

Effectiveness and Safety of Acupotomy Treatment on Shoulder Pain: 25 Multicenter Retrospective Study

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Objective: Shoulder pain is a common complaint in outpatient clinics and can result in an inability to work or perform household activities, leading to significant socioeconomic burden. Acupotomy, as one kind acupuncture that has flat knife-shaped tip, has been widely used for treating shoulder pain. However, despite the widespread use of acupotomy in primary medical institutions, large sample size clinical trials have not sufficiently been performed. In this respect, this multi-center retrospective study aimed to investigate the effectiveness and safety of acupotomy in reducing shoulder pain and disability using data from multi-center primary care clinics.

Methods: This study was conducted in 25 Korean medicine clinics affiliated with the Korean Medical Society of Acupotomy, Republic of Korea, from August 2021 to December 2021. The medical records of patients who visited the clinics complaining of shoulder pain were gathered, and among them were those of patients who underwent acupotomy treatment and those who received acupuncture combined therapy. The Numeric Rating Scale (NRS), SPADI (Shoulder Pain and Disability Index), Range of Motion (ROM) and adverse event were evaluated at each visit. A linear mixed-effects models and paired *t*-test were used to identify the effectiveness of the treatment.

Results: Overall analysis showed that the NRS score of patients decreased from 4.95 ± 1.97 before treatment to 3.78 ± 2.03 after treatment ($n = 332$, difference in NRS score, 1.17; 95% CI: 0.96–1.38, $t = 10.89$ $p < 0.001$). SPADI score decreased from 19.05 ± 20.44 at baseline before treatment to 12.12 ± 17.26 after the last visit, which was statistically significant ($n = 332$, mean difference in SPADI score, 6.93; 95% CI: 4.71–9.15, $t = 6.150$, $p < 0.001$). No serious adverse event was reported in both groups.

Conclusion: This study showed the effectiveness of acupotomy therapy for shoulder pain, and as the treatment sessions increased, the effect of pain reduction and shoulder function improvement were also increased.

Keywords: acupotomy, shoulder pain, retrospective study, multicenter study

Introduction

Shoulder pain is a common complaint in outpatient clinics and can result in an inability to work or perform household activities, leading to significant socioeconomic burden.^{1,2} Most individuals with shoulder pain repeatedly visit outpatient clinic by complaining of pain even 12 months after the initial treatment.³ Prevalence and incidence of shoulder pain are

reported to be substantially different across gender, age, and region; according to a review by Lumie, the incidence is 0.9–2.5%, and the prevalence is 6.9–26%.² Specific causes of shoulder pain are also diverse, and generally include rotator cuff disease, subacromial impingement syndrome, adhesive capsulitis, calcification, and glenohumeral instability.^{4,5}

While imaging examinations such as shoulder magnetic resonance imaging (MRI) are sometimes required to determine the detailed cause, there are also substantial numbers of cases, such as simple muscle pain or minor ligament damage, that do not require such imaging examinations.^{6,7} Therefore, there is a growing need for non-pharmacological and minimally invasive treatments that can improve shoulder pain without the side effects commonly associated with conventional surgical or drug therapy, such as tendon weakening or dose-related risks of cardiovascular or renal disorders.^{8–11} In this study, we aim to show the effectiveness of acupotomy treatment as one of the non-pharmacological intervention methods.

Hence, recent studies have focused on various non-pharmacological conservative treatments such as exercise and stretching, and reported that the effects of such conservative therapies are comparable to that of surgical intervention with similar effects sizes.^{12–14} As a non-pharmacological conservative treatment, acupotomy, which is a new type of acupuncture treatment using a blade-shaped knife, has been widely used.^{15,16} Acupotomy has shown effectiveness on the treating a wide range of musculoskeletal pathologies. These pathologies include frozen shoulder, carpal tunnel syndrome, low back pain, lumbar stenosis, knee osteoarthritis, and tennis elbow.^{17–21} Acupotomy works by dissecting adhesions and releasing contractures of soft tissues, which helps to reduce inflammation, elevate the pain threshold, relieve pain, release adhesion, and reduce abnormal tissue pressure, leading to significant improvements in patients' symptoms and quality of life.^{22–24} In other studies, acupotomy has been proposed as an effective mechanism for treating chronic soft tissue injuries, as the tendon attached to bone undergoes self-repair and self-regulation after injury, leading to the formation of local adhesions, scars, and contractures. The small needle-knife used in acupotomy can release adhesions in the injured tendon, remove scars, cut the neurovascular bundle, and restore local dynamic balance, thereby facilitating treatment.²⁵

However, despite the widespread use of acupotomy in primary medical institutions, several clinical trials were performed in a single institution, making it difficult to follow up on a large scale in the outpatient department.²³ Furthermore, the safety reports were inadequate.²² Therefore, this study aimed to investigate the effectiveness and safety of acupotomy in reducing shoulder pain and disability using data from primary care clinics.

Study registration: Clinical Research Information Service (KCT0007070)

Materials and Methods

Study Design and Patients

We conducted a multicenter, retrospective study to assess the effectiveness and safety of Korean acupotomy treatment for shoulder pain. This study was conducted in 25 Korean medicine clinics affiliated with the Korean Medical Society of Acupotomy, Republic of Korea, from August 2021 to December 2021. The patients' charts from the participating outpatient clinics were reviewed. The records of patients who visited the participating medical institutions due to shoulder pain at least twice during the study period were extracted. Participants received treatments at Korean medicine clinics, according to the protocol of the Korean Medical Society of Acupotomy.

There were no restrictions on the gender, age, or race/ethnicity of the patients who participated, and medical charts of patients who visited Korean Medicine Clinics with shoulder pain as their chief complaint were included as data collection targets and extracted.

Medical records data from 346 patients were collected and included for the selection process. Of these, 14 patients were excluded because the intervention method was different, such as being treated only with acupuncture treatment, starting acupotomy in the middle of the treatment, or receiving acupuncture simultaneously with acupotomy treatment. The remaining 332 patients were analyzed.

This study conforms to the provisions of the Declaration of Helsinki, and the protocol was approved by the institutional review board at Wonkwang University (WKIRB-202201-BM-005). Because this was a retrospective rather

than an interventional study, written informed consent was not required unless specifically requested by the institutional review board or regulatory authority. This study was registered with the Clinical Research Information Service (CRIS) of the Korea National Institute of Health (K-NIH), Republic of Korea (KCT0007070).

Outcomes

The primary outcome, shoulder pain, was measured using a Numerical Rating Scale (NRS) score. NRS is an evaluation tool that rates the intensity of the current pain on a scale of 0 (“no pain”) to 10 (“worst possible pain”).^{26,27} The secondary outcomes included the shoulder joint’s Range of Motion (ROM) and Shoulder Pain and Disability Index (SPADI). ROM is a measurement tool used to measure disability, mobility, and pain in the shoulder joint.^{28,29} Clinicians at the participating medical institutions measured multiple ROMs of the shoulder joint, including external and internal rotation, flexion, extension, abduction, adduction, horizontal adduction, and horizontal abduction. The SPADI comprises 5 items of pain and 8 items of impairment in daily living.³⁰ Each item was evaluated on a scale of 0 to 10; the higher the score, the more severe the symptoms and disability. Among the available techniques to measure shoulder pain and function, SPADI is known to have the advantage of being the easiest and most convenient. Safety outcomes were evaluated with the incidence and type of adverse events, including bleeding, bruising, and itching. Adverse events were classified using a questionnaire from previous studies investigating adverse events in acupuncture.^{31,32} The scales used in this study have been validated through multiple studies, and have shown high reliability and validity. All of the scales have been translated into Korean and validated in clinical studies conducted in Korea. Specifically, for SPADI, high inter-rater reliability was confirmed with an excellent test-retest reliability of the translated versions, ICC(2,1) = 0.991 (95% CI 0.984–.995), and a statistically significant Cronbach’s alpha value of 0.942 ($p < 0.01$).³³

Intervention

Acupotomy

Acupotomy treatment was performed at the Korean medicine clinics participating in this study, according to the treatment protocol of the Korean Medical Society of Acupotomy, an acupotomy-related Korean medicine society; the treatment was performed with a common protocol for shoulder pain. The physicians selected the acupotomy technique based on their clinical judgment after examining the patient’s symptoms, physical examination results, and imaging data.

The acupotomy treatment procedure is mainly performed at the entrapment points of the peripheral nerves, and the damaged areas of the peripheral nerves are determined through a pinch-roll test. The entrapment of the intercostobrachial cutaneous nerve from above the armpit, the suprascapular nerve from above the scapula, and the skin branches of the radial nerve in the triceps area are evaluated. If there is an entrapment point, the adhesion is removed and resolved through the acupotomy treatment at the corresponding site (Figure 1).

The acupotomy needle has thicker and smaller blade-shaped tips that can be used to remove adhesions and release tension in the local muscles and soft tissues, which distinguishes it from manual acupuncture needles. However, it should be noted that there is a higher risk of tissue damage or bleeding when the treatment is performed by an inexperienced practitioner. Despite this, acupotomy treatment has shown advantages over traditional acupuncture needles in terms of resolving adhesions in local muscle and soft tissues or alleviating aseptic inflammation caused by compression.

There was no limit to the number of acupotomy techniques that could be used from the acupotomy therapy list, and the type of acupotomy manual therapy used during each session was recorded. The types and appearance of the acupotomy needle is shown in Figure 2.

Conventional Acupuncture Therapy and Other Interventions

Among the patients with shoulder pain who visited the participating medical institutions and received acupotomy treatment, additional procedures such as manual acupuncture therapy, electroacupuncture therapy, and pharmacopuncture therapy were performed in some cases, and cupping therapy and chuna therapy were performed if necessary. Since this is a retrospective study, there was no limit to the types of procedures, and the group in which acupotomy alone was used was compared to the group in which acupotomy was used together with other interventions.

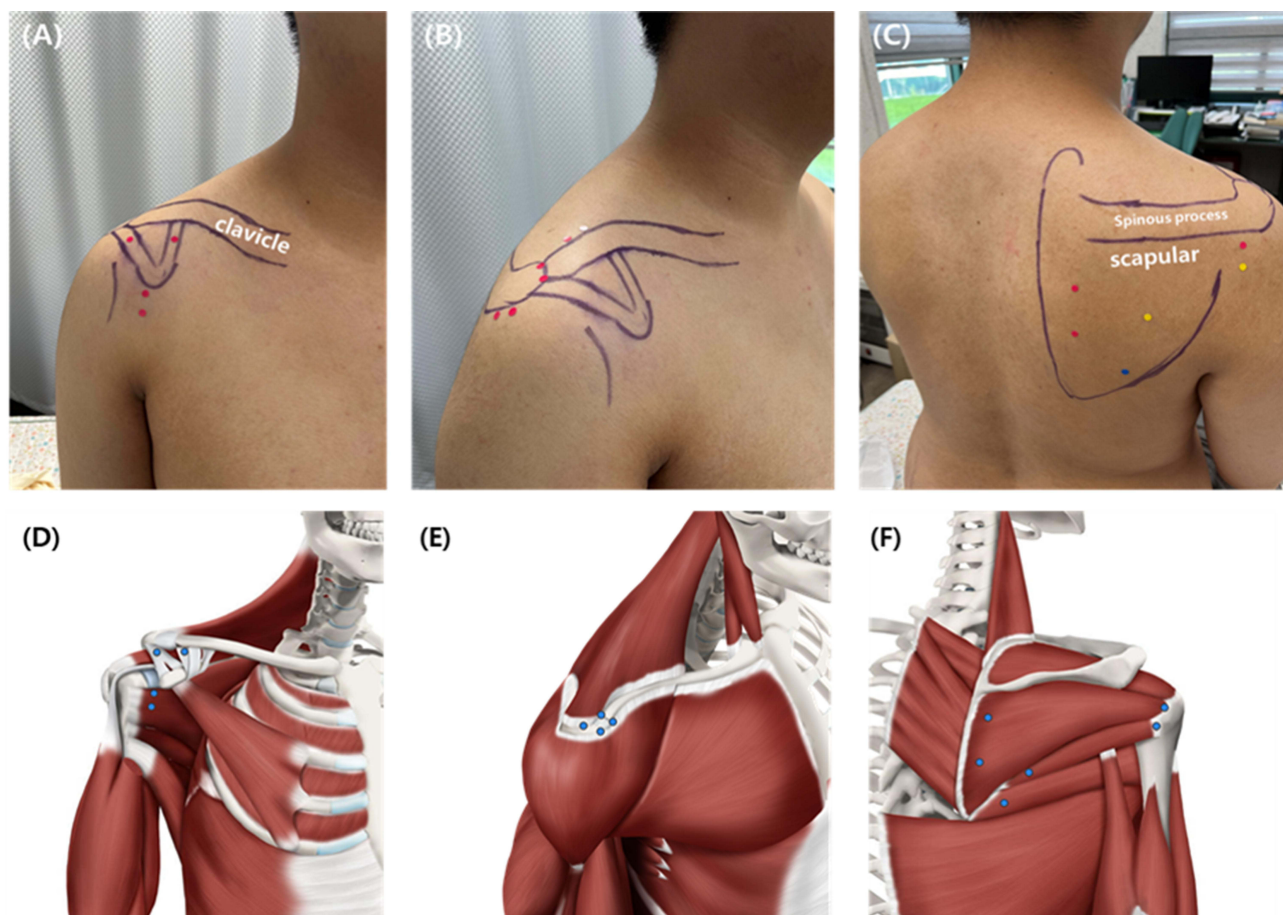


Figure 1 Acupotomy treatment points. **(A)** Anterior view, Coraco-acromial joint and insertion site of subscapularis muscle points were used. **(B)** Lateral view, posterior margin of clavicle and acromioclavicular joint and lateral acromion muscle insertion sites were used. **(C)** Posterior View, Infraspinatus, Teres major, Teres minor muscle were used. **(D)** anatomical image of anterior view **(E)** anatomical image of lateral view **(F)** anatomical image of posterior view.

Notes: The Red, Yellow, and Blue dots represent the representative points used for Acupotomy treatment for Shoulder pain.

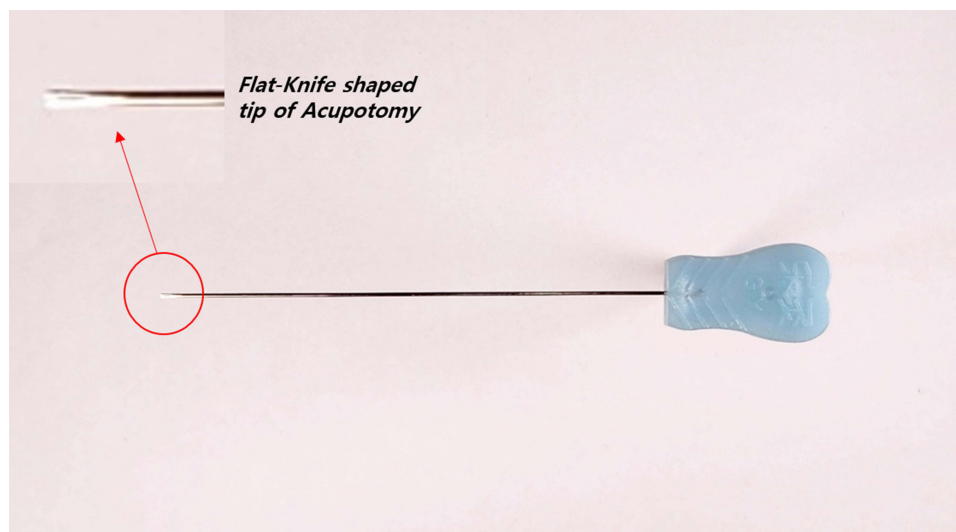


Figure 2 Needle of Acupotomy. Compared to the general acupuncture needle tip, it has a flat-knife shaped tip.

Safety

Of the 1210 acupotomy treatments, 163 adverse events were reported, but no irreversible or serious adverse events were reported. These were classified as bruise, fatigue, itching sense, and continuous pain. In particular, if adverse events were irreversible or interfered with the patient's daily life, they were classified as serious adverse events and divided into "Mild", "Moderate", or "Severe" so that the Korean medical doctor who performed the procedure could record it.^{34,35} The treatment for side effects was marked and recorded as "Icepack", "Compression", "Observation", "Cupping", and "Others" for other treatments.

Sample Size Calculation

"This study is a retrospective study and was not conducted with sample size calculation". It is based on treatment records of patients who visited with shoulder pain during the study period. Since the results were not obtained through prospective patient recruitment, it is difficult to draw definitive conclusions about treatment effectiveness from this study. However, it is possible to identify trends in improvement, and we expect that the results of this study can be utilized to calculate effect sizes for prospective study designs.

Statistical Analysis

Statistical analysis was conducted using the Statistical Package for the IBM SPSS Statistics for Windows, Version 20.0 (Armonk, NY: IBM Corp.). Continuous variables were expressed as means (standard deviations) or medians (quartiles), and categorical variables were expressed as numbers and percentages of patients. Categorical variables were tested using the chi-square test. Paired *t*-test was used for NRS, ROM, and SPADI to compare the primary and secondary outcome measures at baseline and the end of treatment. Linear mixed-effects models were used to compare the trajectory of primary and secondary outcome measures from baseline over the follow-up duration between the treatment groups, participants who received both acupuncture and acupotomy therapies vs those who received acupotomy therapy alone. Statistical significance was set at $p < 0.05$ (two-sided).

Results

Patients' Characteristics

The baseline characteristics of patients in the study are shown in Table 1. Regarding gender, 146 males were treated, with 45.5% in the combined-treatment group, which was higher than 40.7% in the single-treatment group. Among female participants ($n=186$), 54.5% was in the combined-treatment group and 59.3% in the single-treatment group. There was no

Table 1 Baseline Characteristic of the Study Participants ($n=332$)

	Total Analyzed ($n=332$)	Intervention		χ^2 or <i>t</i>	<i>p</i> -value
		Acupotomy Single	Combined Therapy		
Number (%)	332	108 (32.5)	224 (67.5)		
Sex				0.680	0.410
Women	186 (56.0)	64 (59.3)	122 (54.5)		
Men	146 (44.0)	44 (40.7)	102 (45.5)		
Age	57.38±13.12	56.83±12.06	57.65±13.61	-0.530	0.596
Age group				1.022	0.312
<60	178 (53.94)	62 (57.94)	116 (52.02)		

(Continued)

Table 1 (Continued).

	Total Analyzed (n=332)	Intervention		x ² or t	p-value
		Acupotomy Single	Combined Therapy		
≥60	152 (46.06)	45 (42.06)	107 (47.98)		
Height	163.38±9.49	163.58±8.97	163.29±9.73	0.240	0.811
Weight	63.93±11.96	63.03±10.92	64.32±12.4	-0.852	0.395
BMI	23.83±3.11	23.49±3.14	23.98±3.1	-1.232	0.219
BMI group				0.122	0.727
<25	195 (66.33)	61 (67.78)	134 (65.69)		
≥25	99 (33.67)	29 (32.22)	70 (34.31)		
Shoulder pain				4.267	0.118
Both	11 (3.3)	6 (5.6)	5 (2.2)		
Right	181 (54.5)	52 (48.1)	129 (57.6)		
Left	140 (42.2)	50 (46.3)	90 (40.2)		
Treatment tools (All sessions)	1197 Session (98.92%)	348 (28.76%)	849 (70.16%)		

Notes: 38 patients were excluded from the analysis due to missing records of their height and weight.

statistically significant difference in the gender composition in each group ($p = 0.410$). The mean age \pm standard deviation was 57.38 ± 13.12 years. The mean age of the combined-treatment group was 57.65 ± 13.61 and that of the single-treatment group was 56.83 ± 12.06 with no significant difference between the groups ($p = 0.596$). There were 38 patients with missing height and weight information. An analysis of 294 patients showed that 66.33% ($n = 195$) were normal or underweight (Body Mass Index, $BMI < 25.0 \text{ kg/m}^2$), and 33.67% ($n = 99$) were overweight or obese ($BMI \geq 25.0 \text{ kg/m}^2$). Concerning shoulder pain, 54.5% ($n = 181$) of patients complained of pain on the right side, 42.2% ($n = 140$) complained of pain on the left side, and 3.3% ($n = 11$) complained of bilateral pain. The total number of study participants was 332, but only 253 patients made it to Visit 1, 212 patients to Visit 2, 178 patients to Visit 3, 138 patients to Visit 4, and 48 patients to Visit 5. These medical records were analyzed together.

Efficacy Outcome Measures

NRS

First, a paired t -test was performed to compare shoulder pain at baseline after the last visit of the patients. Overall analysis showed that the NRS score of patients decreased from 4.95 ± 1.97 before treatment to 3.78 ± 2.03 after treatment ($n = 332$, difference in NRS score, 1.17; 95% CI: 0.96–1.38, $t = 10.89$, $p < 0.001$). According to the treatment intervention method, the NRS score in the single-treatment group decreased from 5.26 ± 1.92 before treatment to 4.23 ± 2.1 at the last visit, which was statistically significant ($n = 108$, difference in NRS score, 1.03; 95% CI: 0.69–1.37, $t = 5.966$, $p < 0.001$). The NRS score in the combined-treatment group decreased from 4.79 ± 1.98 to 3.56 ± 1.96 at the last visit, which was statistically significant ($n = 224$, difference in NRS score, 1.23; 95% CI: 0.97–1.5, $t = 9.109$, $p < 0.001$) (Table 2).

Gender, age, obesity, and pain were classified and analyzed in the sub-group analysis. Considering the degree of change in NRS scores depending on gender, pain decreased regardless of gender both before and after treatment (Male, $n = 146$, difference in NRS score 1.34, 95% CI: 1.00–1.67, $t = 7.878$, $p < 0.001$; and, Female, $n = 186$, difference in NRS score, 1.03, 95% CI: 0.76–1.30, $t = 7.547$, $p < 0.001$, Supplement 1-1). Regarding age, although there was a statistically significant improvement in both the groups of patients, aged < 60 and ≥ 60 years. (Age < 60

Table 2 Comparison of Changes in NRS and SPADI Scores Between First and Last Visits by Intervention Type

	Number	First Visit	Last Visit	Mean Difference (95% CI)	t	p-value	Interaction p-value
NRS	332	4.95±1.97	3.78±2.03	1.17 (0.96–1.38)	10.89	<0.001	
Intervention							0.372
Acupotomy Single	108	5.26±1.92	4.23±2.10	1.03 (0.69–1.37)	5.97	<0.001	
Combined therapy	224	4.79±1.98	3.56±1.96	1.23 (0.97–1.5)	9.11	<0.001	
p-value		0.044	0.005	0.352			
SPADI	332	19.05±20.44	12.12±17.26	6.93 (4.71–9.15)	6.15	<0.001	
Intervention							0.581
Acupotomy Single	108	22.56±21.84	14.73±18.92	7.83 (3.45–12.21)	3.54	<0.001	
Combined therapy	224	17.35±19.56	10.86±16.29	6.5 (3.96–9.04)	5.04	<0.001	
p-value		0.037	0.069	0.581			

group; $n = 178$, difference in NRS score, 1.18; 95% CI: 0.89–1.47, $t = 8.162$, $p < 0.001$. Age ≥ 60 group; $n = 152$, difference in NRS score, 1.16; 95% CI: 0.85–1.48, $t = 7.209$, $p < 0.001$, [Supplement 1-2](#)). Regarding the classification of patients into overweight or above and normal weight or below, the results showed that the pain level decreased significantly in the overweight/obese group and normal weight/below group (BMI $< 25\text{kg/m}^2$ group, $n = 195$, difference in NRS score 1.17, 95% CI: 0.90–1.44, $t = 8.661$, $p < 0.001$; BMI $\geq 25\text{kg/m}^2$ group, $n = 99$, difference in NRS score, 1.49, 95% CI: 1.08–1.91, $t = 7.128$, $p < 0.001$, [Supplement 1-3](#)). (Table 3) When considering location of the shoulder pain, overall improvement was observed on the left and right side, all of which were statistically significant ([Supplement 1-4](#)).

SPADI

A paired t -test was performed to compare the SPADI score, which represents the shoulder function scores at the baseline, and the change in the shoulder function score after the last visit of the patient. Function improvement was observed in both the single-treatment and combined-treatment groups. In the overall analysis of the entire treatment group, the SPADI score decreased from 19.05 ± 20.44 at baseline before treatment to 12.12 ± 17.26 after the last visit, which was statistically significant ($n = 332$, mean difference in SPADI score, 6.93; 95% CI: 4.71–9.15, $t = 6.150$, $p < 0.001$). In the single-treatment group, the SPADI score before treatment was 22.56 ± 21.84 , which decreased to 14.73 ± 18.92 at the last visit, showing statistical significance ($n = 108$, mean difference in SPADI, 7.83; 95% CI: 3.45–12.21, $t = 3.543$, $p < 0.001$). In the combined-treatment group, the SPADI score before treatment was 17.35 ± 19.56 and decreased to 10.86 ± 16.29 after the completion of treatment, which was statistically significant ($n = 224$, mean difference in SPADI, 6.5; 95% CI: 3.96–9.04, $t = 5.041$, $p < 0.001$). (Table 2, [Supplement 2](#) and [Supplement 3](#)).

Range of Motion

For Range of Motion, active ROM was measured, and shoulder flexion, extension, abduction, adduction, horizontal abduction, horizontal adduction, internal rotation, and lateral rotation were measured. In the collected charts, the result values at the first and third treatments were compared because ROM was not measured at every treatment but only at the first, third, and fifth treatments. Compared to the baseline before treatment, the ROM increased on average after the third treatment, and a statistically significant improvement was observed in flexion, abduction, horizontal abduction, horizontal adduction, internal rotation, and external rotation. In the range of motion (ROM), the acupotomy monotherapy group showed a greater average difference in Flexion, Extension, Abduction, Adduction, Horizontal abduction, Horizontal adduction, and Internal Rotation, with statistically significant differences in Flexion, Abduction, Horizontal abduction,

Table 3 NRS Modeling Linear Mixed Methods

	Model 1 (Unadjusted Model)			Model 2 (Adjusted for Sex, Age)			Model 3 (Adjusted for Sex, Age, Pain Region)			Model 4 (Adjusted for Sex, Age, Pain Region, Obesity)		
	Beta Coefficients	SE	p-value	Beta Coefficients	SE	p-value	Beta Coefficients	SE	p-value	Beta Coefficients	SE	p-value
Intervention												
Acupotomy only	Reference			Reference			Reference			Reference		
Combined therapy	-0.35 (-0.72 to 0.01)	0.19	0.059	-0.3 (-0.67 to 0.07)	0.19	0.11	-0.32 (-0.7 to 0.05)	0.19	0.091	-0.54 (-0.93 to -0.15)	0.2	0.007
Visit												
Baseline	Reference			Reference			Reference			Reference		
Visit 1	-0.42 (-0.7 to -0.15)	0.14	0.003	-0.42 (-0.69 to -0.14)	0.14	0.003	-0.41 (-0.69 to -0.14)	0.14	0.003	-0.5 (-0.8 to -0.2)	0.15	0.001
Visit 2	-0.6 (-0.91 to -0.28)	0.16	<0.001	-0.59 (-0.91 to -0.27)	0.16	<0.001	-0.59 (-0.91 to -0.27)	0.16	<0.001	-0.65 (-1 to -0.31)	0.18	<0.001
Visit 3	-1.04 (-1.39 to -0.69)	0.18	<0.001	-1.04 (-1.38 to -0.69)	0.18	<0.001	-1.03 (-1.38 to -0.69)	0.18	<0.001	-1.14 (-1.52 to -0.75)	0.19	<0.001
Visit 4	-1.87 (-2.25 to -1.49)	0.19	<0.001	-1.87 (-2.25 to -1.48)	0.2	<0.001	-1.87 (-2.25 to -1.48)	0.2	<0.001	-1.99 (-2.42 to -1.57)	0.22	<0.001
Visit 5	-2.18 (-2.95 to -1.41)	0.39	<0.001	-2.17 (-2.94 to -1.4)	0.39	<0.001	-2.17 (-2.94 to -1.4)	0.39	<0.001	-2.25 (-3.04 to -1.46)	0.4	<0.001
Visit (As continuous variable)	-0.42 (-0.51 to -0.34)	0.04	<0.001	-0.42 (-0.5 to -0.34)	0.04	<0.001	-0.42 (-0.5 to -0.34)	0.04	<0.001	-0.45 (-0.54 to -0.35)	0.05	<0.001
Source												
Group	F=1.183, p-value=0.277			F=0.702, p-value=0.402			F=0.854, p-value=0.356			F=1.339, p-value=0.248		
Time	F=18.267, p-value=<0.001			F=18.293, p-value=<0.001			F=18.197, p-value=<0.001			F=15.542, p-value=<0.001		
Group x Time	F=0.184, p-value=0.969			F=0.2, p-value=0.962			F=0.2, p-value=0.963			F=0.526, p-value=0.756		

Internal Rotation, External Rotation, and Internal Rotation. In particular, the combined therapy group exhibited a greater average difference in Internal Rotation. ([Supplement 4](#)).

NRS Modeling

This retrospective study used the linear mixed model because the number of visits according to the chart of patients collected during the study period differed depending on the patients. The linear mixed model is a method of analyzing repeated-measured longitudinal data, which can identify significant factors affecting the result value. The variables used for the analysis were visit number, gender, age, pain region, and obesity. Model 1 was an unadjusted model with no inserted variables, while Model 2 was adjusted for sex and age, Model 3 was adjusted for sex, age, and pain region, and Model 4 was adjusted for sex, age, pain region, and obesity. In each model, the effects of individual variables and treatment intervention methods were not statistically significant, and only the visit number showed a significant difference (Model 1; $F = 20.923$, $p = < 0.001$, Model 2; $F = 20.986$, $p = < 0.001$, Model 3; $F = 20.873$, $p = < 0.001$, Model 4; $F = 15.83$, $p = < 0.001$). ([Table 3](#)) By setting the visit number as a continuous variable, the extent of the decrease in NRS at each visit was analyzed, and it was found that the NRS score decreased by a mean of 0.41 per visit compared to the baseline value (Beta coefficients: -0.41 , 95% CI: $-0.48-0.34$, standard error (SE) = 0.04 , $p < 0.001$). The results of the analysis showed that pain decreased as the number of treatments increased in both the acupotomy single-treatment and combined-treatment groups, and these changes remained the same even after adjusting for gender, age, pain region, and obesity. ([Supplement 5](#)).

Safety

Of the 1210 acupotomy treatments, 335 any adverse events were reported, but no irreversible or serious adverse events were reported ([Table 4](#)). Among the mild side effects, bruising was most frequently reported. Compression and icepack were mainly used as treatments for side effects.

Table 4 Adverse Event

	Treatment Session						
	1st	2nd	3th	4th	5th	Over 6th	Total
Any adverse events							
None	245	227	182	133	109	40	936
Bruise	72	50	40	52	45	2	261
Fatigue	15	11	3	4	4	–	37
Itching sense	2	–	–	–	1	–	3
Continuous pain	21	5	5	2	–	–	33
Others	–	–	–	–	1	–	1
Total events / Total Sessions	110/332	66/265	48/226	58/188	51/157	2/42	335/1210
Treatment							
Icepack	5	7	5	5	5	–	27
Compression	23	11	16	10	11	–	81
Cupping	5	1	1	–	–	–	7
Observation	1	–	2	2	1	–	6
Others	1	2	1	–	1	1	6
Total	35	21	25	17	18	1	117

Discussion

In this study, we used various outcome measurements such as NRS, SPADI, ROM, and adverse events. Regarding efficacy, improvement in the NRS score was found based on the number of treatments, and improvement was also identified in functional scales such as SPADI and ROM. Regarding adverse events, 336 adverse events were identified in a total of 1210 sessions, but no irreversible serious adverse events occurred; most were complications that could be resolved by simple treatments such as icepack and compression. In addition, this study investigated the type of treatment that was performed when adverse events occurred, and it was shown that icepack or compression was used most frequently (117 treatments).

Our research team has collected treatment records of acupotomy involving more than 20 institutions for the first time in East Asia. While there have been a study collecting adverse event cases from a single institution, there has been no case of data collection from multiple institutions for a specific condition.³⁶ Therefore, this study has novelty and provides basic clinical data for future RCT studies.

Acupotomy is a type of treatment that combines the benefits of acupuncture and minimally invasive surgery by using a needle with a knife at the tip.^{37,38} An earlier study reported the effect of acupotomy on shoulder pain treatment, and a clinical study reported the practical effects on frozen shoulder and periartthritis; moreover, acupotomy treatment was more effective than general acupuncture treatment in a meta-analysis.²⁴

Shoulder pain is one of the three most frequently reported diseases among musculoskeletal diseases, and the demand for complementary and alternative medicine is also high, with 1.23 million people annually visiting Korean Medicine clinics for shoulder pain in Korea. Although surgical or drug therapy is widely used for shoulder treatment as conventional therapy, preference and demand for conservative treatments are increasing due to the side effects of steroid injection or surgery.^{13,39} In particular, acupotomy is a type of microsurgery treatment and is known to reduce shoulder pain by lowering the thickness of the coracohumeral ligament, releasing ligament, promoting local blood circulation, and detaching adhesions.^{40,41}

Various clinical studies on the effect of acupotomy treatment have reported effects on knee osteoarthritis and low back pain, but there are few multicenter studies in primary medical institutions, on shoulder pain.^{22,24,38} In a study by Li, retrospective analysis was performed on 120 patients with chronic neck pain, but it was a 12-month long-term follow-up, and no immediate effect was reported according to the treatment session.³⁸ Regarding the adverse events report for acupotomy, except a review by Kwon, most studies were single-center randomized controlled trials and not actual reports from primary care medical clinics.²² Therefore, our research team included 25 Korean Medicine Clinics that use similar methods to acupotomy, under the guidance of the same society.

Previous studies on adverse events have reported 0–8% of incidence for acupotomy and 17 events per 10,000 treatments for acupuncture.²² This study also showed 335 minor adverse events out of 1210 cases, but no irreversible serious adverse events were observed, which supports the safety of acupotomy, similar to the previous study results. However, as the blade used in acupotomy is thicker than that in general acupuncture treatment and the frequency of mild complications is high, attention should be paid during treatment.

Strengths and Limitations

The applicability of acupotomy treatment to shoulder pain in multicenter was identified by reviewing a retrospective chart through the results of this study. In addition, it is a large-scale study compared to previous studies, and significantly, identified the possibility and necessity of a multicenter prospective study in the future. Moreover, this study could supplement the limitations of the existing multicenter retrospective studies, which may have different treatment methods, because the cases were collected from a group of Korean medical doctors using the same treatment protocol and methods. Furthermore, this study used linear mixed models to determine whether a reduction in the NRS scale in shoulder pain could be expected depending on the treatment session; even when variables such as gender, obesity, and age were adjusted, pain reduction was observed as the number of treatments increased. The significance of the results of this study for clinicians, patients, and researchers is that the number of treatment sessions is a key indicator that can impact the improvement of patient symptoms, in addition to the importance of different treatment modalities. This

information can assist clinicians and patients in developing treatment plans based on their therapeutic goals. It is also noteworthy that acupotomy monotherapy showed similar pain relief trends as well as integrated treatment using various modalities such as acupuncture, electro-acupuncture, and cupping in this study. However, in future study designs, evaluating immediate improvement after treatment and increases in range of motion would be necessary to clarify differences between the groups.

This retrospective study has several limitations. First, since the records were from medical institutions specializing in acupotomy treatment, this study analyzed the difference in treatment effects between the group using acupotomy treatment alone and the group using acupotomy treatment in combination with other interventions. A comparison between the acupotomy single-treatment and manual acupuncture single-treatment groups was not conducted in this study, and accordingly, it is necessary to supplement this limitation by designing prospective studies in the future. In addition, since this study collected charts retrospectively, there was a limitation in that the number of patients decreased as patients continued their treatment sessions, and the reason for the decrease could not be identified. However, to interpret such missing values, the analysis was conducted using the linear mixed model, which is a longitudinal data analysis method, and the results are presented to supplement this limitation. Further, we collected charts of patients who complained of “shoulder pain” according to the characteristics of patients who visited primary care clinics, and did not classify or diagnose specific conditions such as rotator cuff tears or impingement syndrome. In the primary care clinic setting, treatment for shoulder pain is typically attempted before requesting imaging studies. This study targeted primary care clinics, so these characteristics were reflected, and we suggest that future prospective studies should use imaging equipment such as ultrasound to classify diseases based on detailed subcategories. In this study, the primary outcome was to implement the same protocol for treatment and evaluate the results in a multicenter primary clinic setting.

In interpreting the results of this study, it should be considered that this is a retrospective analysis; this study was performed on patients treated for shoulder pain for a specific period of time, rather than recruiting patients with specific criteria and following up regularly according to the criteria. In addition, this study has a limitation in that a differential diagnosis was not made using imaging methods for patients complaining of shoulder pain. However, patients visiting primary care clinics mainly complain of “shoulder pain”, and shoulder pain is one of the major classifications of musculoskeletal disease. Therefore, the fact that a detailed diagnosis was not included will be supplemented through further studies.

When comparing the combined-treatment and single-treatment groups, no statistically significant difference was observed between the groups, and the overall improvement in pain scores were found in both groups (Figure 3). For an

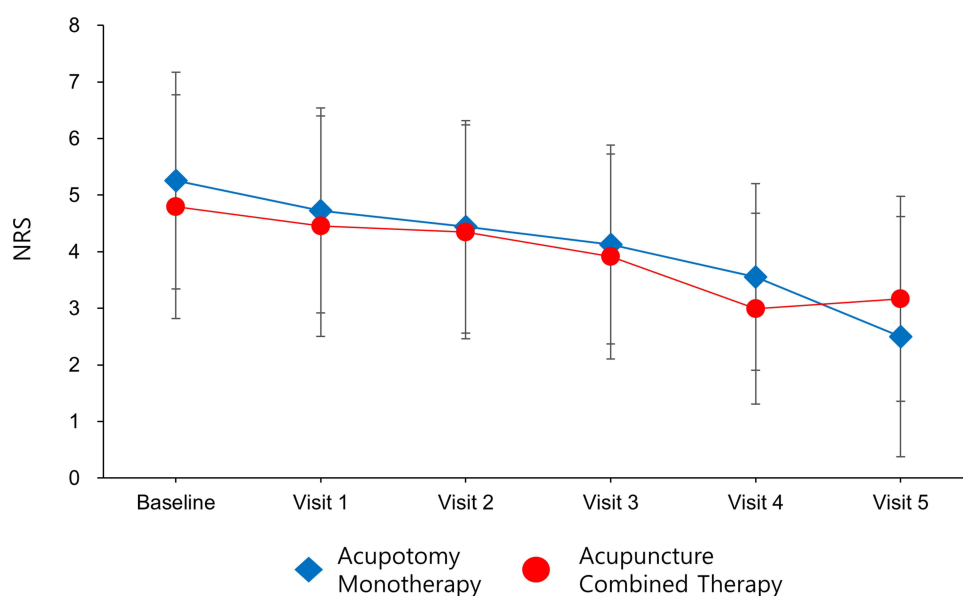


Figure 3 Change of NRS during visit.

accurate analysis, a comparison between the acupuncture single-treatment and acupotomy single-treatment groups should be performed in a further study design.

Future Research and Implications for Clinical Practice

Group comparisons such as acupotomy intervention with another intervention should be performed to compare the effects of acupotomy single-treatment accurately. In addition, as acupotomy requires accurate stimulation of the anatomical structure, a study comparing the difference in effect between ultrasound-guided acupotomy and blinded acupotomy insertion, similar to a recent study, is likely to be meaningful.⁴² Moreover, histological and physiological studies on the effectiveness of acupotomy treatment for shoulder pain that has been clinically acquired should be performed in the future.

This study showed the effectiveness of acupotomy therapy for shoulder pain, and as the treatment sessions increased, the pain reduction effect and improvement of shoulder function scales were observed.

Conclusion

Acupotomy therapy was found to be a safe and effective treatment for shoulder pain, with statistically significant improvements in patients' NRS and SPADI scores. Specifically, the NRS score decreased from 4.95 ± 1.97 to 3.78 ± 2.03 after treatment, while the SPADI score decreased from 19.05 ± 20.44 to 12.12 ± 17.26 after the last visit. No serious adverse events were reported in either group. Various guidelines on pain management recommend conservative treatment strategies prior to drug and surgical interventions.⁴³ These results provide evidence for future studies on the application of acupotomy for shoulder pain, and can assist physicians in making informed clinical decisions.

Data Sharing Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Institutional Review Board Statement

This study conforms to the provisions of the Declaration of Helsinki, and the protocol was approved by the institutional review board at Wonkwang University (WKIRB-202201-BM-005). Because this was a retrospective rather than an interventional study, written informed consent was not required unless specifically requested by the institutional review board or regulatory authority. This study was registered with the Clinical Research Information Service (CRIS) of the Korea National Institute of Health (NIH), Republic of Korea (KCT0007070).

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Disclosure

The authors declare no conflicts of interest in this work.

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