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Original Article

Fu's subcutaneous needling versus massage for chronic non-specific low-back pain: a randomized controlled clinical trial

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Background: Chronic non-specific low back pain (NLBP) affects people of all ages and pose a serious threat to human health. Fu's subcutaneous needling (FSN) has been reported to be effective in treating such disorders, but the control group is lacking. The aim of this randomized parallel study is to compare the long-term efficiency of FSN therapy with massage therapy for treatment of NLBP.

Methods: A total of 60 chronic NLBP patients recruited from Yongchuan Hospital of Chongqing Medical University were randomly assigned to the FSN therapy group or massage therapy group. The main prognostic indicators included pain intensity measured on the visual analog scale (VAS), functional outcomes assessed by the Japanese Orthopedic Association (JOA) scoring system, functional disability estimated using Oswestry Disability Index (ODI), and quality of life evaluated by Short Form Health Survey Questionnaire (SF-36). These indicators were evaluated at baseline, post-treatment, 3 months after treatment, and 12 months after treatment.

Results: After 12 months of follow-up, we found that the 2 treatment regimens exhibited similarly favorable results in terms of all prognostic indicators in comparison with their respective baseline data (all $P<0.01$). However, compared with the massage group, the FSN group showed more significant improvements in VAS, JOA, and ODI at all follow-up time points, as well as SF-36 at post-treatment and 12 months after treatment (all $P<0.05$).

Conclusions: Our findings suggest that FSN therapy is significantly more effective than massage therapy in the improvement of pain intensity, functional outcomes, functional disability, and quality of life in a long-term follow-up. However, future studies with larger sample sizes are needed to corroborate the long-term efficiency of FSN therapy for chronic NLBP.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2100050866.

Keywords: Fu's subcutaneous needling (FSN); massage; chronic non-specific low-back pain

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Introduction

Nonspecific low back pain (NLBP) is a global health issue that affects people of almost all ages and causes deterioration of physiological function and disability (1). It is defined as pain without any specific detectable pathoanatomical cause, mainly affecting the lumbosacral area, located from the bottom of ribs to inferior gluteal fold (2,3). It has been reported that about 70–85% of people will experience NLBP at least once in their lifetime (4). Approximately 90% of NLBP patients recover within a few months of onset (5); however, about 10% of patients develop chronic NLBP, which accounts for more than 90% of the economic burden of back disability (6). Recurrence of NLBP is quite common, with the percentage of recurrent episodes ranging from 20% to 44% within 1 year and the lifetime recurrence rate reaching up to 85% (5,7). It is listed as the fifth most common reason for medical consultation in the United States which imposes a tremendous national burden (8). The direct treatment costs of NLBP are estimated to range from $12 billion to $90 billion per year in the United States (9). Similarly, the total cost of medical care for NLBP patients in the United Kingdom has doubled, increasing from about $500 in 2005 to $1,100 per patient in 2010 (10).

Chronic NLBP is difficult to cure clinically due to its unknown pathogenesis, although effective interventions are available to reduce pain, disability, and its consequences (1). These interventions are generally divided into pharmacological therapies and non-pharmacological therapies. Pharmacological therapies mainly include nonsteroidal anti-inflammatory drugs (NSAIDs) (11), opioids (12), muscle relaxants, and benzodiazepines (13), among others. While non-pharmacological therapies mainly include exercise therapy (14), physical therapy (15), radiofrequency denervation therapy (16), ultrasound therapy (17), acupuncture (18), massage (19), and so on. However, non-pharmacological therapy is emphasized more than pharmacological therapy in the treatment of chronic NLBP (1).

Massage for NLBP is popular in both eastern and western countries because of its considerable analgesic effects and few risks or adverse effects. A systematic review of 22 surveys across 6 eastern and western countries found that the percentage of adults with NLBP who visited a massage therapist within a 12-month period ranged from 0.4% to 20%, while the proportion of older adults ranged from 1.5% to 16.2% (20). Massage is considered to relieve pain symptoms and improve physiological and clinical outcomes by inducing physical and mental relaxation through rhythmic pressing and stroking of the soft tissues of the body (21). It works in a variety of ways, mainly including raising pain thresholds by releasing endorphins and closing pain gates at the spinal cord level (22).

Despite its popularity, there is still controversy regarding the efficacy of massage for chronic NLBP. Data from two studies showed that massage could improve short-term pain relief and function in patients with chronic NLBP compared to other interventions (23,24). Similarly, in the latest systematic review by Cuenca-Martínez, 24 trials were identified, comprising 3,046 patients, which focused on the efficacy of massage for sub-acute and chronic low back pain (LBP) (15). The evidence indicated that massage could improve pain and function only in the short-term. Meanwhile, van Middelkoop *et al.* (25) identified three randomized controlled trials (RCTs), involving 163 chronic NLBP patients, which showed no significant improvement in pain relief in the massage group in comparison with the control group.

Recently, Fu's subcutaneous needling (FSN) therapy has gained popularity for the management of pain-related musculoskeletal diseases (26). It was first described in 1996 by Dr. Fu, who developed the technique based on ashi point therapy and wrist-ankle acupuncture therapy (27). Since then, several clinical studies have reported the technique in knee osteoarthritis, lumbar sprain, chronic low-back pain, and scapulohumeral periarthritis (28-31). Recently, a systematic review revealed that FSN had a reliable therapeutic effect on pain-related diseases in various parts of the human body, even including some pain caused by visceral and neuropathic diseases, such as appendicitis, stomachache, dysmenorrhea, herpes zoster sequela, etc. (32). With the development of FSN, its indications have gradually expanded from an initial focus on pain-related diseases to non-pain diseases, covering 65 kind of diseases in eight major systems of the human body (33). Nevertheless, pain-related musculoskeletal disorders remain the primary indication for FSN therapy.

Dr. Fu reported that FSN therapy had a good immediate analgesic effect in the treatment of LBP, but there was a lack of follow-up results on patients (29). Lu *et al.* (34) investigated the short-term efficacy of FSN therapy in the treatment of chronic LBP and found a reliable pain relief effect; however, their study lacked a control group, functional outcomes, and long-term follow-up results. Therefore, this study was conducted for two purposes: firstly, to investigate the long-term efficiency of massage therapy and FSN therapy for treatment of chronic NLBP,

secondly, to evaluate whether FSN therapy is more effective than massage therapy in the treatment of chronic NLBP.

We present the following article in accordance with the CONSORT reporting checklist (available at https://dx.doi.org/10.21037/apm-21-2986).

Methods

Study design

A randomized parallel design clinical trial was adopted in the study, where eligible participants were randomly divided into 2 equal-sized groups, each receiving either FSN therapy or massage therapy. This study was designed following the standard protocol items for randomized interventional trials (SPIRIT) and the results were reported consistent with the consolidated standards of reporting trials (CONSORT) guidelines (35). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013) (36). The study was approved by the Human Ethics Committee of Yongchuan Hospital of Chongqing Medical University (No. 2019KLS100) and informed consent was taken from all the patients.

Participants

We recruited participants from the Orthopedic Clinic of Yongchuan Hospital of Chongqing Medical University between May 2019 and April 2020. Consecutive individuals with chronic NLBP were screened by a physiotherapist and an orthopedic specialist. The inclusion criteria were as follows: (I) met the diagnostic criteria of chronic NLBP (pain affecting the lumbosacral area and adjacent tissues, located from the bottom of ribs to inferior gluteal fold; (II) had experienced pain lasting longer than 3 months with visual analog scale (VAS) scores of at least 3; (III) no accompanying systemic diseases, such as tumors and tuberculosis; (IV) aged 18–80 years old; (V) voluntarily signed the informed consent. The exclusion criteria were as follows: (I) fear of needles; (II) history of spinal surgery; (III) known or suspected serious spinal pathology (fractures, tumors, rheumatoid arthritis, infectious diseases, ankylosing spondylitis, spinal degeneration with nerve root or cauda equina nerve damage); (IV) accompanied with serious cardiovascular or cerebrovascular diseases; (V) pregnancy; and (VI) coagulation abnormality.

The sample size calculation was based on a pilot study that compared the effects of FSN therapy (5 patients) with massage therapy (8 patients). The VAS score in 3 months was 2.143±1.569 for the FSN therapy group and 3.400±1.430 for the massage therapy group. These variances were used to calculate the sample size needed to detect a change of 1.257 in the VAS score with 80% power and 5% significance. Based on these criteria, 25 patients were needed in each group. No more than 20% of patients we predicted to be lost to follow up. Therefore, 60 patients were recruited for this study.

Randomization and masking

All eligible participants in this study were randomly divided into equally-sized FSN and massage therapy groups. Randomization was performed by a trained evaluator who was not involved in the recruitment of participants, group assignment, and treatment. The random numbers was generated in SPSS software (version 26.0; IBM Corp., Armonk, NY, USA). With regard to the assignment, each participant was given a sealed, opaque envelope that contain information on which group they belong to. Eligible and consenting participants handed the envelope to the researchers, who then passed it on to the clinician for the appropriate intervention. The clinician would then open the envelope and assign the participant to the FSN therapy group or massage therapy group. Through such a method, the researchers are blinded to the group assignment. All measurements were performed exclusively by a trained physiotherapist blinded to group allocation. Given the nature of the intervention, the clinician or the participant could not be blinded to their intervention.

Data collection and outcome measures

Clinical data of participants were collected and collated by a trained researcher. The prognostic indicators in this study mainly included 4 items: pain intensity, functional outcomes, functional disability, and quality of life. The primary endpoints of study were pain intensity, functional outcomes, and functional disability, while the secondary endpoint is quality of life. Pain intensity was measured on a 10-centimeter horizontal VAS, with 0 indicating no pain and 10 indicating the most severe pain. The validity and reliability of the data measured using the VAS was found to be highly reliable (37). Functional outcomes were evaluated according to Japanese Orthopedic Association (JOA) score rating system (38). This scoring system was originally designed to assess LBP and has since been widely used to assess functional outcomes after intervention for lumbar diseases. The JOA scoring system consists of 14 items with a maximum score of 29. The higher the score, the better the function is, whereas the lower the score, the worse the function is. Functional disability was assessed by Oswestry Disability Index (ODI) (39). The ODI scoring system consists of 10 items, each of which has a score of 0 to 5, with the total score expressed as a percentage. A higher score indicated more severe dysfunction. Quality of life was estimated using the Short Form Health Survey Questionnaire (SF-36) (40). The questionnaire consists of 36 items from 8 domains. Each domain is scored on a scale of 0 to 100, with a higher score indicating a better quality of life. The 4 prognostic indicators were evaluated at 4 time points: baseline, post-treatment, 3 months after treatment, and 12 months after treatment.

Intervention

Treatment started immediately after participants had been assigned to their treatment groups. All participants took part in 10 visits over a period of 4 weeks. During the first 2 weeks, each treatment group received 3 treatments per week, 1 day apart in principle. For the next 2 weeks, each treatment group received treatment twice a week, once every 2 days in principle. Interventions for each group are described below.

FSN therapy group

The procedures of FSN therapy were conducted strictly in accordance with the standardized manipulations proposed by Dr. Fu (41). It mainly involved 6 aspects including identifying tightened muscles (TMs), selecting the entry point, FSN manipulation, reperfusion, assessing the tension degree of tightened muscles, and assessment after interventions.

Identification of TMs

The TMs are those muscles that remain in a pathologically tense state when patients are relaxed under the condition that the central nervous system is functioning normally. The essence of the TM is the muscle containing 1 or more myofascial trigger points (MTrPs). Repeated clinical palpation reveals that a TM usually has 5 characteristics: tightness, stiffness, hardness, slipperiness, and pain. The joints associated with TMs are often weak and the range of motion is often reduced. In most cases, TMs are the most common cause of NLBP and the main targets of FSN. To locate the TMs, we should firstly identify the suspected TMs which have an anatomical relationship with the painful area; then exclude irrelevant TMs whose function is irrelevant to the action of restricting movement; and finally confirm the TMs by clinical palpation. According to our clinical experience, the suspected TMs of NLBP usually mainly include: erector spinae, quadratus lumborum, latissimus dorsi, rectus abdominis, oblique abdominis, hip muscles group, and hamstring muscles. Therapists use clinical reasoning to determine which muscles to treat at each session based on findings from the physical and historical examinations.

Selection of entry point

It is not a requirement of FSN that needles are inserted into acupoints or ashi points. Theoretically, the needles can be inserted anywhere surrounding TMs. However, two main principles should be upheld, as follows: (I) for a single small nodule, the entry point should be close to the TM. For a large-sized taut band or nodules cluster, the entry point should be far from the TM; (II) the entry point should avoid scars and hollow or prominent regions.

FSN manipulation

After disinfection of the entry point, the FSN needle is inserted into the subcutaneous layer with the help of a needle inserting device, which is held at a 15–20 degree angle to the local skin (*Figure 1*). After confirming the needle body is entirely inside the subcutaneous layer, the clinician can start the sweeping movement. The medial margin of the thumb and middle finger is used to hold the needle handle, and the tip of the thumb is fixed on the skin as the fulcrum, and then index finger and the ring finger make a repeated sweeping movement in a type of seesaw-like sector. The range of sweeping movement should be as large as possible, generally with the radian between 20° and 25° (*Figure 2*). The process of sweeping movements should be as smooth, slow, and gentle as possible in order to avoid

Figure 1 Manipulation of inserting an FSN needle. FSN, Fu's subcutaneous needling.

Figure 3 Manipulation of reperfusion. This image is published with the patient/participant's consent.

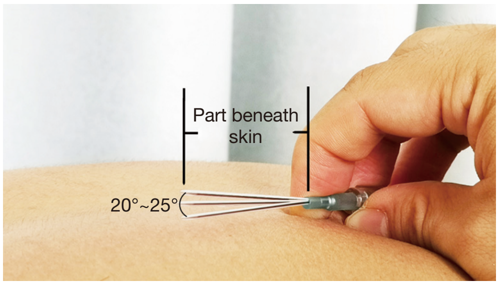

Figure 2 Sweeping movement of an FSN needle. FSN, Fu's subcutaneous needling.

sensations of numbness, swelling, and pain. The frequency of the sweeping movement is about 100 times a minute. The duration of the sweeping movement for 1 insertion point is often less than 2 minutes.

Reperfusion approach

The reperfusion approach, as a key procedure for FSN, is used to make tightened muscles contract vigorously within a short time and then relax in order to supply more blood to the ischemic part. The procedure of the reperfusion approach is that the clinician should guide the patient to achieve maximum isotonic or isometric contraction of the TMs according to the anatomy and function of the TMs (41) (*Figure 3*). It is suggested that the practitioner provides equal force back when the muscles contract. Reperfusion approach is often used during sweeping movements, and it can also be used separately for treatment of mild illnesses.

Assessing the TMs

The clinician should check and assess TMs every 30 seconds during treatment. If the TM is eliminated or the pain symptom is significantly or completely relieved, the treatment can be stopped; otherwise, it should be continued.

Cautions

There are two cautions that should be noted during the treatment of FSN.

(I) Subcutaneous bleeding

During the process of insertion or sweeping movement, the needle may injure the microcapillaries which may lead to subcutaneous bleeding. However, the bleeding usually disappears quickly without any intervention. Practitioners should explain the reasons and assuage the patient's worries and fears. If the local bleeding is serious and causes obvious local swelling and pain, practitioners should withdraw the needle immediately and apply cold compresses to arrest bleeding.

(II) Fainting

A very small number of patients may develop symptoms of needle-related fainting during the treatment. The needling manipulation should be stopped immediately when this condition occurs. The patient should be placed flat on the bed and kept warm. Generally, the patient will recover soon after taking some rest. If the patient's condition does not improve or even worsens, rescuing measures or first aid treatment should be implemented immediately.

Massage therapy group

Swedish massage is one of the most classic massage techniques, and was used in this study. It consists of five main stroking actions to stimulate the circulation of blood through the soft tissues of the body (42). Swedish massage was performed by a professional rehabilitation therapist. Participants in the massage group received the following five basic manipulations: deep stroking, pulling, friction, rolling, and wringing. Certainly, the affected muscle was identified before the manipulations were performed.

Stroking is a one-way operation on the affected muscles, from the proximal to the distal, with the whole hand in contact with the skin and gentle but firm pressure. When performing the rolling and wringing techniques, the therapists' hands were placed on the skin with fingers adducted and thumbs abducted. The thumbs and fingers of both hands were used for managing small muscles and the entirety of both hands for managing large muscles. When rolling, the index finger and thumb of the opposite hand touched each other, forming a diamond. When twisting, the fingers and thumb were squeezed together so that a roll of tissue or muscle gathered between them. The massage was performed in the direction of the muscle fibers, starting at 1 end and ending at the other until the entire area of muscle attachment was covered. Each type of massage was conducted for 3 min, and each session of the 5 massage types took 15 min for each affected muscle.

Statistical analysis

The statistical software SPSS (version 26.0; IBM Corp., Armonk, NY, USA) was used for data analysis. Continuous variables were reported as mean ± standard deviation and were assessed using Student's *t*-test analyses. Categorical variables were expressed as percentage and tested by chi-square test. The differences between groups were analyzed using analysis of variance (ANOVA) with repeated measures and least significant difference (LSD) post-hoc. The estimate values presented with 95% confidence interval (CIs) were shown in column bar graphs. A histogram was constructed using the software GraphPad Prism (GraphPad Software, La Jolla, CA, USA). Statistical significance was defined as P<0.05.

Results

Participant recruitment and flow throughout the study is shown in *Figure 4*. From May 2019 and April 2020, 102 patients who were diagnosed with chronic NLBP in the Department of Orthopedics of Yongchuan Hospital of Chongqing Medical University were recruited in this study. After careful screening, 42 patients were found not to meet the inclusion criteria. A total of 60 patients were finally enrolled in this study and randomly assigned to the massage group (n=30) or the FSN group (n=30). All patients were requested to be followed up for 12 months after treatment. However, 1 patient in each group was lost to follow-up at 12 months after treatment due to the change of telephone number.

The basic demographics of the two groups are described in detail in *Table 1*. The average age of participants in FSN group was 47.667±15.401 years, while that in the massage group was 49.233±13.279 years. The average duration of onset was 21 months in the FSN group and 24 months in the massage group. The proportion of male patients in the FSN group was 57.7%, while that in the massage group was 36.7%. There were no statistically significant differences in regard to all basic demographics between the FSN group and massage group (all P>0.05). There were no complications or adverse effects in either group.

Baseline data and follow-up results of the 4 prognostic indicators are summarized in *Table 2*. Baseline data were not statistically different between the two groups with respect to the pain intensity, functional outcomes, functional disability, and quality of life (all P>0.05). In comparison with respective baseline data, FSN therapy and massage therapy significantly improved outcomes of all 4 indicators at the 3 follow-up time points (including post-treatment, 3 months after treatment, and 12 months after treatment, all P<0.01). However, Compared with the massage group, more significant improvements were observed in the VAS, JOA, and ODI at the 3 follow-up time points and SF-36 at post-treatment and 12 months of post-treatment in the FSN group (all P<0.05). There were no adverse events or complications in either group. Comparison of the four prognostic indicators at different follow-up time points between the two groups is shown in *Figure 5*. As displayed in *Figure 5*, the scores of the 4 indicators in both the FSN group and massage group were significantly improved at different follow-up time points, but the improvement of the FSN group was significantly greater than that of the massage group.

Discussion

The aim of this study was to compare the long-term efficacy of FSN therapy with massage therapy on chronic NLBP. Compared to the respective baseline data, the follow-up results of both groups revealed significant differences in pain intensity, functional outcomes, functional disability, and quality of life in each group. Moreover, the results also showed that improvement of all prognostic indicators was significantly better in the FSN group than in the massage group.

Massage therapy has been shown by many studies to be a safe and effective treatment for chronic NLBP, but its long-

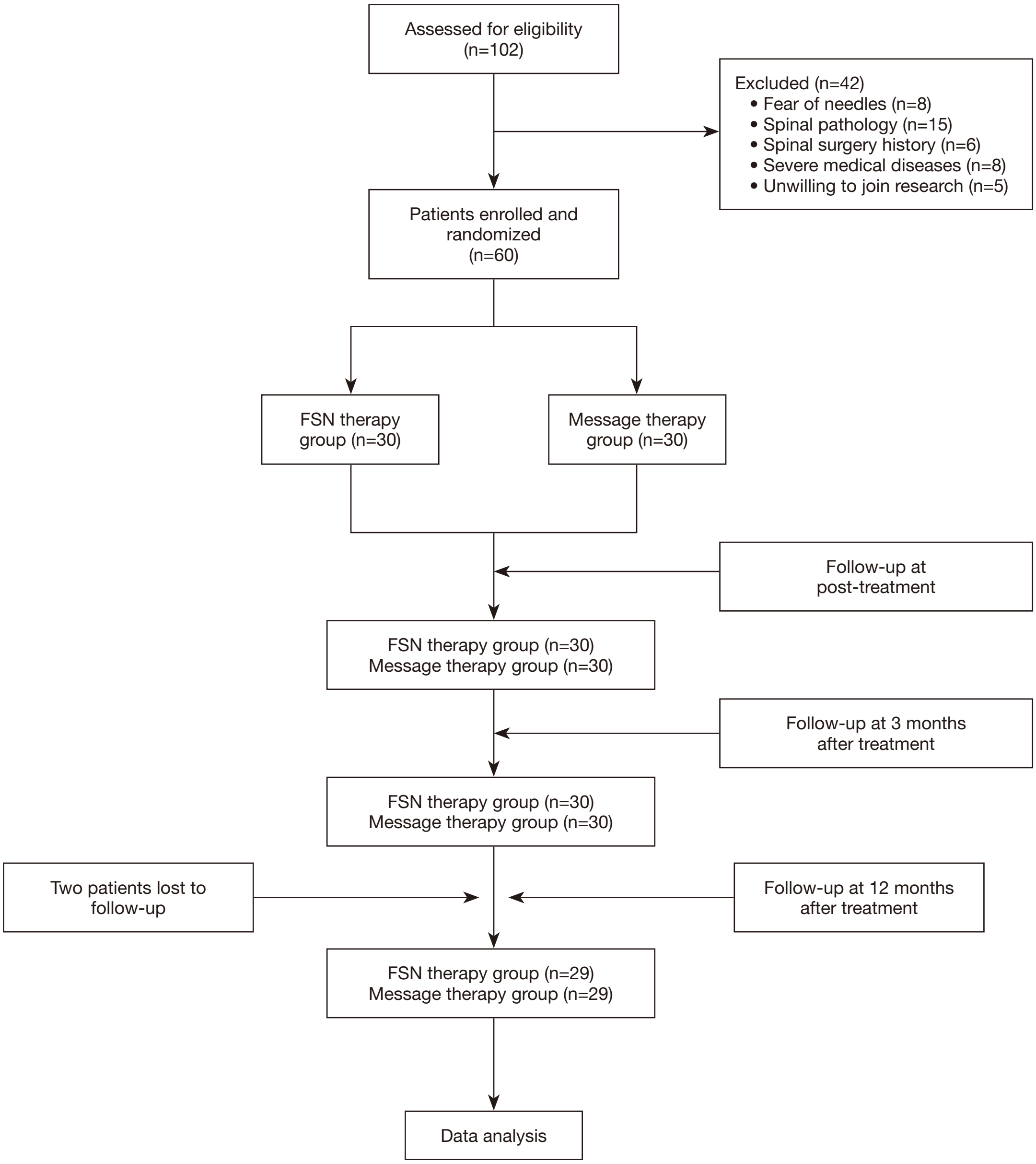

Figure 4 Flow chart of randomization of patients with chronic NLBP. FSN, Fu's subcutaneous needling; NLBP, non-specific low back pain.

Table 1 Comparison of demographic data between FSN group and massage group

Variable	FSN group (n=30)	Massage group (n=30)	$t/\chi^2/Z$	P value
Age (years)	47.667±15.401	49.233±13.279	0.422	0.675[#]
Duration of onset (months)	21 [3–60]	24 [3–72]	0.617	0.537[&]
Gender (%)			1.086	0.297[@]
Male	15 (50.0)	11 (36.7)		
Female	15 (50.0)	19 (63.3)		

[#], Student's *t*-test; [&], Mann-Whitney; [@], chi-square test. FSN, Fu's subcutaneous needling.

Table 2 Comparison of prognostic indicators (VAS, JOA, ODI, and SF-36) for chronic patients at different follow-up time points between FSN group and massage group

Variable	Group	Baseline	Post-treatment	3 months after treatment	12 months after treatment	F value	P value
ODI	FSN	34.548±10.531	7.259±7.699[a]	10.881±9.436[ab]	5.754±6.536[ac]	94.175	<0.001
	Massage	34.391±10.624	13.507±7.914[a]	17.144±10.175[ab]	12.068±9.039[ac]	49.3	<0.001
	t	0.058	–3.100	–2.472	–2.996		
	P	0.954	0.003	0.016	0.004		
VAS	FSN	5.933±1.388	1.500±1.480[a]	2.367±1.903[ab]	1.143±1.458[ac]	83.747	<0.001
	Massage	5.967±1.273	2.967±1.299[a]	3.533±1.252[ab]	2.679±1.657[abc]	45.545	<0.001
	t	–0.097	–4.079	–2.806	–3.682		
	P	0.923	0	0.007	0.001		
JOA	FSN	16.567±5.008	26.433±2.956[a]	25.000±3.639[ab]	27.179±2.019[ac]	83.383	<0.001
	Massage	16.633±4.817	24.500±3.531[a]	23.000±3.974[ab]	24.893±3.315[ac]	40.371	<0.001
	t	–0.053	2.300	2.033	3.116		
	P	0.958	0.025	0.047	0.003		
SF-36	FSN	105.167±14.648	122.633±12.252[a]	119.167±12.600[ab]	123.714±10.070[ac]	63.172	<0.001
	Massage	104.033±9.782	116.233±8.924[a]	114.100±9.546[ab]	117.25±10.316[ac]	46.078	<0.001
	t	0.352	2.313	1.756	2.373		
	P	0.726	0.024	0.084	0.021		

F, ANOVA with repeated measures; t, Student's *t*-test; differences of intra-group using LSD post hoc. "[a]" stands for data comparison with baseline "[b]" stands for data comparison with post-treatment; "[c]" stands for data comparison with 3 months after treatment. There was statistically significant difference for inter-groups data at different follow-up time points. FSN, Fu's subcutaneous needling; ODI, Oswestry Disability Index; VAS, visual analogue scale; JOA, Japanese Orthopedic Association Scores system; SF-36, Short Form Health Survey Questionnaire.

term efficacy is still controversial (15,23-25). The results of the current study support the long-term efficacy of massage in treating chronic NLBP, which can certainly increase the confidence of massage therapists in the treatment of these disorders.

Massage therapy is promising in treating chronic NLBP due to its non-invasiveness and few adverse effects, but its exact mechanism of action is still unclear. Massage has been linked to improved physical and clinical outcomes, relief of pain symptoms through physical and mental relaxation, and increased pain thresholds through the release of endorphins (21). Massage can improve the blood circulation and metabolism of the affected area, thus promoting the elimination of local pain mediators (43,44). The theories of massage analgesia effects mainly include gating theory, serotonin hypothesis, and restorative sleep hypothesis (45). Gating theory holds that massaging a specific area stimulates large-diameter nerve fibers. These fibers have an inhibitory input to T cells (the first cells in the spinal cord to project into the central nervous system). The T-cell activity is suppressed [in contrast, small diameter nerve fibers (nociceptive fibers) have excitatory inputs] and pain is relieved (46). The serotonin hypothesis suggests that massage can increase the levels of the serotonin neurotransmitter, thereby modulating the pain control system (47). The restorative sleep hypothesis declares that since substance P is released during deep sleep deprivation, and massage has the ability to increase restorative sleep, it can reduce the release of substance P and subsequent pain (48). Although these 3 theories can explain the effect of massage analgesia to a certain extent, there is still a long way to go to reveal the real mechanism of massage analgesia.

In recent years, FSN therapy has been widely used in the treatment of pain-related musculoskeletal disorders, but it has mainly been used and reported within China. The

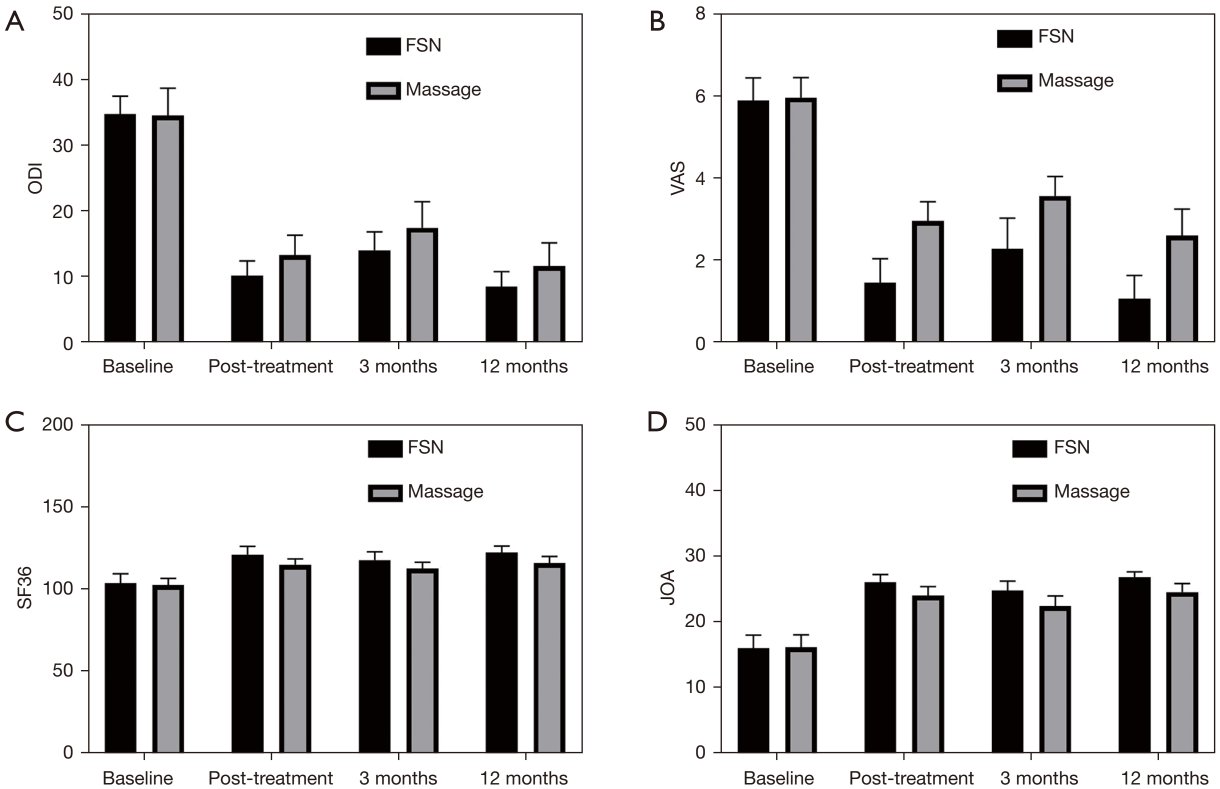

Figure 5 Comparison of 4 prognostic indicators at different follow-up time points between FSN group and massage group. FSN, Fu's subcutaneous needling.

present study is the first of its kind to evaluate the long-term efficacy of FSN therapy for chronic NLBP, achieving a satisfactory therapeutic effect. Previous studies solely focused on the immediate or short-term effects of FSN therapy in the treatment of LBP, and did not categorize LBP rigorously (29,30,33).

The FSN therapy originally developed from traditional Chinese acupuncture, but its theory and manipulation are quite different from that of acupuncture (49). The meridian points for acupuncture are fixed and widely distributed throughout the whole body, which can be difficult to learn and remember. In contrast, FSN needle can be inserted anywhere near a TM with the needle tip pointing towards the TM (50). Additionally, the FSN needle is only inserted into the subcutaneous layer, whereas traditional acupuncture generally involves the fascia and muscle. Traditional acupuncture practices emphasize "fast in and fast out" as well as "twist" manipulation techniques, but FSN therapy requires a smooth, rhythmic sweeping movement from one side to the other. Deqi is also a characteristic feature of traditional acupuncture perceived as a particular sensation (e.g., soreness, aching, numbness, or needle grasp) or by the acupuncturist as a pulling sensation (51). In contrast, deqi is not a feature of FSN therapy, making the technique somewhat easier to perform. In addition, compared with traditional acupuncture techniques, FSN therapy has the advantages of safe operation, quick curative effect and strong reproducibility, making it quickly promoted in clinical practice.

Despite its satisfactory efficacy on painful musculoskeletal disorders, the underlying mechanisms of FSN therapy are still unclear. It is widely accepted that MTrPs are a common cause of musculoskeletal pain conditions and accordingly represent the theoretical basis of many treatments (52,53). This theory is adopted by FSN, wherein initially identified MTrPs become the therapeutic target (54,55) Local MTrP formation decreases the blood supply to neighboring tissues and can produce tissue ischemia and hypoxia. The manipulation of an MTrP in FSN is thought to relieve local muscle tension, subsequently promoting blood circulation and leading to pain relief. However, after reflecting on the MTrP theory, the inventor of FSN proposed the concept of TMs (56). One reason for this change is that the MTrP is a hyperirritable spot concealed in a taut band of a skeletal muscle; however, the clinician palpating a patient is unable to precisely distinguish this "hyperirritable spot". On the contrary, clinicians typically detect sheet or band structures in most cases. Thus, FSN allows targeting of the entire contracted muscle rather than individual MTrPs. The concept of targeting a TM not only clarifies the pathological vector of the disease, but also highlights the involvement of muscle in the disease, causing the clinician to seek out muscles with functional pathological changes rather than a "hyperirritable spot".

Fu and Xu (57) hypothesized that mechanical stimulation with FSN manipulation regulates the homeostasis of loose connective tissue in the subcutaneous layer, which is the material basis for the therapeutic effect of FSN. As is well-known, connective tissue is widely distributed in the outer layers and interspaces of different tissues and organs to form a closely connected network linking different parts of the body. In addition to its powerful regenerative capacity, connective tissues also play important roles in tissue support, protection and defense, nutrient transport, and other functions (58). Accordingly, loose connective tissue provides an anatomical basis for "needling shallow but treating deep." The question has been asked of how FSN manipulation acts on loose connective tissue to activate the body's self-healing ability. Previous studies have shown that connective tissues are very closely related to acupoints, meridians, and acupuncture sensations (59,60). Langevin *et al.* proposed a potential mechanism of acupuncture technique: Loose connective tissue is in a liquid crystal state, with piezoelectric effect and anti-piezoelectric effect. Needle manipulation of connective tissue generates mechanical signals by pulling on collagen fibers, and these signals can be transmitted efficiently into connective tissue cells via needle/tissue coupling (61). An inverse piezoelectric effect occurs when the signal is transmitted to the diseased tissue, which may change the cellular ion channel and cause the cellular response, thus arousing the body's disease-fighting mechanism (62). The cellular response to mechanical signaling may explain at least in part the therapeutic effects of acupuncture occurring both locally and remotely.

Dr. Fu also agrees with this theory and regards it as the potential mechanism of the FSN (57). In a recent study, Fu *et al.* (54) confirmed that the mechanism of FSN therapy is not related to neural activity but to the effect of mechanical stimulation on connective tissue. Moreover, the closer the needle insertion site is to TMs, the stronger the mechanical effect and subsequent therapeutic effect.

The FSN therapy can be seen as a type of "horizontal acupuncture" and theoretically stimulates connective tissues more dramatically than any kind of acupuncture due to the relative size of the manipulation space. This may be why FSN therapy shows a faster and stronger effect relative to acupuncture methods in the treatment of myofascial pain (56). Studies have shown that connective tissue can transmit mechanical signals at 720 mph (1,100 kph), 3 times faster than nervous system conduction, which may be a reason why FSN therapy produces such rapid-onset effects (63).

Although the results of this study are encouraging, there are two limitations. The first limitation is the sample size. Due to the restriction of our outpatient volume, we intake a limited number of chronic NLBP. In addition, some outpatients are not willing to accept acupuncture or massage therapy, which is also one of the reasons for the small sample size. However, prior to the formal study, we conducted a pilot study to evaluate the sample size. Through calculation, the existing sample size fully met the requirements. The second limitation is the inability to blind the therapists and participants to the therapeutic schemes, which might have influenced the final results. Despite these limitations, the present study was a preliminary study which thoroughly investigated long-term efficacy of FSN and massage in the treatment of chronic NLBP patients.

Conclusions

It can be concluded that both FSN therapy and massage therapy have a long-term effect on chronic NLBP. However, FSN therapy is more effective than massage therapy and is recommended as a preferred choice to complementary and alternative therapies for chronic NLBP. Due to the small sample size of this study, additional studies with larger sample sizes are needed to corroborate the long-term efficiency of FSN therapy for chronic NLBP.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Human Ethics Committee of Yongchuan Hospital of Chongqing Medical University (No. 2019KLS100) and informed consent was taken from all the patients.

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