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Effect of abdominal acupuncture combined with routine rehabilitation training on shoulder-hand syndrome after stroke: A randomized controlled trial

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ABSTRACT

Background: Post-stroke shoulder-hand syndrome (SHS) is a common complication after stroke. To date, there is still a lack of consistently effective and good patient compliance methods for SHS.
Methods: Fifty patients with SHS were included in this study. Patients in the control group received rehabilitation training (RT) for 2 weeks; each session was 30 min, 1 time per day, and 5 times per week. Patients in the observation group were additionally given Bo's abdominal acupuncture (BAA) with the same frequency and duration. The primary outcome was the change value in the VAS score from baseline to 2 weeks. The secondary outcomes measured were motor function of the upper limb, shoulder range of motion, ADL, and swelling volume.
Results: Compared with baseline values, the mean VAS score at 2 weeks was reduced by 3.68 in the observation group and by 1.92 in the control group, with a difference between the two groups of 1.84 ($P < 0.001$); the mean MBI score at 2 weeks increased by 10.44 in the observation group and by 4.79 in the control group, with a difference between the two groups of 5.84 ($P = 0.032$); the mean swelling volume at 2 weeks decreased by 9.64 in the observation group and by 3.29 in the control group, with a difference between the two groups of 6.48 ($P < 0.001$). BAA-related adverse events were not found during the study.
Conclusions: BAA combined with RT is superior to RT alone in improving shoulder pain, swelling, and ADL in post-stroke SHS patients.
Trial Registration: ChiCTR2100045464 (www.chictr.org.cn).

1. Introduction

Post-stroke shoulder-hand syndrome (SHS) is a common complication after stroke. Post-stroke SHS mostly occurs in the 1 to 3 months after stroke, and its incidence is as high as 12%−70%.[1–3] SHS after stroke is very difficult to treat after the timely treatment

passes and the disease is present, and its symptoms may last for a long time, resulting in upper limb function limitation and even irreversible permanent apraxia.[4–5] In addition, SHS may hinder the patient's overall recovery, prolong hospital stay, limit the patient's ability of daily living (ADL), reduce the quality of life, and bring a heavy financial burden to the patient and family.

Currently, the common treatment methods for post-stroke SHS include drug therapy, cold-hot water for immersion, physical therapy (PT), occupational therapy (OT), psychotherapy and sympathetic block.[6–7] Although these routine treatment methods have found to be initially effective, their adverse reactions cannot be ignored. Low-dose oral steroids can effectively improve the symp-

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toms of SHS following stroke.[8] For example, to avoid adverse reactions associated with long-term use of drugs, steroids are only suitable for short-term treatment and are considered difficult for long-term treatment of post-stroke SHS.[5] Referral to PT, OT, and psychotherapy as early as possible may potentially prevent the progression of symptoms.[9] However, the shortcomings of these methods, such as high medical costs, increased labor investment, and higher requirements for patient cooperation, have also been called to attention. Furthermore, the expertise of rehabilitation therapists is also different in different regions, which will affect the treatment effect. The incidence of post-stroke SHS is still high, and it is a challenging issue to be solved. To date, there is still a lack of consistently effective and good patient compliance methods for post-stroke SHS.[10]

Bo's abdominal acupuncture (BAA) is a kind of acupuncture therapy that focuses on acupoints on the abdomen to treat various diseases. Compared with traditional acupuncture, BAA is characterized by acupuncture prescription specifications, operating standards, and good patient compliance, which are conducive to the large-scale promotion and application by clinicians.[11] Also, the location of abdominal acupoints is determined by the ruler measurement method, which benefits the accuracy of acupoints and the good repeatability of BAA. Unlike traditional acupuncture, BAA does not require the patient to have a feeling of deqi (e.g. soreness, numbness, and pain). In addition, a previous observational study showed that BAA combined with rehabilitation training has obvious effects on reducing knee pain in patients with knee arthritis.[12] Another randomized controlled trial found that BAA combined with suspension therapy can alleviate the pain and promote the recovery of waist function in non-specific low back pain patients.[13] These studies confirmed that BAA as an adjuvant therapy has analgesic effect, but did not pay attention to post-stroke SHS. High-quality evidence on whether BAA combined with RT can alleviate the pain of post-stroke SHS is still lacking. Therefore, the purpose of this study was to evaluate the effectiveness and safety of BAA combined with RT for post-stroke SHS.

2. Methods

This study was designed as a randomized, controlled, assessor-blinded, single-center, clinical trial. All participants were randomly divided into an observation group (BAA combined with routine RT) and a control group (routine RT). Simple randomization grouping according to the 1:1 allocation ratio was generated by a computer program. Then, random cards with the treatment method were placed into the opaque envelope in numerical order. The outcome assessments were conducted by a rehabilitation physician who was blinded to the group allocation. The data analyst was blinded to the group allocation as well. This study was reviewed and approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine (No. B2017–090–01). All subjects provided written informed consent following the requirements of the Declaration of Helsinki before the trial.

Participants with post-stroke SHS who were hospitalized in the rehabilitation department of Guangdong Provincial Hospital of Chinese Medicine from July 2017 to July 2019 were included in this study.

2.1. Participants

2.1.1. Inclusion criteria
The inclusion criteria included patients who met the recognized diagnostic criteria of "stroke"[14] and "SHS"[15]; patients whose SHS occurred after stroke and was a phase I; patients whose duration of stroke was between 15 days and 6 months; patients who were 20–75 years old; patients who were conscious (Glasgow Coma

Scale $\geq$ 13); and patients voluntarily participating in this study and cooperating with examinations and treatment.

2.1.2. Exclusion criteria
The exclusion criteria included patients with recurrent strokes or patients with recurrent or worsening SHS; patients with severe heart, liver, kidney disease, and moderate to severe infection; patients with severe cognitive impairment or complete aphasia who cannot cooperate with the outcome evaluation; and patients with a shoulder fracture or nerve root cervical spondylopathy.

2.1.3. Sample size calculation
The sample size was calculated based on an expected difference in the VAS score from baseline to 2 weeks between the observation group and the control group. Based on the results of previous studies,[16–17] we assumed that the VAS score difference between baseline and the endpoint would be 4.3 $\pm$ 1.6 in the observation group and 2.9 $\pm$ 1.7 in the control group after 2 weeks of intervention. Thence twenty-two patients in each group were required for a two-sided test with a power of 0.8 and α level of 0.05. Considering a dropout rate of 10%, a total of 50 patients (25 cases in each group) were necessary for this study. We used SPSS software (version 20.0; IBM, Armonk, NY) to calculate the sample size.

2.2. Treatment protocol

The patients in both groups were treated with drugs for secondary prevention of stroke following the "Guidelines and consensus on diagnosis and treatment of cerebrovascular diseases in China".[14] At the same time, standard doses of NSAID drugs (Diclofenac Na or paracetamol) were used for patients.

The patients in the control group were given routine RT according to Brunnstrom staging. Routine RT for upper limbs mainly included i) good limb placement: whether lying down or sitting, the affected limb was kept in a dorsiflexion position and the wrist was placed in a palm extension position. When moving, a sling was used to reduce the load on the shoulder joint. Pulling the affected limb was forbidden. ii) Active and passive exercise training of the upper limbs: the patients were encouraged to perform active exercises or passive training with the help of healthy hands (e.g. Bobath handshake). The occupational therapist could use different equipment (such as skateboards, wooden pegboards, scrubbing boards, and so on) to train the patient's upper limb flexion and extension, hand grasping functions, and ADL. RT was performed by fixed and trained occupational therapists who had over six years of medical experience. The patients received RT for 2 weeks; each session was 30 min and took place 1 time per day and 5 times per week.

The patients in the observation group were given BAA combined with routine RT. The routine RT of the observation group was the same as that of the control group. BAA was performed by a fixed and trained acupuncturist who was registered Chinese medicine practitioner with more than ten years of medical experience. According to the theory of Chinese medicine and the medical experiences of experts, the selected acupoints in this study included CV12, CV10, CV06, CV04, bilateral ST24, bilateral ST26, KI17 on the affected side, AB1, and AB2. The locations of these acupoints were determined based on *Standardized manipulations of acupuncture and moxibustion-Part 16:Abdominal acupuncture* and *WHO Standard Acupuncture Point Locations*.[18–19] The selected acupoints in this study were showed in *Fig. 1*. The patients were in a supine position with the abdomen exposed, then the acupuncturist checked whether there are contraindications for BAA. Without contraindication to BAA, the acupuncturist used a ruler to determine the location of abdominal acupoints. After routine disinfection, the acupuncturist used abdominal acupuncture (size:
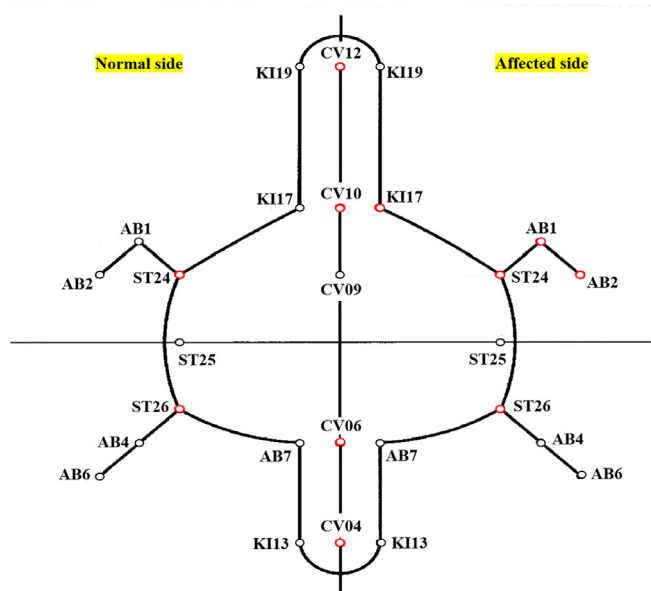
CV12 (Zhongwan) 中脘	On the upper abdomen, 4 B-cun superior to the centre of the umbilicus, on the anterior median line.
CV10 (Xiawan) 下脘	On the upper abdomen, 2 B-cun superior to the centre of the umbilicus, on the anterior median line.
CV06 (Qihai) 气海	On the lower abdomen, 1.5 B-cun inferior to the centre of the umbilicus, on the anterior median line.
CV04 (Guanyuan) 关元	On the lower abdomen, 3 B-cun inferior to the centre of the umbilicus, on the anterior median line.
ST24 (Huaroumen) 滑肉门	On the upper abdomen, 1 B-cun superior to the centre of the umbilicus, 2 B-cun lateral to the anterior median line.
ST26 (Wailing) 外陵	On the lower abdomen, 1 B-cun inferior to the centre of the umbilicus, 2 B-cun lateral to the anterior median line.
KI17 (Shangqu) 商曲	On the upper abdomen, 2 B-cun superior to the centre of the umbilicus, 0.5 B-cun lateral to the anterior median line.
AB1 (Shangfengshidian) 上风湿点	On the upper abdomen, 1.5 B-cun superior to the centre of the umbilicus, 2.5 B-cun lateral to the anterior median line.
AB2 (Shangfengshiwaidian) 上风湿外点	On the upper abdomen, 1 B-cun superior to the centre of the umbilicus, 3 B-cun lateral to the anterior median line.

Note: Acupoints marked in red circles were the locations of the selected acupoints in this study, B-cun, proportional bone cun.

Fig. 1. The location of the selected acupoints.

0.20 mm × 30 mm, produced by Suzhou Hualun Medical Products Co., Ltd.) to insert needles following the sequence of CV12, CV10, CV06, CV04, ST24, ST26, KI17, AB1, and AB2. The needles were perpendicular to the superficial level of the skin and inserted into the subcutaneous area of the above acupoints. After 3–4 min, CV12, CV10, CV06, and CV04 were deeply inserted (depth, 20 - 30 mm). ST24 and ST26 were moderately inserted (depth, 10 - 15 mm). KI17, AB1, and AB2 were shallowly inserted (depth, 5 mm). Subsequently, the acupuncturist adjusted the depths of the needles according to the degree of patient's pain relief. After 30 min of needles retention, the acupuncturist removed all needles in an order of insertion and pressed the acupoints with sterile dry cotton balls for few seconds. The patients received BAA for 2 weeks; each session was 30 min, 1 time per day, and 5 times per week.

2.3. Primary outcome

2.3.1. Shoulder pain

The visual analogue scale (VAS) was used to evaluate the changes in shoulder pain before and after treatment. The VAS score ranges from 0 to 10 points; 0 points indicates no pain, and 10 points indicates the most severe pain.[20] The patients were asked to mark the location of their pain on a 10-cm line, and then the assessor used the rule to measure the length from 0 to the mark

point, which was the pain score. A previous study reported that the minimal important difference (MID) of the VAS in pain was 0.9, with a difference greater than 0.9 predicting a significant effect on pain relief.[21]

2.4. Secondary outcomes

2.4.1. Upper limb motor function

The simplified Fugl-Meyer motor function scale for upper limb (FMA-U) was used to assess the changes in upper limb motor function before and after treatment. This scale has 33 items, each with a score of 0 to 2 points, with a full score of 66 points for the upper limb. A higher FMA-U score indicates less impairment of upper limb motor function.[22]

2.4.2. Shoulder range of motion

A protractor was used to measure the active range of motion (AROM) of the shoulder. Active shoulder flexion, extension, horizontal abduction, external rotation, and internal rotation were examined in all patients. During the measurement, the patients assumed a comfortable position and performed active exercises. The assessor measured the AROM based on the axis of the protractor, the fixed arm, and the moving arm.

2.4.3. The ability of daily living (ADL)

The modified Barthel index (MBI) was used to assess the changes in ADLs before and after treatment. The MBI includes 10 items, such as eating, personal hygiene, bathing, toileting, dressing, anal control, bladder control, bed and chair transfer, level walking, and stairs.[23] The total score of MBI is 100 points. A score greater than 60 indicates that the patient can take care of himself or herself.[23] The lower the score, the more serious the dysfunction.

2.4.4. The volume of swelling

A graduated measuring cylinder was used to assess the volume of swelling of the fingers and hands. This method is considered the gold standard for measuring limb swelling. The patient put his or her hand in a 2000 mL measuring cylinder filled with water. When the water surface was parallel to the first wrist crease line, the assessor measured the volume of the overflowing water. The volume difference between the affected hand and the healthy hand is the swelling volume of the affected hand. The assessor repeated the measurement 3 times.

2.5. Adverse events

The adverse event (AE) case report form was recorded by the assessor during the study. AEs may include dizziness, vertigo, nausea, palpitation, fatigue, bleeding, subcutaneous ecchymosis, infection, etc.

2.6. Statistical analysis

A full analysis set (FAS) was used for the analysis of the primary outcome. Patients who were given at least 1 intervention and were assessed by the VAS at least 1 time after the intervention were included in the FAS. The per protocol set (PPS) was used for the subanalysis of sensitivity. Patients who were given more than eight interventions and were evaluated by the VAS at 2 weeks were included in the PPS.

Descriptive analysis: Continuous variables are presented as the mean ± standard deviation; categorical variables are described by frequencies or ratios (%).

The assumptions of normal distribution of all data were assessed by the Shapiro-Wilk test. For the analysis of the primary outcome, the change in the VAS score from baseline to 2 weeks
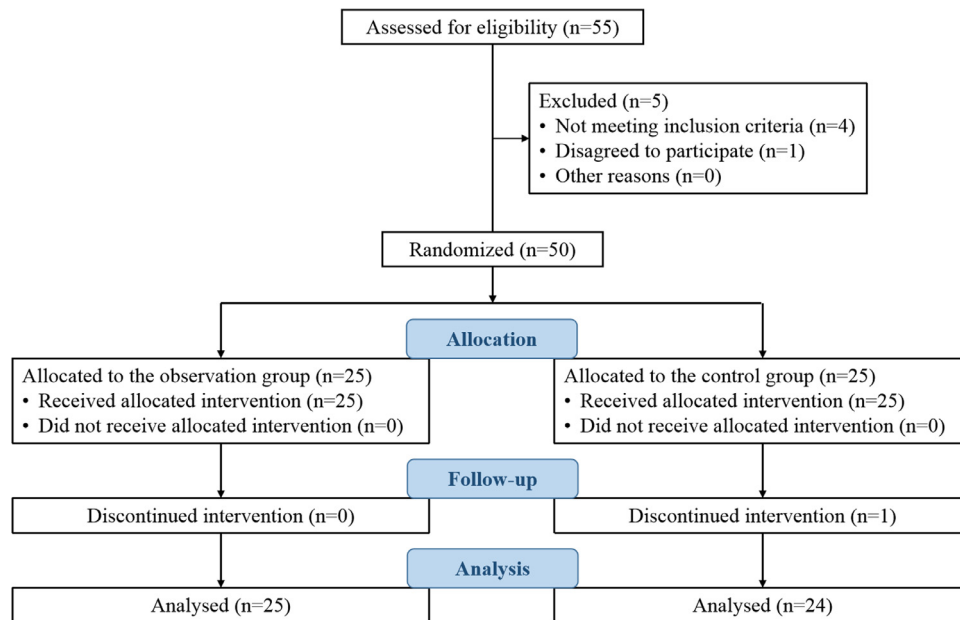
Fig. 2. Flow diagram for randomized subject enrollment in this study.

between the two groups was compared by an independent-sample *t*-test when the data were normally distributed and the variances were homogeneous; otherwise, the Wilcoxon rank-sum test was used.

For the analysis of secondary outcomes (including the FMA-U score, AROM, MBI score, and the volume of swelling), comparisons of the above indicators between the two groups were conducted using independent-sample *t*-tests when the data were normally distributed and the variances were homogeneous; otherwise, the Wilcoxon rank-sum test was used. For the analysis of the safety outcome, the AE ratio between both groups was compared by Fisher's probabilities test when the theoretical frequency was less than five; otherwise, a chi-squared test was performed. We used SPSS software (version 20.0; IBM, Armonk, NY) to manage and analyze the data. A 2-sided $P < 0.05$ was considered significant.

3. Results

Fifty participants were included in the study; 25 were allocated to the observation group, and 25 were allocated to the control group. One participant in the control group was excluded from this study when entering the second day of this study because he had a new cerebral hemorrhage. Ultimately, 49 participants who received a complete treatment program and completed a functional assessment were included in the FAS and PPS. The CONSORT flow diagram is described in *Fig. 2*. Recorded characteristics of the participants included sex, age, body weight, body height, stroke type, duration of stroke, affected hemiplegic side, and Mini-Mental State Examination (MMSE) score. The between-group differences in baseline characteristics were not significant. There were also no between-group differences in VAS score, FMA-U score, MBI score, swelling volume, or AROM at baseline. The demographic and clinical characteristics of both groups are described in *Table 1*.

3.1. Primary outcome

The VAS scores of the two groups at 2 weeks were significantly lower than those at baseline ($P < 0.01$). In addition, the VAS score at 2 weeks in the observation group decreased more than that in the control group (95% CI: −2.44 to −1.28, $P < 0.001$). Compared

with baseline, the mean VAS score was reduced by 3.68 at 2 weeks in the observation group and by 1.92 in the control group, with a difference between the two groups of 1.84 (95% CI: 0.96 to 2.56, $P < 0.001$). The comparisons between VAS scores at baseline and at 2 weeks are shown in *Table 2a*. The changes in VAS score from baseline to 2 weeks are presented in *Table 2b*.

3.2. Secondary outcome

The FMA-U score and MBI of both groups at 2 weeks were significantly higher than those at baseline ($P < 0.05$). However, there were no significant differences in the FMA-U score and MBI score at 2 weeks between the two groups (95% CI: −7.22 to 7.83, $P = 0.935$; 95% CI: −6.89 to 17.01, $P = 0.399$, respectively). Compared with baseline, the mean scores of the FMA-U and MBI increased by 6.20 and 10.44 at 2 weeks in the observation group and 6.42 and 4.79 in the control group, respectively, with a difference between the two groups of 0.04 and 5.84 (95% CI: −3.08 to 2.65, $P = 0.880$; 95% CI: 0.50 to 10.79, $P = 0.032$, respectively).

The AROM of both groups at 2 weeks was significantly higher than that at baseline ($P < 0.05$). However, there were no significant differences in the AROM at 2 weeks between the two groups ($P > 0.05$). Compared with baseline, the mean degree of flexion, extension, abduction, external rotation, and internal rotation increased by 12.40, 7.20, 6.20, 4.72, and 3.96 at 2 weeks in the observation group and 7.92, 6.21, 9.38, 4.25, and 3.50 in the control group, respectively, with a difference between the two groups of 4.8, 1.24, 2.8, 0.64 and 0.6, respectively (95% CI: −2.56 to 11.53, $P = 0.207$; 95% CI: −6.63 to 8.61, $P = 0.795$; 95% CI: −13.54 to 7.19, $P = 0.541$; 95% CI: −4.01 to 4.95, $P = 0.834$; 95% CI: −3.77 to 4.69, $P = 0.828$, respectively).

In terms of swelling volume, there was a significant improvement in both groups at 2 weeks compared with baseline ($P < 0.01$). Moreover, the swelling improvement of the observation group at 2 weeks was significantly better than that of the control group (95% CI: −8.80 to −4.50, $P < 0.001$). Compared with baseline, the mean volume of swelling was reduced at 2 weeks by 9.64 in the observation group and 3.29 in the control group, with a difference between the two groups of 6.48 (95% CI: 4.04 to 8.66, $P < 0.001$).

Table 1

Baseline characteristics of participants

(AROM, active shoulder range of motion; FMA-U, simplified Fugl-Meyer motor function scale for upper limb; MBI, modified Barthel index; VAS, visual analog scale.).

Characteristics	Observation Group ($n = 25$)	Control Group ($n = 24$)	P-value	χ^2/t-value
Gender, n (%)				
Female	9 (36.00%)	10 (41.67%)	0.684*	0.166
Male	16 (64.00%)	14 (58.33%)		
Stroke type, n (%)				
Ischemic	16 (64.00%)	17 (70.83%)	0.610*	0.260
Hemorrhagic	9 (36.00%)	7 (29.17%)		
Affected hemiplegic side, n (%)				
Right	9 (36.00%)	15(62.50%)	0.064*	3.441
Left	16(64.00%)	9(37.50%)		
Body weight, kg, mean ± SD	63.68 ± 11.09	63.46 ± 11.96	0.947#	0.067
Body height, cm, mean ± SD	164.76 ± 8.90	164.50 ± 7.27	0.911#	0.112
Age, years, mean ± SD	59.36 ± 8.73	55.50 ± 8.20	0.118#	1.594
Duration of stroke, day, mean ± SD	59.64 ± 31.07	68.17 ± 41.09	0.416#	−0.822
MMSE, score, mean ± SD	21.00 ± 9.13	21.21 ± 9.73	0.939#	−0.077
VAS, score, mean ± SD	6.32 ± 1.49	6.42 ± 1.21	0.805#	−0.248
Swelling volume, ml, mean ± SD	21.20 ± 3.01	21.50 ± 2.74	0.717#	−0.364
FMA-U, score, mean ± SD	21.48 ± 13.66	20.96 ± 15.50	0.901#	0.125
MBI, score, mean ± SD	54.12 ± 25.94	54.71 ± 24.55	0.935#	−0.081
AROM, degree, mean ± SD				
Flexion	42.60 ± 48.76	48.58 ± 42.52	0.650#	−0.457
Extension	14.40 ± 15.77	15.42 ± 13.38	0.809#	−0.243
Abduction	40.28 ± 29.04	43.04 ± 28.95	0.740#	−0.333
External rotation	10.08 ± 10.37	10.13 ± 9.57	0.987#	−0.016
Internal rotation	8.24 ± 8.61	8.79 ± 9.54	0.833#	−0.213

AROM, active shoulder range of motion; FMA-U, simplified Fugl-Meyer motor function scale for upper limb; MBI, modified Barthel index; VAS, visual analog scale.

* The P value was obtained using a χ^2.

The P value was obtained using an independent t tests; Significance at $P < 0.05$.

Table 2a

The comparisons of clinical assessment scales at 2 weeks

Variables	Observation Group	Control Group	P-value#
VAS, score	2.64 ± 0.95	4.50 ± 1.06	< 0.001
FMA-U, score	27.68 ± 12.55	27.38 ± 13.64	0.935
MBI, score	64.56 ± 19.49	59.50 ± 22.05	0.399
Swelling volume, ml	11.56 ± 3.34	18.21 ± 4.12	< 0.001
AROM, degree			
Flexion	55.00 ± 42.40	56.50 ± 46.30	0.906
Extension	21.60 ± 11.70	21.63 ± 13.30	0.994
Abduction	46.48 ± 30.42	52.42 ± 31.00	0.502
External rotation	14.80 ± 9.73	14.38 ± 9.36	0.877
Internal rotation	12.20 ± 8.18	12.29 ± 9.55	0.971

Data were presented as mean ± SD.

AROM, active shoulder range of motion; FMA-U, simplified Fugl-Meyer motor function scale for upper limb; MBI, modified Barthel index; VAS, visual analog scale.

The P value was obtained using an independent-sample t-test; Significance at $P < 0.05$.

The comparisons of FMA-U score, MBI score, AROM, and swelling volume at 2 weeks are shown in *Table 2a*. The changes in the above scales from baseline to 2 weeks are presented in *Table 2b*.

3.3. Adverse events

One participant in the control group was excluded from this study because he had a new cerebral hemorrhage when entering the second day of this study. This patient did not receive BAA treatment, and his new cerebral hemorrhage was considered to be related to his condition. BAA-related AEs were not found during the study.

4. Discussion

In this study, 49 patients finished the study. The VAS score, FMA-U score, MBI score, AROM, and swelling volume of both

Table 2b

The changes of clinical assessment scales from baseline to 2 weeks

Variables	Observation Group Change from baseline, mean ± SD	Control Group Change from baseline, mean ± SD	Difference from control group in change from baseline, mean (95% CI)	P-value#
VAS, score,	3.68±1.44	1.92±1.35	1.84 (0.96 to 2.56)	< 0.001
FMA-U, score	6.20±5.79	6.42±3.98	0.04 (−3.08 to 2.65)	0.880
MBI, score	10.44±11.40	4.79±5.29	5.84 (0.50 to 10.79)	0.032
Swelling volume, ml	9.64±4.49	3.29±3.47	6.48 (4.04 to 8.66)	< 0.001
		AROM, degree		
Flexion	12.40±13.55	7.92±10.73	4.8 (−2.56 to 11.53)	0.207
Extension	7.20±14.87	6.21±11.34	1.24 (−6.63 to 8.61)	0.795
Abduction	6.20±13.42	9.38±21.83	2.8 (−13.54 to 7.19)	0.541
External rotation	4.72±8.86	4.25±6.48	0.64 (−4.01 to 4.95)	0.834
Internal rotation	3.96±8.78	3.50±5.52	0.6 (−3.77 to 4.69)	0.828

AROM, active shoulder range of motion; FMA-U, simplified Fugl-Meyer motor function scale for upper limb; MBI, modified Barthel index; VAS, visual analog scale.

The P value was obtained using an independent-sample t-test; Significance at $P < 0.05$.

groups at 2 weeks were significantly improved compared with baseline. This indicated that RT or RT plus BAA can significantly reduce shoulder pain and swelling and improve the shoulder range of motion, upper limb motor function, and ADL of patients with post-stroke SHS. The mean differences in the VAS score, MBI score, and swelling volume in the change from baseline from the control group were 1.84, 5.84 and 6.48, respectively. A previous study indicated that the MID of the VAS in pain was 0.9, with differences greater than 0.9 predicting a significant effect on pain relief.[21] The results of this study indicate that BAA combined with RT is superior to RT alone in improving shoulder pain, swelling and ADL in patients with post-stroke SHS.

Although the pathogenesis of SHS is not yet clear, neurogenic inflammation, nociceptive sensitization, vasomotor dysfunction, maladaptive neuroplasticity, and sympathetic nervous system hyperexcitability play important roles in the onset of post-stroke SHS.[24-26] At present, RT is an effective method for treating SHS after stroke. Early good limb placement is an important measure for reducing the disability rate of stroke, repairing damaged motor neurons, and promoting the recovery of motor function, which has a positive effect in the early rehabilitation of hemiplegic patients.[27]

Based on zang-fu theory, the theory of meridian and collaterals, and the shén què (CV08) regulatory system, professor Bo Zhiyun created BAA, which regulates the function of the viscera through acupuncture at acupoints on the abdomen to treat chronic and difficult diseases.[28-29] According to the characteristics of the multilevel spatial structure of abdominal acupuncture treatment, the effects achieved by different acupuncture depths are different.[29] Shallow, moderate, and deep needling regulate the functions of muscles and bones, meridian and collaterals, and zang-fu, respectively. Post-stroke SHS is mainly caused by deficiency of the spleen and kidney, insufficient qi and blood, and obstruction of meridian and collaterals. In this study, CV12, CV10, CV06, and CV04 were deeply inserted to nourish the spleen and kidney and promote the generation of qi and blood. ST24 and ST26 were moderately inserted to promote circulation of qi and blood, and enable qi and blood to arrive at limbs. KI17, AB1, and AB2 were shallowly inserted to improve qi and blood circulation of upper limbs. The combined use of the above acupoints can replenish the spleen and kidney and regulate the circulation of qi and blood to achieve the effect of relieving pain. Besides the above, the effect of acupuncture on post-stroke SHS is related to improving blood rheology, regulating serotonin secretion, and maintaining the balance of ion levels inside and outside the cell.[30] In terms of analgesia, acupuncture can reduce swelling and pain by regulating the levels of serum calcitonin gene-related peptide, substance P, and plasma bradykinin.[31] Another study found that BAA can improve the overall functional state of the cognitive network of the central nervous system, achieve functional reorganization of the cerebral cortex, and promote the recovery of limb motor function.[32] The possible mechanism of BAA combined with RT is as follows: BAA relieves the pain, and then the reduction of pain interrupts the pain brake mode, enhances the active and passive exercise training of the affected limb, restores the "pump" function of the shoulder muscles, promotes the return of blood and interstitial fluid, and reduces the accumulation of pain-causing substances, thereby accelerating the recovery of the motor function of the affected upper limb. The analgesic effect of BAA provides a good basis for improving the efficacy of routine RT on post-stroke SHS.

Previous studies have confirmed that RT, including OT and PT, not only can reduce pain and improve active mobility in CRPS type-I patients within 1 year but also can improve the symptoms of stage I patients with post-stroke SHS.[33-34] However, there are some disadvantages of routine RT for post-stroke SHS patients, such as high treatment cost, long treatment duration, more manpower input, and high requirements for patients' active coopera-

tion ability. BAA with CV10 and KI17 as the main acupoints can relieve neck and shoulder pain, and the total effective rate of immediate analgesia was 96.7%.[35] Moreover, several meta-analysis studies have shown that acupuncture plus RT can improve motor function and ADL and relieve pain in stroke patients with SHS.[36-37] However, the acupuncture used in previous studies was mostly electric acupuncture and traditional acupuncture, which have shortcomings such as pain and poor repeatability.

In this study, patients received routine RT or routine RT plus BAA. The integration of BAA and routine RT has the advantages of shorter treatment duration and fewer adverse reactions, which ensure good patient compliance. In addition, BAA plus routine RT has a significant effect on analgesia and ADL.

There are limitations of this study. First, this study did not establish a false acupuncture control group due to the Chinese patients' current familiarity with acupuncture. Some people may also highly approve of the efficacy of acupuncture in China, which may produce add-on treatment effects. These may lead to bias in the results. To minimize the risk of bias, the outcome assessments were conducted by a rehabilitation physician who was blinded to the group allocation, and the data analyst was also blinded to the group allocation. Second, this study was a prospective randomized controlled single-center trial with a small sample size and an observation period of only 2 weeks, which may cause false-positive results. This study cannot confirm the long-term effect of BAA plus RT in the treatment of post-stroke SHS. Therefore, in the future, multicentre large-sample randomized controlled trials should be conducted to assess its exact effect.

In conclusion, BAA combined with RT was found to be superior to RT alone in improving shoulder pain, swelling, and ADL in post-stroke SHS. The analgesic effect of BAA possibly provides a good basis for improving the efficacy of RT on post-stroke SHS. More multicentre large-sample randomized controlled studies should be performed to explore the exact effect of BAA combined with RT for SHS after stroke.

Author contributions

Conceptualization: JZ, HXC, and ML. Methodology: JZ, HXC, ML, LCZ, and RHP. Formal investigation: CD, QCW, YRA. Data analysis: YRA, YQW, and LML. Writing – original draft: JZ. Writing – review and editing: LML and ML. All authors have read and approved the final manuscript.

Conflict of interests

The authors declare no conflict of interests.

Ethical statement

This RCT was approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine and registered on the Chinese Clinical Trial Registry. Informed consent was obtained from all participants.

Data availability

No additional data are available.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2021.100805.

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