



Original Article

Clinical Study of Acupotomy Treatment for Tarsal Tunnel Syndrome

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ABSTRACT

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Background: Compared with conventional closed therapy, acupotomy has the advantages of lower cost, convenient application, and better single and long-term effects. The aim of this study was to explore the clinical effect of acupotomy in the treatment of Tarsal Tunnel syndrome.

Methods: There were 80 patients enrolled into the study who were randomly assigned to either the acupotomy or closed therapy group, with 40 patients in each group. The acupotomy group was treated once every 6 days, on 3 occasions for the duration of treatment, and the closed therapy group was treated twice a week, for 3 weeks as the course of treatment. The effects of treatment were analyzed and evaluated according to the standard of curative effect.

Results: The “cure rate” of the number of patients in the acupotomy group whose symptoms had completely disappeared (13 patient out of 39) was higher than the closed therapy group (1 patient out of 39), and this difference was significant ($p < 0.01$). The number of patients in the acupotomy group who did not benefit from the therapy (5 patients) was significantly lower than the closed therapy group (15 patients; $p < 0.05$). The total number of patients in the acupotomy group who benefitted from the therapy (34 patients) resulted in an effective rate of 87.18%, which was higher than the closed therapy group (24 patients; 61.53%). The difference was statistically significant ($p < 0.05$).

Conclusion: Acupotomy is effective in the treatment of Tarsal Tunnel syndrome, was superior to traditional closed therapy, and is worthy of clinical application.

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Introduction

Tarsal Tunnel syndrome is a painful foot condition where the tibial nerve is compressed, in the tarsal tunnel. It is common in young adults, heavy manual workers, and long-distance runners, and common symptoms are long-term plantar numbness and pain [1]. There are a variety of clinical methods to treat the disease, such as closed treatment of local pain points and open surgical treatment, but the long-term effect of closed treatment is poor and relapses are typical, and surgical decompression, although effective for the condition, is traumatic to many patients [2]. Acupotomy therapy, which combines acupuncture using a surgical scalpel procedure, and has been shown to be an effective treatment of peripheral nerve entrapment syndrome caused by slow injury of the motor system [3].

In clinics, the application of acupotomy in the treatment of Tarsal Tunnel syndrome has achieved good results in its analgesic effect and relief of dysfunction. This clinical study compared closed

treatment and acupotomy treatment in 80 patients with Tarsal Tunnel syndrome.

Materials and Methods

General data

The 80 cases in this study included patients who had visited the Department of Orthopedics, General Hospital of Beijing military region, and the outpatients for the Department of Acupuncture and Moxibustion, Department of Traditional Chinese Medicine, Beijing University of Traditional Chinese Medicine, from December 2015 to December 2017.

There were 80 patients who met the diagnostic criteria and inclusion criteria, and were randomly divided into the acupotomy group, and the closed therapy group, using a random number table, with 40 patients in each group.

Among the 80 patients, there were 41 cases of right foot Tarsal

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Tunnel syndrome, 38 cases of left foot and 1 case of both feet. There were 40 males and 40 females. In the acupotomy group, there were 22 males and 18 female patients, with an average age of 46.875 ± 9.255 years. In the closed therapy group, there were 18 male patients and 22 female patients, with an average age of 46.9 ± 9.438 years. Among the 80 patients, there were 35 mild cases, 31 moderate cases and 14 severe cases, only 1 patient had bilateral ankle joint disease at the same time, and the rest were unilateral. The shortest course of the illness in the 80 patients was 0.5 months, and the longest was 36 months.

There was 1 patient in the acupotomy group who interrupted the therapy due to fear of the acupotomy treatment, and therefore 39 cases qualified for analysis. One patient in the closed therapy group was excluded because of long-term travel during the treatment, and therefore 39 cases qualified for analysis.

The general data of the 2 groups was compared, and gender was tested using the chi-square test, whilst age and course of treatment were compared using the rank sum test, showing no significant difference between study groups ($p > 0.05$).

The study was approved by Beijing University of Chinese Medicine review board and written informed consent was obtained from all participants.

Diagnostic criteria for Tarsal Tunnel syndrome

Diagnostic criteria used in Western medicine

With reference to Practical Orthopedic Neurological Injury Localization Diagnostics [4], and Clinical Diagnosis and Treatment Guidelines-Pain Fascicles [5], and Tarsal Tunnel syndrome, the proposed criteria for diagnosis was as follows:

- (1) The principal complained of numbness and pain in the sole of their foot or ankle, which was aggravated after weight-bearing or exercise, and slightly relieved after rest.
- (2) Physical examination showed swelling and tenderness behind the medial malleolus using the positive nerve percussion test (Tinel Sign), muscle strength was generally not affected, and a decreased sensation was observed in the calcaneal branch of the posterior tibial nerve and its main branches, medial plantar nerve, and lateral plantar nerve.
- (3) Electromyography examination of nerve conduction velocity and sensory test of the affected foot evoked potential latency which prolonged or disappeared, and denervated changes such as spontaneous fibrillation potential appeared in the abductor pollicis brevis muscle.
- (4) Auxiliary examination using X-ray or computerized tomography scans for partial cases showed localized lesions in the ankle canal, with bone spurs or bone bridges formed on the medial side of the calcaneus. Under high-frequency ultrasound, some cases showed thickening of the outer nerve membrane, thickening of the diameter, uneven internal echo, and unclear nerve boundaries.

Diagnostic criteria of traditional Chinese medicine

The diagnostic basis for Tarsal Tunnel syndrome (ZY/T001.1-94) was adopted in the Standard of Diagnosis and Therapeutic Effect of Diseases and Syndromes of Traditional Chinese Medicine [6].

- (1) History of trauma or chronic strain.
- (2) It usually occurs in young adults, and middle-aged men, mostly manual workers and generally unilateral.
- (3) Plantar and medial heel pain, numbness, obvious after fatigue, relief after rest, toe canal percussion radiated pain to the sole of the foot and heel.
- (4) Electromyography examination for tremor of the foot minor

muscle, innervated by the medial plantar nerve and the lateral plantar nerve.

Criteria of severity classification

According to the different symptoms, Tarsal Tunnel syndrome was divided into mild, moderate, and severe types [4].

Mild symptoms included discomfort, pain and numbness in the sole of the foot and inner ankle, which was aggravated after standing or walking for a long time, relieved after rest or removal of shoes, and some patients showed foot varus position when walking in order to relieve pain.

Moderate symptoms were characterized by aggravation of symptoms, continuous burning pain present during rest or sleep, patients with a history of painful awakening at night, and in order to relieve or reduce pain, patients often shook or massaged their calves. The compression of the posterior tibial artery and vein showed circulatory disturbance, such as local acid distension, and poor venous reflux.

Severe types had aggravated symptoms described for moderate and mild conditions, and autonomic nerve disorder symptoms such as dry and shiny skin in the nerve control area, peeling, less sweating and atrophy of the internal muscle of the foot.

Inclusion criteria

- (1) Fulfilled the diagnostic criteria for Tarsal Tunnel syndrome using traditional Chinese medicine or Western medicine.
- (2) Aged 30 to 70 years.
- (3) Have not recently taken analgesics.
- (4) Be of clear mind and have normal stable vital signs.
- (5) Agree to participate in the study and voluntarily sign informed consent forms.
- (6) Meet the above diagnostic criteria and exclude patients with other systemic diseases and will participate in clinical research [7].

Exclusion criteria

- (1) Women who are pregnant, breastfeeding or preparing for pregnancy.
- (2) Acute ankle injury, ankle tuberculosis, tumor, stroke sequelae.
- (3) Patients with mental illness or serious diseases such as cardiovascular, cerebrovascular, lung, liver, kidney, or hematopoietic system.
- (4) Ankle pain caused by rheumatism and rheumatoid arthritis.
- (5) Injury in the operation site [8].

Culling criteria

After inclusion, other therapeutic drugs or methods were used, which was contrary to the original scheme of clinical trial.

Shedding standard

- (1) During the period of treatment and observation, the participants who used or received therapy other than those prescribed in this study.
- (2) The participants who were required to stop the treatment due to the occurrence of dizziness or stagnation of needle during the acupotomy treatment.
- (3) Those who left Beijing for various reasons (such as poor "curative effect" or business trips) were requested to withdraw

- from the study and so did not complete the treatment course.
- (4) Participants who developed or continued to exacerbate serious complications during study treatment.
 - (5) In the study and observation, the participants that had poor compliance and could not be observed or were lost to follow-up.
 - (6) The causes of cases lost to shedding should be recorded in the observation table. The patients who had received more than half of the course of treatment were assessable cases, and those who had received less than half of the course of treatment were used as the evaluation of adverse reactions, not as the evaluation of the “curative effect.”

Treatment methods

Acupotomy therapy

The basic scheme of acupotomy in the treatment of Tarsal Tunnel syndrome:

- (1) Principles used include Dredge qi and blood, release adhesion to relieve entrapment.
- (2) Environmental requirements should include paying attention to environmental hygiene, avoiding pollution, disinfection using ultraviolet light, conducting the treatment in a minimally invasive treatment room or outpatient operating room [9].
- (3) Body surface localization of the operation point.
The tip of the medial malleolus connects with the stop point of the Achilles tendon. The intersection point between the line and the posterior and inferior edge of the medial malleolus is the starting point of the split ligament, which is the first entry point. The intersection point between the line and the inner edge of the calcaneus is the second entry point, at the stop point of the split ligament. The tip of the medial malleolus connects with the medial process of the calcaneal tubercle. The intersection of the line and the inferior edge of the medial malleolus is at the starting point of the split ligament, which is the third entry point. The intersection with the medial edge of the calcaneus is at the stop point of the split ligament, which is the fourth entry point (Fig. 1).
- (4) The patient's operation position.
The patient lies on the treatment bed with the affected side down and the medial malleolus of the affected foot facing upwards [10]. The ankle is padded and stabilized with a pillow.

- (5) Disinfection and anesthesia of the operation site.
The operation site was routinely disinfected, and anaesthetized with a 0.5% lidocaine local injection, then the aseptic towel was spread with the treatment point in the middle of the hole in the towel [11].
- (6) Operation.
 - ① Type I, No. 4 acupotomy scalpel needles were used to loosen tissue along the 4 points of the scalpel needle (Fig. 2).
 - ② The acupotomy treatment was perpendicular to the skin with the edge of the acupotomy scalpel needle parallel to the split ligament. The acupotomy scalpel needle was inserted according to the 4-step procedure of the acupotomy treatment closed operation. The acupotomy scalpel needle was passed through the skin, subcutaneous tissue, and fascia, reaching the bone surface, and explored downward along the bone. When there was a sense of toughness under the acupotomy scalpel needle, it had reached the split ligament. 2-3 scalpel needles were removed using a transverse method and longitudinal stripping method, and the range was not more than 0.5 cm.
 - ③ After the procedure, the acupotomy scalpel needles were pulled out, local pressure was applied to stop the bleeding, and the pinprick was covered with a band-aid.
- (7) Course of treatment.
The treatment interval was usually once a week, with between 1-3 treatment times according to the course of recovery. In this study, mild types of Tarsal Tunnel syndrome were “cured” in patients one time, in moderate types 2 times, and in severe types 3 times.

Control group

Use the closed therapy.

- (1) Drugs included triamcinolone acetonide acetate injection (Zhejiang Xianju Pharmaceutical Co., Ltd.), lidocaine hydrochloride injection (Shandong Hualu Pharmaceutical Co., Ltd.), and 0.9% sodium chloride injection (China Otsuka Pharmaceutical Co., Ltd.).
- (2) The operation posture was the same as that of the treatment group, and the tenderness point is selected between the starting and ending points of the split ligament. After routine disinfection, triamcinolone acetonide acetate injection (1 mL), lidocaine hydrochloride injection (2 mL), 0.9% sodium chloride injection (2 mL was mixed to total 5 mL solution). An acupotomy scalpel needle was inserted into the posterior

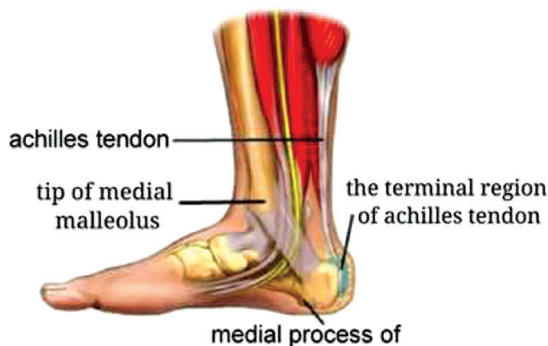


Fig. 1. Body surface localization of the operation point.

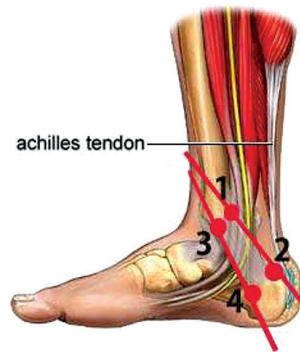


Fig. 2. Acupotomy needle (Type1No 4.1.0*50mm).

edge of the medial malleolus. If no blood was drawn back, the closed treatment was performed. Treatment was performed twice a week, for 3 weeks to complete the course of treatment.

Observation index

Basic security indicators

- (1) The pulse, rate of respiration, blood pressure and heart rate were measured and recorded before and after treatment.
- (2) Adverse reactions such as massive bleeding, dizzy needle, and shock would have been recorded during the treatment. In this study, except for 1 patient in the acupotomy group who did not complete the treatment because of fear, there were no adverse reactions before or after the operation.

Evaluation standard of the “curative effect”

Evaluation of the “curative effect” of Tarsal Tunnel syndrome was referred to in the industry standard of traditional Chinese medicine, the standard of diagnosis and the “curative effect” of diseases and syndromes in traditional Chinese medicine issued by the State Administration of Traditional Chinese Medicine in 1994.

In patients cured of symptoms, there was no local swelling, no soreness and pain when standing and walking, no numbness, or abnormalities observed when electromyography was performed.

In patients that showed improvement in symptoms, local swelling and pain was relieved, there was still a feeling of soreness when walking too much or standing for too long, and improvement was observed when electromyography was performed.

Effective treatment was used to describe patients whose ankle pain was relieved and the ankle’s range of motion had partially improved.

In cases where the treatment was ineffective the patient was not

healed, symptoms had not improved, and the electromyography confirmed this.

Statistical methods

All data were processed by SPSS Version 18.0 (SPSS Inc., Chicago, IL, USA). Comparisons between the measurement data groups before and after treatment were performed using the paired *t* test. The total “effective rate” of data was tested using chi-square test, and the “curative effect” between the groups was tested using the pairwise rank sum test. The differences were considered to be statistically significant when $p < 0.05$.

Results

The “curative effects” of the 2 groups were compared (Fig. 3, Table 1). As can be seen from Figure 3, the “cure rate” of the acupotomy group (13 patients) was higher than the closed therapy group (1 patient) and this difference was significant ($p < 0.01$). In addition, the “invalid rate” of the acupotomy group was lower (5 patients) than the closed therapy group (15 patients), and this difference was significant ($p < 0.05$). It can be seen from Table 1 that the total “effective rate” of the acupotomy group ($n = 34$) was 87.18%. It was higher than the total “effective rate” of 61.53% in the closed therapy group. The difference was statistically significant ($p < 0.05$), which showed that the acupotomy group was significantly more effective in the treatment of Tarsal Tunnel syndrome, and the overall effect of the acupotomy group was significantly better than the closed therapy group.

Discussion

Tarsal Tunnel syndrome belongs to the category of “injured tendons” in traditional Chinese medicine [12]. Grand Simplicity of Inner Canon of Huangdi believes that evil attacks the tendon as if it was a disease, and this cannot be transferred, so the sickness is the pain. The tendon injuries are collateral damage, and the qi and blood movement is obstructed. The pain is caused by incompatibility, so the main symptoms of tendon disease, are pain and adverse joint movements [13]. Acupotomy in the treatment of Tarsal Tunnel syndrome can improve the patient’s symptoms and their quality of life. Compared with conventional therapy, acupotomy has the advantages of low cost, convenience, and a better single and long-term effect [14,15]. Due to the differences in diagnostic criteria and evaluation criteria of ankle canal syndrome, the excellent and good rates in this group of cases may be subjective to some extent. Therefore, further analysis and research on a larger sample are needed in the future.

Conflicts of Interest

The authors have no conflicts of interest to declare.

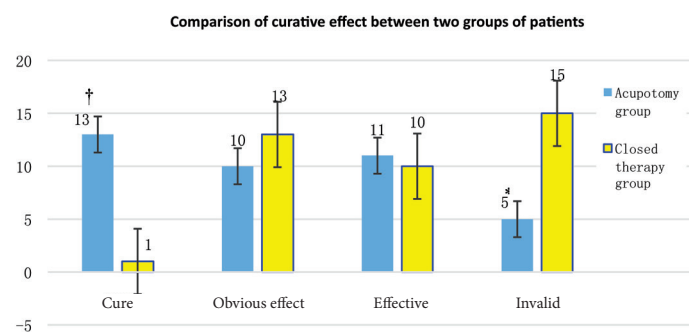


Fig. 3. Comparison of curative effect between the two groups of patients.

Table 1. Comparison of Curative Effect Between the Two Groups [Case(%)].

	Cure	Obvious effect	Effective	Invalid	Total efficiency
Acupotomy group	13 [†]	10	11	5 [*]	87.17 [*]
Closed therapy group	1	13	10	15	61.53

Note: compared with closed therapy. * $p < 0.05$, [†] $p < 0.01$.

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