBP patients have idiopathic pain. Although there are many potential sources of LBP, this study will be targeting somatic dysfunction. The idea is that people with mechanical LBP will have a loss of inter-segmental range of motion; restrictions that contribute to the mechanical etiology. This study is not trying to treat the LBP per se, but trying to resolve any somatic dysfunction that is impeding the ability to self-heal. There are four major types of somatic dysfunction and they consist of tissue-texture changes, asymmetries, restrictions, and tissue tenderness.

1.5 Low Back Pain Treatment

LBP has a plethora of treatment options that physicians recommend. The type of treatment for LBP is a decision that the individual, along with the treating physician, has to make. Treatments include, but are not limited to drug therapy (e.g, non-steroidal anti-inflammatory drugs (NSAIDs), opioids, muscle relaxants), injections (e.g, corticosteroid), physical therapy, massage, and manual manipulation. Manual manipulation is the
treatment option this study will focus on and is the most contested intervention for chronic low back pain (CLBP) (Bonica’s Encyclopedia, 2010).

Manipulation offered by osteopathic physicians (DOs) is called Osteopathic Manipulative Treatment (OMT). Although NSAIDs are often solely used to treat LBP, taken on a daily basis they can cause adverse effects such as gastrointestinal irritation and subsequent ulcers, edema, and hypertension. Since OMT is known to reduce LBP, complimenting OMT with conventional NSAID treatment may reduce the need for continual use.

Since the number of DOs in the United States has been increasing at a higher rate than allopathic physicians, and considering LBP is the most common condition amongst patients seeing a DO, there is a need to continue evaluating the efficacy of OMT in reducing both LBP and daily NSAID use. Since osteopathic physicians offer conventional and complimentary therapy, they can reduce healthcare costs acquired by sending patients to separate manual medicine professionals and allopathic physicians. It is known that osteopathic physicians reduce hospital admissions, referrals, radiographs, and prescribing medications to patients with LBP (Earley, 2010).

1.6 Osteopathic Manipulative Treatment

The philosophy of osteopathy focuses on treating the origin of disease rather than only treating the symptoms. It emphasizes that the musculoskeletal system is the primary machinery for life, and the whole body is interconnected. Osteopathic techniques address dysfunction in order to maintain the body’s homeostasis. Osteopathic manipulative
treatment is a modality commonly used by osteopathic physicians to complement conventional treatment for chronic low back pain patients.

Osteopathic manipulative treatment is direct care, which involves using the hands to diagnose, treat, and prevent somatic dysfunction. Somatic dysfunction can be defined as “Impaired or altered function of related components of the somatic system: skeletal, arthrodial, and myofascial structures, and their related vascular, lymphatic, and neural elements” (Clinical Guideline Subcommittee 2010). OMT can help persons of all ages and can be used to ease pain and promote healing. When applicable, OMT can supplement or even replace drug therapy (Earley and Luce, 2010).

1.7 Preliminary Studies

Most people experience their first LBP episode at an early age and LBP frequently reoccurs throughout the adult life leading to chronic conditions (Jenkins, 2002). These clinical problems lead to the greatest medical costs and explain why CLBP is the most commonly studied condition (Earley, 2010). Although, optimal treatment for patients with CLBP remains a challenge for osteopathic physicians, research has steadily increased in the last decade investigating OMT as a complimentary treatment.

A systematic review by Licciardone et al (2005) found six OMT trials studying the efficacy of OMT in reducing low back pain. The overall results distinctly showed a statistically significant (P <0.05) reduction in low back pain with OMT. Thus, Licciardone et al (2005) believed that OMT could possibly eliminate or reduce the need for analgesics.
A randomized controlled trial (RCT) performed by Hoehler et al (1981), found that manipulation alleviates LBP when comparing manipulation with a placebo treatment. Also, an osteopathic study by Cleary and Fox (1994) found that OMT reduced menopausal symptoms, such as spinal ache and neurological irritation at the spinal level. Additionally, Anderson et al (1999) RCT found that daily use of NSAIDs and muscle relaxants were significantly (P <0.001) less in OMT patients compared to standard care patients. Finally, it has been reported that OMT plus usual care provided better one-month outcomes in back pain and fewer cotreatments compared to usual care alone (licciardone et al, 2003)

A more recent systematic review by Orrock et al, (2013) included recent studies assessing the efficacy of OMT as a treatment modality for chronic non-specific low back pain (CNSLBP). CNSLBP is a diagnosis of exclusion. Physicians have to rule out pain caused by a suspicious or confirmed serious pathology (‘red flag’). Red flags are serious medical conditions and include, cancer, infections, fractures, or any other type of trauma that mimics mechanical LBP. Orrock et al (2013) found two trials that qualified for review, but both differed in their conclusions. The Licciardone et al (2003) investigation found that the OMT group was similar in effect to a sham group while Chown et al (2008) found that there was a similarity of OMT with exercise and physiotherapy.

Recently Licciardone et al (2013) published the Osteopathic Trial with results concluding that OMT significantly reduces CNSLBP with less frequent use of prescription drugs. The results showed that OMT was efficacious for short-term pain relief when it was used to compliment co-treatments for CNSLBP. This trial met the Cochrane Back Review Group criteria for a medium effect size for both moderate and
substantial improvements in LBP. Most importantly was the less frequent use of prescription drugs (i.e. NSAIDs) in OMT patients. These findings corroborate the clinical relevance for reduction in LBP. Further, this trial validates why most LBP patients are cited seeing an osteopathic physician and why a majority of the patients that osteopaths examine are suffering from LBP. Also, this trial justifies why osteopathic physicians prescribe less medications. OMT that reduces pain warrants a better prognosis without the need to take pain medication, such as NSAIDs.

In patients who underwent elective transabdominal hysterectomy, Goldstein et al. (2005) showed a significant (p < 0.05) decrease in postoperative morphine use when OMT was employed in combination with pre-emptive morphine. Reductions in morphine use occurred at 24 and 48 hours after multiple OMT treatments compared to SHAM treatment (figures 1 and 2); in addition, at 48 hours morphine blood levels were lower (figure 3).

Figure 1. First 24 hours after surgery (0-24 hours): total postoperative dose of morphine sulfate (mg/kg).
Figure 2. Second 24 hours after surgery (25-48 hours): total postoperative dose of morphine sulfate (mg/kg).

Figure 3. Twenty-four hours after surgery: patients' postoperative morphine blood concentrations (ng/mL).
A recent study by Heymann et al (2013) investigated acute nonspecific LBP by comparing spinal manipulation to the NSAID drug dicoflenac. They found that the spinal manipulation group had significantly better pain outcomes than the dicoflenac (NSAID) group. Also, spinal manipulation proved to be more clinically efficacious than the placebo group. This study by Heymann et al motivated the design of this thesis. Since manipulation has a better efficacy than NSAIDs when treating nonspecific LBP, then complementing standard NSAID treatment with manipulation should decrease daily NSAID use in patients suffering from CNSLBP.

Finally, a retrospective observational study by Prinsen et al (2014) found that pain and medication use (analgesics, anti-inflammatory agents, muscle relaxants) is lower in patients who received OMT, which aligned with previous RCTs. Data were abstracted from medical records of families that participated in The American Osteopathic Association Clinical Assessment Program (AOA-CAP) between 2006 and 2007. These records revealed reduced use of analgesic medications, anti-inflammatories, and muscle relaxants, inferring that patients were in less pain. This study was a novel approach, but such results continue to solidify the fact that more research is needed to test OMT reducing NSAID use.

1.8 Purpose of Study

The purpose of this pilot study is to determine if a combination of muscle energy and soft tissue techniques can specifically reduce the amount of daily NSAID use in
patients suffering from CNSLBP. Pre-treatment and post-treatment NSAID use will be documented on a daily pain and medication diary and compared to assess the efficacy of OMT in reducing daily NSAID use. Also, data will be recorded to determine if OMT reduces pain. Pre-treatment and post-treatment pain levels will be recorded and assessed. Additionally, evaluation will be of a standard protocol for treatment of CNSLBP. To the best of our knowledge, this is the first time that OMT has been deployed on CNSLBP patients to specifically assess a reduction in the amount of NSAIDs taken daily.
Chapter 2. Materials and Methods

2.1 Project Approval

Philadelphia College of Osteopathic Medicine (PCOM) Institutional Review Board (IRB) approved this investigation and its consent form (Appendix A) on September 11, 2013.

2.2 Personnel

Donald Allison, DO, performed OMT for the study at the PCOM Osteopathic Manipulative Medicine (OMM) department.

2.3 Patient Recruitment

Dr. Allison recruited his new CNSLBP patients to be in this study. Patients were given a pain and medication diary (Appendix B) each week to assess pain and medication use. Additionally, patients needed to meet inclusion and exclusion criteria.
2.3.1 Inclusion Criteria

Chronic low back pain \( \geq 3 \) months
Currently taking an NSAID to relieve pain
OMT is appropriate therapy
Eighteen years of age or older
Patient:
   able to self-report pain levels,
   able to request medications, and
   naïve to OMT

2.3.2 Exclusion Criteria

Current antidepressant therapy
Current opioid use
Concurrent manipulation (e.g. physical therapy, chiropractor, rolfing, acupuncture, acupressure, or massage therapy)
Lumbar spinal surgery (e.g., fusion)
Spinal stenosis
Previous or current malignancies in lumbar-sacral region
Previous diagnosis of Complex Regional Pain Syndrome (CRPS)
Pregnancy
Unable to maintain pain and medication diary
Unable to show up to scheduled appointments
Unreliable transportation
Involved in any medical malpractice litigation

2.4 Patient Confidentiality

Signed consent documents and pain and medication diaries were kept in a locked file cabinet. Excel files are accessible only to study personnel and protected by passwords and access privileges.

2.5 Experimental Design

Once patients were recruited, Dr. Allison was to discuss this study with the new patient. All potential patients were given a week to take home, read and share the consent form with any family members or friends.

2.5.1 Pre-Treatment Evaluation

Dr. Allison was to determine if patients met all inclusion and exclusion criteria by asking compliancy questions, and performing a personal history and physical exam.

2.5.1.1 Compliancy Questions

Questions regarding compliancy were asked during the pre-treatment evaluation.
They were:

_____ 1. Will you be able to maintain a daily pain and medication diary?
_____ 2. Will you be able to show up to scheduled appointments?
_____ 3. Will you have reliable transportation to get to and from PCOM?

2.5.1.2 Health History Assessment

A verbal detailed health history was documented, obtaining demographic characteristics, lifestyle, past medical and surgical history, and medications.

2.5.1.3 Physical Examination

Dr. Allison performed a physical examination on each patient to check reflexes and muscle strength; these data were recorded.

2.5.2 Evaluation of Somatic Dysfunction

Somatic dysfunction was assessed after the physical examination. An osteopathic structural exam was performed for tissue texture change, asymmetry, restriction, and tenderness in the lumbar-sacral region. The somatic dysfunction found was documented.

2.5.3 Phase 1 – Baseline 14 Days

Once patients were cleared and evaluated for somatic dysfunction, baseline data were obtained using a pain and medication diary. This information was obtained during the two weeks prior to initiation of OMT. Patients were given a pain and medication diary each week to fill out and return upon appointment. It was designed to record daily
pain levels from a 11-point 10 log scale and to document the amount of NSAIDs used per day. Additionally, patients documented any other pain reduction modalities for each day (e.g., ice pack, heat). Once a baseline was obtained over the two-week period, OMT began.

2.5.4 Phase 2 – Treatment 28 Days

Patients were to be randomly assigned into one of two experimental groups after being cleared for the study. The treatment group consisted of two specific OMT techniques and the control group consisted of a sham OMT therapy. The control group, were to all receive standardized sham OMT and treatment group, were to all receive standardized OMT.

2.5.4.1 Muscle Energy Technique

1. Physician positions the patient to the restrictive barrier

2. Patient pushes into the direction of the ease of motion against physicians’ resistance three to five times for three to five seconds

3. Physician reassesses patient for symmetry

2.5.4.2 Soft Tissue Technique

1. Patients lie in the prone position

2. Physician massages low back to loosen the muscles

These OMT techniques were chosen because they have shown to resolve somatic dysfunction, thereby the body’s ability to maintain homeostasis and enhance its innate
ability for self-healing. This is accomplished by restoring normal range of motion, reducing static asymmetries, restoring normal tissue texture, and decreasing tenderness. The idea is that people with mechanical LBP will have a loss of inter-segmental range of motion/restrictions, which are contributing to the mechanical etiology. The focus is to try to resolve any somatic dysfunction that is impeding their ability to self-heal.

The control group was to involve a sham therapy, which required being positioned similarly to the muscle energy and soft tissue techniques, but only provided pressure in the amount of the physician’s hands for 30 seconds and without movement.

Each group was to receive 8 treatments over the course of four weeks with two treatments per week. Treatments were all 15 minutes in length. Throughout this treatment phase, patients continued to receive weekly pain and medication diaries to continue documenting pain and medication levels for comparison.

2.6 Data Organization

Daily NSAID use and pain scores were recorded on pain and medication diaries. These data were imported into an excel document for comparison.

2.7 Data Analyses

Data will be analyzed and quantified by using percent reduction in medication and pain scores.
Chapter 3. Results

The flow of patients through the experiment is shown in figure 4. Altogether, one (50%) of the two persons who were recruited was randomized into the treatment group.

Characteristics were of patient one: 24 years of age, male, Caucasian, back pain greater than three months with ibuprofen used as needed, and no comorbid conditions.
Table 1 exhibits results of the osteopathic structural exam for the first two weeks (baseline). The patient presented with a right anterior innominate and outflare and had a decrease in sacral motion. These pelvic dysfunctions were treated with the standard muscle energy technique. The inferior paraspinal muscles exhibited a generalized hypertonicity that was treated with a soft tissue myofascial technique.

<table>
<thead>
<tr>
<th>Dysfunction</th>
<th>OMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right anterior innominate</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Right outflare</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Sacral motion</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Generalized paraspinal hypertonicity</td>
<td>Soft Tissue</td>
</tr>
</tbody>
</table>

Table 2 represents results of the osteopathic structural exam for weeks three and four and the treatment phase had commenced at this point. During these two weeks of treatment, the patient still presented with all the same dysfunctions, but with an additional L 3-5 NSL R."
Table 3. A list of dysfunction and appropriate OMT

<table>
<thead>
<tr>
<th>Dysfunction</th>
<th>OMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior left innominate</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Left inflare</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Tender left Iliolumbar ligament</td>
<td>Muscle Energy</td>
</tr>
<tr>
<td>Generalized Paraspinal Hypertonicity</td>
<td>Soft Tissue</td>
</tr>
</tbody>
</table>

Table 3 exhibits results from the osteopathic structural exam for the final two weeks (weeks five and six). After two weeks of treatment the patient began displaying a posterior left innominate with a left inflare. The patient was finally diagnosed with a tender left iliolumbar ligament. Once the study was complete, the patient began being treated for a left tender iliolumbar ligament.

![Figure 5](image_url)  

*Figure 5. Percent change in daily NSAID use compared to baseline. Values presented are arithmetic averages.*

Figure 5 shows an increasing trend over time with regard to the amount of NSAIDs taken on a daily basis for low back pain. After obtaining a two-week baseline,
the following week (week three), when compared to the baseline showed a 25% reduction in daily Ibuprofen use. The next week (week four), it quickly rose by 50% compared to the baseline. Week five showed a 25% reduction in daily Ibuprofen use. Last, the final week (week six) showed an overall 12% increase in daily NSAID use from the start of the study to the end of the study.

Figure 6. Percent change in daily pain scores compared to baseline. Values presented are arithmetic averages.

*Figure 6* demonstrates an increasing trend over time with regard to daily pain scores for low back pain. When compared to baseline data, week three presented an initial 58% reduction in daily pain. The following week (week four) exhibited a 10% increase in pain from a 2.6 to 2.9 on a 10-cm visual analog scale. The subsequent week (week five) showed a 4.5% reduction in pain compared to baseline. Finally, the last week (week six) displayed an overall 61% increase in pain from 2.6 to 4.2.
This pilot study is unique in being the first to address the efficacy of OMT in specifically reducing daily NSAID use in CNSLBP. The study was limited to a sample size of one patient in the treatment group and none in the sham control group. When the study commenced, a sample size of 20 was the goal. The rationale was to have ten treatment patients to compare with ten sham control patients.

Recruitment issues developed immediately after this study was approved by the IRB. The OMM administrative staff was not helpful to recruit new patients as planned. Recruitment then became the sole job of the physicians, which proved difficult. A total of two patients were recruited with only one completing the study. One patient withdrew due to no longer needing an NSAID to treat pain. Since there was only one treatment patient and nothing to compare it to, the results for this study were limited.

4.1 The Patient

The patient was 24 years of age, male, took Ibuprofen as needed, and was an active soccer player. He presented with CNSLBP and was given an osteopathic structural exam. Asymmetries were noted in the lumbosacral region and generalized paraspinal hypertonicity. The physician noted the etiology of this patient’s LBP to be from an iliolumbar ligament strain that did not explicitly exclude him from the study. This diagnosis is usually not treated with a muscle energy technique and could have had better results with another OMT therapy. Our standard OMT could have been aggravating this
type of dysfunction. This is one of the issues with applying a standard OMT therapy to a
wide-spectrum disorder like low back pain. There are many tissues and structures in the
lumbosacral region that can present with somatic dysfunction and the type and location of
dysfunction will dictate the kind of OMT used to treat.

For each successive treatment, the patient continued to present these dysfunctions
throughout the study. He played soccer three days a week and between each treatment.
This competitive activity combined with the clear diagnosis of iliolumbar ligament strain
can account for the continuous discomfort and somatic dysfunction. If the patient
abstained from all competitive sports during treatment, then the dysfunction could have
been resolved by the OMT, and ultimately relieved the pain he was experiencing.

4.2 Results

The data collected were reported as percent reduction. The original design would
have had statistical analyses comparing the treatment group to the control group, but had
to troubleshoot due to only one patient completing the study. An increasing trend in daily
NSAID use for low back pain is shown in figure 5. Additionally, an increasing trend in
daily pain scores for low back pain is shown in figure 6.

The overall increasing trend in Figure 5 confirms the null hypothesis that there
will be no reduction in daily NSAID use. Baseline data were averaged and showed a
daily NSAID use of 225 mg. The first week of treatment (week 3) showed promising
results of a 25% reduction. This reduction could have been a placebo effect, where the
patient initially thought he was getting better due to being touched by a physician. The
following week (week 4) showed a vast increase of 50%, which can be explained by muscle energy technique initially causing soreness due to the force the physician places on the body. On the other hand, this can be explained as the dysfunction getting worse due to the standard OMT being used. In week 5, the patient once again had a 25% reduction, which was initially thought to be the actual treatment working. This follows the pattern we were looking for, where there is an initial decrease, followed by an increase due to the force of muscle energy, and then a reduction due to structures returning to homeostasis. But, the final week the patient presented with a 12% increase from baseline suggesting an overall increase in daily NSAID use over the total six-week study. This increase in overall daily NSAID use can be translated into the patient being in more pain due to standard OMT aggravating the inflamed iliolumbar ligament. Also, the competitive soccer combined with this clear diagnosis of iliolumbar ligament strain can account for the continuous discomfort and somatic dysfunction.

The trend in figure 6 follows the same trend as figure 5. This increasing trend in daily pain scores over the six-week study period was expected to follow the same trend as daily NSAID use. This increase can be rationalized the same way. Once again this trend confirms the null hypothesis, that there will be no difference in daily pain scores.

Despite the unfavorable findings, it would be a leap to state that OMT, when complemented with standard low back pain therapy, does not benefit in decreasing low back pain or daily NSAID use. The data represented in figures 5 and 6 came from one patient and had no control to compare to. Additionally, the data is so limited due to the small sample size that a percent reduction from many patients would be needed to make an assumption about the OMT. Finally, since the patient presented with an inflamed
iliolumbar ligament that requires other OMT and possibly steroids, this patient’s data would not be accurate to use to assess daily NSAID reduction.

Previous studies have confirmed the benefit of pain reduction and consequently analgesic reduction when complementing standard low back pain therapy with OMT. Licciardone et al (2013) osteopathic trial investigated pain score reductions and other outcome differences between CNSLBP patients who received OMT versus a sham OMT. This study had a sample size of 455 and proved statistical significance in decreased pain scores over time and overall improvement with OMT compared to the sham OMT. This study clearly exhibits OMT benefiting patients with CNSLBP and pain reduction over time. Thus, our study would need a larger sample size and a better design in order to refute the benefits OMT has on CNSLBP patients.

4.3 Limitations

There were several limitations and factors that attenuated the potential benefit of OMT in this study. First, the small sample size did not allow for sufficient amount of data to be gathered to confirm or refute the null hypothesis. The patient recruitment was originally planned to be from the OMM secretarial staff, but immediately after the study was approved the staff refused to recruit their new CNSLBP patients. Also, the study was not approved by the IRB until January 2014, which left only 4 months to recruit patients.

Second, before the study commenced, there was difficulty homogenizing for type of NSAID to be used. It was difficult to decide on limiting the study to one NSAID or leave the door open to any NSAID. Accepting any NSAID into the study would have
created statistical entropy, so the decision was to select one. The drug selected was ibuprofen due to dosing purposes. Eliminating some of the most popular NSAIDs, such as naproxen had to occur because their dosing is once every 12-24 hours leaving only a few doses per day to analyze for a percent reduction. Another difficulty was if new patients were already taking naproxen because switching them to ibuprofen would increase the amount of pills per day compared to naproxen. This would be bad science and most likely contributed to the small sample size.

Third, it was difficult to standardize OMT for CNSLBP patients. It was hypothesized that a muscle energy and soft tissue technique would be appropriate for patients suffering from CNSLBP. OMT for low back pain has a “treat what you find” method due to the vast amount of structures and dysfunctions in the lumbosacral region and one of the potential benefits would be to standardize a therapy specifically for LBP patients. Heymann et al (2013), found a significant pain decrease when applying high-velocity low amplitude OMT technique compared to the NSAID diclofenac. Future research can be geared towards this technique rather than muscle energy and soft tissue techniques. Additionally, there was no OMT training for hand placement or time for the specific techniques the physicians used. The physicians seemed to be troubled and resistant to having a standard therapy for treating CNSLBP once the study began due to the vast heterogeneity in dysfunctions.

Fourth, the control consisted of a sham OMT therapy. This is one of the many difficulties with OMM clinical research. Patients suffering from low back pain are randomized into a sham therapy, which is not a satisfactory control. Sham therapies are unsatisfactory because the patient will be touched in some form. Although the physician
will only apply pressure in the amount of their hands, pressure is still being applied potentially changing myofascial structures.

4.4 Difficulties with Clinical Research

Clinical research presents many difficulties and one of the major issues that attenuated our study was patient recruitment. A systematic review done by McDonald et al (2006) concluded that most clinical trials experience recruitment difficulties. This review showed that 41% of trials that begin to recruit are delayed and 63% exhibited early recruitment problems. Additionally, only 31% of trials reach their recruitment goal while 34% of trials have to revise recruitment targets mostly leading to worse outcomes. These issues with recruiting can be caused by researchers and clinicians tending to overestimate patient availability, indifferent project managers, and screening negligence. A factor that is associated with successful recruitment is having a dedicated principal investigator.

Tramm et al (2013), found a majority of recruitment issues stemming from design flaws. Overestimation of available participants is one of the most common issues and is known as ‘Lasagna’s Law’. Specific recruitment strategies must be selected appropriately. At the top of the list for recruitment strategy is a flyer for clinical staff and patients (Tramm et al, 2013). Flyers are a great way of letting people know a study is actively taking place. Another strategy is employing extra staff (Tramm et al, 2013). Hiring a research coordinator can alleviate much stress from the secretarial staff and research team. A single person who is organized and dedicated to patient recruitment
would be much more professional. Finally, having a weekly investigator/recruitment meeting is a great strategy for improving patient recruitment (Tramm et al, 2013). Weekly meetings create more homogeneity for all the investigators and promote more initiative for obtaining patients.

Another strategy for increasing patient recruitment is incentives (Tramm et al, 2013). Rewarding the recruiting staff and patients is a great way for increasing sample size. It can promote better work ethic from the recruiting staff and also make them feel appreciated. Incenting the patients to be a part of a study will show they have value and meaning in the research.

**4.5 Difficulties with OMM Clinical Research**

In the recent past, research has not been a traditional component to the osteopathic profession but it is currently trying to change this (Earley, 2010). Although improvements in the amount and quality of osteopathic research have been achieved, there are still limitations dealing with blinding and sham manipulation. OMM clinical research follows the pharmacological research design of placebo and the double-blinded methodology. It is impossible to follow this double-blinded approach in OMM due to the physician employing a real OMT to some patients versus a sham OMT to others. Also, the placebo being a sham manipulation is hotly contested compared to a pharmacological placebo, since the physician will apply pressure to the underlying myofascial tissue potentially increasing the placebo affects.
4.6 Future Research

Future research assessing the benefits of OMT on reducing daily NSAID use in CNSLBP patients requires a better design. Patient recruitment remains the priority since the study obtained only one patient. Although patient recruitment may seem simple, it has presented as a much more complex issue. It requires a group effort and an excellent strategy for obtaining and maintaining patients.

The research team can benefit from weekly meetings discussing the current status and future directions of the project. Informing all parties will create a more professional and structured environment that future patients will notice. If a patient senses any lack of communication between the physicians and the research team they will be more likely to opt out of the study. Creating an environment that appears thorough and well organized will only enhance the amount of future patients for the study.

One of the reasons why this study failed was due to other physicians not joining into this project. A collaborative effort with equal distribution is necessary. This study could have benefited from a research coordinator. Hiring a work-study student as a research coordinator would help immensely when it comes to recruiting patients. Frequent phone calls to patient referral sites and a direct line for patients to call about the study would create better logistics for obtaining patients. Also, including several post-doctoral fellow students to perform the OMT would allow for a greater sample size.

Once a team is formed, a collective effort into organizing an excellent logistical protocol for patient recruitment is required. In this study, logistical preparation for patient recruitment failed. Only new patients from one site were recruited. Multiple PCOM sites
would need to be informed personally and distribution of flyers to all these sites a priority. Including students at PCOM to be eligible for the study would also increase the sample size. A flyer could include the current study taking place and a number to call with designated hours to enroll or request information.

Once patients are enrolled in the study, protected time for the post-doctorial fellow students and physicians would be needed. Setting time aside for certain days and hours to see patients will create a structured environment for the research team and patients. Again, a research coordinator would be valuable here for scheduling patients.

Besides patient recruitment, the limiting exclusion criteria may have contributed to the small sample size. Patients were to be naïve to OMT, which limited us to only new patients. Not eliminating previous or current OMM patients from the study would most likely increase the sample size. Controlling the distribution of naïve to non-naïve patients would eliminate any significant difference between groups. Stratifying the groups if needed would reduce the randomization, but would be necessary to have a sufficient sample size.

Finally, the post-doctorial fellows and physicians need to be trained on proper hand placement and timing for a standard OMT and sham OMT deployment. This training will assure each patient is receiving the same treatment between the treatment and control groups. Additionally, deciding whether the muscle energy and soft tissue techniques or the high-velocity low amplitude technique has better efficacy for LBP patients is required.
4.7 Conclusion

In conclusion, with the limited amount of data we obtained from this study, there can be no assessment made about the benefits OMT have on reducing daily NSAID use and pain in patients suffering from CNSLBP. However, with a better recruitment strategy, logistics, and a less limiting exclusion criteria this study has great potential for benefiting those suffering from CNSLBP.
References


Prinsen, K. J., Hensel, L. K., & Snow, J. R. (2014). OMT associated with reduced analgesic prescribing and fewer missed work days in patients with low back pain:

INFORMED CONSENT FORM

TITLE OF STUDY
Osteopathic Manipulative Medicine (OMM) and Reduction of NSAID Use in Low Back Pain: A Pilot Study

TITLE OF STUDY IN LAY TERMS
Does Osteopathic Manipulative Treatment (OMT) lower the amount of non-steroidal anti-inflammatory drugs (NSAIDS) taken by patients having low back pain for 3 or more months?

PURPOSE
The purpose of this research is to find out if NSAID (pain reliever) use and pain can be reduced by using specific OMT techniques to treat chronic lower back pain. Also, we are trying to obtain a standard OMT therapy for low back pain patients.

You are being asked to be in this research study because you presently have consistent lower back pain greater or equal to 3 months, you are currently taking an NSAID, such as ibuprofen, to relieve pain and OMT is an appropriate therapy for you. For you to be in this study, you must be 18 years of age or older, able to self-report pain levels, able to request medications, have never had OMT as a treatment modality, and be willing to try osteopathic manipulative treatment as a modality to reduce pain and NSAID usage. If at any time you are unable to keep a pain diary or show up for scheduled appointments, or have unreliable transportation you cannot be in this study. Similarly, if you are currently taking medicine for depression or narcotics, or receiving another type of manipulation (e.g. physical therapy, chiropractor, rolling, acupuncture, acupressure, or massage therapy) you cannot be in this study. Finally, if you had low-back surgery, have spinal stenosis, have had cancer in the lower back, have been diagnosed with complex regional pain syndrome (CRPS), are pregnant, or involved in any medical malpractice lawsuit, you cannot be in this study.

INVESTIGATOR(S)
Principal Investigator: Dr. Donald Allison, DO
Co-Investigator: Frederick Goldstein, PhD, FCP

01/10/14
The treatment you are being asked to volunteer for is part of a research project.

If you have questions about this research, you can call Dr. Allison at (215) 871-6425.

If you have any questions or problems during the study, you can ask Dr. Allison, who will be available during the entire study. If you want to know more about Dr. Allison’s background, or the rights of research subjects, you can call the PCOM Research Compliance Specialist at (215) 871-6782.

**DESCRIPTION OF THE PROCEDURES**

If you decide to be in this study, you will be asked to keep a daily pain and medicine diary, come to two appointments in the first two weeks to give information on pain and medicine use, and come to eight OMT appointments. The eight OMT appointments will be twice a week for the following four weeks. Please bring your pain/medicine diary to each of these visits. You should take pain medicine during the study as needed and record it in the pain/medicine diary.

In this study, you will be asked to lie down on a treatment table where the physicians will perform massaging techniques as well as exercises where you will be asked to push against the physician's hands.

If you meet the requirements to be in this study, you will be randomly assigned to either the treatment group or the sham group.

The study will take about 30 minutes for each session. There will be 11 session(s) over the course of 7 weeks, for a total of 6.5 hours (Including the time to fill out daily pain/medication diary) of your time.
POTENTIAL BENEFITS

You may be able to take less pain medication, which would also mean fewer possible side effects. You may have less pain. You may not benefit from being in this study. Other people in the future may benefit from what the researchers learn from the study.

RISKS AND DISCOMFORTS

You may have a minor ache in the area being touched by the doctors. The osteopathic manipulative treatment being used usually produces no side effects.

ALTERNATIVES

The other choice is to not be in this study. You can continue taking your daily NSAID to reduce pain, as needed. You can have OMT without being in the study.

PAYMENT

You will not be paid for being in this study. You will be given 8 free osteopathic manipulative treatments over a span of 4 weeks.

CONFIDENTIALITY

All information and records relating to your participation will be kept in a locked file. Only the researchers, members of the Institutional Review Board, and the U.S. Food and Drug Administration will be able to look at these records. If the results of this study are published, no names or other identifying information will be used.

REASONS YOU MAY BE TAKEN OUT OF THE STUDY WITHOUT YOUR CONSENT

If health conditions occur that would make staying in the study possibly dangerous to you, or if other conditions occur that would damage you or your health, the researchers may take you out of this study.

In addition, the entire study may be stopped if dangerous risks or side effects occur in other people.
NEW FINDINGS

If any new information develops that may affect your willingness to stay in this study, you will be told about it.

INJURY

If you are injured as a result of this research study, you will be provided with immediate necessary care.

However, you will not be reimbursed for care or receive other payment. PCOM will not be responsible for any of your bills, including any routine care under this program or reimbursement for any side effects that may occur as a result of this program.

If you believe that you have suffered injury or illness in the course of this research, you should notify the PCOM Research Compliance Specialist at (215) 871-6782. A review by a committee will be arranged to determine if the injury or illness is a result of your being in this research. You should also contact the PCOM Research Compliance Specialist if you believe that you have not been told enough about the risks, benefits, or other options, or that you are being pressured to stay in this study against your wishes.

VOLUNTARY PARTICIPATION

You may refuse to be in this study. You voluntarily consent to be in this study with the understanding of the known possible effects or hazards that might occur during this study. Not all the possible effects of the study are known.

You may leave this study at any time.

If you drop out of this study, there will be no penalty or loss of benefits to which you are entitled.
I have had adequate time to read this form and I understand its contents. I have been given a copy for my personal records.

I agree to be in this research study.

Signature of Subject: __________________________

Date: ___/___/_____ Time: __________ AM/PM

Signature of Investigator or Designee __________________________
(circle one)

Date: ___/___/______ Time: __________ AM/PM
Appendix B

A RESEARCH STUDY TO REDUCE NSAID USE IN PATIENTS HAVING CONSISTENT LOW BACK PAIN

PAIN AND MEDICATION DIARY - WEEK ONE

YOU WILL GET A SEPARATE DIARY FOR EVERY WEEK

If you have any questions or concerns about this research, please call the Principal Investigator for this study, Dr. Donald Allison, Assistant Professor, PCOM Department of Osteopathic Manipulative Medicine 4170 City Ave, Suite 320 at 215-871-6425

Before you turn to the next page, please answer these questions:

DID ANYTHING HAPPEN TO YOU THIS WEEK THAT GAVE YOU MORE PAIN? FOR EXAMPLE, DID YOU FALL DOWN?

PLEASE CHECK ONE: __ NO __ YES

IF YOU CHECKED 'YES', PLEASE WRITE DOWN WHAT HAPPENED.
Please complete the following information.

Patient Name: __________________________

Telephone Number(s): Home: __________ Work: __________

Date you started to write your information on this form: ______________________

<table>
<thead>
<tr>
<th>WEEK</th>
<th>ONE</th>
<th>How many NSAID tablets did you use today?</th>
<th>How would you score your pain this morning?</th>
<th>How would you score your pain this afternoon?</th>
<th>How would you score your pain tonight?</th>
<th>Use any other methods of pain relief (e.g. ice pack or heat) today?</th>
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Pain Scale

0 1 2 3 4 5 6 7 8 9 10

I have no pain

I have the worst pain I ever had

Date Completed: ______________________

After you complete this page, please bring it with you – in the envelope we gave you – to each of your visits at PCOM Rowland Hall, Suite 320.

Thank you for choosing to be in our study.

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