SOUTH BAYLO UNIVERSITY

Effects of Acupuncture with Shao Yao Gan Cao Tang on Quadratus Lumborum

Pain: A Randomized Controlled Clinical Trial

by

JUNG IN CHOI

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South Baylo University at Anaheim, 2022

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ABSTRACT

The purpose of this study is to investigate the effects of traditional herbal medicine, *Shao Yao Gan Cao Tang* combined with Acupuncture in treating patients with low back pain due to Quadratus Lumborum Muscle disorders. The study consisted of 16 participants who are between the ages of 18 and 55, are not currently taking any pain medications or diuretics, do not have any underlying disease such as hypertension, heart disease, kidney disease, hypokalemia, or diabetes, without severe cognitive or mental disorders. These participants were randomly allocated into two groups at a 1:1 ratio: experimental and control group. The experimental group (*n*=8) was treated with Acupuncture with intervention of herbal medicine, *Shao Yao Gan Cao Tang*, while the control group (*n*=8) was treated with Acupuncture without herbal medicine intervention. The effects of treatments were evaluated with Visual Analogue Scale (VAS) before and after each treatment, Oswestry Disability Index (ODI) before 1st treatment and after the 4th treatment, and Range of Motion (ROM) on flexion, extension, left lateral flexion, and right lateral flexion of the lumbosacral using goniometer before and after treatment of 1st and 4th treatments. Treatments were conducted twice a week for two weeks total for each group, with each treatment duration of

20 minutes for each participant. ROM of extension and ROM of left lateral flexion have been excluded from the statistical analysis of the result because they already had significant differences before treatment. The experimental group showed a higher cumulative VAS difference, with the experimental group 2.6 ± 1.41 and the control group 2.0 ± 1.31 ($p=0.373$). The ODI difference of the experimental group was 7.1 ± 3.87 and 6.0 ± 4.69 for the control group ($p=0.609$). The ROM of lumbar flexion difference of the experimental group was -4.38 ± 10.84 and 3.13 ± 14.62 for the control group ($p=0.263$). The ROM of right lateral flexion difference of the experimental group was 2.50 ± 9.26 and 0.63 ± 7.29 for the control group ($p=0.659$).

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I. INTRODUCTION

Low back pain is described as the most common musculoskeletal disorder that affects the majority of adults in the population. According to studies between 1966 and 1998, adults from developed countries have reported that the prevalence of bothersome low back pain has been estimated at 25%, acute low back pain developing into chronic low back pain that persists for one year has been estimated at 50%, and lifetime prevalence has been estimated up to about 85%.[1,55]

Low back pain can be categorized as acute, subacute, or chronic. Chronic low back pain is a pain that continues for at least 12 weeks or longer.[1] Low back pain is defined as a disorder of the lumbosacral spine which includes the lumbar region and the sacrum, which supports most of the upper body weight. It has been the second most common symptom-related reason that patients seek their primary care physician for.[56] Low back pain represents a major social and economic problem because low back pain is still common in adults between the ages of 30 and 50 during their most economically productive years. The best example would be absenteeism at work, in which an injured worker is unable to perform his or her job due to low back pain.[1,43]

Conventional treatment for chronic low back pain includes both pharmacologic and non-pharmacologic options. Regardless of etiology or the duration of low back pain, first-line pharmacologic treatment involves the use of acetaminophen and NSAIDs. Skeletal muscle relaxants, benzodiazepines, tricyclic antidepressants (TCAs), or opioids may be an option for those who suffer from low back pain.[23,43] As for non-pharmacologic treatment, Acupuncture can be a first-line therapeutic intervention for patients who's experiencing low back pain.[2,57]

The lower back supports the spine with a large and complex group of muscles.[31]

1

Iliopsoas, Multifidus, Gluteals, and Quadratus Lumborum (QL) muscles are the four most common muscles that are responsible for lower back.[58] Among them, the quadratus lumborum muscles reside in the deep and posterior, lateral, and inferior areas of the spine, attached to the inferior margin of the 12th rib, upper four lumbar transverse processes, iliac crest and iliolumbar ligament.[25] This thick, square-shaped muscle contributes to the movement and stabilization of the spine and the pelvis. This muscle is very susceptible to pain formation since it easily contracts while sitting, standing, and walking. Pain usually occurs due to overuse, weakness or tension of this muscle. Standing in the same position for over time will not only reduce the blood flow in this muscle but also cause the pain. Also, if other back extensor muscles such as Erector Spinae become weaker, it will put a load of pressure on the Quadratus Lumborum muscle and be the initiator of pain.[19.25.27,28.53.54]

Traditional Oriental Medicine sees pain as the result of internal disharmony which causes blockage of the body's vital energy, known as Qi. Qi, in Traditional Oriental Medicine, is the vital energy that flows in the body through the 12 primary and 8 secondary meridians. The insertion of fine sterilized Acupuncture needles at specific points on the skin called acupoints restores the proper flow of *Qi*.[59] In *Huang Di Nei Jing* (黃帝內經 *"The Yellow Emperor's Classic of Medicine"*) Chapter 41, this whole chapter talks about the Acupuncture treatment of back pain which relates low back pain to foot taiyang bladder channel, foot shaoyang gallbladder channel, foot yangming stomach channel, foot shaoyin kidney channel, foot jueyin liver channel, yangwei channel, dai channel, and ren channel.[37] Also, according to *Donguibogam* (東醫寶鑑) which is known as an encyclopedic source of Oriental medical knowledge and techniques, categorize low back pain into 10 different type: due to Kidney Deficiency, due to phlegm-fluid retention, due to food accumulation, due to damp-heat, due to cold-dampness, due to wind, due

to dampness, due to sprain, due to blood stasis, and due to Qi.[31,32]

Regardless of the Eastern Medicine differential diagnosis, the most common symptoms of the low back pain is correlated with Quadratus Lumborum Muscle disorder. According to the various studies, Shao Yao Gan Cao Tang (芍藥甘草湯) has been used to treat muscular tension, spasm, and pain.[18,39,40,43,44,52,60] Therefore, this study investigates whether utilization of Shao Yao Gan Cao Tang (芍藥甘草湯) in conjunction with Acupuncture treatment enhances the effectiveness compare to Acupuncture alone in Quadratus Lumborum muscle disorder treatment. Through this verification, it is intended to be useful for future clinical use and related research.

OBJECTIVES

The objective of this study is to investigate the comparison effectiveness of Acupuncture treatment on Quadratus Lumborum pain with and without Shao Yao Gan Cao Tang.

1. To analyze the effects of Acupuncture and intervention of *Shao Yao Gan Cao Tang* with Acupuncture on Lower back pain by comparing Visual Analog Scale (VAS) before and after the treatments;

2. To analyze the effects of Acupuncture and intervention of *Shao Yao Gan Cao Tang* with Acupuncture on Lower back pain by comparing Range of Motion (ROM) before and after the treatments;

3. To analyze the effects of Acupuncture and intervention of *Shao Yao Gan Cao Tang* with Acupuncture on Lower back pain by comparing Oswestry Lower Back Pain Disability Questionnaire (ODI) before and after the treatments;

LITERATURE REVIEW

Low back pain, also called lumbago, is defined as a musculoskeletal symptom which may be either acute or chronic. Human's spine consists of 7 cervical vertebrae in the neck region, 12 thoracic vertebrae in the middle back, 5 lumbar vertebrae in lower back, and one sacrum with a coccyx. Among these vertebrae, the lumbar vertebrae carry the greatest amount of body weight. Therefore muscles and other connective tissues surrounding lumbar vertebrae are more easily susceptible to injury once they become weak. The lumbar region of the spine, mostly known as lower back, consists of five vertebrae referred to as L1~L5. They naturally have a slight inward curve known as lordosis. Besides these five vertebrae, the lower back is also composed of the spine, muscle (including ligaments-to hold the vertebrae in place, and tendons-to attach and situate muscles to the spinal column), intervertebral discs which look like rubbery pads to maintain the spaces between each vertebrae that act like shock absorbers throughout the spinal column, cushioning the bones as the body moves, and nerves that's rooted to the spinal cord controlling body movements and sending signals from body to the brain. They are mechanical in nature to fit together and move the body.[1,26]

1. Low Back Pain in Western Medicine

1.1. Etiology of Low Back Pain

There are several mechanical causes that produce the low back pain. The main causes are due to congenital issues, injuries, degenerative problems, nerve and spinal cord issues, and non-spine sources. Congenital issues can be irregularity in skeletal disorders such as Scoliosis (side-way curvature of the spine), Kyphosis (excessive outward curve of the spine), Lordosis (excessive inward curvature of the lower back), or other congenital abnormalities of the

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spine.[1,3,61] The low back pain due to injuries can be from ligaments sprain (ligaments are overstretched or torn), tendons or muscle strain (tears in tendons or muscle), sudden contraction of a muscle also known as muscle spasms, and traumatic injury such as Motor Vehicle Accidents (MVAs), sports injury, falling from height that can also injure ligaments, tendons, muscle, or even spine which cause discs to herniate or rupture. Degenerative problems that cause low back pain can be subdivided into a few conditions: intervertebral disc degeneration, spondylosis, arthritis or other inflammatory disease. Intervertebral disc degeneration is a common condition characterized by wear down of one or more of the discs that separate the bones of the spine as a normal process of aging and losing their cushioning function. Spondylosis is the general degeneration of any region of the spine most common in the neck and lower back. It is associated with natural effects of aging in the joints, discs, and bones of the spine as people get older. Arthritis or other inflammatory conditions in the spine including osteoarthritis, rheumatoid arthritis, and spondylitis is a type of inflammation of the vertebrae. Nerve and spinal cord problems cause low back pain in various conditions such as spinal nerve compression, inflammation or injury, sciatica which in medical terminology defines as radiculopathy where the sciatic nerve that travels through the buttocks and extends down the back of the leg is pressed, spinal stenosis which is the narrowing of the spaces within spine that can put pressure on the spinal cord and nerves, spondylolisthesis which happens when one of the vertebrae slips out of place and pinches the nerves exiting the spinal column, herniated or ruptured discs which occur when the rubbery discs are compressed and bulge outward causing a portion of the nucleus pushes through a crack in the annulus of the disc. There are other nerve and spinal cord related disorders that cause low back pain such as disorders due to infections. The infections can be osteomyelitis which is an infection in a bone, discitis which is an infection in the intervertebral

discs, or sacroiliitis which is an infection in the sacroiliac joints connecting the lower spine to the pelvis. Other nerve and spinal cord related disorders are cauda equina syndrome and osteoporosis. Cauda equina syndrome is a condition in which a ruptured disc pushes into the spinal canal and presses on the bundle of nerve roots in the lumbar and sacral spine. Osteoporosis occurs when the body loses too much bone density and strength to the point where it can lead to painful fractures of the vertebrae. Last but not least, lower back pain should be distinguished from non-spine causes such as kidney stones, endometriosis, fibromyalgia, tumors, or pregnancy.[3,61]

1.2. Symptoms of Low Back Pain

The symptoms of the low back pain depend on the underlying causes of the pain and its range can go from minor aches to severe, debilitating and even frightening.[1] The characteristics of lower back pain may be dull, achy, stinging or burning pain that radiates down to the side or back of the legs or sometimes down to feet, which may include numbness or tingling sensations. Also, the symptoms may include muscle spasms, tightness, pain that gets worse after sitting or standing for long periods of time, or sometimes people with low back pain may have difficulty standing up straight, walking, bending forward, backward, changing position from standing to sitting or vice versa. Depending on onset and duration of the low back pain, it can be described as acute or chronic. Acute low back pain is defined as pain that lasts less than 12 weeks. Chronic low back pain is defined as pain occurring for more than 3 months or 12 weeks, which may persist after the underlying cause of acute low back pain has been treated.[1,2,3,4,7,26,59]

1.3. Diagnosis of Low Back Pain

Diagnosis of low back pain is based on a complete past medical history and physical examination to narrow down possible causes of pain. During the patient's medical history intake, the patient will be asked to provide information about their current symptoms, activities of daily living (ADL), their sleeping posture or any injury history. The physical examination for low back pain may include palpation, neurologic exam, range of motion test (ROM), reflex test, or leg raise test. Diagnostic imaging tests are not mandatory but may be necessary to be ordered in some cases to find any tissue pathology and rule out specific causes of pain. Common imaging tests include: X-rays, Computerized Tomography (CT), myelograms, and Magnetic Resonance Imaging (MRI). X-rays are used to look at the bones of the spine that show bone abnormalities such as arthritis, bone spurs, fractures, or even tumors. A computerized tomography, or CT, provides a cross-sectioned view of the spine. This diagnostic imaging test is able to show soft tissue structures that are hard to be seen on standard X-rays. A Magnetic Resonance Imaging scan, or MRI, provides a detailed spinal structures image without using radiation unlike X-rays. With MRI scan, any abnormalities with bony structures and soft tissues such as muscles, ligaments, tendons, and intervertebral discs may be detected. Sometimes myelograms are performed with X-ray or CT scans. In this procedure, a dye is injected into the spinal canal around nerve roots and highlights spinal structures which help give the image to be seen more clearly. When signs of inflammation, infection, cancer, or arthritis is suspected, a blood test may be ordered as well.[3,4,6,24,57]

1.4. Lower Back Pain Treatment in Western Medicine

In Western Medicine, there are several treatment options available for low back pain both surgical and non-surgical depending on the conditions of the patients.[3] In treating low back pain

non-surgically, over-the-counter pain medications are most commonly and easily considered. The most common medications that low back pain patients seek or are prescribed are acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, opioids, and topical pain relief such as pain relieving cream, ointment, gel, patches, or sprays which may provide feelings of warmth or cold in order to numb the sensation of pain temporarily. Acetaminophen's mechanism is to interfere with pain signals that are being sent to the brain. NSAIDs such as aspirin, ibuprofen, and naproxen alleviate low back pain from swollen muscles or nerves. These over-the-counter pain medications are often effective immediately. However, they all have side effects such as high risk of gastrointestinal or liver problems, if taken long-term or taken with underlying disease.[35,36] Heat or ice therapy is also often used as early treatments for low back pain. Usually ice therapy is used up to 72 hours from the beginning of injury because that is when the inflammation or swelling is at the worst for acute low back pain. Heat therapy relaxes tense muscles and helps increase blood flow. At times, alternating heat and ice therapy may be helpful when returning to activity.[3,7] During an acute stage of low back pain, exercising, bed rest, or surgery are not recommended. Additional supportive therapy could be wearing back braces, epidural steroid injections, or some alternative treatments such as acupuncture, manual manipulation, transcutaneous electrical nerve stimulation (TENS), physical therapy, massage, and exercise treatment. The epidural steroid injections are injected directly into the outer part of the dural sac that surrounds the spinal cord. An injection or series of injections can temporarily lessen pain by reducing inflammation. Many people still seek physical therapy even after receiving the injection. TENS is a non-pharmacological intervention that generates electrical impulses to reduce pain. Exercise is one of the therapies because chronic low back pain is closely related with weakness in back and abdominal muscles. It is reported that the strength and

endurance of the lumbar muscles do affect the stability of the lumbar spine. McKenzie exercise, or strengthening core or abdominal muscles may alleviate the low back pain. Surgery may become necessary if the pain is not resolved after about 6 to 12 week course of non-surgical treatments or therapies. Physicians should not force patients to get surgery. Instead, it is always the patient's decision to have low back surgery only under the recommendation of the physicians.[3]

2. Low Back Pain in Eastern Medicine

2.1. Diagnosis of Low Back Pain

In Eastern Medicine, there are many etiology associated with low back pain such as excessive physical work, excessive sexual activity, pregnancy and childbirth, invasion of external cold and dampness, or inadequate exercise.[15] According to *Chinese Acupuncture and Moxibustion*, the most common etiological factors of low back pain are invasion of exogenous pathogenic cold and damp, deficiency of Kidney Qi, and sprain or contusion.[16] According to *The Practice of Chinese Medicine*, the four most common pathological conditions of low back pain are described as invasion of cold dampness, Qi and Blood stagnation, Kidney deficiency, and Liver-Qi stagnation.[15] In *Huang Di Nei Jing* 黃帝內經 "*The Yellow Emperor's Classic of Medicine*" Chapter 41, this whole chapter talks about the acupuncture treatment of back pain which relates low back pain to foot taiyang bladder channel, foot shaoyang gallbladder channel, foot yangming stomach channel, foot shaoyin kidney channel, foot jueyin liver channel, yangwei channel, dai channel, and ren channel.[37] Also, according to *Donguibogam* (東醫寶鑑) which is known as an encyclopedic source of Oriental medical knowledge and techniques, categorize low back pain into 10 different type: due to Kidney Deficiency, due to phlegm-fluid retention, due to

food accumulation, due to damp-heat, due to cold-dampness, due to wind, due to dampness, due to sprain, due to blood stasis, and due to Qi.[31,32]

Cold-dampness can cause both acute and chronic backache. The pain is usually worse in the morning and gets better with light exercise movement. The pain is also relieved by application of heat and is worse when the weather is cold and damp. In cold-dampness retention, there may be a prevalence of either cold or dampness. When cold predominates over dampness, the characteristic of pain would be stiffness and contraction of the back muscles and the pain is more severe, and is aggravated by rest and improved by movement. It also responds to application of heat, such as a hot bath or hot pack. When dampness predominates over cold, there may be swelling, numbness and a feeling of heaviness. Patients with this pattern may have a Tight-Full pulse especially on the left rear position.[15,31,32]

Stagnation of Qi and Blood is characterized by a severe, stabbing pain which becomes worse with resting and better with light exercise, however condition would become worse with overexertion. It is tender to touch, and unlike the retention of cold-dampness, pain does not respond to changes in weather or application of heat. Low back pain due to Qi and Blood stagnation gets worse with standing or sitting. There is also marked rigidity and stiffness of the back muscles and inability to flex, extend or turn the waist. Usually Qi and Blood stagnation in low back pain is from acute cases due to sprain and strain. In chronic cases, repeated strain may cause recurrent attacks of backache, especially when there is underlying disease of Kidney deficiency. Patients with this pattern may have Wiry pulse especially on the left rear position.[15,31,32]

The most common cause of chronic low back pain out of these pathological conditions is closely associated with Kidney deficiency for the lumbus is the seat of the kidney. The

characteristic of pain is dull and comes in bouts. This pain definitely gets better with resting and worse when the person overworks because over strain and stress consume essence and Qi. It is also aggravated by frequent sexual activity due to depletion of Kidney Qi and it will fail to nourish and strengthen the back muscles. There may be a cold sensation in the back if the pain is due to Kidney-Yang deficiency. A slight but not a significant improvement may show with the application of heat. A Kidney deficiency can also form the background that facilitates invasions of cold-dampness and repeated strains. Obviously a low back pain from Kidney deficiency is more common in middle-aged or elderly people. However, young people can still suffer low back pain due to Kidney deficiency if they have hereditary or congenital deficiency of Kidney. Also, if a child grew up doing a lot of physical work or exercise around the time of puberty, this may seriously weaken the Kidney Qi.[15,31,32]

Liver Qi stagnation can cause acute or chronic backache. Since the Liver controls sinews, the pathology of Liver-Qi stagnation may affect the sinews of the spine, causing contraction, spasm and stiffness. Also, since the Liver's main direction of action may be placed both in the middle and the lower burner, it may affect the intestines and genital system in both men and women. When Liver-Qi stagnates in the lower burner, it can affect the lower back, causing contraction of the sinews, spasm and stiffness. Patients with this pattern may have Wiry pulse. However in practice, these patterns are frequently combined with underlying pattern of Kidney deficiency. When Kidney is deficient, the tongue may be Pale. It may be without tongue coating in case of Kidney-Yin deficiency. The pulse of Kidney deficiency would be deep and weak.[15,31,32]

2.2. Treatment of Low Back Pain in Eastern Medicine

In Eastern Medicine, Acupuncture has been known as a non-surgical conservative treatment for low back pain. The treatment methods include Acupuncture therapy, herbal medicine, Moxa, Tuina, Cupping, Electro-Acupuncture, Guasha, exercise, and more. When compared to Western medicine, Acupuncture treatment has relatively fewer side effects and sequelae.[38,59] There are different Acupuncture techniques where the Acupuncture points can be used on local painful area called 'Ashi points', which means muscle problems can be treated by kneeling the local points or some Acupuncture points can be used to treat disorders of the areas far away from where they are located. These are known as the distal points.[16]

When giving herbal medicine, it is important to differentiate which pattern the backache is coming from.[15] According to *Dongui Bogam* (東醫寶鑑), in case of lower back pain due to Kidney Deficiency, the herbal prescription Qing E Wan, Jia Wei Qing E Wan, Zhuang Ben Dan, Jiu Wei An Shen Wan, Bai Bei Wan, Du Chong Wan, Bu Shen Tang, or Bu Sui Dan may be used. The herbal prescriptions for lower back pain due to phlegm-fluid retention are Er Chen Tang, Gung Ha Tang, or Kong Xian Dan. For lower back pain due to food accumulation, herbal prescription Su Xiao San can be used. For lower back pain due to damp-heat, Er Chao Cang Bai San, Qi Wei Cang Bai San, Dang Gui Nian Tong Tang, San Hua Shen You Wan, or Wei Shen San may be used. For lower back pain due to cold-dampness, Jia Wei Long Hu San may be used. For lower back pain due to wind, Jia Wei Long Hu San may be used. For lower back pain due to dampness, Zhu Fu Tang, Tong Jing San, or Chuan Xiong Rou Gui Tang may be used. For lower back pain due to sprain, Du Huo Ji Sheng Tang, Ru Xiang Chen Tong San, Ru Shen Tang, Shu Jin San, Li An San, or Shen Qu Jiu may be used. For lower back pain due to blood stasis, Po Xue San Teng Tang, Chuan Xiong Rou Gui Tang, or Di Long San may be used. For lower back pain due to Qi, Tiao Qi Tang may be used.[31]

2.3. Shao Yao Gan Cao Tang

Shao Yao Gan Cao Tang is composed of only two herbs, Shao Yao *(Paeoniae radix)* and Zhi Gan Cao (*Glycyrrhizae Uralensis radix; also known as licorice)*, 2:1 ratio respectively. This herbal prescription helps to relieve pain by regulating nutrients Qi.[31,39] This herbal prescription is widely prescribed to treat various types of muscle pain and cramps, gynecological disease, and even arthritic disease.[40,41,42,46,52] Shao Yao's main action is to nourish the Blood, preserve Yin, soften the Liver and alleviates pain. It also regulates the Liver and Spleen therefore nourishes the sinews. The main action of Zhi Gan Cao is to tonify and augment the Qi of the Middle Jiao, especially of the Spleen. Together the herbal formula Shao Yao Gan Cao Tang's main action is to soften the Liver, nourish the Blood and Yin, moderate painful spasms, relieve pain, harmonize the Middle Jiao, and replenish Body Fluids. [44] Paeoniflorin is the major bioactive component in Shao Yao (*Paeoniae radix*) which works as anticoagulant, neuromuscular blocking, immunoregulatory, and has anti-hyperglycaemic effects. In Zhi Gan Cao (*Glycyrrhizae Uralensis radix*), Glycyrrhizic acid plays as the major bioactive component which works as anti-inflammatory, has hepatoprotective activity, forms peptic ulcers, and inhibits blood coagulation. [45,46,47,48,49,50] However, this glycyrrhizic acid can increase blood pressure, reduce potassium level, and increase sodium which can cause edema. Therefore, patients with low potassium, high sodium levels, high blood pressure, angina, or renal failure should be extra cautious when intaking this herb and long term intake is inhibited. Since it has the action of possible increasing blood pressure, it should not be taken with medication for hypertension or arrhythmia. Also, it should not be taken with Digoxin, Digitalis, laxatives, or diuretics because it will reduce potassium levels even more. There is a study that shows that when licorice was taken

together with a contraceptive pill, it caused edema and increased blood pressure. There is similar action of antidepressant in the licorice so it should not be taken with monoamine oxidase inhibitors (MAOI).[51]

Quadratus Lumborum muscle

As shown in Figure 1, Quadratus Lumborum muscle is the deepest muscle of the posterior abdominal wall, lying deep inside the abdomen and dorsal to the iliopsoas muscle. The shape of this muscle is irregularly quadrilateral and broader below than above. It extends from the iliac crest and iliolumbar ligament to the inferior border of the 12th rib for about half its length and the transverse processes of L1~L4. Subcostal nerve from T12 and anterior rami of spinal nerves from L1~L4 innervates this muscle. This muscle's main action has bilateral contraction and unilateral contraction. It fixes the 12th rib during inspiration, acts as a major stabilizer of the lumbar spine, it helps with trunk extension. It also unilaterally raises pelvis, helps with lumbar spine lateral flexion. Blood supply to this muscle comes from the subcostal artery, lumbar arteries, median sacral, and iliolumbar artery.[53]
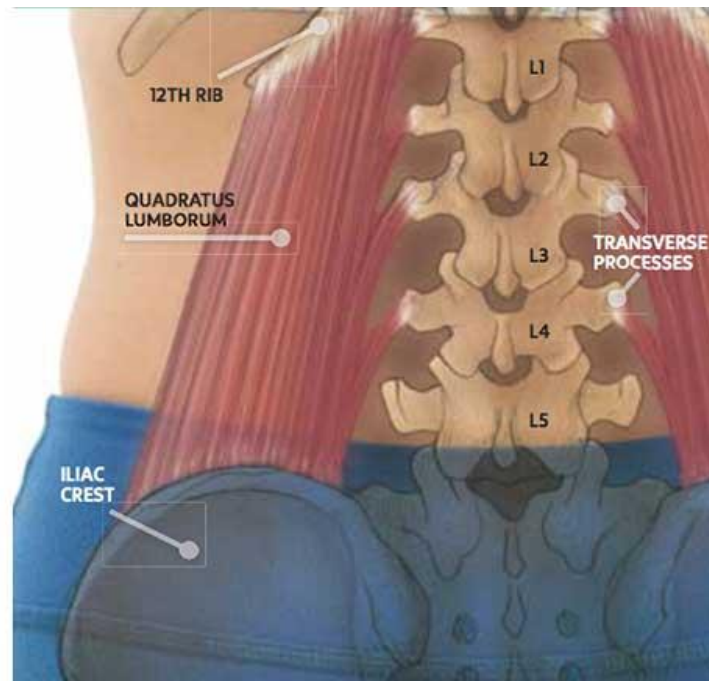
Figure 1. Quadratus Lumborum

Overuse, stress, and strain can cause pain in the Quadratus Lumborum muscle. Sometimes this muscle becomes too weak and also causes pain and stiffness. Staying in one position such as sitting down for long periods of time can reduce blood flow in the Quadratus Lumborum or lumbar region. Any repetitive motions or activities, and weaken muscles in the lower lead into poor posture. Improper moving motion in twisting, bending, or lifting creates more tension and can make the Quadratus Lumborum too tight and overcompensate stabilizing the spine and pelvis. Often patients with scoliosis, unequal leg length, or injury due to accidents also have pain in this muscle.[54]

As shown in Figure 2, stressed or injured Quadratus Lumborum muscle induce trigger points which may produce pain when it's stimulated. The quality of these trigger points may be deep aches in the lumbar region, or stabbing pain in the hip or pelvis area.[27] Once the Quadratus Lumborum remains untreated, it can cause stress to not only low back but also to the other areas

of the body such as hip joint, buttocks, thighs, sacroiliac joint, and abdominal.[54]
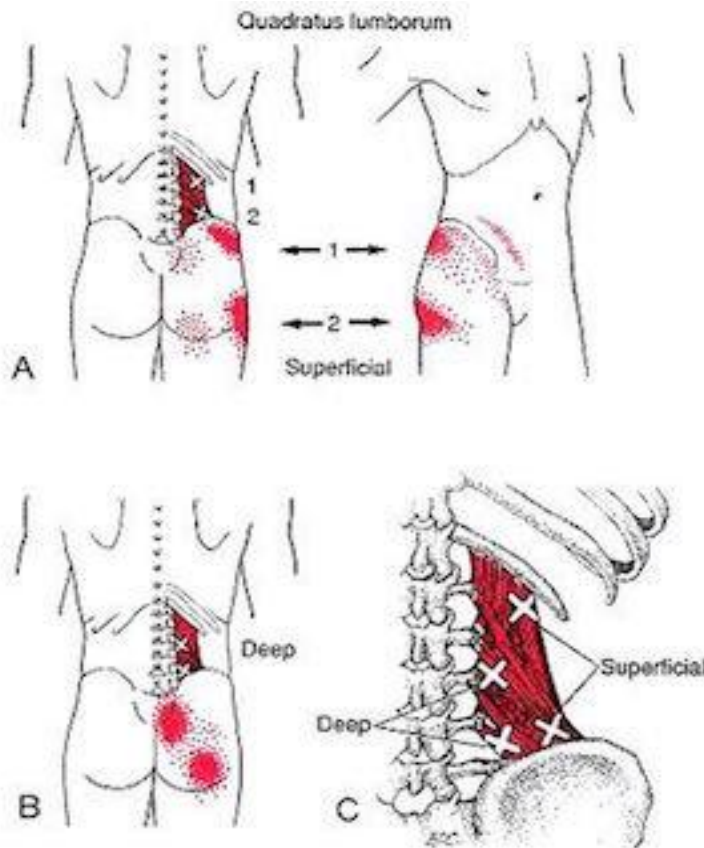
Figure 2. Quadratus Lumborum Trigger Points

For example, low back pain occurs from not only bending or twisting, but also when coughing or

sneezing, the Quadratus Lumborum muscle is one of the muscles that needs to be examined.

Therefore it is important to look for any tender points by palpating the patients since Quadratus

Lumborum pain can cause complications once the body becomes misaligned and imbalanced.[54]

II. MATERIALS AND METHODS

Materials

Shao Yao Gan Cao Tang

In this study, HanZung granules of Shao Yao Gan Cao Tang were distributed. Each participant in the experimental group was administered 3g three times a day for 2 weeks.

Acupuncture Needle

The needle used in this study was the needle that's manufactured by DBC. All needles were sterilized disposable stainless steel. 0.25x30mm, 0.25x40mm, or 0.25x50mm gauge needles were used depending on the patient's physical features. Needles that are used in this study were discarded in a biohazard sharp container immediately after each treatment. Every needle was handled as recommended and regulated by CCAOM's CNT 7th Manual.

Figure 3. DBC Needle.

1. **Study Design**

   As shown in Figure 4, this study is designed as a randomized controlled trial with 16 participants randomly allocated into two groups, the Control Group (n=8) and Experimental Group (n=8). The main comparisons were the mean difference between groups to explore the significant effect of Acupuncture on chronic low back pain throughout the treatment. The Control Group was treated with traditional acupuncture whereas the Experimental Group was treated with a combination of traditional acupuncture with intervention of Shao Yao Gan Cao Tang. Each group was treated for twice a week for 2 weeks total. The retention of Acupuncture needles was 20 minutes for each session. The evaluations were done two times, pre-treatment and post-treatment. All evaluations were done using Visual Analogue Scale (VAS), Range of Motion (ROM), Oswestry Disability Index (ODI). These evaluating forms are attached in Appendices-3,4,5,6,7.

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┌─────────────────────────────┐
│   Patients with low back pain │
│   due to Quadratus Lumborum   │
└─────────────────────────────┘
              │
              ▼
     ┌──────────────────┐
     │  Randomization    │
     │    (n=16)         │
     └──────────────────┘
        │            │
        ▼            ▼
┌──────────────┐  ┌──────────────────┐
│ Control Group │  │ Experimental Group │
│    (n=8)      │  │      (n=8)         │
└──────────────┘  └──────────────────┘
      │                   │
      ▼                   ▼
┌──────────────┐  ┌──────────────────┐
│ VAS & ROM & ODI│ │ VAS & ROM & ODI   │
│   Pre-Test    │  │    Pre-Test       │
└──────────────┘  └──────────────────┘
      │                   │
      ▼                   ▼
┌──────────────┐  ┌──────────────────────┐
│ Intervention of│ │ Intervention of Acupuncture│
│  Acupuncture   │ │     (x2 / 2weeks)         │
│ (x2 / 2 weeks) │ │          +                │
│               │ │  Shao Yao Gan Cao Tang    │
│               │ │  (3times a day / 2weeks)  │
└──────────────┘  └──────────────────────┘
      │                   │
      ▼                   ▼
┌──────────────┐  ┌──────────────────┐
│ VAS & ROM & ODI│ │ VAS & ROM & ODI   │
│   Post-Test   │  │    Post-Test      │
└──────────────┘  └──────────────────┘
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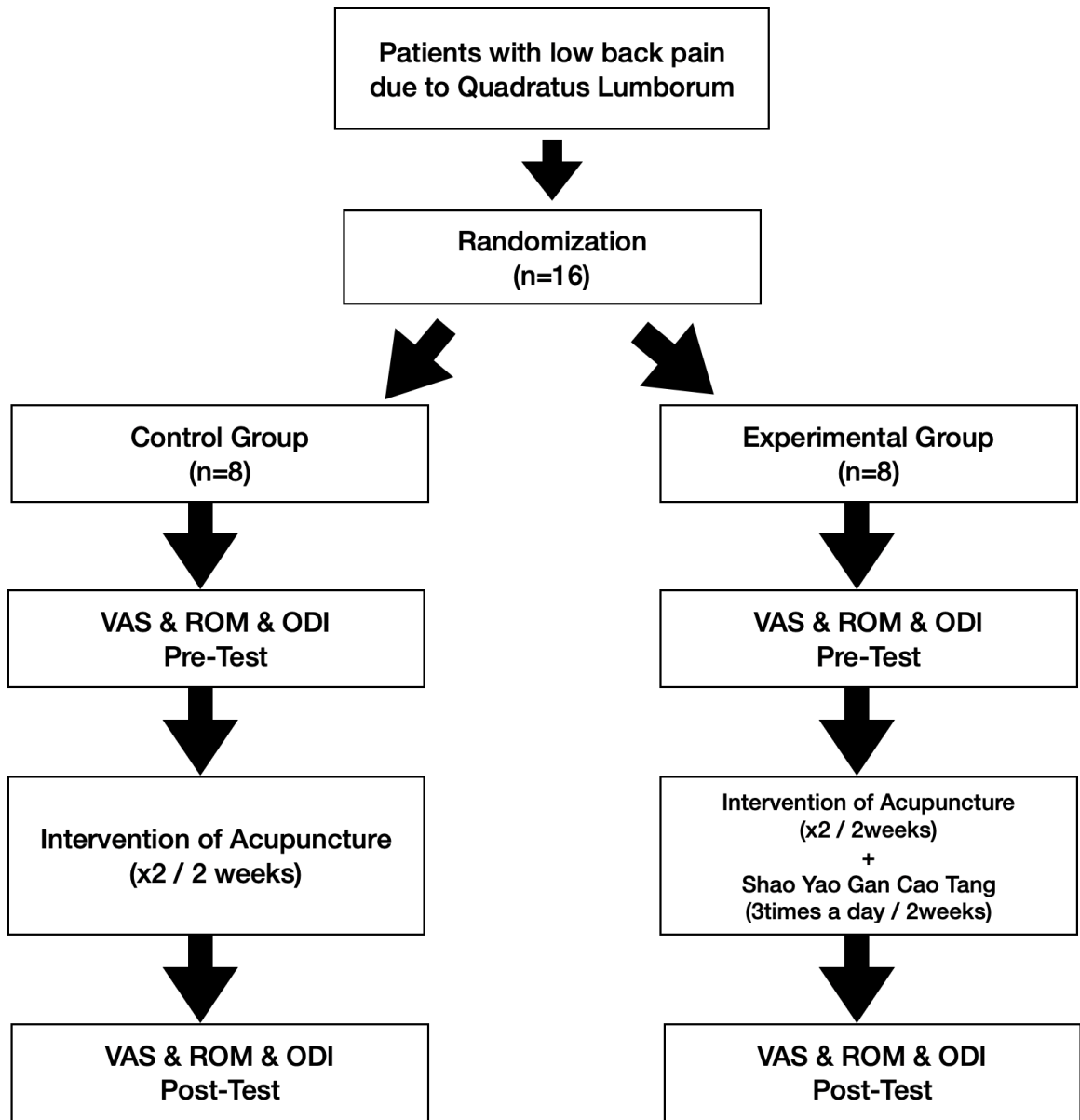
Figure 4. Schematic Diagram of Study Process

2. Staging Criteria

The severity criteria of pain in VAS scores are distributed as none, tolerable, mild, moderate, or severe. Here are the following cut points on the 10-cm line VAS scale (Appendix-3): no pain (0cm), tolerable pain (1-3cm), mild pain (3-5cm), moderate pain (5-8cm), and severe pain (8-10cm) as shown in Table 1. The scale must be shown to each patient.

Table 1. Staging Criteria for Chronic Low Back Pain

Stage	Pain Level
Normal	0 - 3
Mild	3-5
Moderate	5-8
Severe	8-10

3. Patient Eligibility and Exclusion Criteria

1) Inclusion criteria

Patients who participated were those who have been experiencing low back pain in Quadratus Lumborum muscle region upon palpation with VAS (Visual Analogue Scale) score of 3 or above, and between the ages of 18 and 55. All participants were assigned into two groups: control group and experimental group, regardless of their gender, ethnicity, or occupation. The purpose and procedure of this study were explained to all the participants and they were asked to sign the Informed Consent Form (Appendix-1) voluntarily.

2) Exclusion criteria

The excluded patients from this study were patients who are in the criteria having low back pain associated with ankylosing spondylitis, cancer or tumor, have skin disorder, currently taking any pain medications or diuretics, any underlying diseases such as hypertension, heart disease, kidney disease, hypokalemia, diabetes, severe cognitive or mental disorders, had been undergone surgery on the spine or treated with steroid injection to reduce low back pain symptom within 6 months prior to the participation, in pregnancy, or who refuses to sign the Informed Consent Form voluntarily.

4. Location of Procedure

Treatment for this study was conducted at Joseph Kim Chiropractic & Acupuncture Clinic in Fullerton, California.

5. Randomization Procedure and Stratification

1) Randomization

Randomization of participants is divided by entering numbers, odd numbers fall into the experimental group whereas even numbers fall into the control group.

2) Blinding

Because of the unique characteristics of the Acupuncture and herbal medicine prescription used in this trial, it is difficult to blind the researcher administering the Acupuncture treatments or the participants.

6. Treatment Program

1) Acupuncture Intervention

All participants received Acupuncture treatments two times a week. As shown in Table 2, the acupoint selection for Acupuncture for the control group and experimental group was as follows: the principal acupoints include: Shenshu (BL23), Dachangshu (BL25), Guanyuanshu (BL26), Weizhong (BL40), Zhishi (BL52), Kunlun (BL60), Mingmen (DU4), Yaoyan (M-BW-24), Taixi (KD3), Houxi (SI3), Shenmai (BL62), and Yanglingquan (GB34). The Urinary Bladder Meridian points on the back are located right on the Quadratus Lumborum muscle and regardless of differentiation, general point prescription was suggested in Chinese Acupuncture and Moxibustion (CAM) which is the textbook in Eastern Medicine education in the U.S..[16] Retention of the needles was for 20 minutes with even method.

The Acupuncture intervention was twice a week for a total of 2 weeks, during which each participant received 4 treatment sessions.

Table 2. Acupuncture Points: Location and Indication.

Points	Location	Indication
TCM Acupoints		
Shenshu (BL23)	1.5 cun lateral to *Mingmen (DU4)*, at the level of the lower border of the spinous process of L2 vertebra.	Nocturnal emission, impotence, enuresis, irregular menstruation, leukorrhea, **low back pain**, weakness of the knee, blurring of vision, dizziness, tinnitus, deafness, edema, asthma, diarrhea
Dachangshu (BL25)	1.5 cun lateral to *Yaoyangguan (Du3)*, at the level of the lower border of the spinous process of the L4 vertebra.	**Low back pain,** borborygmus, abdominal distension, diarrhea, constipation, muscular atrophy, pain, numbness and motor impairment of the lower extremities, sciatica.
Guanyuanshu (BL26)	1.5 cun lateral to the Governor Vessel, at the level of the lower border of the spinous process of the L5 vertebra.	**Low back pain**, abdominal distension, diarrhea, enuresis, sciatica, frequent urination.
Weizhong (BL40)	Midpoint of the transverse crease of the popliteal fossa, between the tendons of m. biceps femoris and m. semitendinosus.	**Low back pain**, motor impairment of the hip joint, contracture of the tendons in the popliteal fossa, muscular atrophy, pain, numbness and motor impairment of the lower extremities, hemiplegia, abdominal pain, vomiting, diarrhea, erysipelas.
Zhishi (BL52)	3 cun lateral to *Mingmen (DU4)*, at the level of the lower border of the spinous process of the L2 vertebra.	Nocturnal emission, impotence, enuresis, frequency of urination, dysuria, irregular menstruation, **pain in the back** and knee, edema.

Kunlun (BL60)	In the depression between the tip of the external malleolus and Achilles' tendon.	Headache, blurring of vision, neck rigidity, epistaxis, pain in the shoulder, **back** and arm, swelling and pain of the heel, difficult labour, epilepsy.
Mingmen (DU4)	Below the spinous process of the L2 vertebra.	**Stiffness of the back, lumbago**, impotence, nocturnal emission, irregular menstruation, diarrhea, indigestion, leukorrhea.
Yaoyan (M-BW-24)	About 3.5-4 cun lateral to the lower border of the spinous process of the L4 vertebra. The point is in the depression appearing in a prone position.	**Lumbar pain**, frequency of urine, irregular menstruation.
Taixi (KD3)	In the depression between the tip of the medial malleolus and Achilles' tendon.	Sore throat, toothache, deafness, tinnitus, dizziness, spitting of blood, asthma, thirst, irregular menstruation, insomnia, nocturnal emission, impotence, frequency of micturition, **pain in the lower back.**
Houxi (SI3)	When a loose fist is made, the point is on the ulnar end of the distal palmar crease, proximal to the fifth metacarpophalangeal joint, at the end of the transverse crease and the junction of the red and white skin.	Pain and rigidity of the neck, tinnitus, deafness, sore throat, mania, malaria, **acute lumbar sprain**, night sweating, febrile diseases, contracture and numbness of the fingers, pain in the shoulder and elbow.
Shenmai (BL62)	In the depression directly below the external malleolus.	Epilepsy, mania, headache, dizziness, insomnia, **backache**, aching of the leg.
Yanglingquan (GB34)	In the depression anterior and inferior to the head of the fibula.	Hemiplegia, weakness, numbness and pain of the lower extremities, swelling and pain of the knee, beriberi, hypochondriac pain, bitter

taste in the mouth, vomiting, jaundice, infantile convulsion. (**Influential Point of Tendon**)

7. Dosage Modification/Adverse Effects

Although Acupuncture is relatively safe and free from side-effects, according to the research, few adverse effects of about 8.6~10.7% are likely to occur. Possible adverse effects during Acupuncture treatment are fainting, stuck needle, bent needle, broken needle, hematoma such as bruising, and/or after-effect such as uncomfortable feelings such as soreness and pain after withdrawal of the needle which may persist for a long period of time.[15]

Possible adverse effects of Shao Yao Gan Cao Tang may include blood pressure increase, potassium level decrease, sodium level increase, and edema.[44,51]

8. Treatment Evaluation

1) Goal of Treatment

- The treatment is evaluated as success when Visual Analogue Scale (VAS) reaches at pain level 2 or less, VAS ≤ 2.

- ODI result is reduced 10% from the beginning.

2) Primary outcomes

- As shown in Appendix-3, Visual Analogue Scales (VAS) was used as a psychometric measuring instrument in this study to document the severity of pain in individual patients both before the Acupuncture treatment and after the

Acupuncture treatment. The pain in individual patients is completely

subjective. Zero pain level is indicated as "No Pain" on VAS scale, whereas

worst pain is indicated as "Unbearable" on VAS scale. In order to minimize

the errors from patients expressing their pain level in numbers, the ruler

calibration was omitted. Instead, the individual patient's pain level is

determined by having them mark their subjective pain level with a sticker or a

pen on the horizontal 10-cm line and measure the distance (cm) between the

"no pain" anchor and the patient's mark, providing a range of scores from

0-10. In this way, change in each individual's pain level can be explained in

detail as (mm) or in decimals in (cm) in this study. Each distance indicates no

pain at 0cm, tolerable pain at 1-3 cm, mild pain at 3-5 cm, moderate pain at

5-8 cm, and severe pain at 8-10 cm as shown in Table 1.

3) **Secondary outcomes**

- Range of Motion (ROM)

  o   As shown in Figure 5 & 6, two inclinometers were used to measure the

  range of motion in each participants' lumbar flexion, extension, left

  lateral and right lateral before and after treatment and compared with

  normal range that is shown in Table 3. Each ROM measurement is

  recorded using Appendix-4.

Image reference: Baseline® Bubble Inclinometer, 2-piece Set

Figure 5. Two Inclinometers

Figure 15-8 Two-Inclinometer Technique for Measuring Lumbar Flexion and Extension

The inclinometers are placed over T12 and the sacrum (S1), the anatomical landmarks.

a. neutral position

b. flexion

c. extension

d. straight leg raising (used for validation purposes)

a. neutral position
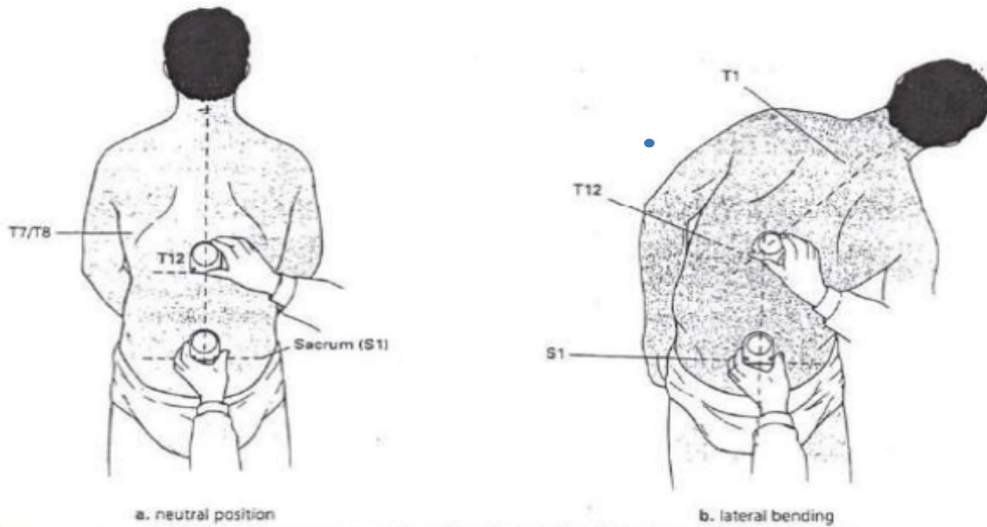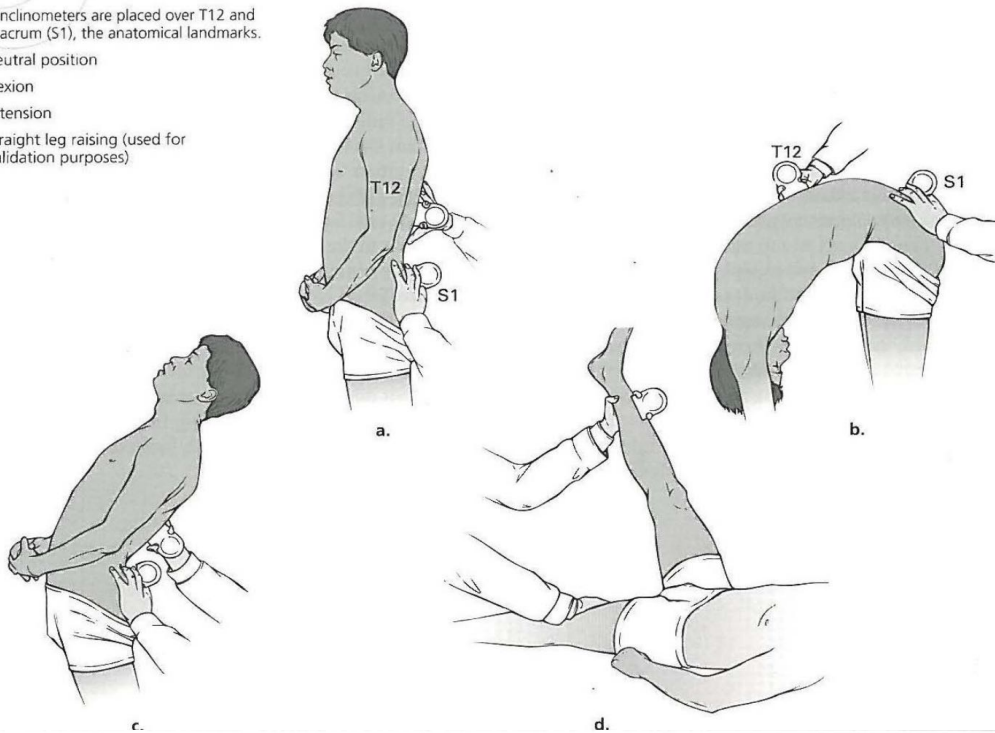
b. lateral bending

Image reference: *Guides to the impairment rating of the lumbar spine - coa.org*. (n.d.). Retrieved December 17, 2022, from

https://coa.org/docs/2010-Annual-Meeting/Thursday/Thurs5PaulWakimDO.pdf

Figure 6. Two-Inclinometer Technique for measuring Lumbar Flexion, Extension, and Lateral Bending

Table 3. Normal Range of Motion for Lumbosacral Examination

Motion	Normal ROM
Flexion	60°
Extension	25°
Left Lateral	25°
Right Lateral	25°

- Oswestry Disability Index 2.0 (ODI)

    o ODI is an evaluating tool to measure each participant's functional disability in activities of daily living. It is made with 10 sections of questionnaires, the 6 statements in each section are scored from 0 to 5 with the first statement scoring 0 and the last at 5. If the participant checked more than one box, take the highest score. This makes the maximum participant's total score as 50.

    The calculation of ODI score is if all 10 sections are completed the score is calculated as follows:

    Example: $\dfrac{(16 \text{ TOTAL SCORED}) \times 100}{50 \text{ (TOTAL POSSIBLE SCORE)}} = 32\%$

    If one section is omitted or not applicable, the score is calculated as follows:

    Example: $\dfrac{(16 \text{ TOTAL SCORED}) \times 100}{45 \text{ (TOTAL POSSIBLE SCORE)}} = 35.5\% = 36\%$

    Interpretation of scores are explained in Appendix-8.

All the primary and secondary outcomes were evaluated on the first visit of the treatment, and the last visit of the treatment (on 2nd week).

9. Serial Measurement/Study Calendar

1) Data collection points

To obtain the results from this trial, all data are collected during the pre-treatment, and post-treatment.

- Pre-treatment: First week on the intervention before treatment (Initial visit).
- Post-treatment: Week 2 (total twice a week for 2 weeks)

10. Statistical Analysis

1) Analysis parameters

The results of this experiment were statistically processed and graphed using R version 4.1.0 (2021-05-18) -- "Camp Pontanezen". All statistical analyzes were tested for significance at the $\alpha=0.05$ level.

2) Analysis of datasets and missing data

The missing data comes from the best case where early termination occurs due to early recovery, for example, a participant's pain level reduced from 8 to 2 before their 4th treatment, are analyzed by the last observation carried forward (LOCF) method, which has been widely used in clinically experimental studies. On the other hand, missing data due to reasons such as participants dropping out or rejecting were treated as the worst case.

3) Statistical analysis method

In order to compare the continuous, ordinal outcomes before and after treatment between groups, paired *t*-test is used. The independent *t*-test was used to compare the primary and secondary outcomes between groups. The chi-square test was used to compare binary results (when VAS score reaches 2 or less).

4) Effect Size

The effect size of acupuncture treatment depends on the type of variable. Relative Risk Ratio (RR), Odds Ratio (OR), and Relative Risk Reduction (RRR) are calculated by the dichotomous variable, and Mean Difference (MD) and Standardized Mean Difference (SMD) are calculated by the continuous variable.

As shown in Table 4, the primary and secondary outcome variables were converted to dichotomous value, 'cured' or 'uncured' depending on whether the targeted goal was reached, VAS ≤ 2 respectively. Then, RR, OR, and RRR were determined according to formulas (1) and (2) in Table 5, respectively. Meanwhile, MD of primary and secondary variables between groups were calculated from each Mean Change (MC) before and after the treatment within-group as shown in formula (4).

Table 4. 2×2 Contingent Table to Analyze the Dichotomous Result of Acupuncture Treatment in Terms of VAS for Chronic Low Back Pain.

	Uncured (VAS ≥ 3)	Cured (VAS ≤ 2)	Total
Experimental Group	a	b	a+b
Control Group	c	d	c+d

Table 5. Calculation Process of Relative Risk (RR) Odds Ratio (OR) and Relative Risk Reduction (RRR) of Pain in Terms of the VAS score after Acupuncture Treatment for Chronic Low Back Pain.

Effect Size	Definition	Calculation Equation	
Relative Risk (RR) =	$\dfrac{\text{Risk from Experimental Group}}{\text{Risk from Control Group}}$	$= \dfrac{a/(a+b)}{c/(c+d)}$	(1)
Odds Ratio (OR) =	$\dfrac{\text{Odds from Experimental Group}}{\text{Odds from Control Group}}$	$= \dfrac{a/b}{c/d}$	(2)
Relative Risk Reduction (RRR) =	$\dfrac{\text{Absolute Risk Reduction}}{\text{Risk from Control Group}}$	$= \dfrac{\lvert a/(a+b)-c/(c+d)\rvert}{c/(c+d)}$	(3)
Mean Difference (MD)=	$\text{Mean Change}_{exp}\,(M_{before}-M_{after}) - \text{Mean Change}_{control}\,(M_{before}-M_{after})$		(4)
Standardized Mean Difference (SMD)=	$\dfrac{\text{Mean Difference (MD)}}{SD^{*}}$		(5)

*pooled standard deviation

11. Data recording, Management, Monitoring

A modified South Baylo University (SBU) Patient Progress Form was used as a Case Report Form (CRF) as shown in Appendix-2 to manage research data. All data consistency is maintained by double entry of data that two people enter independently. Once the data is entered into the CRF, any changes can be tracked in the CRF to ensure the accuracy of the data. All data are verified by three people: the Principal Investigator of the study, the supervisor, and the Clinic Director of SBU.

12. Ethics

With the Informed Consent Form attached in Appendix-1, this proposal paper was evaluated by the Institutional Review Board (IRB) of South Baylo University.

III. RESULTS

The study examined 16 patients with lower back pain due to Quadratus Lumborum muscle disorders. 8 of the patients were only treated by traditional Acupuncture and they are considered as a control group, and the other 8 patients were treated by traditional Acupuncture with intervention of herbal medicine, *Shao Yao Gan Cao Tang* and they are considered as an experimental group. The groups were divided randomly, and each patient does not know which group they are participating in. Both groups of participants received 2 Acupuncture treatments for 2 weeks and it started from March 2022 to June 2022. The participants were explained about the study, and filled out the consent forms. VAS, ROM, and ODI were used as statistical data, and VAS was collected before and after each treatment everytime they came in. ROM was collected before and after treatment of 1st and 4th treatments for each person. ODI was collected before the 1st treatment and after the 4th treatment.

3.1 Homogeneity Test

3.1.1 Homogeneity Test for Patient's General Properties

The gender, onset, and age of patients in the control and experimental group are outlined through a homogeneity test for general characteristics as shown in Table 6-1. The p-value for Fisher's Exact Test was greater than 0.05, confirming that the experiment was performed under the same conditions for the two variables.

Table 6-1. Homogeneity Test for Patients' General Characteristics

		EG	CG	p-value*
Gender	Male	6	2	0.132
	Female	2	6	
Onset	< 3 months	6	6	1.000
	≥ 3 months	2	2	
Age	20s	4	1	
	30s	4	3	0.113
	40s	0	1	
	65s	0	3	

* Fisher's Exact Test

3.1.2. Homogeneity Test for Variables

The VAS, ROM and ODI of each measurement variable in the control and experimental groups are outlined through a homogeneity test for measurement variables between CG and EG before the treatment, as shown in Table 6-2. The p-values for VAS, ROM of lumbar flexion, ROM of lumbar right lateral flexion, and ODI were greater than 0.05, confirming that two groups were tested under the same condition at the start of the treatment. Since the p-values of ROM of lumbar extension and ROM of lumbar left lateral flexion of Homogeneity test were not greater than 0.05, they have been excluded from the statistical analysis of the result because they already have significant differences before treatment.

Table 6-2. Homogeneity Test for Variables before Treatment

Variables	EG	CG	p-value
VAS	4.4 ± 1.41	5.0 ± 2.27	0.699**
ROM_FLX	48.8 ± 9.91	45.6 ± 12.94	0.596*
ROM_EXT	21.3 ± 7.91	11.3 ± 5.82	0.020**
ROM_RLF	31.3 ± 9.16	23.8 ± 10.61	0.152*
ROM_LLF	35.6 ± 8.21	20.6 ± 8.21	0.002*
ODI(%)	14.9 ± 8.03	23.4 ± 11.78	0.100*

* Independent Samples t-Test
** Mann–Whitney U test

3.2 VAS

3.2.1. Change of VAS Before and After Treatment

VAS Difference = VAS (before nth Tx) - VAS (after nth Tx)

Visual Analogue Scale (VAS) value was measured to assess the symptom severity in individual patients with lower back pain due to Quadratus Lumborum muscle disorders. Table 6.3 compares the results of the experimental group with those of the control group by measuring the change of VAS difference in every Acupuncture session before and after treatment. When assumption of normality was met, the VAS value before and after treatment was evaluated using the Paired Samples t-test. When assumption of normality was not met, the Wilcoxon Signed Rank Test was used. As shown in Table 6.3, the VAS value in the experimental group decreased from 4.4 ± 1.41 to 2.8 ± 1.16 after the first treatment, showing a decrease of 1.6 ± 0.52 ($p=0.012$). The value decreased from 3.8 ± 1.16 to 3.1 ± 0.99 after the second treatment, showing a decrease of 0.6 ± 0.52 ($p=0.037$). The value decreased from 3.1 ± 1.36 to 2.4 ± 0.92 after the third treatment, showing a decrease of 0.8 ± 0.71 ($p=0.020$). The value decreased from 2.9 ± 1.13 to 1.8 ± 0.89 after the fourth treatment, showing a decrease of 1.1 ± 0.35 ($p=0.008$). There was a significant difference after each treatment in the experimental group. The result of comparing VAS value of pre-treatment and after the second week of treatment decreased from 4.4 ± 1.41 to 1.8 ± 0.89. VAS value in the control group decreased from 5.0 ± 2.27 to 4.0 ± 1.60 after the first treatment, showing a decrease of 1.0 ± 0.76 ($p=0.007$). The value decreased from 4.4 ± 1.92 to 3.1 ± 1.46 after the second treatment, showing a decrease of 1.2 ± 0.71 ($p=0.002$). The value decreased from 4.5 ± 1.60 to 3.6 ± 1.19 after the third treatment, showing a decrease of $0.9 \pm$

0.64 (p=0.026). The value decreased from 3.9 ± 1.96 to 3.0 ± 1.41 after the fourth treatment,

showing a decrease of 0.9 ± 0.64 (p=0.026). The result of comparing the VAS value of

pre-treatment and post-treatment in the control group decreased from 5.0 ± 2.27 to 3.0 ± 1.41.

There was a significant difference of VAS after each treatment in the control group. Figure 7.1

displays VAS values before and after each treatment using the bar graph, and Figure 7.2 displays

a VAS before 1st and after each treatment using the line graph.

Table 6.3. VAS before and after each treatment and its difference

Group	Treatment	Before	After	Difference	p-value
EG	1st	4.4 ± 1.41	2.8 ± 1.16	1.6 ± 0.52	0.012**
	2nd	3.8 ± 1.16	3.1 ± 0.99	0.6 ± 0.52	0.037**
	3rd	3.1 ± 1.36	2.4 ± 0.92	0.8 ± 0.71	0.020*
	4th	2.9 ± 1.13	1.8 ± 0.89	1.1 ± 0.35	0.008**
CG	1st	5.0 ± 2.27	4.0 ± 1.60	1.0 ± 0.76	0.007*
	2nd	4.4 ± 1.92	3.1 ± 1.46	1.2 ± 0.71	0.002*
	3rd	4.5 ± 1.60	3.6 ± 1.19	0.9 ± 0.64	0.026**
	4th	3.9 ± 1.96	3.0 ± 1.41	0.9 ± 0.64	0.026**

* Paired Samples t-Test
**Wilcoxon signed ranks test
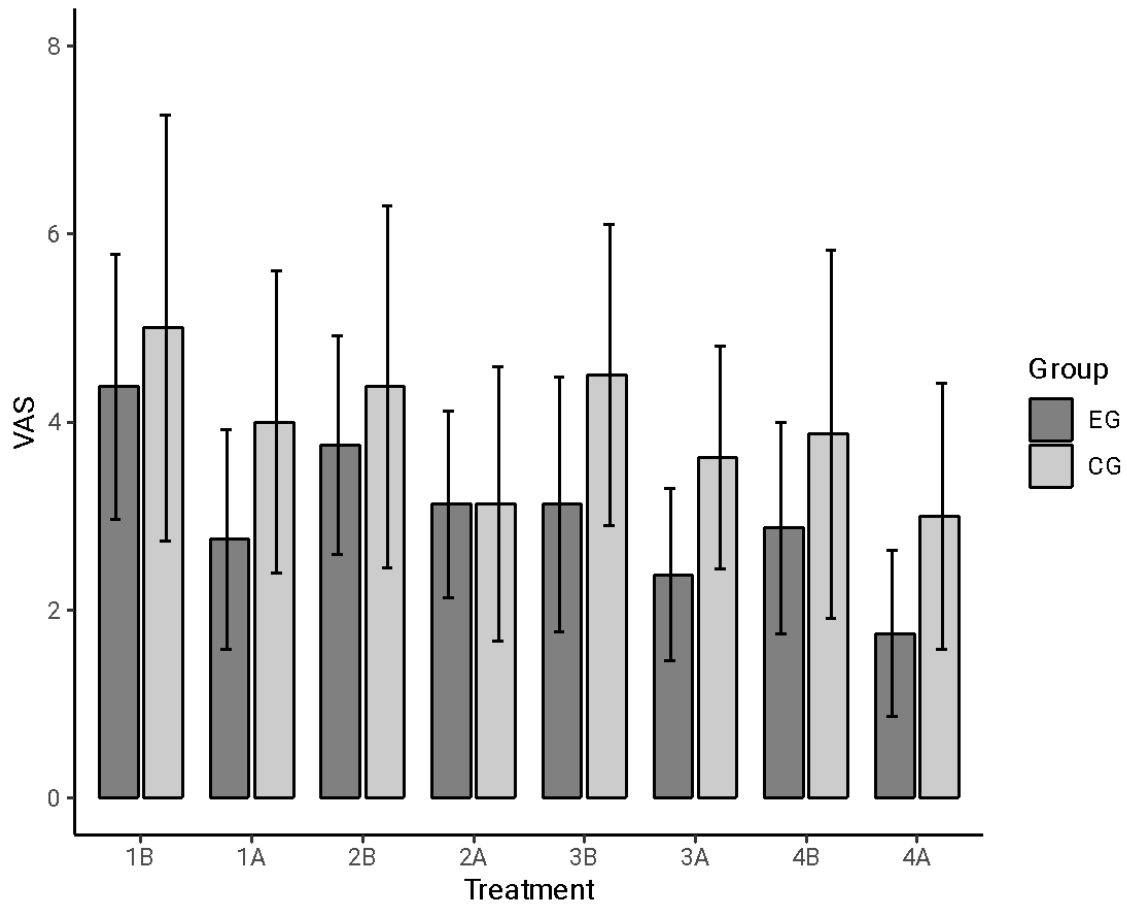
Figure 7.1 Bar graph of VAS before and after each treatment
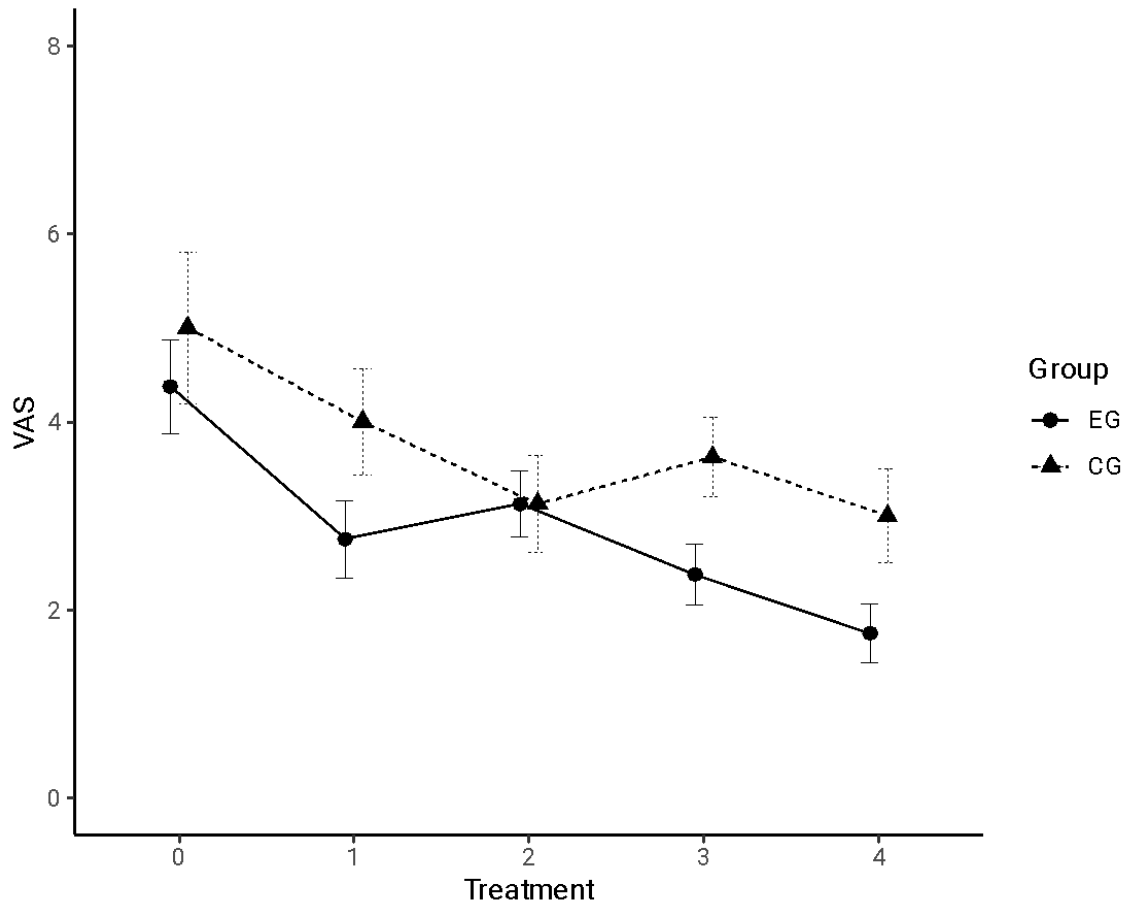
Figure 7.2 Line graph of VAS before 1st and after each treatment

3.2.2 Cumulative VAS difference

Cumulative VAS Difference = VAS before 1st Tx – VAS After nth Tx.

As shown on Table 6-4, in comparing the VAS value of the experimental and control groups, the difference after the first treatment of the experimental group was 1.6 ± 0.52 and 1.0 ± 0.76 for the control group ($p=0.074$). After the second treatment the cumulative VAS difference was 1.2 ± 1.28 for the experimental group and 1.9 ± 2.30 for the control group ($p=0.957$). After the third treatment, the cumulative VAS difference was 2.0 ± 1.31 for the experimental group and 1.4 ± 2.07 for the control group ($p=0.482$). After the fourth treatment, the cumulative VAS difference was 2.6 ± 1.41 for the experimental group and 2.0 ± 1.31 for the control group ($p=0.373$). The experimental group appeared to have a higher cumulative treatment effect than the control group in every treatment except in the second treatment. (Table 6-4). However, according to the test, there was no significant difference between the two groups ($p>0.05$). Figure 7.3 shows a bar graph of the cumulative VAS difference of experimental group and control group for the treatment.

Table 6-4. Cumulative VAS difference and comparison between groups

Treatment	EG	CG	p-value*	Cohen's d**
Before 1st - After 1st	1.6 ± 0.52	1.0 ± 0.76	0.074	0.965
Before 1st - After 2nd	1.2 ± 1.28	1.9 ± 2.30	0.957	0.336
Before 1st - After 3rd	2.0 ± 1.31	1.4 ± 2.07	0.482	0.361
Before 1st - After 4th	2.6 ± 1.41	2.0 ± 1.31	0.373	0.460

* Independent Samples t-Test
** Effect size using Cohen's d

Cumulative VAS Difference for Treatment
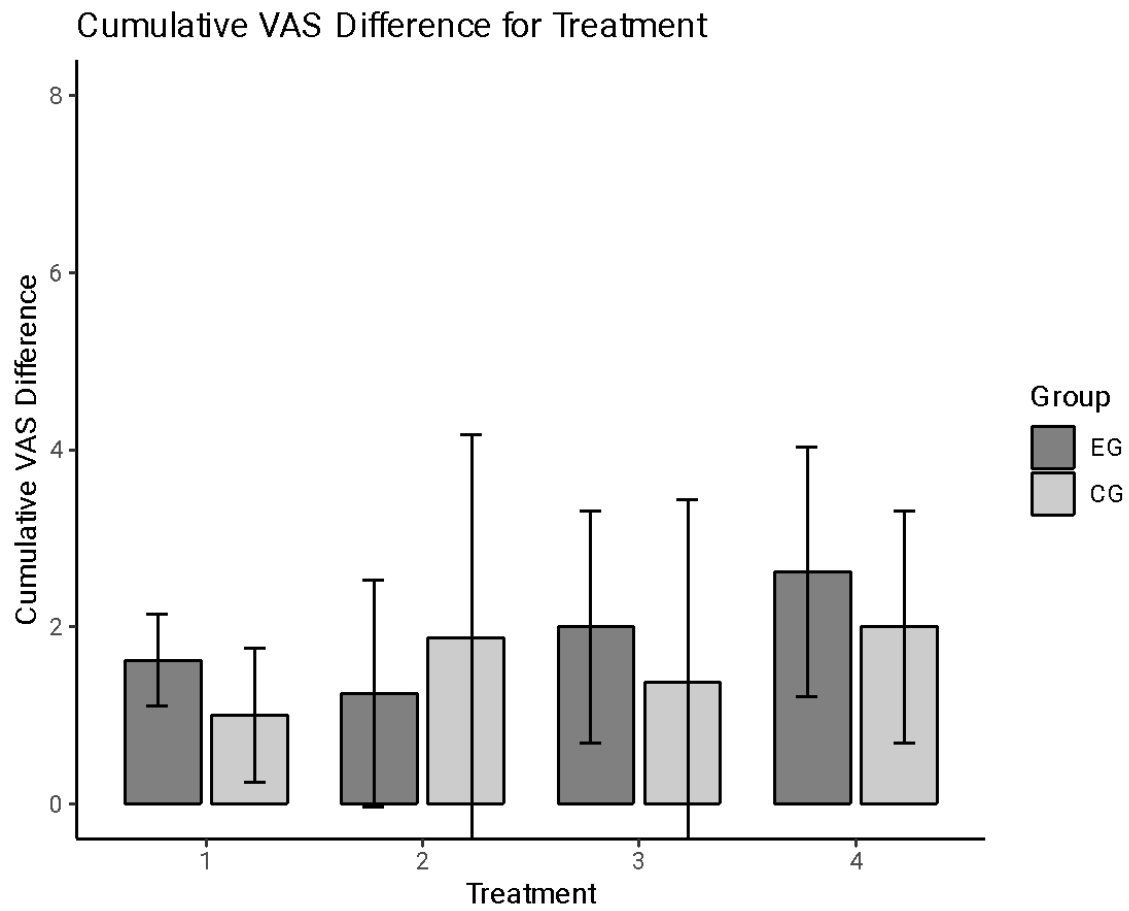
Figure 7.3. Bar graph of cumulative VAS difference for treatment.

3.2.3 Cohen's d on Cumulative Difference

$$d = \frac{M_2 - M_1}{\sqrt{\dfrac{SD_1{}^2 + SD_2{}^2}{2}}}$$

M1: Mean of EG, M2: Mean of CG

SD1: Standard deviation of EG, SD2: Standard deviation of CG

CD: Cohen's d

$CD < 0.2$ Negligible

$CD < 0.5$ Small

$CD < 0.8$ Medium

Otherwise Large

As shown on Figure 7.4, Cohen's distance was used to compare the effectiveness of the experimental group treatment to that of the control group treatment. Cohen's distance was 0.965 (Large) in the first treatment, 0.336(Small) after the second treatment, 0.361(Small) after the third treatment, 0.460(Small) after the fourth treatment, showing the effect size of cumulative VAS difference was small except the first treatment. Figure 7.4 shows the line graph of Cohen's d on Cumulative VAS Difference.
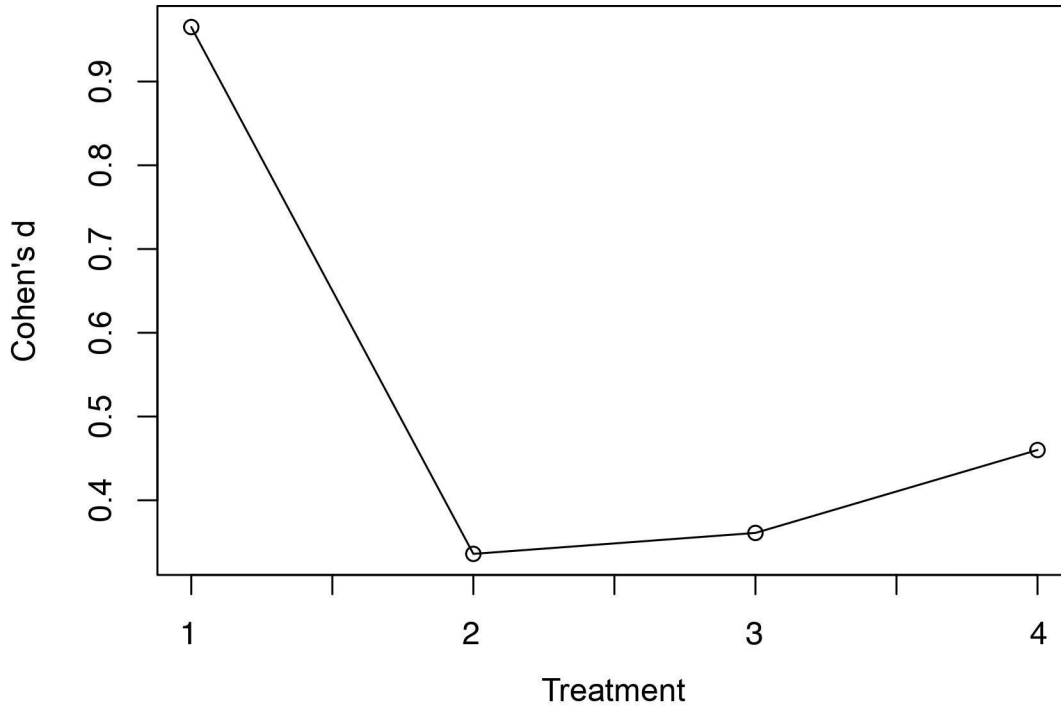
Figure 7.4. Line graph of Cohen's d for cumulative VAS difference.

3.3 ODI

3.3.1. Change of ODI Before and After Treatment within groups

ODI value (%) was measured to assess the symptomatic relief of patients with lower back pain due to Quadratus Lumborum muscle disorders. Table 6-5 compares the results of the experimental group with those of the control group measuring the change of ODI difference before the very first and fourth treatment session.

When comparing the ODI values (%) of before and after treatment between the experimental group and the control group as shown in Table 6-5, the ODI values (%) of the experimental group decreased from 14.9 ± 8.03 to 7.8 ± 5.39 ($p=0.001$) and those of the control group decreased from 23.8 ± 11.78 to 17.8 ± 9.08 ($p=0.009$) after the treatment respectively. The results of both the control group and the experimental group appeared to be statistically very significant according to the Paired Samples t-Test.

Figure 7-5 is a bar graph that indicates ODI before and after treatment between the experimental group and the control group. Figure 7-6 is a boxplot of ODI before and after treatment between the experimental group and the control group.

Table 6-5. ODI (%) Before and After Treatment and it's Difference

	EG	CG	p-value**	Cohen's d
Before Tx	14.9 ± 8.03	23.8 ± 11.78	0.100	0.883
After Tx	7.8 ± 5.39	17.8 ± 9.08	0.018	1.339
Difference	7.1 ± 3.87	6.0 ± 4.69	0.609	0.256
p-value*	0.001	0.009		

* Paired Samples t-Test
** Independent Samples t-Test
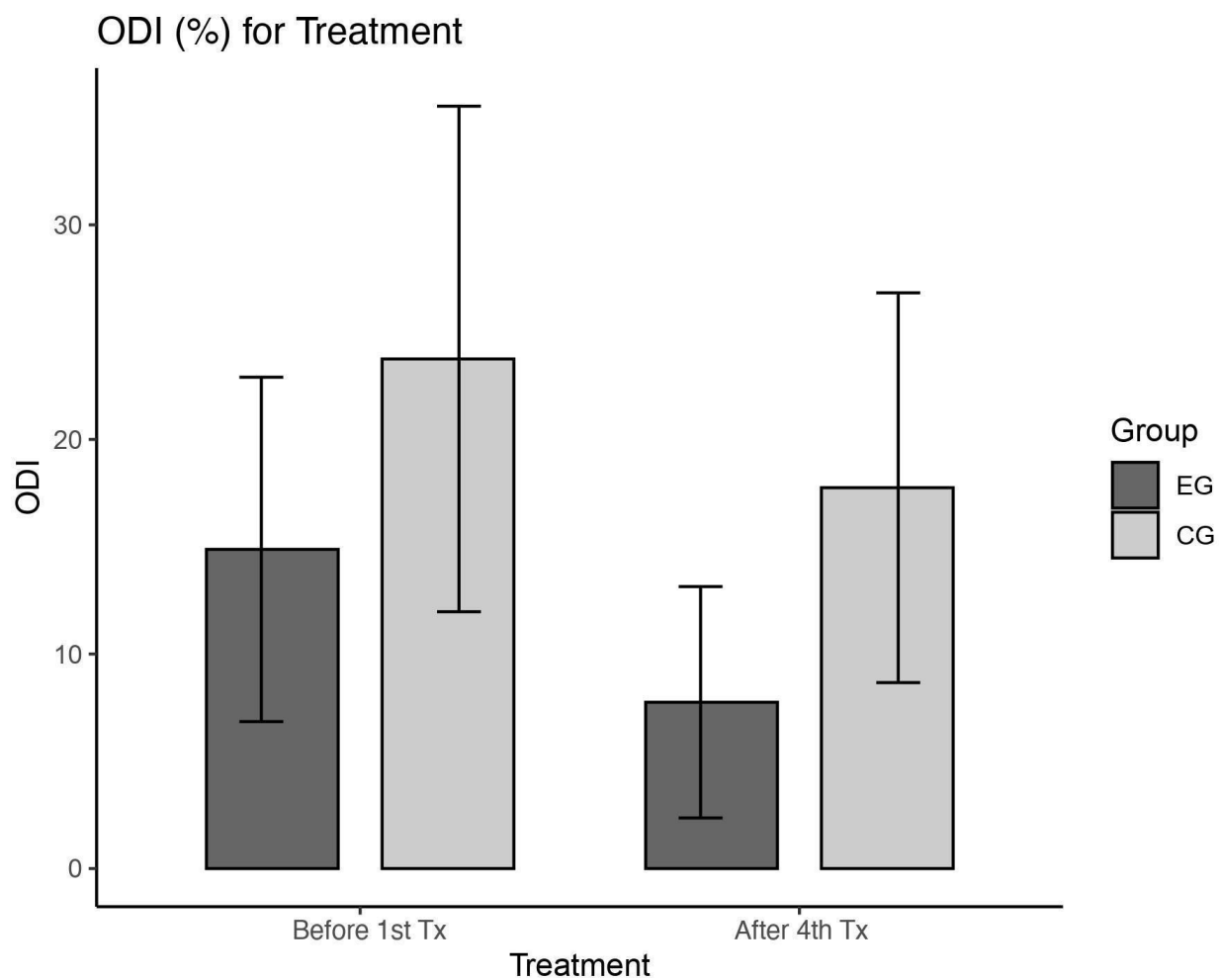
Figure 7-5. Bar graph of ODI (%) before and after treatment.
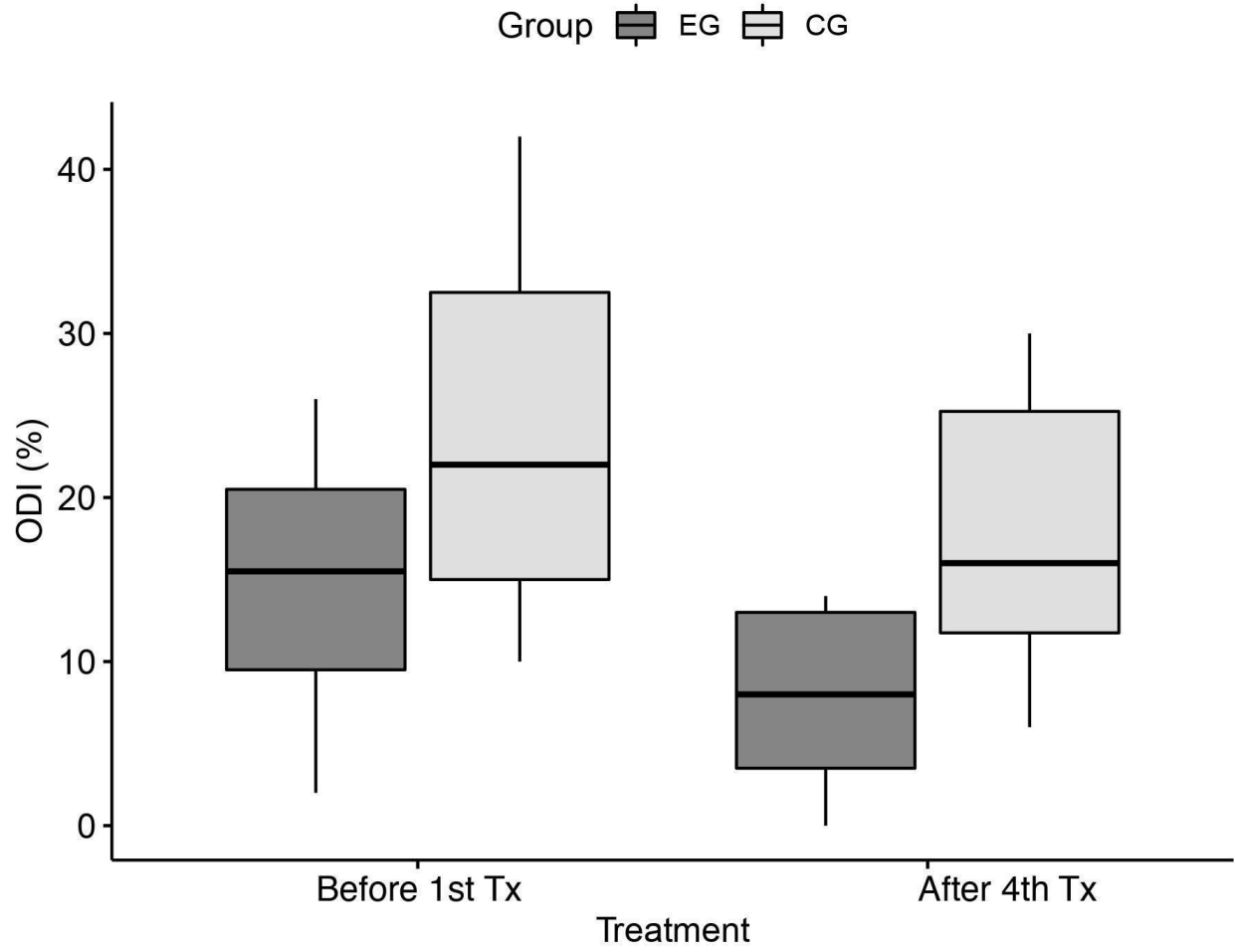
Figure 7-6. Boxplot of ODI (%) before and after treatment.

3.3.2. Comparison of ODI between groups

The Independent Samples t-Test was conducted to compare if there would be any significant difference in ODI between the two groups before treatment, after treatment, and its difference. As shown in Table 6-5, the ODI before treatment was 14.9 ± 8.03 for the experimental group and 23.8 ± 11.78 for the control group ($p=0.100$) where there was no significant difference. However, when the ODI after treatment between two groups were compared, the result for the experimental group was 7.8 ± 5.39 and 17.8 ± 9.08 for the control group ($p=0.018$) which appeared to be statistically significant according to the Independent Samples t-Test. When the ODI's difference was compared, the result was 7.1 ± 3.87 for the experimental group and 6.0 ± 4.69 for the control group ($p=0.609$). There was no significant difference.

As shown in Table 6-5, Cohen's distance was used to test effect size of the experimental group treatment to that of the control group treatment. Cohen's distance before the treatment was 0.883(Large), 1.339(Very Large) after the treatment, and 0.256(Small) for the difference.

Figure 7-7 shows a bar graph of ODI difference between the experimental group and the control group before and after treatment. Figure 7-8 shows a boxplot of ODI difference between the experimental group and the control group before and after treatment.
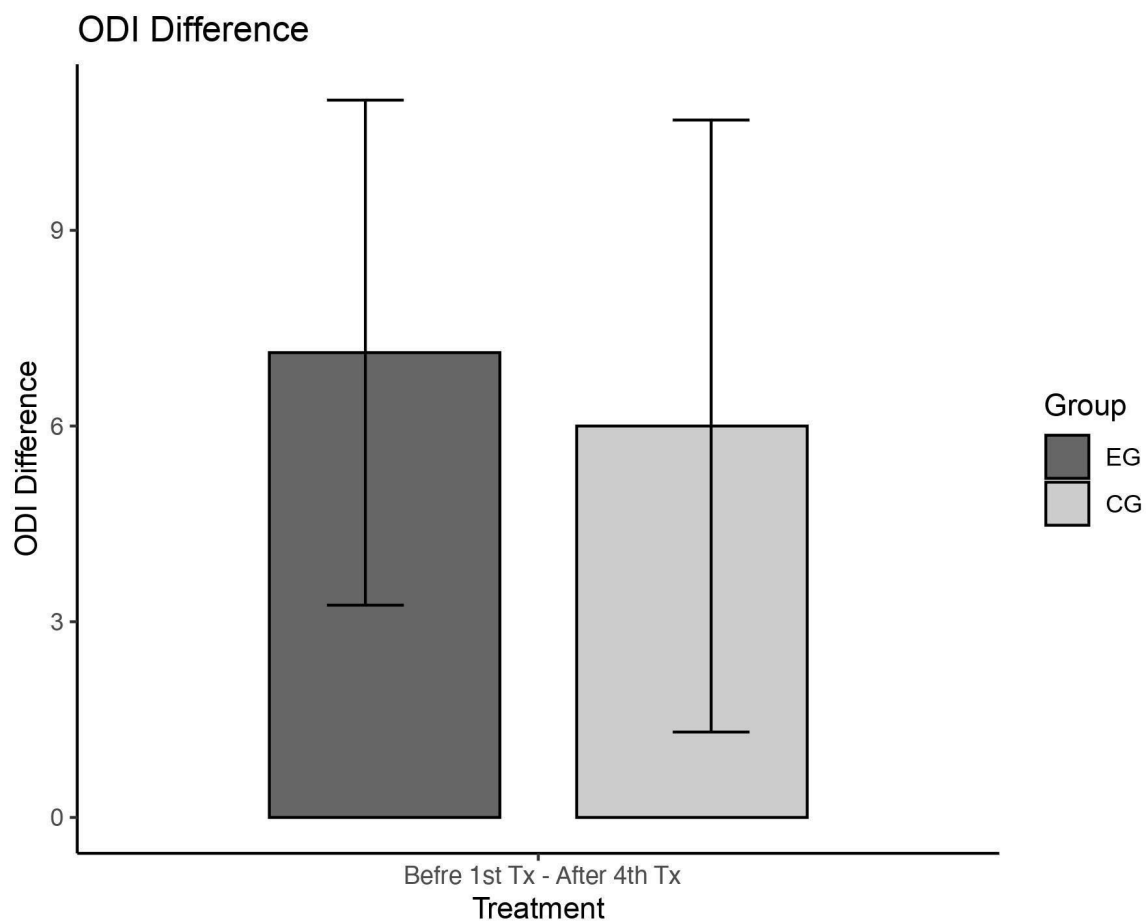
Figure 7-7. Bar graph of ODI difference between before and after treatment.
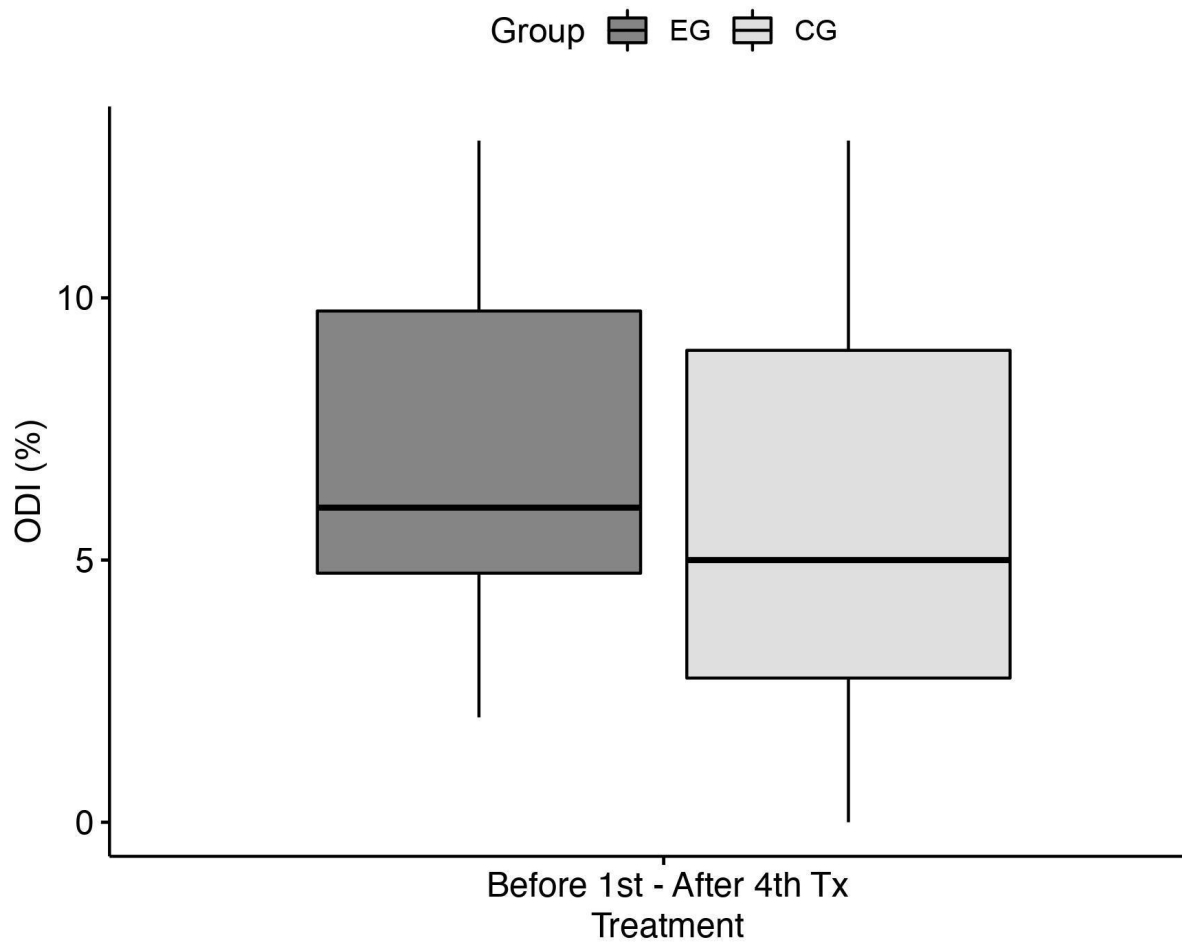
Figure 7-8. Boxplot of ODI difference between before and after treatment.

3.4 ROM of Lumbar Spine

3.4.1 Flexion

3.4.1.1 Change of Flexion before and after treatment within groups

The values for Flexion were measured to assess the range of motion of lumbar spine flexion of patients with lower back pain due to Quadratus Lumborum muscle. Table 6-6 compares the results of the experimental group with those of the control group measuring the change of ROM of lumbar flexion difference before the very first and fourth treatment session.

When comparing the Flexion values of before and after treatment between the experimental group and the control group as shown in Table 6-6, the Flexion values of the experimental group decreased from 48.75 ± 9.91 to 44.38 ± 13.21 ($p=0.345$) and those of the control group increased from 45.63 ± 12.94 to 48.75 ± 8.35 ($p=0.565$) after the treatment respectively. There was no significant difference between the results of both the control group and the experimental group according to the Paired Samples t-Test.

Figure 7-9 is a bar graph that indicates Flexion before and after treatment between the experimental group and the control group.

Table 6-6. Flexion Before and After Treatment and it's Difference

	EG	CG	*p*-value*	Cohen's d
Before Tx	48.75 ± 9.91	45.63 ± 12.94	0.596	0.271
After Tx	44.38 ± 13.21	48.75 ± 8.35	0.442	0.395
Difference***	-4.38 ± 10.84	3.13 ± 14.62	0.263	0.584
p-value**	0.345	0.565		

* Independent Samples t-Test
** Paired Samples t-Test
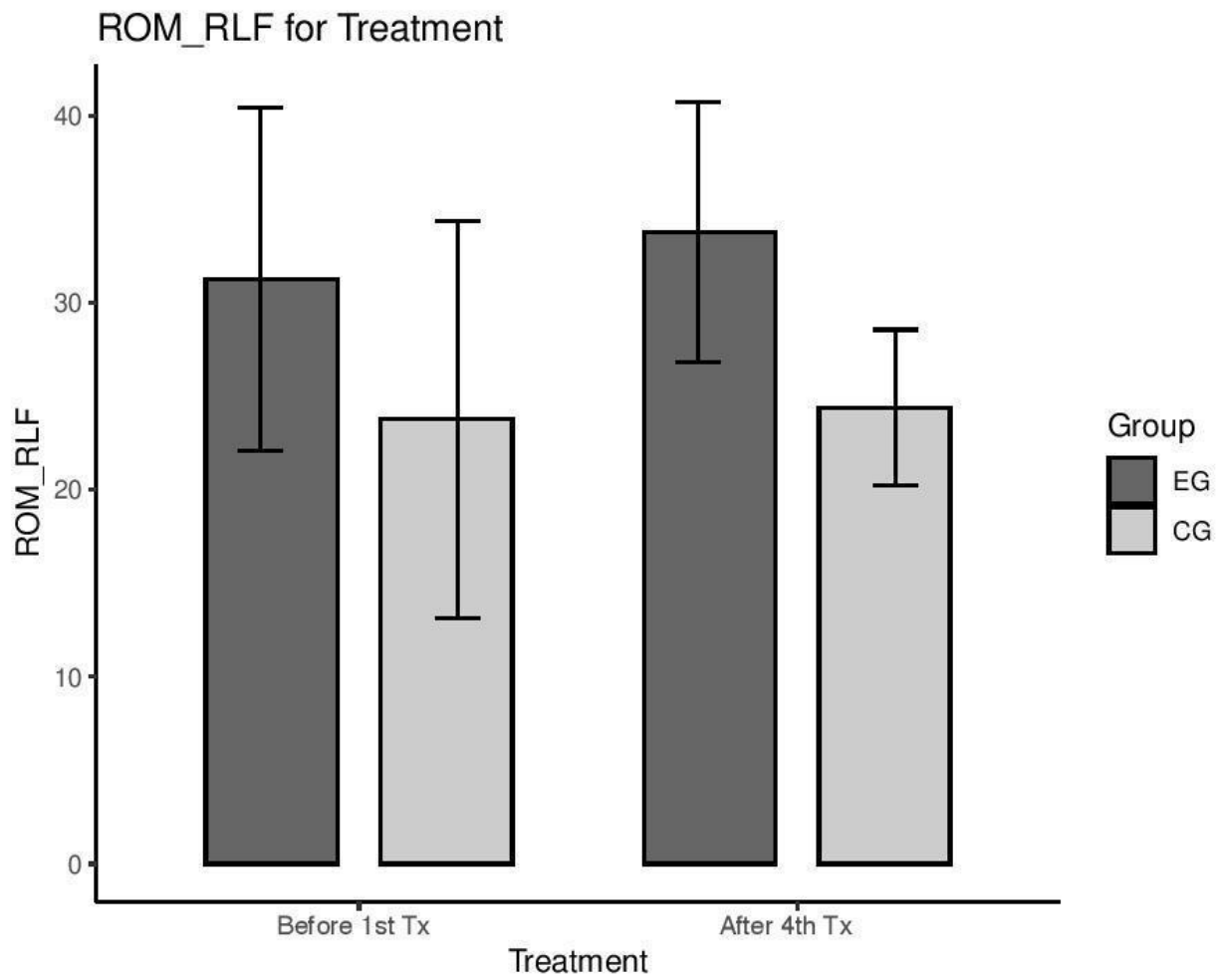*** Difference = After Tx - Before Tx
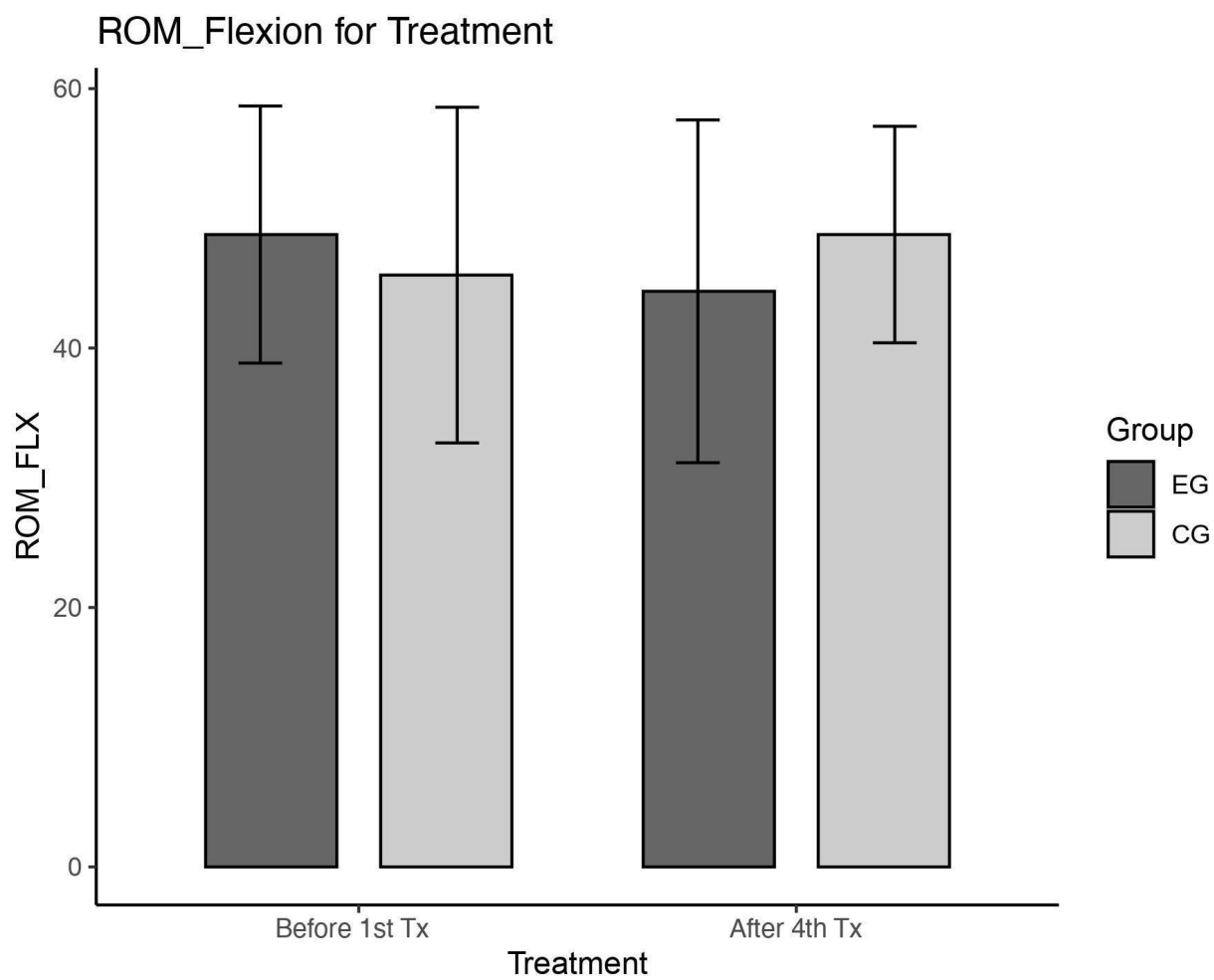
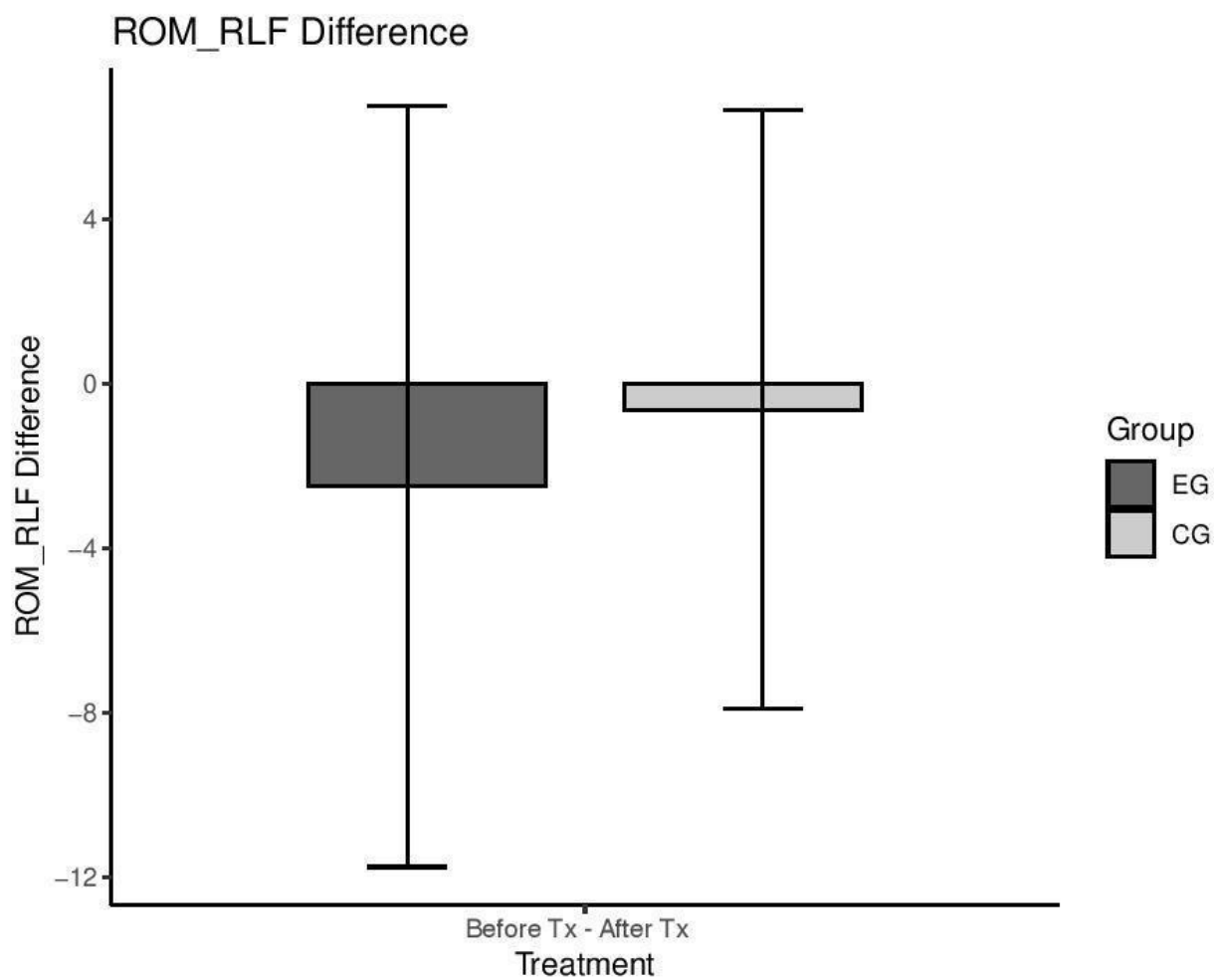Figure 7-9. Bar graph of Flexion before and after treatment.
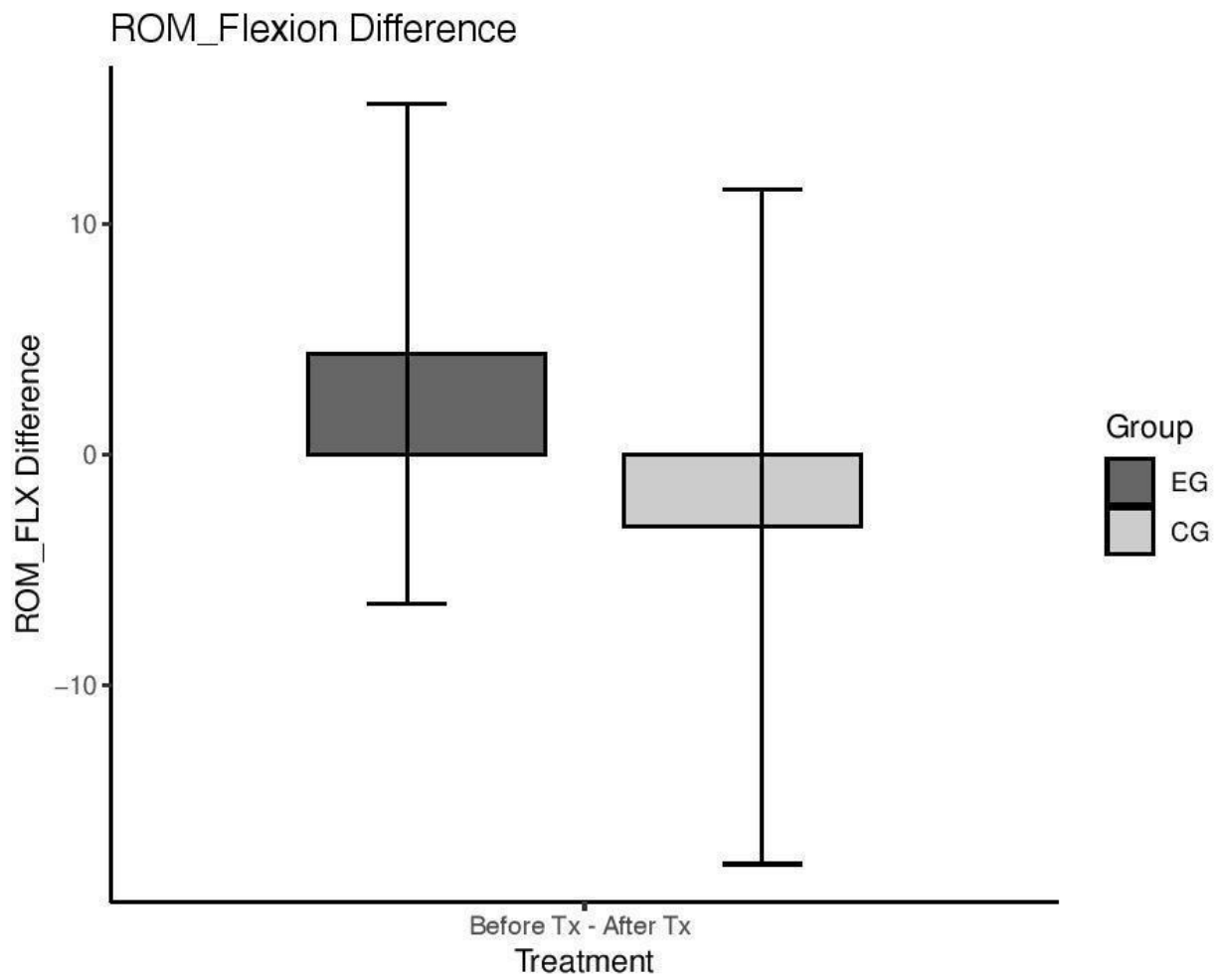
Figure 7-10. Bar graph of Flexion difference between before and after treatment.

3.4.1.2 Change of Flexion between groups

The Independent Samples t-Test was conducted to compare if there would be any significant difference in Flexion between the two groups before treatment, after treatment, and its difference. As shown in Table 6-5, the Flexion before treatment was 48.75 ± 9.91 for the experimental group and 45.63 ± 12.94 for the control group (p=0.596) where there was no significant difference. Also, when the Flexion after treatment between two groups were compared, the result for the experimental group was 44.38 ± 13.21 and 48.75 ± 8.35 for the control group (p=0.442) where there was no significant difference according to the Independent Samples t-Test. When the Flexion's difference was compared, the result was -4.38 ± 10.84 for the experimental group and 3.13 ± 14.62 for the control group (p=0.263). There was no significant difference.

As shown in Table 6-6, Cohen's distance was used to test effect size of the experimental group treatment to that of the control group treatment. Cohen's distance before the treatment was 0.271(Small), 0.395(Small) after the treatment, and 0.584(Medium) for the Flexion difference.

Figure 7-10 shows a bar graph of Flexion difference between the experimental group and the control group before and after treatment.

3.4.2 Right Lateral Flexion (RLF)

3.4.2.1 Change of RLF before and after treatment within groups

The values for ROM were measured to assess the range of motion of right lateral flexion of patients with lower back pain due to Quadratus Lumborum muscle. Table 6-7 compares the results of the experimental group with those of the control group measuring the change of ROM for right lateral flexion (RLF) of lumbar spine difference before the very first and fourth treatment session.

When comparing the RLF values of before and after treatment between the experimental group and the control group as shown in Table 6-7, the RLF values of the experimental group increased from 31.25 ± 9.16 to 33.75 ± 6.94 ($p=0.469$) and those of the control group increased from 23.75 ± 10.61 to 24.38 ± 4.17 ($p=0.815$) after the treatment respectively. There was no significant difference between the results of both the control group and the experimental group according to the Paired Samples t-Test.

Figure 7-11 is a bar graph that indicates ROM of RLF before and after treatment between the experimental group and the control group.

Table 6-7. RLF Before and After Treatment and it's Difference

	EG	CG	p-value*	Cohen's d
Before Tx	31.25 ± 9.16	23.75 ± 10.61	0.152	0.757
After Tx	33.75 ± 6.94	24.38 ± 4.17	0.014	1.637
Difference***	2.50 ± 9.26	0.63 ± 7.29	0.659	0.224
p-value**	0.469	0.815		

* Independent Samples t-Test
** Paired Samples t-Test
*** Difference = After Tx - Before Tx

Figure 7-11. Bar graph of RLF before and after treatment.

Figure 7-12. Bar graph of RLF difference between before and after treatment.

3.4.2.2 Change of RLF between groups

The Independent Sample t-Test was conducted to compare if there would be any significant difference in ROM of RLF between the two groups before treatment, after treatment, and its difference. As shown in Table 6-7, the RLF before treatment was 31.25 ± 9.16 for the experimental group and 23.75 ± 10.61 for the control group (p=0.152) where there was no significant difference. Also, when the RLF after treatment between two groups were compared, the result for the experimental group was 33.75 ± 6.94 and 24.38 ± 4.17 for the control group (p=0.014) where there was significant difference according to the Independent Samples t-Test. When the RLF's difference was compared, the result was 2.50 ± 9.26 for the experimental group and 0.63 ± 7.29 for the control group (p=0.659). There was no significant difference.

As shown in Table 6-7, Cohen's distance was used to test effect size of the experimental group treatment to that of the control group treatment. Cohen's distance before the treatment was 0.757(Medium), 1.637(Very Large) after the treatment, and 0.224(Small) for the RLF difference.

Figure 7-12 shows a bar graph of ROM of RLF difference between the experimental group and the control group before and after treatment.

IV. DISCUSSION

There are several diverse muscles which cause low back pain. This study focuses on low back pain due to Quadratus Lumborum muscle which is the deepest muscle of the posterior abdominal wall, lying deep inside the abdomen and dorsal to the iliopsoas muscle.[53] This study's purpose is to compare the effectiveness of Acupuncture treatment on Quadratus Lumborum pain with and without Shao Yao Gan Cao Tang.

VAS was measured and collected before and after each treatment for both experimental and control groups. The result of VAS in both groups decreased when compared from pre-treatment on the 1st visit and post-treatment on the 4th visit. ODI was collected before the 1st treatment and after the 4th treatment for both experimental and control groups and the result of ODI in both groups decreased. ROM was collected before and after treatment of 1st and 4th treatments for each person. ROM of lumbar right lateral flexion in both experimental and control groups increased. Unexpectedly, only the ROM of lumbar flexion before treatment in the experimental group actually decreased after treatment whereas there was still an increase in the control group when compared before and after treatment.

This unexpected result of the ROM of lumbar flexion in the experimental group may be due to discomfortness in the lumbar region coming from prolonged prone position while receiving the acupuncture treatment. Limited research study time and lack of gathering the number of enough participants due to the pandemic may be another factor to bring this result. Considering increasing dosage of the herbal formula granules may bring significant results in the future as well.

According to Table 4, (2×2 Contingent Table to Analyze the Dichotomous Result of Acupuncture Treatment in Terms of VAS for Chronic Low Back Pain)

	Uncured (VAS ≥ 3)	Cured (VAS ≤ 2)	Total
Experimental Group	2	6	8
Control Group	4	4	8

According to Table 5, (Calculation Process of Relative Risk (RR) Odds Ratio (OR) and Relative Risk Reduction (RRR) of Pain in Terms of the VAS score after Acupuncture Treatment for Chronic Low Back Pain)

Effect Size	Definition	Calculation Equation
Relative Risk (RR) =	$\dfrac{\text{Risk from Experimental Group}}{\text{Risk from Control Group}}$	$= \dfrac{2/8}{4/8} = 0.5$
Odds Ratio (OR) =	$\dfrac{\text{Odds from Experimental Group}}{\text{Odds from Control Group}}$	$= \dfrac{2/6}{4/4} = 0.33$
Relative Risk Reduction (RRR) =	$\dfrac{\text{Absolute Risk Reduction}}{\text{Risk from Control Group}}$	$= \dfrac{|2/8-4/8|}{4/8} = 0.5$

Relative Risk (RR) compares the risk from the experimental group to risk from the control group. Risk from the experimental group was 0.25=25% and from the control group was 0.5=50%. The relative risk ratio of these two risks is 0.5. The risk ratio is less than 1.0 indicating a decreased risk of bad outcome, which means that the treatment in the experimental group is likely to be more effective than the control group.[62,63] Odd Ratio (OR) is used to find the probability of an outcome of VAS score between the experimental and control group. OR less

than 1 indicates decreased occurrence of uncured lower back pain.[64] Relative Risk Reduction

(RRR) indicates how much the treatment reduced the risk of bad outcomes in the experimental

group relative to the control group. According to Table 5, the relative risk reduction was

0.5=50%.[63]

V. CONCLUSION

This study consists of 16 participants who are between the ages of 18 and 55, are not currently taking any pain medications or diuretics, do not have any underlying disease such as hypertension, heart disease, kidney disease, hypokalemia, or diabetes, without severe cognitive or mental disorders. The effects of a total of four treatments were evaluated with Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), and Range of Motion (ROM).
The findings were as follows:

The VAS value of the experimental group decreased from 4.4 ± 1.41 to 1.8 ± 0.89, when compared from pre-treatment on the 1st visit to the post-treatment on the 4th visit. Likewise, the VAS value of the control group decreased from 5.0 ± 2.27 to 3.0 ± 1.41. After four treatments, the cumulative VAS difference was 2.6 ± 1.41 for the experimental group and 2.0 ± 1.31 for the control group ($p=0.373$). According to the result, there was no significant difference between the two groups ($p>0.05$).

The ODI before treatment was 14.9 ± 8.03 for the experimental group and 23.8 ± 11.78 for the control group ($p=0.100$) where there was no significant difference. However, when the ODI after treatment between two groups were compared, the ODI value for the experimental group decreased to 7.8 ± 5.39 and the ODI value for the control group decreased to 17.8 ± 9.08 ($p=0.018$) which appeared to be statistically significant. When the ODI's difference was compared, the result was 7.1 ± 3.87 for the experimental group and 6.0 ± 4.69 for the control group ($p=0.609$) where there was no significant difference.

Since the p-values of ROM of lumbar extension and ROM of lumbar left lateral flexion of Homogeneity test were not greater than 0.05, they have been excluded from the statistical

analysis of the result because they already have significant differences before treatment. When comparing the flexion values of before and after treatment between the experimental group and the control group as shown in Table 6-6, the ROM flexion values of the experimental group decreased from 48.75 ± 9.91 to 44.38 ± 13.21 (p=0.345) and those of the control group increased from 45.63 ± 12.94 to 48.75 ± 8.35 (p=0.565) after the treatment respectively. There was no significant difference between the results of both the control and the experimental group.

ROM of lumbar right lateral flexion values of the experimental group increased from 31.25 ± 9.16 to 33.75 ± 6.94 (p=0.469) and those of the control group increased from 23.75 ± 10.61 to 24.38 ± 4.17 (p=0.815) after the treatment respectively. There was no significant difference between the results of both the control and the experimental group.

There was a decrease in the values of VAS and ODI when comparing the measurement from the pre-treatment of the 1st session and post-treatment of the 4th session in both experimental and control groups. There was an increase in ROM flexion in the control group, an increase in ROM RLF before and after treatment in both groups. However, ROM flexion before and after treatment in the experimental group has slightly decreased.

This study concludes that the utilization of 3 mg of Shao Yao Gan Cao Tang (芍藥甘草湯) per treatment in conjunction with Acupuncture does not show markedly measurable enhancement regarding the effectiveness of treatment compared to Acupuncture alone in Quadratus Lumborum muscle disorder treatment.

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APPENDIX-1. Informed Consent Form

Informed Consent Form

You are invited to participate in a research study about "Effects of Acupuncture with Shao Yao Gan Cao Tang on Quadratus Lumborum Pain: A Randomized Controlled Clinical Trial".

Total goal of this research study is to verify the comparison effectiveness of Acupuncture treatment in low back pain with or without herbal prescription.

The study design is that the patient with low back pain will receive Acupuncture treatment with or without herbal medicine. The treatment will be total 8 times, twice a week for 4 weeks.

This study is being conducted by Jung In Choi, L.Ac.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and Asian Medicine.

By Participating in this research, it is possible that you will be at greater risk than you would otherwise be. For example, your condition will not get better and that the medicine or treatment does not work, possible adverse effects may include blood pressure increase, potassium level decrease, sodium level increase, and edema. If, however, any of these adverse effects occur, follow up treatments will be offered to make you feel more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law. The information that we collect from this research project will be kept confidential. Your information collected during the research will be

put away and no-one but the researchers will be able to access it. Any information about you will have a file number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Jung In Choi, L.Ac.

If you have any questions about this study, please contact Jung In Choi, L.Ac., at 714-309-7626 and junginc1123@gmail.com. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Cho, Chair of the South Baylo University Institutional Review Board (IRB) at 213-738-0712 or khcho@southbaylo.edu.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

_____   _____
Name of Participant (Print)   Name of Witness (Print)

_____   _____
Signature of Participant   Signature of Witness

_____   _____
Date: Day/Month/Year   Date: Day/Month/Year

Statement by the researcher/person taking consent:
I have accurately explained the information sheet to the
potential participant. I confirm that the participant was given
an opportunity to ask questions about the study, and all the
questions asked by the participant have been answered correctly
and to the best of my ability. I confirm that the individual has
not been coerced into giving consent, and the consent has been
given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Jung In Choi, L.Ac.

_____
Print Name Researcher (Print)

_____
Signature of Researcher

_____
Date: Day/Month/Year

APPENDIX-2. Data(Case Report) Forms

Case Report Form   Time_____:_____am/pm

Patient's Name _____   Date _____/_____/_____   File # _____

"S"

-Subjective

Complaint

How do you feel since last time treatment?
□Resolved   □Improved   □Slightly Improved   □Unchanged

Chief Complaint _____

_____

Present Illness & Physical Examination _____

_____

_____

_____

_____

_____

-Vital Signs

Heart Rate_____BPM   **Heart Rhythm**___*Normal/Abnormal*___   **Respiratory Rate**_____BPM

BP_____/_____mmHg   **Temperature**_____℉   etc._____

_____

"O"

-Objective

Findings

Tongue_____

Pulse *Lt:*_____   *Rt:*_____

"A"

-Assessment

AOM Diagnosis_____

_____

Western Medical Diagnosis *(Only if the patient brings in)* _____

"P"

-Treatment

Plan

Treatment Principles _____

_____

Acupuncture Points Lt:_____

  Rt:_____

  Middle:_____   **No. of Needles:**_____

Auricular Acupuncture / Seeds_____

Herbal Treatment:._____

_____

Other Treatment: ☐H.P ☐Acupressure ☐Tui-na ☐E.A ☐Moxa ☐Cupping ☐Taiji 1 ☐Taiji 2

Recommendations _____

Name of Practitioner: _____   LAc

APPENDIX-3. Pre And Post Visual Analogue Scale (VAS)

PRE AND POST VISUAL ANALOGUE SCALE

NAME _____ DATE _____ DATE OF INJURY _____

PRE-TREATMENT VAS

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

FOLD HERE---

POST-TREATMENT VAS (fold in half when completing post-test VAS)

Please place a mark through the line below that most accurately represents the pain level that you are feeling *RIGHT NOW*. Please note that "UNBEARABLE PAIN" is located on the right hand side of the line and "NO PAIN" is located on the left.

No Pain _____ Unbearable

APPENDIX-4. Range of Motion (ROM)

1st Treatment

Motion	Normal Range of Motion	Pre-Treatment	Post-Treatment
Flexion	60°		
Extension	25°		
Left Lateral	25°		
Right Lateral	25°		

4th Treatment

Motion	Normal Range of Motion	Pre-Treatment	Post-Treatment
Flexion	60°		
Extension	25°		
Left Lateral	25°		
Right Lateral	25°		

OSWESTRY DISABILITY INDEX 2.0

NAME_____ **DATE**_____ **SCORE**_____

PLEASE READ: Could you please complete this questionnaire. It is designed to give us information as to how your back (or leg) trouble has affected your ability to manage in everyday life.

Please answer ***every section***. Mark ***one box only*** in each section that most closely describes you ***today***.

SECTION 1 - Pain Intensity A ☐ I have no pain at the moment. B ☐ The pain is very mild at the moment. C ☐ The pain is moderate at the moment. D ☐ The pain is fairly severe at the moment. E ☐ The pain is very severe at the moment. F ☐ The pain is the worst imaginable at the moment.	*SECTION 6 - Standing* A ☐ I can stand as long as I want without extra pain. B ☐ I can stand as long as I want but it gives me extra pain. C ☐ Pain prevents me from standing for more than 1 hour. D ☐ Pain prevents me from standing for more than 1/2 hour. E ☐ Pain prevents me from standing for more than 10 minutes. F ☐ Pain prevents me from standing at all.
SECTION 2 - Personal Care (washing, dressing, etc.) A ☐ I can look after myself normally without causing extra pain. B ☐ I can look after myself normally but it is very painful. C ☐ It is painful to look after myself and I am slow and careful. D ☐ I need some help but manage most of my personal care. E ☐ I need help every day in most aspects of self care. F ☐ I do not get dressed, wash with difficulty☐ and stay in bed.	*SECTION 7 - Sleeping* A ☐ My sleep is never disturbed by pain. B ☐ My sleep is occasionally disturbed by pain. C ☐ Because of pain I have less than 6 hours' sleep. D ☐ Because of pain I have less than 4 hours' sleep. E ☐ Because of pain I have less than 2 hours' sleep. F ☐ Pain prevents me from sleeping at all.
SECTION 3 - Lifting A ☐ I can lift heavy weights without extra pain. B ☐ I can lift heavy weights, but it causes extra pain. C ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table. D ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned. E ☐ I can only lift very light weights, at the most. F ☐ I cannot lift or carry anything at all.	*SECTION 8 - Sex Life (if applicable)* A ☐ My sex life is normal and causes me no extra pain. B ☐ My sex life is normal, but causes some extra pain. C ☐ My sex life is nearly normal but is very painful. D ☐ My sex life is severely restricted by pain. E ☐ My sex life is nearly absent because of pain. F ☐ Pain prevents any sex life at all.
SECTION 4 - Walking A ☐ Pain does not prevent me from walking any distance. B ☐ Pain prevents me from walking more than one mile. C ☐ Pain prevents me from walking more than 1/4 mile. D ☐ Pain prevents me from walking more than 100 yards. E ☐ I can only walk while using a stick or crutches. F ☐ I am in bed most of the time and have to crawl to the toilet.	*SECTION 9 - Social Life* A ☐ My social life is normal and causes me no extra pain. B ☐ My social life is normal, but increases the degree of pain. C ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., sport, etc. D ☐ Pain has restricted my social life and I do not go out as often. E ☐ Pain has restricted my social life to my home. F ☐ I have no social life because of the pain.
SECTION 5 - Sitting A ☐ I can sit in any chair as long as I like. B ☐ I can only sit in my favorite chair as long as I like. C ☐ Pain prevents me from sitting more than 1 hour. D ☐ Pain prevents me from sitting more than 1/2 hour. E ☐ Pain prevents me from sitting more than ten minutes. F ☐ Pain prevents me from sitting at all.	*SECTION 10 - Traveling* A ☐ I can travel anywhere without pain. B ☐ I can travel anywhere but I gives extra pain. C ☐ Pain is bad but I manage journeys over 2 hours. D ☐ Pain restricts me to journeys of less than 1 hour. E ☐ Pain restricts me to short necessary journeys under 30 minutes. F ☐ Pain prevents me from traveling except to receive treatment.

COMMENTS: _____

_____

_____

_____

_____

Roland, M. and J. Fairbank (2000). "The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire." Spine 25(24): 3115-24.

APPENDIX-6. Oswestry Disability Index 2.0 (Korean version)

OSWESTRY DISABILITY INDEX 2.0 (한국어)

성함: _____ **날짜:** _____ **점수:** _____

- 본 설문지는 당신이 허리의 문제로 인해 일상 생활에서 얼마나 제한이 있는지를 알기 위해 제작되었습니다.
- **모든 문항**에 답하여 주시되, 각 문항 마다 **오늘의 상태**에 가장 적합한 **한 칸**에만 표기하십시오.

제 1 항 - 통증 정도	☐0 나는 현재 통증이 전혀 없다. ☐1 현재 매우 가벼운 통증이 있다. ☐2 현재 통증이 조금 있다. ☐3 현재 통증이 조금 심하다. ☐4 현재 통증이 아주 심하다. ☐5 현재 통증이 상상할 수 없이 심하다.
제 2 항 - 개인 위생 (씻기, 옷 입기 등)	☐0 나는 별다른 통증이 없이 나 자신을 챙길 수 있다. ☐1 보통 나 자신을 챙길 수 있으나, 통증이 있다. ☐2 나 자신을 챙기는데 고통스러워서, 천천히 조심스럽게 해야 한다. ☐3 통증 때문에 어느 정도 도움이 필요하거나, 혼자서 할 수는 있다. ☐4 매일 도움이 없이는 나 자신을 챙기기가 어렵다. ☐5 옷을 입거나 씻는 게 어렵고, 보통은 누워있다.
제 3 항 - 물건 들기	☐0 나는 무거운 물건을 통증 없이 들 수 있다. ☐1 무거운 물건을 들 수 있으나, 약간 통증이 있다. ☐2 통증 때문에 바닥에 있는 무거운 물건을 들지 못하나, 들기 쉬운 곳에 있으면 들 수 있다. ☐3 통증 때문에 무거운 물건을 들 수 없지만, 들기 쉬운 곳에 있는 무겁지 않은 물건은 들 수 있다. ☐4 아주 가벼운 물건만 들 수 있다. ☐5 아무것도 들거나 나를 수 없다.

제 4 항 - 걷기	☐0 나는 걷는데 아무런 지장이 없다. ☐1 통증 때문에 1 mile 이상 걷지 못한다. ☐2 통증 때문에 1/4 mile 이상 걷지 못한다. ☐3 통증 때문에 100 yards 이상 걷지 못한다. ☐4 지팡이나 목발이 있어야만 걷는다. ☐5 대부분 자리에 누워있으며, 화장실도 기어가야 한다.
제 5 항 - 앉기	☐0 나는 어떤 의자에서든지 오래 앉아 있을 수 있다. ☐1 편한 의자라면 오래 앉아 있을 수 있다. ☐2 통증 때문에 1시간 이상 앉아 있을 수 없다. ☐3 통증 때문에 30분 이상 앉아 있을 수 없다. ☐4 통증 때문에 10분 이상 앉아 있을 수 없다. ☐5 통증 때문에 전혀 앉아 있을 수 없다.
제 6 항 - 서있기	☐0 나는 통증 없이 얼마든지 서 있을 수 있다. ☐1 오래 서 있을 수 있으나 약간 통증이 있다. ☐2 통증 때문에 1시간 이상 서 있을 수 없다. ☐3 통증 때문에 30분 이상 서 있을 수 없다. ☐4 통증 때문에 10분 이상 서 있을 수 없다. ☐5 통증 때문에 전혀 서 있을 수 없다.
제 7 항 - 잠자기	☐0 나는 통증 없이 잘 잔다. ☐1 통증 때문에 가끔 잠자는 데 방해를 받는다. ☐2 통증 때문에 6시간 이상 잠을 자지 못한다. ☐3 통증 때문에 4시간 이상 잠을 자지 못한다. ☐4 통증 때문에 2시간 이상 잠을 자지 못한다. ☐5 통증 때문에 전혀 잠을 자지 못한다.
제 8 항 - 성생활 (해당 시)	☐0 나는 정상적으로 성생활을 하고 통증이 없다. ☐1 정상적으로 성생활을 하나 가끔 통증을 느낀다. ☐2 거의 정상적으로 성생활을 하나 통증을 심하게 느낀다. ☐3 통증 때문에 성생활이 매우 제한적이다. ☐4 통증 때문에 성생활을 거의 할 수 없다. ☐5 통증 때문에 성 관계를 전혀 갖지 않는다.

제 9 항 - 사회생활	☐0 나는 밖에서 사람들과 어울리는 데 지장이 없다. ☐1 밖에서 사람들과 어울리는데 지장은 없으나, 그로 인해 통증이 심해진다. ☐2 밖에서 사람들과 어울리는데 지장은 없으나, 통증 때문에 운동하는 데에는 지장이 있다. ☐3 통증 때문에 밖에서 사람들과 어울리는데 지장이 있으며, 자주 외출하지 못한다. ☐4 통증 때문에 집에서만 사람들과 어울린다. ☐5 통증 때문에 사람들과 전혀 어울리지 못한다.
제 10 항 - 여행	☐0 나는 통증 없이 어디든 여행할 수 있다. ☐1 어디든 여행할 수 있으나, 약간 통증이 있다. ☐2 통증은 있으나, 2시간 이상 차를 탈 수는 있다. ☐3 통증은 있으나, 1시간 이상 차를 탈 수 없다. ☐4 통증은 있으나, 30분 이상 차를 탈 수 없다. ☐5 통증 때문에 치료를 받으러 가는 일 외에는 차를 탈 수 없다.

APPENDIX-7. Oswestry Disability Index 2.0 (Spanish version)

OSWESTRY DISABILITY INDEX 2.0 (en Español)

Nombre: _____ **fecha:** _____ **puntaje:** _____

- Este cuestionario esti se para darnos información sus problemas de espalda afectan su capacidad para manejarse en la vida diaria.
- Responda cada pregunta y seleccione solo **una** respuesta para cada pregunta que describa con mayor exactitud su situación **hoy**.

P1. Intensidad del dolor	☐0 No siento dolor en este momento ☐1 El dolor es muy leve en este momento ☐2 El dolor es moderado en este momento ☐3 El dolor es bastante intenso en este momento ☐4 El dolor es muy intenso en este momento ☐5 El dolor es el peor imaginable en este momento
P2. Cuidado personal (lavarse, vestirse, etc.)	☐0 Puedo ocuparme normalmente sin causar dolor adicional. ☐1 Puedo ocuparme normalmente pero me resulta muy doloroso. ☐2 Es doloroso ocuparme y soy lento y cuidadoso. ☐3 Necesito algo de ayuda pero puedo manejar la mayoría de mi cuidado personal. ☐4 Necesito ayuda todos los días en la mayoría de los aspectos del cuidado personal. ☐5 No me visto, me lavo con dificultad y permanezco en cama.
P3. Levantar (objetos)	☐0 Puedo levantar pesos pesados sin sentir dolor adicional. ☐1 Puedo levantar objetos pesados pero siento dolor adicional. ☐2 El dolor me impide levantar objetos pesados del suelo, pero puedo arreglármelas si están ubicados convenientemente, por ej. sobre una mesa. ☐3 El dolor me impide levantar pesos pesados pero puedo arreglármelas con pesos livianos a medianos si están ubicados convenientemente. ☐4 Solo puedo levantar pesos muy livianos. ☐5 No puedo levantar ni cargar nada.

P4. Caminar	☐0 El dolor no me impide caminar ninguna distancia. ☐1 El dolor me impide caminar más de una milla. ☐2 El dolor me impide caminar más de un cuarto de milla. ☐3 El dolor me impide caminar más de 100 yardas. ☐4 Solo puedo caminar con bastón o muletas. ☐5 Estoy en cama la mayoría del tiempo y tengo que arrastrarme hasta el baño.
P5. Sentarse	☐0 Puedo sentarme en cualquier silla tanto como guste. ☐1 Puedo sentarme en mi silla favorita tanto como guste. ☐2 El dolor me impide sentarme más de 1 hora. ☐3 El dolor me impide sentarme más de media hora. ☐4 El dolor me impide sentarme más de 10 minutos. ☐5 El dolor me impide sentarme.
P6. Pararse	☐0 Puedo pararme todo lo que desee sin sentir dolor adicional. ☐1 Puedo pararme todo lo que quiera pero siento dolor adicional. ☐2 El dolor me impide pararme más de 1 hora. ☐3 El dolor me impide pararme más de media hora. ☐4 El dolor me impide pararme más de 10 minutos. ☐5 El dolor me impide pararme.
P7. Dormir	☐0 El dolor nunca me perturba el sueño. ☐1 Mi sueño se ve perturbado ocasionalmente por el dolor. ☐2 Debido al dolor, duermo menos de 6 horas. ☐3 Debido al dolor, duermo menos de 4 horas. ☐4 Debido al dolor, duermo menos de 2 horas. ☐5 El dolor me impide dormir.
P8. Vida sexual (si es aplicable)	☐0 Mi vida sexual es normal y no causa dolor adicional. ☐1 Mi vida sexual es normal y causa algo de dolor adicional. ☐2 Mi vida sexual es casi normal pero es muy dolorosa. ☐3 Mi vida sexual está gravemente afectada por el dolor. ☐4 Mi vida sexual está prácticamente ausente por el dolor. ☐5 El dolor me impide tener una vida sexual.

APPENDIX-8. Scoring Methods for the Oswestry Disability Index 2.0 (ODI)

SCORING METHOD FOR
THE OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

1. Each of the 10 sections is scored separately (0 to 5 points each) and then added up (max. total = 50).

   EXAMPLE:

Section 1. Pain Intensity	Point Value
A. ____ I have no pain at the moment	0
B. ____ The pain is very mild at the moment	1
C. ____ The pain is moderate at the moment	2
D. ____ The pain is fairly severe at the moment	3
E. ____ The pain is very severe at the moment	4
F. ____ The pain is the worst imaginable	5

2. If all 10 sections are completed, simply double the patients score.

3. If a section is omitted, divide the patient's total score by the number of sections completed times 5.

   FORMULA: $\dfrac{\text{PATIENT'S SCORE}}{\text{\# OF SECTIONS COMPLETED X 5}} \times 100 = \text{_____ \% DISABILITY}$

   EXAMPLE:

   If 9 of 10 sections are completed, divide the patient's score by 9 X 5 = 45; if

   Patient's Score: 22

   Number of sections completed: 9 (9 X 5 = 45)

   22/45 X 100 = 48 % disability

4. Interpretation of disability scores (from original article):

SCORE	INTERPRETATION OF THE OSWESTRY LBP DISABILITY QUESTIONNAIRE
0-20% Minimal Disability	Can cope w/ most ADL's. Usually no treatment needed, apart from advice on lifting, sitting, posture, physical fitness and diet. In this group, some patients have particular difficulty with sitting and this may be important if their occupation is sedentary (typist, driver, etc.)
20-40% Moderate Disability	This group experiences more pain and problems with sitting, lifting and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.
40-60% Severe Disability	Pain remains the main problem in this group of patients by travel, personal care, social life, sexual activity and sleep are also affected. These patients require detailed investigation.
60-80% Crippled	Back pain impinges on all aspects of these patients' lives both at home and at work. *Positive intervention is required*.
80-100%	These patients are either bed-bound or exaggerating their symptoms. This can be evaluated by careful observation of the patient during the medical examination.

Roland, M. and J. Fairbank (2000). "The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire." Spine 25(24): 3115-24.