

SOUTH BAYLO UNIVERSITY

**Non-inferiority of Moving Cupping to Acupuncture on Shoulder Pain
in Middle-Aged and Older Adults**

by

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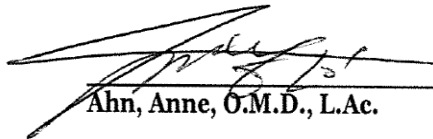
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ABSTRACT

In order to evaluate the non-inferior effectiveness of moving cupping to acupuncture treatment on shoulder pain in middle aged and elderly participants, pilot scale randomized controlled trial was conducted with twenty participants aged between 35 to 75 years old divided into two groups in 1:1 ratio. Each participant in Acupuncture group (Group A) had Acupuncture treatment on SJ-14, LI-15, LI-16, GB-21, LI-4, LI-11, SJ-5, ST-38, SP-9, SP-6, and ST-40 for 20 minutes as well as infrared heat during acupuncture treatment on shoulder, while participants in Moving Cupping group (Group B) had treatment of moving cupping for approximately 20 minutes. All participants from both groups had two sessions a week for two weeks. Outcomes of NPS (Numeric Pain Scale), ROM (Range of Motion) and SPADI (Shoulder Pain and Disability Index) were measured before and after each treatment. ROMs were measured using a goniometer for Shoulder Flexion, Extension, Abduction and Adduction. After treatment of total four sessions the Mean difference (MD) of NPS in Group A was 3.9 ± 1.5 ($p < 0.05$), where the

MD in Group B was 4.9 ± 1.9 ($p < 0.05$). However there was no statistical significant difference between two groups. The Total treatment effect on MD of SPADI in Group B was 32.7 ± 12.6 ($p < 0.05$) and 37.7 ± 14.7 ($p < 0.05$) in the Group A. Group was 5.0 ± 2.1 ($p < 0.05$) slightly higher than group A. But, there was no statistical significant difference between two groups. ROM in Group B showed slightly higher effect in first two treatments but, in total there were no significant differences compared to Group A. It was concluded that effectiveness of moving cupping is non-inferior to acupuncture in treating shoulder pain in middle aged and elderly participants. However, larger scale trial is necessary to confirm the equivalence or non-inferiority.

TABLE OF CONTENTS

ABSTRACT	
I. INTRODUCTION	4
LITERATURE BACKGROUND	
OBJECTIVES OF THE STUDY	
II. MATERIALS AND METHODS	16
III. RESULTS	28
IV. DISCUSSION	37
V. CONCLUSION	39
REFERENCES	41
APPENDICES	46

I. INTRODUCTION

These days the most common shoulder pain in middle aged and elderly patients is Frozen Shoulder. Frozen shoulder is an underreported and underdiagnosed symptom that is especially common in middle aged to older adults. It is a condition that affects shoulder joint and areas of shoulder. It usually involves pain and stiffness that develops gradually, gets worse and then finally goes away. This can take anywhere from a few months to 3 years. Frozen shoulder is also known as adhesive capsulitis. The term "frozen shoulder" is often used incorrectly for arthritis, but these two conditions are unrelated. Frozen shoulder refers specifically to the shoulder joint, while arthritis may refer to other or multiple joints. Frozen shoulder most commonly affects people between the ages of 40 and 60, and occurs in women more often than men. In addition, people with diabetes are at an increased risk for developing frozen shoulder. Frozen shoulder is estimated to affect about 3 percent of people. It can affect one or both shoulders.^{7,9)}

Frozen shoulder is most likely diagnoses based on signs, symptoms, and a physical exam. It is a persistently painful, stiff shoulder joint and limited ROM. Signs and symptoms develop gradually, and usually resolve on their own. The severity of frozen shoulder is determined by a basic test by presses and moves certain parts of the arm and shoulder. Structural problems can only be identified with the help of imaging tests, such as an X-ray or Magnetic Resonance Imaging (MRI).^{11,22)}

Frozen shoulder symptoms are usually classified in three stages, as they worsen gradually and then resolve within anywhere from a number of months to 3 years. First stage is "Freezing stage" that any movement of shoulder causes pain, and shoulder's

range of motion starts to become limited. Second stage is “Frozen stage” that pain may begin to diminish during this stage. However, shoulder becomes stiffer, and using it becomes more difficult. At last third stage is “Thawing stage” where the range of motion in shoulder begins to improve.^{35, 41)}

There are many other types of shoulder pain diagnoses as Bursitis, Tendinitis, Tendon Tears, Impingement, Instability, Arthritis and Fracture.⁵⁾

Bursae are small, fluid-filled sacs that are located in joints throughout the body, including the shoulder. They act as cushions between bones and the overlying soft tissues, and help reduce friction between the gliding muscles and the bone. Sometimes, excessive use of the shoulder leads to inflammation and swelling of the bursa between the rotator cuff and part of the shoulder blade known as the acromion. The result is a condition known as sub-acromial bursitis. Bursitis often occurs in association with rotator cuff tendinitis. The many tissues in the shoulder can become inflamed and painful. Many daily activities, such as combing your hair or getting dressed, may become difficult.^{5, 17, 40)}

Tendinitis is a result of a wearing down of the tendon that occurs slowly over time, much like the wearing process on the sole of a shoe that eventually splits from overuse.¹²⁾ Generally, tendinitis is one of two types:

Acute - Excessive ball throwing or other overhead activities during work or sport can lead to acute tendinitis.

Chronic - Degenerative diseases like arthritis or repetitive wear and tear due to age, can lead to chronic tendinitis. The most commonly affected tendons in the shoulder are the four rotator cuff tendons and one of the biceps tendons. The rotator cuff is made up of four small muscles and their tendons that cover the head of your upper arm bone and

keep it in the shoulder socket. Your rotator cuff helps provide shoulder motion and stability.

Splitting and tearing of tendons may result from acute injury or degenerative changes in the tendons due to advancing age, long-term overuse and wear and tear, or a sudden injury. These tears may be partial or may completely split the tendon into two pieces. In most cases of complete tears, the tendon is pulled away from its attachment to the bone. Rotator cuff and biceps tendon injuries are among the most common of these injuries.^{13, 16)}

Shoulder impingement occurs when the top of the shoulder blade (acromion) puts pressure on the underlying soft tissues when the arm is lifted away from the body. As the arm is lifted, the acromion rubs, or "impinges" on, the rotator cuff tendons and bursa. This can lead to bursitis and tendinitis, causing pain and limiting movement. Over time, severe impingement can even lead to a rotator cuff tear.^{13, 19)}

Shoulder instability occurs when the head of the upper arm bone is forced out of the shoulder socket. This can happen as a result of a sudden injury or from overuse. Shoulder dislocations can be partial, with the ball of the upper arm coming just partially out of the socket. This is called a subluxation. A complete dislocation means the ball comes all the way out of the socket. Once the ligaments, tendons, and muscles around the shoulder become loose or torn, dislocations can occur repeatedly. Recurring dislocations, which may be partial or complete, cause pain and unsteadiness when raise arm or move it away from body. Repeated episodes of subluxations or dislocations lead to an increased risk of developing arthritis in the joint.^{9, 33)}

Shoulder pain can also result from arthritis. There are many types of arthritis. The most common type of arthritis in the shoulder is osteoarthritis, also known as "wear and tear" arthritis. Symptoms, such as swelling, pain, and stiffness, typically begin during middle age. Osteoarthritis develops slowly and the pain it causes worsens over time. Osteoarthritis, may be related to sports or work injuries and chronic wear and tear. Other types of arthritis can be related to rotator cuff tears, infection, or an inflammation of the joint lining. Often people will avoid shoulder movements in an attempt to lessen arthritis pain. This sometimes leads to a tightening or stiffening of the soft tissue parts of the joint, resulting in a painful restriction of motion.^{29, 34, 37)}

Fractures are broken bones. Shoulder fractures commonly involve the clavicle (collarbone), humerus (upper arm bone), and scapula (shoulder blade). Shoulder fractures in older patients are often the result of a fall from standing height. In younger patients, shoulder fractures are often caused by a high energy injury, such as a motor vehicle accident or contact sports injury. Fractures often cause severe pain, swelling, and bruising about the shoulder.^{5, 10)}

Similarly, in oriental medicine, differentiation of the diagnostic patterns associated with Shoulder pain is necessary for correct diagnosis. The most common etiology for Shoulder pain in old age is damp bi -syndrom on shoulder and qi & blood stagnation.

In this study patients aged between 35 to 70 years old who has shoulder pain diagnosed from damp Bi-syndrome on shoulder and Qi & Blood stagnation was randomly separates to 1:1 ratio of two groups in Group A and Group B. Group A had treatment of only Acupuncture and Group B had treatment of only Moving Cupping.

The purpose of this study was to investigate the non-inferior or equivalent effectiveness of moving cupping to acupuncture treatment on shoulder pain as well as to investigate acupuncture points using for acupuncture treatment.

LITERATURE BACKGROUND

The most common shoulder pain Frozen shoulder, also known as adhesive capsulitis, is a condition characterized by stiffness, pain and limits your range of motion in shoulder joint. Signs and symptoms typically begin gradually, worsen over time and then resolve, usually within few months to three years. The risk of developing frozen shoulder increases if you're recovering from a medical condition or procedure that prevents you from moving arm such as a stroke or a mastectomy.^{26, 30)}

The shoulder is made up of three bones: The shoulder blade, the collarbone, and the upper arm bone, or humerus. The shoulder has a ball-and-socket joint. The round head of the upper arm bone fits into this socket. Connective tissue, known as the shoulder capsule, surrounds this joint. Synovial fluid enables the joint to move without friction.^{39, 42)}

The causes of frozen shoulder are not fully understood. There is no clear connection to arm dominance or occupation. A few factors may put more at risk for developing frozen shoulder. Frozen shoulder occurs much more often in people with diabetes. The reason for this is not known. In addition, diabetic patients with frozen shoulder tend to have a greater degree of stiffness that continues for a longer time before "thawing." Some additional medical problems associated with frozen shoulder include hypothyroidism, hyperthyroidism, Parkinson's disease, and cardiac disease. Frozen shoulder can develop after a shoulder has been immobilized for a period of time due to surgery, a fracture, or other injury. Having patients move their shoulders soon after injury or surgery is one measure prescribed to prevent frozen shoulder.^{2, 6)}

In frozen shoulder, the shoulder capsule thickens and becomes stiff and tight. Thick bands of tissue called adhesions develop. In many cases, there is less synovial fluid in the joint. The hallmark signs of this condition are severe pain and being unable to move shoulder either on own or with the help of someone else. It develops in three stages:

Stage 1: Freezing

In the "freezing" stage, It slowly have more and more pain. As the pain worsens, The shoulder loses range of motion. Freezing typically lasts from 6 weeks to 9 months.

Stage 2: Frozen

Painful symptoms may actually improve during this stage, but the stiffness remains. During the 4 to 6 months of the "frozen" stage, daily activities may be very difficult.

Stage 3: Thawing

Shoulder motion slowly improves during the "thawing" stage. Complete return to normal or close to normal strength and motion typically takes from few months to 3 years.

Frozen shoulder occurs when the connective tissue enclosing the joint becomes thickened and tight. Treatment for frozen shoulder involves range-of-motion exercises and, sometimes, corticosteroids and numbing medications injected into the joint capsule. In a small percentage of cases, arthroscopic surgery may be indicated to loosen the joint capsule so that it can move more freely. It's unusual for frozen shoulder to recur in the same shoulder, but some people can develop it in the opposite shoulder. There are several ways to relieve pain and alleviate the condition.^{13, 19)}

Painkillers: Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, are available to purchase over-the counter or online, and may reduce inflammation and alleviate mild pain.^{1,9)}

Acetaminophen (Paracetamol, Tylenol) is recommended for extended use, and is also available to purchase over-the counter or online.^{13, 18)}

Prescription painkillers, such as codeine, an opiate-based painkiller, may reduce pain.⁹⁾

Hot or cold compression packs: These can help reduce pain and swelling. Alternating between the two may help.^{20, 21)}

Corticosteroid injections: A type of steroid hormone that reduces pain and swelling, these may be injected into the shoulder joint to alleviate pain.^{20, 21)}

However, repeated corticosteroid injections are discouraged as they can have adverse effects, including further damage to the shoulder.^{20, 21)}

Transcutaneous electrical nerve stimulation (TENS): This works by numbing the nerve endings in the spinal cord that control pain. The TENS machine sends small to electrodes, or small electric pads, that are applied to the skin on the affected shoulder.^{20, 21)}

Physical therapy: This can provide training in exercises to maintain as much mobility and flexibility as possible without straining the shoulder or causing too much pain.^{20, 21)}

Shoulder manipulation: The shoulder joint is gently moved while the patient is under a general anesthetic.^{20, 21)}

Shoulder arthroscopy: A minimally invasive type of surgery used in a small percentage of cases. A small endoscope, or tube, is inserted through a small incision into the shoulder joint to remove any scar tissue or adhesions.^{20, 21)}

Blood Flow Is Essential Healing for Frozen Shoulder: Need to promote healthy blood flow to the frozen shoulder joint. Blood Flow Stimulation Therapy (BFST) gives Frozen Shoulder the nutrient-rich, oxygenated blood flow it needs to heal quickly and completely.^{33, 36)}

Additional blood flow is exactly what Frozen Shoulder needs to start moving again. Unfortunately, since the shoulder is unable to move, it will have very limited blood flow. While physical activity promotes blood flow, this could make condition worse.^{22, 35)}

Cupping is placing glass, bamboo or plastic jars on the skin and creating a vacuum by suctioning out the air. The underlying tissue is raised, or sucked, partway into the cup. Treatment usually feels tight sensation in the area of the cup. Often, this sensation is relaxing and soothing. Cups may be moved around or left in place. They may remain on the body briefly or for longer amounts of time. It is similar but inverse of massage. Rather than applying pressure to muscles, the suction cup uses pressure to pull skin, tissue and muscles upward. It was developed thousands of years ago and though the techniques have modernized, the original philosophy remains the same.^{38, 43)}

Cupping helps balance yin and yang or the negative and positive within the body. Restoring balance between these two extremes is thought to help with the body's resistance to pathogens as well as its ability to increase blood circulation to the area where the cups are placed. This may relieve muscle tension, which can improve overall

blood flow and promote cell repair. It may also help form new connective tissues and create new blood vessels in the tissue. ^{8, 23)}

Cupping causes the skin to temporarily turn red, blue or purple, especially if there is an injury or energetic blockage under the area that was cupped. The skin discoloration can last anywhere from a few hours to a couple of weeks, but is rarely painful. Once the marks have cleared, the procedure can be repeated until the condition or ailment is resolved. ^{14, 27)}

The purpose of cupping is to enhance circulation, help relieve pain, remove "heat" and pull out the toxins that linger in body's tissues. Cupping has numerous benefits that can help remove toxins from the body and stimulate the flow of fresh blood, lymph, and Qi to the affected area and throughout the body. It often works wonders for patients with the flu, colds, coughs, back and muscle pain, poor circulation, anxiety, red itchy skin conditions (though cups are not applied to inflamed areas), allergies, fevers, aches and myriad other pains. ^{2, 6)}

There are a number of methods of cupping. The two most common cupping treatments are "fixed cupping" and "moving cupping."

* Fixed Cupping:

The cups are placed on a selected area of your body and then left in place without being moved.

* Moving Cupping:

As the name implies, use massage oil or cream on the skin in selected places, puts the cups over the areas to be treated and then slides them around that region of the

body(most commonly the back and shoulder). The cups slide easily because the oil or cream has lubricated skin of the body. ^{2,8)}

Cupping is fairly safe, but should be noted that not be used on patients who bleed easily and/or cannot stop bleeding, have skin ulcers, sunburn, wound, internal organ disorder and experienced recent trauma. It is unwise to cup over large blood vessels as well. Pregnant women should be cupped with extreme caution and never on their abdomen or lower back. Cupping could have side effects in the area where the cups applied on skin can cause mild discomfort, burns, bruises and skin infection. ^{6, 13)}

In this study participants aged between 35 years old to 75 years old who has shoulder pain diagnosed from damp Bi-syndrom on shoulder and qi & blood stagnation will be randomly separates to two groups of Group A and Group B. Group A will get treatment of only Acupuncture and Group B will only have treatment of Moving Cupping. Acupuncture is a non-drug therapy being used more and more to treat shoulder pain. It is thought that acupuncture works either by releasing chemical compounds in the body that relieve pain, by overriding pain signals in the nerves or by allowing energy (Qi) or blood to flow freely through the body.

An electro-acupuncture (EA) may be used to the points [SJ-14 (Jian Liao), LI-15 (Jian Yu)], [LI-16 (Ju Gu) and GB-21 (Jian Jing)], improve frozen shoulder by delivering electric stimulation to the local muscle that relate and joints the shoulder, which are responsible for movements of the shoulder. The other acupuncture points LI-4 (He Gu), LI-11 (Qu Chi), SJ-5 (Wai Guan), ST-38 (Tiao Kou), SP-9 (Yin Ling Quan), SP-6 (San Yin Jiao) and ST-40 (Feng Long) are correspond to the most common basic eastern diagnosis of damp Bi -syndrome on shoulder, Qi & Blood stagnation . ^{13, 32)}

OBJECTIVES

The purpose of this study is to investigate the effectiveness of moving cupping during treatment of shoulder pain and to investigate acupuncture points using for acupuncture treatment.

It is aimed to confirm effectiveness of cupping and acupuncture treatment.

The objectives of this study are as follows:

1. Determine whether moving cupping and acupuncture reduces the pain and increases of ROM in middle-aged and older adults shoulder pain.
2. Evaluate the effectiveness of moving cupping and acupuncture on reduces the pain and increases ROM that influences the quality of living.
3. Compare the non-inferior effect of moving cupping treatment vs. acupuncture treatment.

II. MATERIALS AND METHODS

1. Study Design

This study was designed as pilot scale randomized controlled trial to investigate the non-inferiority of moving cupping to acupuncture treatment on shoulder pain in middle aged and elderly participants. As shown in Figure 1, a total of 20 participants were randomly assigned to two groups on a 1:1 ratio by using random number generator of IBM SPSS Statistics software V22. The group A (n=10) was received acupuncture treatment at SJ-14 (Jian Liao), LI-15 (Jian Yu), LI-16 (Ju Gu), GB-21 (Jian Jing), LI-4 (He Gu), LI-11 (Qu Chi), SJ-5 (Wai Guan), ST-38 (Tiao Kou), SP-9 (Yin Ling Quan), SP-6 (San Yin Jiao), ST-40 (Feng Long). The group B (n=10) was received only moving cupping treatment. Participants of both Group A and Group B had treatment sessions twice a week for 2 weeks that was total of 4 treatments for each participant. (Fig. 1) The goal treatment for this clinical trial was to have participants to reach the NPS (Numeric Pain Scale) levels to lower than 3 (1 to 10 scales of NPS) and increases of the ROM to 85% and higher.

2. Participants

Participants were patients at the CS Acupuncture & Wellness Clinic in Anaheim who volunteer to be screened for eligibility and participate in the research. For inclusion in the study, they were must fulfill the following criteria: (1) at least 35 years of age and younger than 75 years of age; (2) shoulder pain that has a limited range of motion; (3) not taking medication to treat shoulder pain or that which may affect shoulder pain; (4) no

history of any relate to shoulder surgery; and (5) no serious cognitive or mental disorders. Exclusions criteria :(1) during or progress of plan pregnancy; (2) serious other illness may effect treatment of clinical trial.

In total of 20 participants human races were 13 Latino, 7 Asians comes to 65% Latino and 35% Asians. By randomly separated to 1:1 ratio of two groups in Group A had 6 Latino, 4 Asian comes to 60% Latino, 40% Asian and Group B had 7 Latino, 3 Asian comes to 70% Latino, 30% Asian. (Table 1) Gender and Ages of total 20 participants are shown in Table 2.

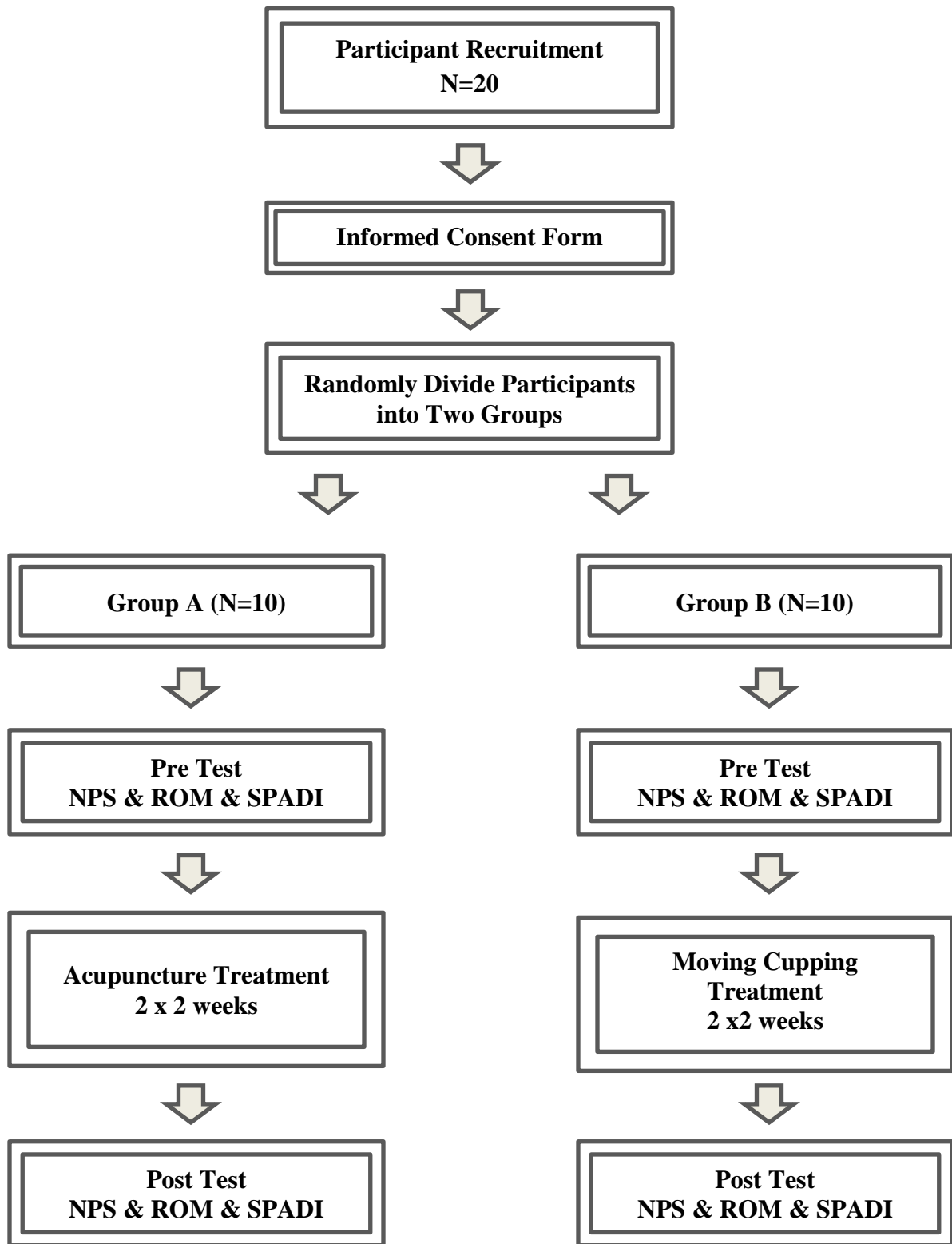


Figure 1. Schematic Diagram of Research Design

Table 1. Distribution by Gender and Age

Age Group	Group A		Group B		Total
	Female	Male	Female	Male	
35 - 40	4	1	3	2	10
41 - 45	2	0	0	0	2
46 - 50	0	0	0	1	1
51 - 55	0	1	2	0	3
56 - 60	0	0	0	0	0
61 - 65	0	0	1	0	1
66 - 70	2	0	0	0	2
71 - 75	0	0	1	0	1
Total	8	2	7	3	20

Table 2. Distribution by Ethnicity

Ethnicity	Group A		Group B	
	N	%	N	%
Latino	6	60	7	70
Asian	4	40	3	30

3. Acupuncture Protocol

(1) Point Location

The selected acupuncture points were determined according to the proportional *cun* measurement system. The locations, functions and needling method of SJ-14 (Jian Liao), LI-15 (Jian Yu), LI-16 (Ju Gu), GB-21 (Jian Jing), LI-4 (He Gu), LI-11 (Qu Chi), SJ-5 (Wai Guan), ST-38 (Tiao Kou), SP-9 (Yin Ling Quan), SP-6 (San Yin Jiao) and ST-40 (Feng Long) are on Table 3. For the Group B were received treatment of moving cupping on areas of back from shoulder around (LI-16 (Ju Gu), GB-21 (Jian Jing)), scapular area and following spine (C7 to T7) on UB line. (Fig. 2)

(2) Intervention

0.25 × 40mm Dong Bang (DBC plus) needles used for treatment of all acupuncture. All needles are stainless steel filiform needles that have been sterilized by gamma irradiation.

The depth of needle insertion was as in needling method on Table 3. Once inserted, the needle was manipulated to elicit a *deqi* response from the participant.

Insertion of needles was about 20minutes. (Table 3)

Moving Cupping was used standard diameter 2.0 inch plastic suction cup and hand held vacuum pump was used for suction the air out of the cup. Suctioning air out of cup was varies one to two pumps. Each Moving Cupping was moves on directions up to 10 times for 5 times. The total Moving Cupping treatment was took approximately 20 minutes. (Fig. 2)

Table 3. Acupuncture Points Used for the Treatment of Shoulder Pain.^{1, 9)}

POINT	LOCATION	FUNCTIONS	NEEDLING METHOD
SJ-14 (Jian Liao)	On the shoulder, posterior to LI-15 (Jianyu), in the depression inferior and posterior to the acromion when the arm is abducted.	1. Dispels wind and damp (in channel/joint; arthritis in shoulder, shoulder impairment). 2. Invigorates Qi, Blood and relieves pain (for shoulder trauma, arthritis, Bi disease, rotator cuff).	Perpendicularly 0.5 – 0.7 cun
LI-15 (Jian Yu)	Antero-inferior to the acromion, on the upper portion of m. deltoideus. When the arm is in full abduction, the point is in the depression appearing at the anterior border of the acromioclavicular joint.	1. Courses/Moves wind and quickens/dredges the connecting vessels. 2. Benefits the joint, especially shoulder. 3. Dispels pathogens and resolves heat (swollen painful joints, scrofula-TB of lymph nodes).	Perpendicularly or Obliquely 0.8 – 1.5 cun
LI-16 (Ju Gu)	In the upper aspect of the shoulder, in the depression between the acromial extremity of the clavicle and the scapular spine.	Courses channel and connecting Vessels	Perpendicularly 0.5 – 0.7 cun
GB-21 (Jian Jing)	On the shoulder, directly above the nipple, at the midpoint of the line connecting DU-14 (Dazhui) and the acromion, at the highest point of the shoulder.	1. Clears and invigorates channel (relieves stiffness of neck, shoulders, upper back, difficulty turning neck). 2. Dissolves phlegm (swollen nodes around neck, scrofula, masses in breast, fibrous masses). 3. Promotes lactation, promotes labor (relieves placenta).	Perpendicularly 0.3 – 0.5 cun
LI-4 (He Gu)	On the dorsum of the hand, between the 1 st and 2 nd metacarpal bones, approximately in the middle of the 2 nd metacarpal bone on the radial side.	1. Disperses wind, resolves exterior and regulates surface for sweating or stop sweating (beginning of cold and later stages if heat in lungs). 2. Free channel and connection vessels. 3. Relieves pain and calms spirit (antispasmodic). 4. Clear Lung heat.	Perpendicularly 0.5 -1.0 cun
LI-11 (Qu Chi)	Elbow flexed, the point is in the depression at the lateral end of the transverse cubital crease, midway between LU-5 (Chize) and the lateral	1. Eliminate wind and exterior condition. 2. Cools pathogenic heat (internal and external) 3. Opens up the joints (pain in elbow/arm; facial paralysis).	Perpendicularly 1.0 – 1.5 cun

	epicondyle of the humerus.	4. Resolves dampness (skin rashes, damp heat in skin). 5. Regulates the blood flow (hypertension).	
SJ-5 (Wai Guan)	2 cun proximal to the dorsal crease of the wrist, on the line connecting SJ-4 (Yangchi) and the tip of olecranon, between the radius and ulna.	1. Dissipates wind and resolves exterior (raises sweat, reduce inflammation). 2. Moves Qi in channel (pain in arm, wrist joint, one-sided headache, migraine). 3. Regulates Shao Yang (alternating chills and fever, nausea, vomiting).	Perpendicularly 0.5 - 1.0 cun
ST-38 (Tiao Kou)	5 cun inferior to ST-36 (Zu San Li), one finger width lateral to the anterior crest of the tibia	1. Relaxes muscles and tendons. 2. Warms channels and dissipates cold.	Perpendicularly 0.5 – 1.0 cun
SP-9 (Yin Ling Quan)	On the lower border of the medial condyle of the tibia, in the depression posterior and inferior to the medial condyle of the tibia.	1. Benefits the lower jiao and transforms damp (candida). 2. Benefits urination. 3. Dispels wind cold in channel (in knee and lower leg). * For Dampness in the body.	Perpendicularly 0.5 – 1.0 cun
SP-6 (San Yin Jiao)	3 cun directly above the tip of the medial malleolus, posterior to the medial border of the tibia.	1. Strengthens Spleen and transforms damp. 2. Spreads Liver Qi (abdominal pain, dysmenorrhea). 3. Benefits the Kidney (Yin deficiency – night sweats, 5 center heat, nocturnal emissions); supports and tones blood.	Perpendicularly 0.5 – 1.0 cun
ST-40 (Feng Long)	8 cun superior to the tip of the external malleolus, lateral to ST-38 (Tiaokou) about two finger-breadth lateral to the anterior border of the tibia.	1. Transforms phlegm and dampness (includes nodules);(Phlegm in channels-numbness; Phlegm in joints – arthritis; Phlegm on organs – stones). 2. Calm the spirit (anxiety, fear due to phlegm). 3. Harmonizes the Stomach (vertigo, dizziness, knot in ST) * The phlegm point.	Perpendicularly 0.5 – 1.0 cun



(Example of Normal Cupping)



(Example of Moving Cupping)

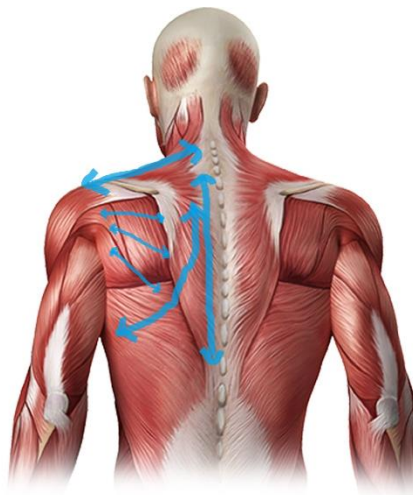


Figure 2. Moving Cupping Used for the Treatment of Shoulder Pain.^{20, 22)}

4. Treatment scale measurement

In this clinical trial study used three different types of Treatment scale measurement that is NPS (Numeric Pain Scale), ROM (Range Of Motion) and SPADI (Shoulder Pain and Disability Index). Each measurement has been taken Pre- Treatment and Post- Treatment.

(1) NPS (Numeric Pain Scale)

NPS scores for stiffness of shoulders were given on scales of 1 to 10 on horizontal line, where left was 0 and indicated no feeling, and right was 10 and indicated most strong pain. NPS has been evaluated Pre (Before) and Post (After) each Treatment. (Fig. 3)

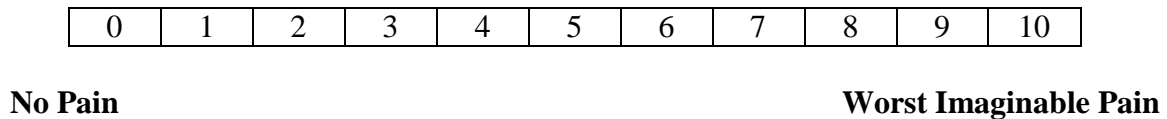


Figure 3. NPS (Numeric Pain Scale) Diagram

(2) ROM (Range Of Motion)

ROM has been measured Pre (Before) and Post (After) each Treatment and Goniometer was used to measure “Range Of Motion”. A normal range of motion is Flexion (180°), Extension (50°), Abduction (180°) and Adduction (50°). (Table 4)

Table 4. ROM (Range Of Motion) Chart

ROM	Flexion	Extension	Abduction	Adduction
Normal Degree	180°	50°	180°	50°
Patient				

(3) SPADI (Shoulder Pain and Disability Index)

SPADI has 13 questions that each on scales of 1 to 10, where 0 indicate no pain and 10 indicate most strong pain. SPADI was evaluated Pre (Before), Post (After) of each Treatment and all 13 questions to calculate the average to used. (Table 5)

Table 5. SPADI (Shoulder Pain and Disability Index) Chart

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10
Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds?	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

5. Statistical Analysis

IBM SPSS Statistics software V22 was used for data analysis. Mean and descriptive statistics (means \pm standard deviation) were calculated for all parameters.

Depending on the results of normality test, statistical methods between parametric and non-parametric analysis were determined. Paired t-test and Independent t-test were performed for the mean change within-group and mean difference between-groups for parametric variables, respectively, and Wilcoxon Signed Rank test and Mann Whitney U-test for non-parametric variables, respectively. From the dichotomous value, the treatment effect on group A over group B was calculated using 2X2 Table (Table 6) and following equation;

Table 6. 2X2 Table to Analyze the Treatment Effect of Acupuncture on Various Clinical Conditions

	Pain (NPS>3)	No Pain (NPS \leq 3)	Total
Acupuncture (Group A)	a	b	a+b
Moving Cupping (Group B)	c	d	c+d
Total	a+c	b+d	a+b+c+d

$$\text{Risk Ratio (RR)} = (\text{Group B Risk})/(\text{Group A Risk})$$

$$\text{Risk Reduction in Group B} = 1-(c/c+d)$$

Risk Reduction in Group A = $1 - (a/a+b)$

Odds Ratio (OR) = $(a \times d) \div (b \times c) = 1$

6. Determination of non-inferiority of Moving Cupping to Acupuncture

The non-inferiority of Moving Cupping to Acupuncture was determined by employing the method of da Silva with the following equation:

$$(1) \quad Z = \frac{(P_M - P_A + \delta)}{\sqrt{\frac{P_M(1-P_M)}{n_M} + \frac{P_A(1-P_A)}{n_A}}}$$

$$(2) \quad LB = P_M - P_A - Z_{1-\alpha} \sqrt{\frac{P_M(1-P)}{n_M}}$$

7. Ethics

This study was conducted in accordance with the Declaration of Helsinki. This study was conducted after getting approval from the Institutional Review Board of South Baylo University on DEC, 30, 2018.

III. RESULTS

Subjects

Total 20 shoulder pain participants (age range, 35-75 years) diagnosed damp Bi-syndrom on shoulder and qi & blood stagnation participated in were recruited to participate in this study. The ethnicity of participants was composed of 13 Latino (65%) and 7 Asians (35%). Participants were randomly divided into two groups of “Group A” and “Group B”. After randomization, Group A has 6(60%) Latino, 4(40%) Asian and Group B has 7(70%) Latino, 3(30%) Asian respectively.

Gender and Ages of the total 20 participants are shown in Table 2. (Table. 2)

Only Acupuncture treatment was applied to the participants in Group A and only Moving Cupping was employed to the participants in Group B in total of 20 participants.

Outcomes

1. Effect of NPS (Numeric Pain Scale)
 - (1) Treatment rate in NPS based on Dichotomous Data

Table 7. Treatment rate in NPS (Numeric Pain Scale)

	Pain (NPS>3)	No Pain (NPS≤3)	Total
Acupuncture (Group A)	1	9	10
Moving Cupping (Group B)	1	9	10
Total	2	18	20

Risk Ratio (RR) = (Group 2 Risk)/(Group 1 Risk) = $1/10 \div 1/10 = 1$

Risk Reduction in Moving Cupping Group = $9/10 = 90\%$

Risk Reduction in Acupuncture Group = $9/10 = 90\%$

- The risk of having pain with moving cupping treatment was the same as the risk in the Acupuncture group.

Based on table above risk ratio (RR) in Acupuncture group (Group A) after 4th treatment was calculated as 10% which same outcome as the ratio in Moving Cupping (Group B) was 10% after 4th treatments. Therefore the relative risk ratio (RR) was determined as 1.0.

$$\text{Odds Ratio (OR)} = (1 \times 9) \div (9 \times 1) = 1$$

(2) Treatment rate in NPS based on Continuous Data

Table 8. Mean and stand deviation of treatment in Groups

NPS	Mean	SD	N
Acupuncture (Group A)	3.9	1.5	10
Moving Cupping (Group B)	4.9	1.9	10

As shown table 8 above the Mean difference of treatment in Acupuncture group (Group A) was 3.9 ± 1.5 ($p < 0.05$), where the Mean difference in Moving Cupping group (Group B) was 4.9 ± 1.9 ($p < 0.05$). The effect on Mean difference of NPS (Numeric Pain Scale) in Moving Cupping (Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups.

(3) Effect of treatment on effect size

Effect size (Standardized Mean Difference)

$SMD = (\text{mean of moving cupping group} - \text{mean of Acupuncture group}) \div (\text{pooled standard deviation of both groups})$

$$SMD = (4.9 - 3.9) \div 1.8 = 0.56$$

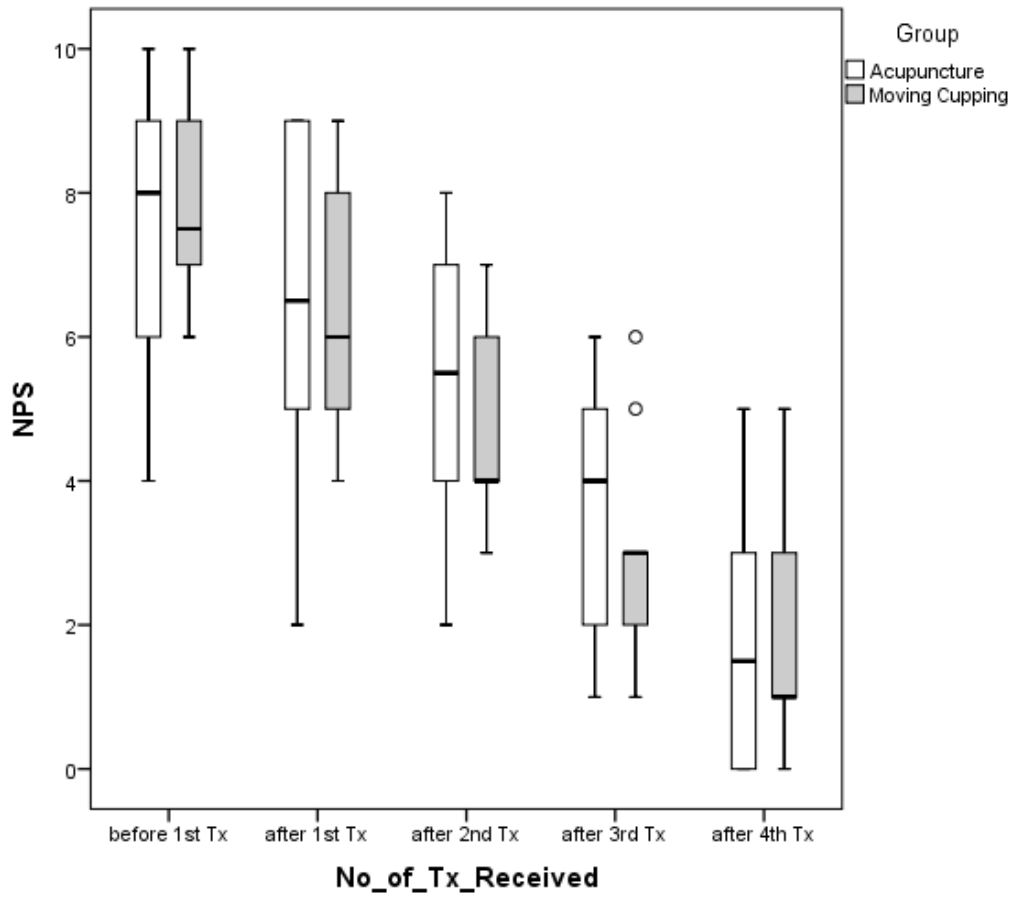
Table 9. Effect size in Descriptors for magnitudes of $d = 0.01$ to 2.0

Effect size	D	Reference
Very small	0.01	Sawilowsky, 2009
Small	0.20	Cohen, 1988
Medium	0.50	Cohen, 1988
Large	0.80	Cohen, 1988
Very large	1.20	Sawilowsky, 2009
Huge	2.0	Sawilowsky, 2009

Cf. Cohen's d - Effect size ²⁵⁾

The effect size was calculated as 0.56 in according to the following above equation and based on descriptors for magnitudes chart above the effect size was determined as Medium in reference of Cohen 1988.

Table 10. NPS (Numeric Pain Scale) – Boxplot Graph



To see the prognosis of NPS (Numeric Pain Scale) as shown table 10 above the boxplot graph clearly show that between the group A and group B NPS (Numeric Pain Scale) outcome is not to see the non-inferiority.

2. Effect of SPADI (Shoulder Pain and Disability Index)

(1) Treatment rate in SPADI (Shoulder Pain and Disability Index)

Table 11. Mean and stand deviation of SPADI treatment in Groups

SPADI	1 st Treatment		2 nd Treatment		3 rd Treatment		4 th Treatment	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Acupuncture (Group A)	9.1	7.6	8.8	4.3	6.5	4.2	8.3	4.1
Moving Cupping (Group B)	12.0	8.0	10.0	5.0	8.0	4.0	8.0	5.0

As shown table 11 the 1st treatment effect mean of Acupuncture group (Group A) was 9.1 ± 7.6 ($p < 0.05$), where the effect of Mean difference in Moving Cupping group (Group B) was 12.0 ± 8.0 ($p < 0.05$), 2nd treatment effect mean of Acupuncture group (Group A) was 8.8 ± 4.3 ($p < 0.05$), where the effect of Mean difference in Moving Cupping group (Group B) was 10.0 ± 5.0 ($p < 0.05$), 3rd treatment effect mean of Acupuncture group (Group A) was 6.5 ± 4.2 ($p < 0.05$), where the effect of Mean difference in Moving Cupping group (Group B) was 8.0 ± 4.0 ($p < 0.05$) and 4th treatment effect mean of Acupuncture group (Group A) was 8.3 ± 4.1 ($p < 0.05$), where the effect of Mean difference in Moving Cupping group (Group B) was 8.0 ± 5.0 ($p < 0.05$). The effect on Mean difference of SPADI (Shoulder Pain and Disability Index) in Moving Cupping

(Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups.

3. Effect of ROM (Range Of Motion)

Table 12. Mean change and stand deviation of ROM measurements in Groups

ROM	1 st Treatment	2 nd Treatment	3 rd Treatment	4 th Treatment	Total Treatment
Acupuncture (Group A)	F : 6.0 ± 6.0	F : 5.0 ± 6.0	F : 2.0 ± 3.0	F : 3.0 ± 3.0	F : 26.0 ± 6.0
	E : 7.0 ± 13.0	E : 5.0 ± 8.0	E : 1.0 ± 7.0	E : 5.0 ± 5.0	E : 6.0 ± 4.0
	Ab : 3.0 ± 5.0	Ab : 6.0 ± 7.0	Ab : 3.0 ± 3.0	Ab : 4.0 ± 4.0	Ab : 30.0 ± 9.0
	Ad : 0.0 ± 8.0	Ad : 6.0 ± 7.0	Ad : 1.0 ± 6.0	Ad : 1.0 ± 6.0	Ad : 6.0 ± 3.0
Moving Cupping (Group B)	F : 15.0 ± 8.0	F : 9.0 ± 5.0	F : 6.0 ± 4.0	F : 4.0 ± 5.0	F : 32.0 ± 13.0
	E : 8.0 ± 8.0	E : 8.0 ± 4.0	E : 4.0 ± 5.0	E : 5.0 ± 5.0	E : 5.0 ± 3.0
	Ab : 12.0 ± 11.0	Ab : 7.0 ± 6.0	Ab : 4.0 ± 4.0	Ab : 4.0 ± 4.0	Ab : 29.0 ± 14.0
	Ad : 8.0 ± 10.0	Ad : 4.0 ± 5.0	Ad : 7.0 ± 8.0	Ad : 4.0 ± 7.0	Ad : 5.0 ± 3.0

As shown table above the 1st treatment ROM effect mean of Acupuncture group (Group A) was F : 6.0 ± 6.0 (p<0.05), E : 7.0 ± 13.0 (p<0.05), Ab : 3.0 ± 5.0 (p<0.05), Ad : 0.0 ± 8.0 (p<0.05), where the effect of ROM Mean difference in Moving Cupping group (Group B) was F : 15.0 ± 8.0 (p<0.05), E : 8.0 ± 8.0 (p<0.05), Ab : 12.0 ± 11.0 (p<0.05), Ad : 8.0 ± 10.0 (p<0.05), 2nd treatment ROM effect mean of Acupuncture group (Group A) was F : 5.0 ± 6.0 (p<0.05), E : 5.0 ± 8.0 (p<0.05), Ab : 6.0 ± 7.0

($p < 0.05$), Ad : 6.0 ± 7.0 ($p < 0.05$), where the effect of ROM Mean difference in Moving Cupping group (Group B) was F : 9.0 ± 5.0 ($p < 0.05$), E : 8.0 ± 4.0 ($p < 0.05$), Ab : 7.0 ± 6.0 ($p < 0.05$), Ad : 4.0 ± 5.0 ($p < 0.05$), 3rd treatment ROM effect mean of Acupuncture group (Group A) was F : 2.0 ± 3.0 ($p < 0.05$), E : 1.0 ± 7.0 ($p < 0.05$), Ab : 3.0 ± 3.0 ($p < 0.05$), Ad : 1.0 ± 6.0 ($p < 0.05$), where the effect of ROM Mean difference in Moving Cupping group (Group B) was F : 6.0 ± 4.0 ($p < 0.05$), E : 4.0 ± 5.0 ($p < 0.05$), Ab : 4.0 ± 4.0 ($p < 0.05$), Ad : 7.0 ± 8.0 ($p < 0.05$) and 4th ROM treatment effect mean of Acupuncture group (Group A) was F : 3.0 ± 3.0 ($p < 0.05$), E : 5.0 ± 5.0 ($p < 0.05$), Ab : 4.0 ± 4.0 ($p < 0.05$), Ad : 1.0 ± 6.0 ($p < 0.05$), where the effect of ROM Mean difference in Moving Cupping group (Group B) was F : 4.0 ± 5.0 ($p < 0.05$), E : 5.0 ± 5.0 ($p < 0.05$), Ab : 4.0 ± 4.0 ($p < 0.05$), Ad : 4.0 ± 7.0 ($p < 0.05$). Total treatment ROM effect mean of Acupuncture group (Group A) was F : 26.0 ± 6.0 ($p < 0.05$), E : 6.0 ± 4.0 ($p < 0.05$), Ab : 30.0 ± 9.0 ($p < 0.05$), Ad : 6.0 ± 3.0 ($p < 0.05$), where the effect of ROM Mean difference in Moving Cupping group (Group B) was F : 32.0 ± 13.0 ($p < 0.05$), E : 5.0 ± 3.0 ($p < 0.05$), Ab : 29.0 ± 14.0 ($p < 0.05$), Ad : 5.0 ± 3.0 ($p < 0.05$). The effect on Mean difference of ROM (Range Of Motion) in Moving Cupping (Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups.

4. Determination of non-inferiority of Moving Cupping to Acupuncture

The results of determination of non-inferiority of Moving Cupping to Acupuncture is shown by the following equation.

$$\begin{aligned}
(1) Z &= \frac{(P_M - P_A + \delta)}{\sqrt{\frac{P_M(1-P_M)}{n_M} + \frac{P_A(1-P_A)}{n_A}}} \\
&= \frac{0.2}{\sqrt{\frac{0.9 \times 0.1}{10} + \frac{0.9 \times 0.1}{10}}} \\
&= \frac{0.2}{\sqrt{\frac{0.18}{10}}} \\
&= \frac{0.2}{\sqrt{0.018}}
\end{aligned}$$

$$Z = 1.49$$

$$\begin{aligned}
(2) \text{LB} &= P_M - P_A - Z_{1-\alpha} \sqrt{\frac{P_M(1-P)}{n_M}} \\
&= 0.9 - 0.9 - Z_{1-0.5} \sqrt{0.018} \\
&= -Z_{0.95} \times 0.134 \\
&= -1.64485 \times 0.134 \\
&= -0.22068
\end{aligned}$$

IV. DISCUSSION

Shoulder pain causes severe discomfort and reduces the ability to work. It's origin is multifactorial and not always clear. There are no universally accepted guidelines for the conventional treatment of shoulder pain. The primary aim of this clinical research study was to determine whether moving cupping only treatment is effective enough to control the shoulder pain compare to acupuncture only treatment. In this study randomly selected ages between 35 years of age and younger than 75 years of age who has shoulder pain that has a limited range of motion, not taking medication to treat shoulder pain or that which may affect shoulder pain, no history of any relate to shoulder surgery and no serious cognitive or mental disorders.

About the Mean difference of treatment in Acupuncture group (Group A) was 3.9 ± 1.5 ($p < 0.05$), where the Mean difference in Moving Cupping group (Group B) was 4.9 ± 1.9 ($p < 0.05$). The effect on Mean difference of NPS (Numeric Pain Scale) in Moving Cupping (Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups.

About the Total treatment effect on Mean difference of SPADI (Shoulder Pain and Disability Index) in Moving Cupping (Group B) was 32.7 ± 12.6 ($p < 0.05$) and slightly higher than the Acupuncture group (Group A) 37.7 ± 14.7 ($p < 0.05$). But, there was no statistical significant difference between two groups.

About the ROM (Range Of Motion) in Moving Cupping (Group B) was slightly higher effect in first two treatments but, again in total there were no significant differences compare with Acupuncture group (Group A).

SPADI index, generally about both groups of control and acupuncture, they had an improvement after treatment but in the acupunctured group the amount of this reduction was higher, but there was no meaningful difference between acupunctured and control group about this item.

The study results showed that total treatments of Moving Cupping (Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups.

The total outcome of results clearly shows that non-inferiority was expected but in result of Lower Bound was -0.22068 and it is slightly lower than results expected so, in power it cannot be non-inferiority.

This clinical research was non-inferiority fail because of there was low number (20 total in two groups of Group A and Group B for 1:1 ratio) of participants. If there was more participants in this clinical trial than Moving Cupping could be equivalent or non-inferior modality compare to Acupuncture. Moving cupping only treatment has significant similarity effect on shoulder pain compare with Acupuncture only treatment.

V. CONCLUSION

Twenty selected “Shoulder Pain” patients aged between 35 years to 75 years old randomly divided into 1:1 ratio of two groups in Acupuncture only group (Group A) and Moving Cupping only group (Group B) has been treated for total of 4 treatments and found these outcome of results.

1. The results of NPS (Numeric Pain Scale) clearly show that within the group every treatment has effect but between the groups Moving Cupping (Group B) was slightly higher than the Acupuncture group (Group A). However there was no statistical significant difference between two groups. The results of determination of non-inferiority of Moving Cupping to Acupuncture was $Z = 1.49$ and $LB = -0.22$. Relative risk ratio (RR) was determined as 1.0 and Odds Ratio (OR) was 1.0.
2. Total treatment effect on Mean difference of SPADI (Shoulder Pain and Disability Index) in Moving Cupping (Group B) was 32.7 ± 12.6 ($p < 0.05$) and slightly higher than the Acupuncture group (Group A) 37.7 ± 14.7 ($p < 0.05$). But, there was no statistical significant difference between two groups.
3. ROM (Range Of Motion) in Moving Cupping (Group B) was slightly higher effect in first two treatments but, in total there are no significant differences compare with Acupuncture group (Group A).

4. In this clinical research was non-inferiority fail because of there was low number (20 in total) of participants. If there was more participants than Moving Cupping could be equivalent or non-inferior modality compare to Acupuncture.

5. Moving cupping only treatment has non-inferior or equivalent effect on shoulder pain compare with Acupuncture only treatment and look forward to see more clinical trial research with large number of participants in the future.

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APPENDIX

List of Appendix

1. Informed Consent Form
2. NPS (Numeric Pain Scale) & Shoulder ROM (Range Of Motion)
3. SPADI (Shoulder Pain and Disability Index)

APPENDIX 1

Informed Consent Form

You are invited to participate in a research study on the “Effectiveness of Moving Cupping and Acupuncture on Shoulder Pain in Middle-Aged and Older Adults”.

Total goal of this research study is to compare effectiveness of Traditional Acupuncture and moving cupping therapy on the treatment of shoulder pain.

The study design is that the participants with shoulder pain mainly, random selected in both Group A and Group B will be 1:1 ratio. Group A will get Common (Body, Traditional) acupuncture treatment for the shoulder and Group B will receive moving cupping therapy on the shoulder respectively. The treatment will be total 4 times, twice a week in total treatment of 2 weeks.

This study is being conducted by Ki Hyun 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. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. 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. There is, for example, a risk that your condition will not get better and that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The study will be conducted between Oct 2018 and Mar 2019. If you agree to take part in this study, your involvement will last approximately four weeks. You will be asked to return to the clinic four times, and each clinic visit will take approximately 40 minutes.

Acupuncture involves the insertion of a thin needle at the surface of the body and manipulation of the needle to induce a mild to moderate sensation of tingling, heaviness, numbness, distention, or electric shock. These sensations may still be present after removal of the needles. Bruising and/or tenderness may occur at the site of needle insertion.

Moving cupping involves the suction of skin at the surface of the body and Cupping causes the skin to temporarily turn red, blue or purple, especially if there is an injury or energetic blockage under the area that was cupped. The skin discoloration can last anywhere from a few hours to a couple of weeks, but is rarely painful. Cupping is fairly safe, but should be noted that not be used on participants who bleed easily and/or cannot stop bleeding, have skin ulcers, sunburn, wound, internal organ disorder and experienced recent trauma.

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. Information about you that will be collected during the research will not put away and no-one but the researchers will be able to see it. Any information about you will have a 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 Ki Hyun Choi, L.Ac.

If you have any questions about this study, please contact Ki Hyun Choi, L.Ac. at 1-714-349-1679 and drpsy7@hanmail.net. If you have more questions or concerns regarding your rights as a subject in this study, you may contact Dr. Jaejong Kim, Chair of the South Baylo University Institutional Review Board (IRB) at 1-213-738-0712 or jaejongkim621@gmail.com.

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.

Print Name of Participant _____

Signature of Participant _____

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 ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

APPENDIX 2

NPS (Numeric Pain Scale)

NPS scores for stiffness of shoulders were given on scales of 1 to 10 on horizontal line, where left was 0 and indicated no feeling, and right was 10 and indicated most strong pain.

0	1	2	3	4	5	6	7	8	9	10
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No Pain

Worst Imaginable Pain

Shoulder ROM (Range Of Motion)

Use Goniometer to measure "Range Of Motion". A normal range of motion is Flexion (180°), Extension (50°), Abduction (180°) and Adduction (50°).

ROM	Flexion	Extension	Abduction	Adduction
Normal Degree	180°	50°	180°	50°
Patient				

DATE: _____

SIGNATURE: _____

APPENDIX 3
Shoulder Pain and Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

Pain scale

How severe is your pain?

Circle the number that best describes your pain where:

0 = no pain and 10 = the worst pain imaginable

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

Disability scale

How much difficulty do you have?

Circle the number that best describes your pain where:

0 = no difficulty and 10 = so difficult it requires help

Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds?	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

DATE: _____

SIGNATURE: _____