

A pilot study of ultrasound-guided acupotomy for the treatment of frozen shoulder

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Abstract

This study retrospectively analyzed the feasible effectiveness of ultrasound-guided acupotomy (USGAP) for the treatment of frozen shoulder (FS). A total of 36 patients with FS were analyzed in this retrospective study. All 36 patients received extracorporeal shock-wave therapy (ESWT). In addition, 18 of them also underwent USGAP intervention and were assigned to a treatment group, while the other 18 patients did not receive such intervention and were assigned to a control group. The primary efficacy endpoint was pain intensity, as measured by the Numeric Rating Scale (NRS). The secondary efficacy endpoint was assessed by the score of shoulder pain and disability index (SPADI). Furthermore, the adverse events were also documented during the treatment period. All efficacy endpoints were measured after the treatment. After treatment, patients who received USGAP exerted better efficacy endpoints in pain relief, as measured by NRS scale ($P < .01$), and shoulder disorders, as evaluated by SPADI ($P < .01$), than subjects who did not receive USGAP. Additionally, no adverse events occurred in either group. The results of this study indicated that USGAP may be used for the treatment of FS effectively. More studies are still needed to warrant the present results.

Abbreviations: ESWT = extracorporeal shock-wave therapy, FS = frozen shoulder, NRS = Numeric Rating Scale, SPADI = score of shoulder pain and disability index, USGAP = ultrasound-guided acupotomy.

Keywords: effectiveness, frozen shoulder, pain, ultrasound-guided acupotomy

1. Introduction

Frozen shoulder (FS) is one of the most common pain disorders among adult population, especially for males.^[1–3] It often manifests with pain, joint movement limitations, and muscle weakness without fracture and dislocation.^[4–6] It has been reported that its prevalence ranges from 2% to 5% of the general population, specifically in the age range of 40 to 60 years old.^[7–8] The movement restrictions often present as flexion, extension, and external rotation.^[9–11] Thus, this condition often greatly affects the quality of life in patients with FS.^[12,13]

Several managements are available for the treatment of FS disorder, such as medication (nonsteroidal anti-inflammatory drug, and steroid), physical exercise, joint manipulation, chiropractic intervention, stretching, physical therapy, massage, therapeutic ultrasound, extracorporeal shock-wave therapy (ESWT), acupotomy, moxibustion, and acupotomy.^[14–24] Of

these, acupotomy is a very promising candidate for the treatment of FS. However, there is still limited evidence to support the effectiveness of acupotomy, especially for ultrasound-guided acupotomy (USGAP). Thus, in this pilot study, we firstly investigated the possible effectiveness of USGAP therapy for patients with FS.

2. Methods and design

2.1. Ethics

The ethics of this pilot study was approved by the Ethical Committee of Yan'an People's Hospital, and Xi'an Gaoxin Hospital. The informed written consent was waived, because this study just analyzed the data from the previous medical records.

2.2. Sample size

The present pilot study explored the possible effectiveness of USGAP for patients with FS, and the feasibility of large clinical trial. The desired sample size of this pilot study is 36, 18 patients each group, and assumed 20% dropout rate,^[25] which is the minimum required sample size to investigate the effectiveness of USGAP. All 36 patient records were collected from two centers, and 18 records from each center.

2.3. Design

This pilot study was designed as a retrospective study, and all patients were performed from April 2017 to March 2018 at the Yan'an People's Hospital, and Xi'an Gaoxin Hospital. A total of 36 eligible patients were analyzed in this study. All eligible patients were assigned to a treatment group (received ESWT and USGAP) and a control group (received ESWT alone) according to the different therapies they received. Both groups were treated for

Editor: Qinhong Zhang.

The authors have no conflicts of interest to disclose.

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How to cite this article: Cao XY, Zhao HY. A pilot study of ultrasound-guided acupotomy for the treatment of frozen shoulder. *Medicine* 2019;98:42(e17632).

Received: 29 November 2018 / Received in final form: 3 September 2019 /

Accepted: 24 September 2019

<http://dx.doi.org/10.1097/MD.0000000000017632>

a total of 4 weeks. All efficacy endpoints were evaluated after 4-week treatments.

2.4. Patient selection

This study analyzed 36 eligible patients with FS. All patients had confirmed diagnosis of FS according to the physicians specializing in Orthopedics or Physical Medicine.^[26] In addition, patients were considered if they had pain and stiffness conditions over the affected shoulder region for more than 3 months without pain resting.^[27] Patients were excluded if they had history of shoulder surgery, fracture, joint dislocation, rheumatoid arthritis, osteoarthritis, cervical radiculopathy or shoulder limitations because of the stroke, spinal cord injury, or other disorders that can result in this condition.^[26–29] In addition, patients were also excluded if they received other medications, or acupuncture during the study period, or had insufficient information.

2.5. Treatment schedule

In this study, we only selected worst side the shoulder for the treatment. All patients in both groups received ESWT with 3000 pulses of 0.11 mJ/mm² at a frequency of 15 Hz, and 3 bar pressure. It was applied using Pain Treatment System of Radial Shockwave Device (SonoThera, HanilTM Co LTD, South Korea). All patients were treated once weekly for a total of 4 weeks. In addition, patients in the treatment group also received USGAP intervention. All procedures of acupotomy were performed according to the guidelines of The Principles of acupotomy.^[30]

Procedures of USGAP as follows:

- (1) The attacked location was identified through physical examination and A-shi acupoint was located with palpation.
- (2) Ultrasound check was used to further identify the operating acupoints by confirming the adhesive tissues of the affected location.
- (3) Operating positions were examined by ultrasound within the affected areas while the shoulder joint was divided into upper, medial, lower, and lateral areas. The affected areas with the identified operating acupoints were marked with gentian violet. No more than 5 operating acupoints were marked in each area.
- (4) After sterilization, the needles were inserted with the help of an ultrasonic probe. Once the needle reached to the adhesive tissues, it was manipulated to detach any adhesive tissues.
- (5) All needles were manipulated without retain. They were removed after treatment, and pressure was applied to all acupoints for 3 minutes to avoid bleeding. Next, a sterile material was applied to the manipulated area.
- (6) Four acupotomy treatments were administered, one session weekly for a total of four weeks. They were all performed using disposable sterilized acupotomy needles (1.2 mm width, 75 mm length; Hansung Precision Manufacture, Seoul, South Korea).

2.6. Efficacy endpoints measurement

The primary efficacy endpoint was pain intensity. It was measured by Numeric Rating Scale (NRS). The secondary efficacy endpoint of shoulder disorder was evaluated by the score of shoulder pain and disability index (SPADI). In addition,

Table 1

Patient characteristics.

Characteristics	Treatment group (n = 18)	Control group (n = 18)	P value
Mean age (year)	50.2 (9.4)	48.9 (10.1)	.69
Gender			
Male	11 (61.1)	13 (72.2)	.48
Female	7 (38.9)	5 (27.8)	.48
BMI (kg/m ²)	24.6 (2.8)	24.3 (3.1)	.76
Duration of disease (month)	5.8 (2.2)	6.2 (2.5)	.61
Previous medication used	13 (72.2)	15 (83.3)	.43
Pain intensity			
NRS	6.5 (1.7)	6.7 (2.0)	.75
Shoulder disorder			
SPADI pain	61.8 (11.4)	63.0 (11.8)	.76
SPADI disability	52.3 (11.9)	53.4 (11.1)	.77
SPADI total	54.9 (12.2)	56.1 (12.6)	.77

Data are present as mean±standard deviation or number (%).

BMI = body mass index, NRS = numeric rating scale, SPADI = score of shoulder pain and disability index.

adverse events were also recorded during the study period. All outcomes were measured after 4 weeks treatment.

2.7. Statistical analysis

All data were analyzed using SPSS Statistics 19.0 (IBM Corp., Armonk, NY) by a statistician. All continuous data was operated using Mann–Whitney *U* test. All categorical data was performed using Fisher exact test. The statistical significance was set as $P < .05$ in the present study.

3. Results

The characteristics and demographics of all included patients are showed in Table 1. The comparisons of all these values did not differ significantly between the treatment group and the control group in this study (Table 1).

After treatment, patients in the treatment group exerted better efficacy endpoints in NRS ($P < .01$, Table 2), and SPADI score (pain, $P < .01$; disability, $P < .01$; total, $P < .01$; Table 3), than patients in the control group.

During the treatment period, no adverse events were recorded. No death associated with interventions occurred in either group. No subjects quitted the therapies in this retrospective study.

4. Discussion

FS is a very complicated disorder. Although previous studies have reported that a variety of treatments are available to manage such

Table 2

Comparison of NRS between 2 groups.

NRS	Treatment group (n = 18)	Control group (n = 18)	P value
After treatment	2.7 (1.5)	4.3 (1.8)	<.01
Difference from prior treatment	−3.8 (−6.3, −2.0)	−2.4 (−4.1, −1.7)	<.01
Difference between groups		−1.4 (−2.0, −0.6)	<.01

Data are present as mean(standard deviation) or mean (range). NRS = numeric rating scale.

Table 3
Comparison of SPADI between two groups.

SPADI	Treatment group (n=18)	Control group (n=18)	P value
After treatment			
Pain	33.5 (13.3)	47.7 (14.6)	<.01
Disability	28.8 (12.2)	42.3 (15.0)	<.01
Total	30.4 (12.2)	43.2 (13.9)	<.01
Difference from prior treatment			
Pain	-28.3 (-46.8, -19.6)	-15.2 (-22.2, -9.2)	<.01
Disability	-23.5 (-35.9, -16.6)	-11.1 (-19.8, -7.3)	<.01
Total	-24.6 (-34.1, -15.7)	-12.9 (-20.7, -6.8)	<.01
Difference between groups			
Pain		-13.1 (-17.8, -8.5)	<.01
Disability		-12.4 (-16.9, -8.1)	<.01
Total		-11.7 (-15.3, -7.8)	<.01

Data are present as mean(standard deviation) or mean (range). SPADI=score of shoulder pain and disability index.

condition, their efficacy is still limited and also accompanied with lots of adverse events, especially for medications.^[14–23] Thus, more effective therapies with fewer adverse events are still needed to be explored for such disorder.

Acupotomy therapy is reported to treat many kinds of disorders, including a variety of pain conditions, such as back pain, leg pain, knee pain, and cervical spondylotic radiculopathy.^[31–34] All these studies achieved promising outcome results. Furthermore, several other studies also reported that if acupotomy intervention was applied under the guide of ultrasound, the effectiveness may be more satisfied.^[35,36]

Presently, no study has explored the effectiveness of USGAP for the treatment of FS. Thus, this pilot study firstly investigated its feasible effectiveness for treating patients with FS. Fortunately, the results of the present study are promising, although a small number of patients were included. The results of this study may provide helpful evidence for the clinical practice of FS. At the same time, it may also provide useful clue for the further studies.

The results of the present pilot study showed promising efficacy endpoints in shoulder pain intensity relief, as measured by the NRS scale, and also in shoulder disorder enhancement, as evaluated by the SPADI scale. The results of the present pilot study indicated that USGAP may utilize to treat FS effectively.

Although the present study achieved satisfied results, it still suffered from several limitations. First, the sample size of this study is pretty small, because this is a pilot study, and it just aimed to investigate the feasible effectiveness of USGAP for the treatment of FS. Second, the study period is quite short with 4 weeks treatment only, and no follow-up visits were applied after the treatment session. Third, this study had insufficient efficacy endpoints evaluation, because this is a retrospective study, and all the outcome data came from the completed medical records. Fourth, no randomization was applied in the present study, which may affect the risk of patient selections.

5. Conclusion

The findings of the present study demonstrated that USGAP may be utilized as an effective treatment for FS. However, more studies are still needed to warrant the present results.

Author contributions

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