

Analysis of the Influence of Internal Heat Needling and Warming Need Moxibustion on Inflammation and Serum indexes of Patients with Shoulder Pain after Stroke Based on Acupoint Injection

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Keywords

Internal hot needling, Warming needle moxibustion, Ozone acupoint injection, Shoulder pain after stroke, Inflammation

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Abstract

Objective The effects of internal heat needling, warming needle moxibustion and ozone acupoint injection on inflammatory response and serum indexes in patients with shoulder pain after stroke are explored to provide reference for clinical treatment of stroke sequelae. **Methods** 183 post-stroke shoulder pain patients who received rehabilitation in our hospital from June 2018 to June 2020 were selected and randomly divided into three groups, A, B, and C, with 61 cases in each group. Treatments in groups A, B and C were ozone acupoint injection, warming needle moxibustion combined with ozone acupoint injection, an internal heat needling combined with ozone acupoint injection, respectively. The clinical efficacy, visual analogue scale (VAS), Fugl Meyer assessment (FMA), activities of daily living (ADL) score, serum, inflammation-related indicators and adverse reactions were compared among the three groups. **Results** The total clinical effective rate was the highest in group C, and the lowest in group A. After treatment, the VAS score, serum interleukin 6 (IL-6) and tumor necrosis factor- α (TNF- α) levels were the lowest in group C and the highest in group A; on the contrary, the FMA, ADL, serum endorphin (β -EP), enkephalin (ENK), and dynorphin (Dyn) levels were the highest in group C and the lowest in group A. The incidence rate of adverse reactions was notably higher in group B than in groups A and C. **Conclusion** The internal heat needling based on the acupoint injection could effectively relieve the pain of patients with post-stroke shoulder pain, improving mobility of the affected limb, reducing the inflammatory reaction and strengthening the analgesic effect, with few adverse reactions.



Introduction

Shoulder pain is one of the common complications of stroke, and its clinical symptoms are mainly manifested by shoulder joint pain, etc. Post-stroke shoulder pain causes a significant reduction in active muscle activity in the affected upper limb, which, if left untreated, can lead to loss of muscle strength, muscular atrophy and even flaccid paralysis, resulting in irreversible lesions and threatening patients' quality of life [1]. With the development of traditional Chinese medicine (TCM), TCM rehabilitation therapy plays an important role in the treatment of post-stroke complications. Ozone acupoint injection is a product born from the combination of the TCM meridian theory and modern medicine, and is widely applied in the clinical treatment of pain diseases [2]. However, there are currently limitations to the efficacy of simple acupoint injection due to the complicated causes of post-stroke shoulder pain, which involve multiple factors such as microcirculatory disturbance, nervous lesion, muscle adhesion and inflammatory edema. Hence, it is necessary to further explore safe and effective rehabilitation therapies to improve the overall condition of shoulder pain [3]. Internal heat needling and warming needle moxibustion are both rehabilitation therapies that exert an effect on relieving convulsion and activating collaterals through thermal conduction and acupuncture. Combined with acupoint treatment, they can relieve muscle tension and spasm and alleviate the symptoms of swelling and pain [4]. However, the comparative effectiveness and safety of above treatments in post-stroke shoulder pain remains unclear. Based on this, this study explored the effects of internal heat needling, warming needle moxibustion and ozone acupoint injection on inflammatory response and serum indexes in patients with shoulder pain after stroke, hoping to provide valuable information for reference in the clinical treatment of stroke sequela.

Information and methods

Basic information

A total of 183 cases patients with shoulder pain who received rehabilitation therapy after stroke in our

hospital from June 2018 to June 2020 were selected and randomly divided into three groups A, B and C, with 61 cases in each group. There was no statistically significant difference between the three groups in terms of basic information such as gender, age, duration of disease and affected limb ($P>0.05$), and the data were clinically comparable, as detailed in Table 1. The study was approved by the Ethics Committee of the hospital, with informed consent form all patients.

Diagnostic standards: the Western medical diagnosis met the diagnostic criteria for stroke as described in *Various Types of Cerebrovascular Disease Diagnosis* of the fourth National Conference on the diagnosis of cerebrovascular disease [5]; the TCM diagnosis met the relevant criteria in *Diagnosis and Evaluation Standard of Stroke Diseases* [6]; patients with post-stroke shoulder pain met the relevant criteria set by the China rehabilitation research center, including one-side shoulder and hand pain, skin flushing, limited flexure of fingers, local woundless infection and onset within 1 to 3 months after stroke.

Inclusion criteria: patients with stroke who met the diagnostic criteria of TCM and Western medicine and suffered from shoulder and hand pain; patients with no previous history of mental illness, clear consciousness and stable vital signs; patients without given oral analgesic medication; patients with complete clinical information. Exclusion criteria: patients with combined malignancy and severe impairment of vital organ functions such as heart, liver and kidney; patients with recent trauma to the single sided shoulder and hand or a history of surgical procedures at the treatment site; patients with other serious complications of stroke.

Methods

Group A

The patients were given ozone acupoint injection. Briefly, iodophor was used to sterilize five acupoints including Jianyu (LI15), Jianliao (SJ14), Jianzhen (SI9), Binao (LI14) and Ashi. Then, each acupoint was injected with 3 ml of ozone by syringe (0.3 mm diameter, 30 mg/ml), once every other day, for total 1

month.

Group B

The patients were given warming needle moxibustion combined with ozone acupoint injection. After regularly disinfection, disposable acupuncture needle (Hwato, Suzhou Medical Supplies Factory Co., Ltd, 0.3 mm × 40 mm) was pierced straight into the acupoint about 30 mm. Using even reinforcing-reducing method, the needle was inserted and twisted for 2 minutes until the patient felt a sense of soreness and swelling. After that, the needle was retained in the acupoint, and a 20 mm long moxa stick was inserted into the needle handle, with the stick vertically above 30 mm from the skin and an insulating plate on the skin. The needle was allowed to pull out after the moxa sticks have burned out and the needle handle has cooled down. After 15 minutes, ozone acupoint injection was administered in the same way as in group A. The combined treatment was performed once every other day, for total 1 month.

Group C

The patients were given internal heat needling combined with ozone acupoint injection. Firstly, ozone was injected into the acupoints in the same way as in group A, and the patients were required to wait for 30 minutes after injection. Subsequently, 1% lidocaine was used for local application of anesthesia after disinfection. Then, 4 to 6 internal heat acupuncture needles (Jiake, Jining Jiake Medical Technology Co., Ltd, 0.7 mm × 110 mm) were pierced into the skin around the acupoint at a distance of about 10 mm, with the direction of entry being oblique along the tendon into the periosteal attachment. After that, the needles were linked with matched acupuncture treatment instrument (K-40) which was set at 42°C with a heating time of 20 minutes. After removed needles, the needle hole was disinfected and covered with a sterile dressing. Ozone acupoint injection was given once every other day, and internal heat needling was given once a week on the day of the injection, both for 1 month of continuous treatment. The three groups were not given any analgesic

medication during the treatment.

Observation and assessment

Clinical efficacy

The clinical efficacy of patients was assessed according to *Diagnosis and Evaluation Standard of Stroke Diseases* [6]. Cured: shoulder pain disappeared or largely disappeared. Improved: shoulder pain alleviated. Not improved: symptoms have not improved or have even worsened. Total effective rate = (cured + improved) number of cases/total number of cases × 100%.

VAS, FMA and ADL measurements

Before and after treatment, visual analogue scale (VAS) was applied to assess the patient's improvement in pain. A 10 cm vernier caliper with 11 numbers from 0-10 was used and the patient chose a number to represent their pain level, with higher numbers indicating more intense pain [7]. The upper limb motor function was evaluated using Fugl Meyer assessment scale (FMAS) including extensor and flexor movements, hyperreflexia and finger movement, with a total score of 66 points, with higher scores representing better upper limb motor function [8]. Activity of daily living (ADL) score was employed to assess the patient's self-care ability, including washing, dressing, toileting, walking on level ground and walking up and down stairs, etc. A total score of 100 points was used, with higher scores indicating greater self-care ability [9].

Serum and inflammatory indicators

Before and after treatment, 5 ml of elbow venous blood was taken from each fasting patient in the three groups, and was performed centrifugation (3000 r/minute, 15 minutes) for obtaining serum which was then stored in a refrigerator at -20°C. Enzyme linked immunosorbent assay (ELISA) was conducted to detect serum endorphin (β-EP), enkephalin (ENK), and dynorphin (Dyn) levels in the serum, and the ELISA kit was purchased from Shanghai Hepeng Biotechnology Co., Ltd. Radioimmunoassay (RIA) was performed to analyze interleukin 6 (IL-6) and

tumor necrosis factor- α (TNF- α) levels in the serum, and the RIA kit was obtained from Nanjing Jiancheng Bioengineering Insititute. All relevant tests were carried out in strict accordance with the reagent instructions.

Adverse reactions

During treatment, adverse reactions were collected and recorded in all three groups, including burns, scalds, bruises and hematoma.

Statically analysis

SPSS software (version 20.0, IBM, USA) was used for statistical analysis. Count data were compared

using χ^2 test. Quantitative data was demonstrated as the mean \pm standard, with comparison using the *t*-test. The pairwise comparison between groups was tested by least significant difference (LSD) or Tamhane. There was statistical significance if $P < 0.05$.

Results

Comparison of clinical efficacy between the three groups

The total clinical efficiency in group C was significantly higher than that in groups A and B, and the total clinical efficiency in group B was significantly higher than that in group A ($P < 0.05$), as shown in Table 2.

Table 1. Comparison of basic information of the three groups

groups	cases	gender (case)		age (year)	duration of disease (month)	affected limb (case)	
		male	female			left	right
group A	61	31	30	62.74 \pm 8.56	3.45 \pm 1.02	30	31
group B	61	33	28	63.84 \pm 9.20	3.62 \pm 1.15	34	27
group C	61	29	32	61.63 \pm 8.72	3.32 \pm 1.04	28	33
χ^2/F		0.525		0.955	1.202	1.224	
<i>P</i>		0.769		0.387	0.303	0.542	

Table 2. Comparison of clinical efficacy between the three groups [case (%)]

groups	cases	cured	improved	not improved	total effective rate
group A	61	10 (16.39)	25 (40.98)	26 (42.62)	35 (57.38)
group B	61	17 (27.87)	30 (49.18)	14 (22.95)	47 (77.05) ^a
group C	61	32 (52.46)	25 (40.98)	4 (6.56)	57 (93.44) ^{ab}
χ^2		21.783			
<i>P</i>		0.000			

Note: Compared to group A: ^a $P < 0.05$; Compared to group B: ^b $P < 0.05$

Comparison of VAS, FMA and ADL scores between the three groups

Before treatment, there was no significant difference in the comparison of VAS, FMA and ADL scores between the three groups ($P > 0.05$). After treatment, VAS scores were significantly lower in all three groups than before treatment, and significantly lower in group C than in groups A and B, and significantly lower in group B than in group A ($P < 0.05$). After treatment, the FMA and ADL scores were

significantly higher in all three groups than before treatment, and significantly higher in group C than in groups A and B, and significantly higher in group B was than group A ($P < 0.05$), as shown in Table 3.

Comparison of serum indicators between the three groups

Before treatment, there was no significant difference in β -EP, ENK, and Dyn levels between the three groups ($P > 0.05$). After treatment, β -EP, ENK, and

Dyn levels were significantly higher in all three groups than before treatment, and significantly higher in group C than in groups A and B, and significantly

higher in group B than in group A ($P < 0.05$), as shown in Table 4.

Table 3. Comparison of VAS, FMA and ADL scores between the three groups (point)

group	cases	VAS		FMA		ADL	
		pre-treatment	post-treatment	pre-treatment	post-treatment	pre-treatment	post-treatment
group A	61	6.14±1.73	2.94±0.83 ^c	24.36±4.52	32.73±6.84 ^c	42.73±6.72	55.38±10.82 ^c
group B	61	6.56±1.52	2.43±0.68 ^{ac}	25.14±5.38	38.44±5.79 ^{ac}	43.48±7.25	61.77±9.66 ^{ac}
group C	61	6.38±1.84	1.56±0.48 ^{abc}	25.67±4.85	42.38±6.39 ^{abc}	42.26±7.33	68.74±8.37 ^{abc}
<i>F</i>		0.935	64.491	1.090	35.562	0.458	29.140
<i>P</i>		0.394	0.000	0.338	0.000	0.634	0.000

Note: Compared to group A: ^a $P < 0.05$; Compared to group B: ^b $P < 0.05$

Table 4. Comparison of serum indicators between the three groups (pg/ml)

groups	cases	β-EP		ENK		Dyn	
		pre-treatment	post-treatment	pre-treatment	post-treatment	pre-treatment	post-treatment
group A	61	684.74±85.76	894.59±96.77 ^c	45.34±8.62	60.22±7.59 ^c	75.34±12.35	103.37±16.46 ^c
group B	61	695.34±92.88	984.34±85.97 ^{ac}	44.38±7.84	68.38±6.74 ^{ac}	77.20±10.28	121.44±15.72 ^{ac}
group C	61	703.58±97.38	1095.33±120.78 ^{abc}	46.28±9.33	75.34±10.56 ^{abc}	76.38±9.55	138.42±18.50 ^{abc}
<i>F</i>		0.641	59.041	0.741	48.853	0.455	65.350
<i>P</i>		0.528	0.000	0.478	0.000	0.635	0.000

Note: Compared to group A: ^a $P < 0.05$; Compared to group B: ^b $P < 0.05$

Comparison of inflammatory indicators between the three groups

Before treatment, there was no significant difference in IL-6 and TNF-α levels between the three groups ($P > 0.05$). After treatment, IL-6 and TNF-α levels were significantly lower in all three groups than before treatment, and significantly lower in group C than in groups A and B, and significantly lower in group B than in group A ($P < 0.05$), as shown in Table

5.

Comparison of adverse reactions between the three groups

During treatment, there was statistically significant difference in the incidence of adverse reactions between the three groups, with the incidence in group B being significantly higher than that in groups A and C ($P < 0.05$), as shown in Table 6.

Table 5. Comparison of inflammatory indicators between the three groups

groups	cases	IL-6 (pg/ml)		TNF-α (ng/ml)	
		pre-treatment	post-treatment	pre-treatment	post-treatment

group A	61	88.46±13.45	57.64±10.33 ^c	34.56±6.75	23.50±6.24 ^c
group B	61	86.74±14.20	48.38±8.68 ^{ac}	35.26±7.76	18.74±4.49 ^{ac}
group C	61	85.94±15.84	37.34±7.25 ^{abc}	33.94±8.20	12.46±3.15 ^{abc}
<i>F</i>		0.479	80.563	0.461	81.314
<i>P</i>		0.620	0.000	0.631	0.000

Note: Compared to group A: ^a*P*<0.05; Compared to group B: ^b*P*<0.05; compared to pre-intervention, ^c*P*<0.05

Table 6. Comparison of adverse reactions between the three groups [case (%)]

groups	cases	burns	scalds	bruises	hematoma	total
group A	61	0 (0.00)	0 (0.00)	4 (6.56)	1 (1.64)	5 (8.20)
group B	61	2 (3.28)	4 (6.56)	8 (13.11)	2 (3.28)	16 (26.23) ^a
group C	61	0 (0.00)	1 (1.64)	5 (8.20)	1 (1.64)	7 (11.48) ^b
χ^2						7.065
<i>P</i>						0.029

Note: Compared to group A: ^a*P*<0.05; Compared to group B: ^b*P*<0.05

Discussion

The pathogenesis of post-stroke shoulder pain includes endogenous factors such as adhesive capsulitis and brachial plexus injury, as well as pathogenic factors such as shoulder subluxation and abnormal muscle tone, which may also coexist, making shoulder pain more difficult to treat. Therefore, multimodality therapy is mainly used to treat currently clinical post-stroke shoulder pain [10,11]. Ozone acupoint injection therapy is based on the strong oxidizing property of ozone, and acts as a chemical acupuncture and moxibustion during local soft tissue injection, where the ozone entering the body can activate inhibitory interneurons and exert analgesic and anti-inflammatory effects [12]. Additionally, on the basis of ozone acupoint injection, this study combined it with internal heat needling and warming needle moxibustion, respectively. Warming needle moxibustion is an irritation therapy commonly used in TCM acupuncture and moxibustion, which has the effect of dispelling cold pathogen, warming channels and relieving pain. Internal heat needling, also known as percutaneous skeletal muscle lysis, is a new acupuncture therapy developed from warming needle moxibustion, in which needles are used to penetrate the skeletal muscle in the ischemic spasm to create trauma and induce the regeneration of skeletal muscle and blood vessels in the affected limb, while

using a heating and temperature control system to reduce the tension and inflammation of the spastic degenerated muscle, and thereby to achieve the therapeutic purpose [13]. The results of this study showed that the total clinical efficiency in group C was significantly higher than that in groups A and B, and the total clinical efficiency in group B was significantly higher than that in group A, suggesting that ozone acupoint injection combined with internal heat needling or warming needle moxibustion could effectively relieve clinical symptoms in patients with post-stroke shoulder pain, and the efficacy is better than ozone injection alone. Besides, the efficacy of combined internal heat needling was found to be superior to combined warming needle moxibustion, which was similar to the findings of Yang Liu et al [14].

In TCM, post-stroke shoulder pain is considered to be arthralgia and hemiplegic shoulder caused by yin deficiency of liver and kidney leading qi-blood stasis and obstruction. Hence, it is the result of stagnation of the tendons and veins due to poor qi flow, which gradually progresses to chronic pain that affects the functional recovery of the patient’s upper limb as well as daily life. This show that the treatment of post-stroke shoulder pain primarily relies on ameliorating blood circulation, relieving pain and improving the patient’s quality of life [15]. Our study

found that VAS, FMA and ADL scores were significantly higher in group C than in groups A and B, and significantly higher in group B than group A, indicating that compared to acupoint injection combined with warming needle moxibustion, acupoint injection-based internal heat needling exerts a better effect on alleviating shoulder pain, improving the motor function of the upper limb and enhancing self-care ability. Moreover, clinical studies have shown that endogenous opioid peptides play an important role in the pain regulation of the body's nervous system. β -EP, ENK and Dyn are all classical opioid peptides that bind to μ receptors, δ receptors and κ receptors respectively and exert analgesic effects which are positively correlated with their expression levels [16]. Our study found that after treatment, β -EP, ENK, and Dyn levels were significantly higher in group C than in groups A and B, and significantly higher in group B than in group A, revealing that the combination of internal heat needling and ozone acupoint injection could increase secretion of β -EP, ENK and Dyn in the patient's brain, and its analgesic effect is superior to the other two treatments. Ozone is found to have an analgesic effect by stimulating inhibitive interneurons to release analgesic substances like β -EP. Based on this, internal heat needling and warming needle moxibustion contain both acupuncture and heating properties, which could accelerate local soft tissue blood circulation in patients with post-stroke shoulder pain through heat conduction, regulate blood viscosity and improve neurological function at the same time. The acupuncture action helps to loosen local soft tissue adhesions and reduce muscle tone, which is in line with the TCM treatment of warming channels to relieve pain and regulating qi flow to invigorate blood. Experimental animal studies have shown that internal heat needling therapy could effectively promote vascular renewal in rats with chronic soft tissue injury, improve blood supply to soft tissues and significantly relieve muscle contracture and pain [17]. Furthermore, internal heat needling requires more needles to acupuncture points compared to warming needle moxibustion, resulting in an advantage in terms of the

amount of acupoints, stimulation intensity, stimulation area and heat penetration [18]. Therefore, the combination of internal heat needling and ozone acupoint injection could further relieve pain symptoms of patients and improve their self-care ability and quality of life.

Inflammatory injury of soft tissues is an important trigger for shoulder pain that further exacerbate joint fixation and muscle contracture of the patient, thereby promoting the development of adhesive capsulitis. This demonstrates that inflammatory response and shoulder pain are mutually dependent, and that effective controlling inflammatory response to relieve pain is crucial to improving the prognosis of patients with shoulder pain after stroke [19]. TNF- α is a polypeptide cytokine secreted by monocytes and macrophages and is involved in a variety of activities such as body infection and immune response. IL-6 is an important mediator in the acute inflammatory response, stimulating inflammatory cell aggregation, activation and the release of inflammatory transmitters. When TNF- α and IL-6 are overexpressed in the patient's body, they can induce inflammatory injury of tissues and accelerate the progression of the disease. Therefore, it is important to effectively balance inflammatory factor levels during the treatment of post-stroke shoulder pain. The results of this study showed that after treatment, IL-6 and TNF- α levels were significantly lower in group C than in groups A and B, and significantly lower in group B than in group A, suggesting that the combination of internal heat needling and ozone acupoint injection could effectively reduce the inflammatory response of the body in patients with post-stroke shoulder pain, and the efficacy is better than the combination with warming needle moxibustion or ozone acupoint injection alone. When injected into the body, ozone has the effect of stimulating the overexpression of oxidative enzymes and is able to neutralize the oxygen radicals produced during the inflammatory response in order to reduce oxygen radical-induced body injury, thereby affecting the synthesis and release of inflammatory cytokines in the local soft tissues [20]. Compare with warming needle moxibustion, internal

heat needling can regulate and maintain the temperature of the needle tip as an appropriately constant temperature conduction helps to control the excitability of γ neurons and attenuate the efferent impulses of α neurons in the tissue, thus reducing muscle and fibrous tissue tension, effectively relieving tissue adhesions and contractures, improving the local microenvironment, and further inhibiting the expression of IL-6 and TNF- α . Additionally, our study found that the incidence rate of adverse reactions in group B being significantly higher than that in groups A and C, demonstrating that adding internal heat needling to the fundamental treatment of ozone acupoint injection on post-stroke shoulder pain has a safe and reliable therapeutic effect by significantly strengthening efficacy without increasing the risk of adverse reactions. The increase in adverse reactions such as burns, scalds and bruises in patients during the combined warming needle moxibustion may be due to the difficulty in controlling the surface temperature of the moxa stick as it burns, causing injury to the surrounding skin. However, resistance wires in the needle used in the internal heat needling allow for uniform heating thus effectively reducing such incidents and providing safety during treatment for patients with shoulder pain.

In conclusion, compared with simple ozone acupoint injection therapy and acupoint injection-combined warming needle moxibustion therapy, the internal heat needling based on the acupoint injection could effectively relieve the pain of patients with post-stroke shoulder pain, improve mobility of the affected limb, help to reduce the inflammatory reaction, strengthen the analgesic effect, exerting a high safety in treatment with few adverse reactions.

Acknowledgement

Not applicable.

Conflict of Interest

The authors declare no conflicts of interest.

Author Contributions

Conceptualization, Data curation and Writing-Original

draft, J.W; Writing-review and editing, M.Y.F; All authors have read and agreed to the published version of the manuscript.

Ethics Approval and Consent to Participate

The study was approved by the Medical Ethics Committee, and the patients were informed and consented.

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Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

Supplementary Material

Not applicable.

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