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Original Article

Effects of catgut implantation of acupoints selected at the urinary bladder meridian and acupuncture on patients with calcaneodynia and AOFAS-AH & VAS scores

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Abstract: Objective: This study was designed to explore the effects of catgut implantation of acupoints selected at the urinary bladder meridian by and acupuncture on patients with Calcaneodynia and on their AOFAS-AH (American Orthopaedic Foot and Ankle Society Ankle-Hindfoot) & VAS (Visual Analogue Score). Methods: A total of 300 patients with Calcaneodynia from the Department of Acupuncture and Moxibustion of Cangzhou Central Hospital were included and randomized into the Catgut Implantation Group (CIG, n=100), Acupuncture Group (AG, n=100) and Control Group (CG, n=100) by a Random Number Table. Patients in the CIG were treated by catgut implantation of acupoints selected at the urinary bladder meridian, patients in the AG were treated by acupuncture, and patients in the CG were orally administered non-steroidal anti-inflammatory analgesics. The 3 groups were compared for effective rate, scores of simplified McGill scale and AOFAS-AH, and changes in clinical syndromes before and after treatment. Results: The effective rate was 86.00% (86/100) in the CG, 96.00% (96/100) in the CIG ($P<0.05$), and 92.00% (92/100) in the AG. After treatment, the CIG yielded lower PRI sensory and mood scores as a part of the simplified McGill Scale, VAS and PPI scores, as well as scores of pain, swelling and functions but higher AOFAS-AH functional scores as compared with the CG ($P<0.05$) and the AG. Conclusion: Catgut implantation at urinary bladder meridian has demonstrated significant efficacy in patients with Calcaneodynia, reflected as significant alleviation of clinical syndromes such as pain and swelling, and improvement of joint functions.

Keywords: Catgut implantation, acupoints, urinary bladder meridian, acupuncture, calcaneodynia, efficacy, AOFAS-AH, VAS

Introduction

Calcaneodynia, also known as painful heel, is a general term of painful diseases around the heel, and a common ankle disease seen in the orthopedics clinic. The disease mainly causes pain, swelling, difficulties in walking, and painful heel sensations upon touching the ground. Clinical practice has discovered that, the disease is associated with an incidence rate of about 10%, and is mainly found in middle-aged and senior males between 40 and 70. Its incidence in the male is about 2 times higher than in the female. Calcaneodynia is characterized by slow onset, migration, and significant difficulties in treatment, and will gradually worsen during progression, significantly affecting a patients' normal life [1-3].

In the study of the etiology and pathogenesis of Calcaneodynia, western doctors have pointed out that, while lesions in the calcaneus and the soft tissues thereunder may induce the disease, its fundamental reason lies in the long-term impact from our body weight, which results in tissue deformation, and consequently, inflammation and pain. In western medicine, the therapeutic tools available for Calcaneodynia are quite simple, and include oral administration of non-steroidal anti-inflammatory analgesics, calcaneal spur resection, calcaneus lateral and lateral cutaneous neurotomy, calcaneus decompression drilling, local closure, physiotherapy, infrared therapy and extracorporeal shock wave therapy, etc. [4-6]. However, it is also found in clinical practice that drug therapy is associated with a long treatment cycle and

significant side effects, while repeated closure treatment will increase the risk of aponeurosis rupture, and high recurrence rate after a surgery. Therefore, it is urgent to find a more effective and safe therapeutic treatment method for calcaneodynia [7, 8].

In traditional Chinese medicine, calcaneodynia is classified as "arthromyodynia", "atrophic debility of bones" and "injury of the tissues". It is a result of various factors including infirmity at a senior age, deficiency and obstruction of kidney-qi, undernourished muscles and bones, invasion of wind-cold-wetness evil, obesity, and long standing [9]. Catgut implantation at the acupoint is defined as stimulating patients' acupoints with needles and medicated threads according to the acupuncture theories to achieve balance of *Yin* and *Yang*, regulation of qi and blood, and relaxation of meridians. Catgut implantation at acupoints is a new comprehensive discipline combining acupuncture and catgut implantation. It is extensively applied in the treatment of diseases such as insomnia, chronic gastritis, and osteoporosis [10, 11]. Through the present study, patients with Calcaneodynia benefited significantly from catgut implantation at the urinary bladder meridian, including marked alleviation of pain and swelling, and improvement of joint functions.

Materials and methods

General materials

A total of 300 patients treated in the Department of Acupuncture and Moxibustion of Cangzhou Central Hospital due to calcaneodynia were included and equally randomized into the CIG, AG and CG by a Random Number Table.

Inclusion criteria: (1) compliance with the diagnosis criteria for Calcaneodynia (calcaneal hyperosteogeny) in the *Special Manual for TCM Identification of Diseases in Orthopedics and Traumatology*; (2) aged between 45 and 65 years; (3) clear consciousness to cooperate with the investigation; (4) provision of informed consent; (5) approval from the Ethics Committee of the Cangzhou Central Hospital; (6) disease in one foot or inclusion of only one foot as the evaluation index.

Exclusion criteria: (1) complication with metal disorders, malignant tumors, severe liver and kidney dysfunctions, systematic or local muscle dysfunction; (2) allergic to the drug studied; (3) calcaneodynia due to trauma, gout, calcaneal osteomyelitis; (4) poor treatment adherence.

Removal criteria: (1) at the request of patients; (2) poor treatment adherence; (3) involvement in other therapies not studied herein.

Methods

The 300 patients with Calcaneodynia were divided into the CIG (n=100), AG (n=100) and CG (n=100). Patients in the CG were orally administered aceclofenac capsules (manufacturer: Guangzhou Baiyunshan Guanghua Pharmacy Co., Ltd., specification: 50 mg/capsule, approval document No.: GZZZ H20050479) at a dose of 100 mg/time, 2 times/d for 20 d.

Patients in the AG were treated by acupuncture according to following steps: disinfect and acupuncture Ashi, Kunlun, Taixi, Shenmai, Zhaohai and Dazhong at the proximal end of heel with "Huacheng" 0.35 mm × 40 mm disposal acupuncture needles. The needles were inserted into the acupoints rapidly and withdrawn slowly after retention of 30 min. A course of treatment consisted of 10 days, and efficacy was observed after 2 courses of treatment.

Patients in the CIG were treated by acupoint selection at urinary bladder meridian according to following steps: acupoints such as Heel, Kidney and Bladder on ears were pricked with three - edged needles, and a small amount of blood was squeezed out. After that, at the distal end of urinary bladder meridian, Geyu, Ganyu, Shenyu and Pangguangyu, Weizhong, Chengshan, and Feiyang were disinfected and injected with 0# collagen line through 9# disposal thread-embedding needle with bush. The needle point was dressed with a woundplast, and efficacy was observed 20 d later.

Observation indexes and evaluation criteria efficacy

Efficacy was evaluated at 20 d, and classified into marked effective, effective and ineffective. Marked effective is defined as the basic elimination of heel pain, no obvious pain upon pressure and nor difficulty in walking; effective is judged based alleviation of heel pain as compared with the conditions before treatment, upturns in pain upon pressure regardless of its existence, and partial recovery of walking capacity; ineffective means instead of any im-

Table 1. Comparison amongst the 3 groups for general clinical data ($\bar{x}$ ± s)/[n (%)]

General Clinical Data		CIG (n=100)	AG (n=100)	CG (n=100)	F/X^2	*P*
Gender	Male	56 (56.00)	55 (55.00)	57 (57.00)	0.121	0.767
	Female	44 (44.00)	45 (45.00)	43 (43.00)		
Average age (y)		56.88±4.98	57.01±3.99	56.90±4.21	0.025	0.975
Educated background	Illiterate	11 (11.00)	11 (11.00)	14 (14.00)	0.891	0.672
	Primary school	43 (43.00)	44 (44.00)	44 (44.00)		
	Junior middle school	20 (20.00)	17 (17.00)	16 (16.00)		
	Senior high school and over	26 (26.00)	28 (28.00)	26 (26.00)		
Marital status	Married	89 (89.00)	88 (88.00)	90 (90.00)	0.241	0.897
	Unmarried	11 (11.00)	12 (12.00)	10 (10.00)		
Average course of disease (month)		30.88±3.76	29.98±4.01	30.45±3.87	1.345	0.262

Table 2. Comparison amongst the 3 groups for effective rate [n (%)]

Group	n	Marked	Effective	Ineffective	Effective Rate
CIG	100	90 (90.00)	6 (6.00)	4 (4.00)	96 (96.00)*
AG	100	85 (85.00)	7 (7.00)	8 (8.00)	92 (82.00)
CG	100	80 (80.00)	6 (6.00)	14 (14.00)	86 (86.00)

Note: *P<0.05 vs CG.

provement, the heel pain progresses with marked pain on pressure and difficulty in walking. Efficacy = (number of marked effective cases + effective cases)/total cases × 100%.

Changes in the simplified McGill scale scores before and after treatment

Before and at 20 d after treatment, patients' conditions were evaluated with the simplified McGill scale which consists of 3 dimensions, pain rating index (PRI), visual analogue scale (VAS) and present pain intensity (PPI). PRI includes 11 perceptual words and 4 emotional words, each valuing between 0 and 3. VAS is a mark on a 10 cm straight line from 0-10; with 0 indicating no pain and 10 the most possible intolerable pain. Patients reflect their pain intensity subjectively. PPI is based on a 5-point system covering no pain, moderate pain, discomfort, affliction, devilishness and baryodynia [12].

AOFAS-AH scores before and after treatment

Before, at 10 d and 20 d after treatment, the ankle function was scored by the AOFAS-AH scale which consists of 9 dimensions including functions and autonomic activities, maximum walking distance and abnormal gait. The scale has a full mark of 100. A higher score indicates better ankle-foot functions [13].

Changes in clinical syndromes before and after treatment

The clinical syndrome evaluation scale developed by He Gaozhou was applied to evaluate the pain, swelling and functions of the 3 groups before and at 20 d after treatment. Each dimension of the scale had a value between 0 and 4, and a higher score indicates worse syndromes.

Statistical analysis

Statistical analysis was performed with SPSS 22.0. In the case of numerical data it was expressed as $\bar{x}$ ± s, intergroup and intragroup comparison studies were carried out through independent-samples t test, and comparison of differences amongst the 3 groups was carried out through F (Variance Ratio) test; in the case of nominal data it was expressed as [n (%)], intergroup and intragroup comparison studies were carried out through chi-aquared test, and intragroup comparison studies at multiple points were carried out thorough ANVOA. For all statistical comparisons, significance was defined as P<0.05 [14].

Results

Comparison for general clinical data

Through statistics and comparison, the general clinical data such as proportions of genders, average age and course of disease of the 3 groups were not statistically different (P>0.05) but comparable (**Table 1**).

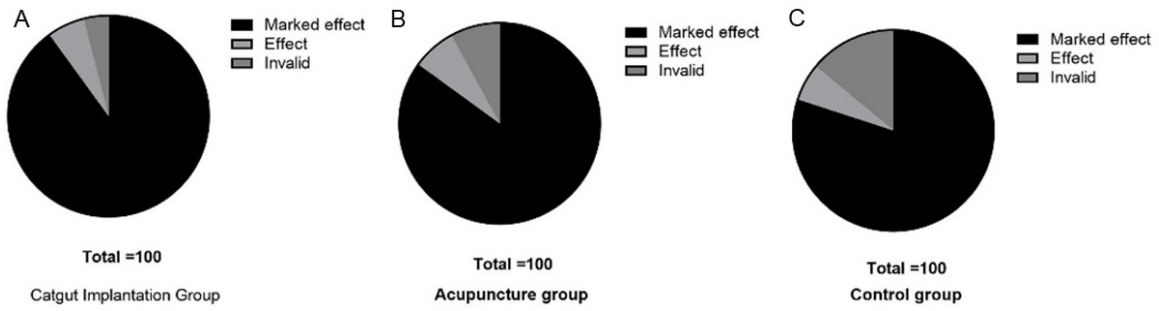

Figure 1. Comparison amongst the 3 groups for effective rate. The number of marked effective, effective, ineffective cases, and the effective rate were 90, 6, 4 and 96.00% in the CIG, 85, 7, 8 and 92.00% in the AG, 80, 6, 14 and 86% in the CG, respectively. P<0.05 as compared between the CG and the CIG for effective rate.

Table 3. Comparison amongst the 3 Groups for the Scores of Simplified McGill Scale before and after Treatment ($\bar{x} \pm s$)

Score of the simplified McGill scale		CIG (n=100)	AG (n=100)	CG (n=100)
PRI sensory	Before treatment	22.98±2.88	23.01±2.76	23.10±2.61
	After treatment	10.98±1.02*,#	13.08±1.88*	14.81±1.98*
	T	39.276	29.735	25.306
	P	<0.001	<0.001	<0.001
PRI emotional	Before treatment	6.78±1.09	6.88±1.11	6.92±1.03
	After treatment	3.09±0.98*,#	3.87±0.87*	4.98±1.01*
	T	25.174	21.343	13.448
	P	<0.001	<0.001	<0.001
VAS	Before treatment	7.02±0.43	6.89±0.51	6.91±0.44
	After treatment	3.08±0.12*,#	3.98±0.14*	4.21±0.21*
	T	88.256	54.985	55.38
	P	<0.001	<0.001	<0.001
PPI	Before treatment	3.59±0.21	3.61±0.19	3.54±0.20
	After treatment	1.10±0.21*,#	1.49±0.19*	1.55±0.21*
	T	83.843	78.898	68.621
	P	<0.001	<0.001	<0.001

Note: compared with AG, *P<0.05, and compared with CG, #P<0.05.

Comparison for efficacy

Based on follow-up records, the effective rate was 86.00% (86/100) in the CG, 96.00% (96/100) in the CIG (P<0.05), and 92.00% (92/100) in the AG (**Table 2** and **Figure 1**).

Comparison for simplified McGill scale scores before and after treatment

According to the scale, the 3 groups demonstrated no statistical difference in the PRI sensory and emotional scores, VAS and PPI scores before treatment (P>0.05). At 20 d after treatment, those scores reduced to the lowest level in the CIG as compared with that of the AG and the CG (P<0.05) (**Table 3** and **Figure 2**).

Comparison for AOFAS-AH scores before and after treatment

In terms of AOFAS-AH scores, no statistical difference was revealed amongst the 3 groups before treatment (P>0.05), but an intragroup elevation was observed after treatment. For intergroup comparison, the CIG had the highest scores at 20 d after treatment as compared with the AG and the CG (P< 0.05) (**Table 4** and **Figure 3**).

Comparison for changes in clinical syndromes before and after treatment

Statistical differences in scores of pain, swelling and functions were not observed amongst the 3 groups before treatment, but were at 20 d after treatment based on obvious reductions (P<0.05) (**Table 5** and **Figure 4**).

Discussion

Calcaneodynia, also known as heel pain, is defined as diseases with pain and walking difficulty as typical symptoms caused by chronic strain around the calcaneus nodule. Most patients have complications with bony spurs at the bone nodule. The disease occurs frequently in obese individuals aged 40-60, especially in the female. Clinical research has found that the disease has the characteristics of occult onset,

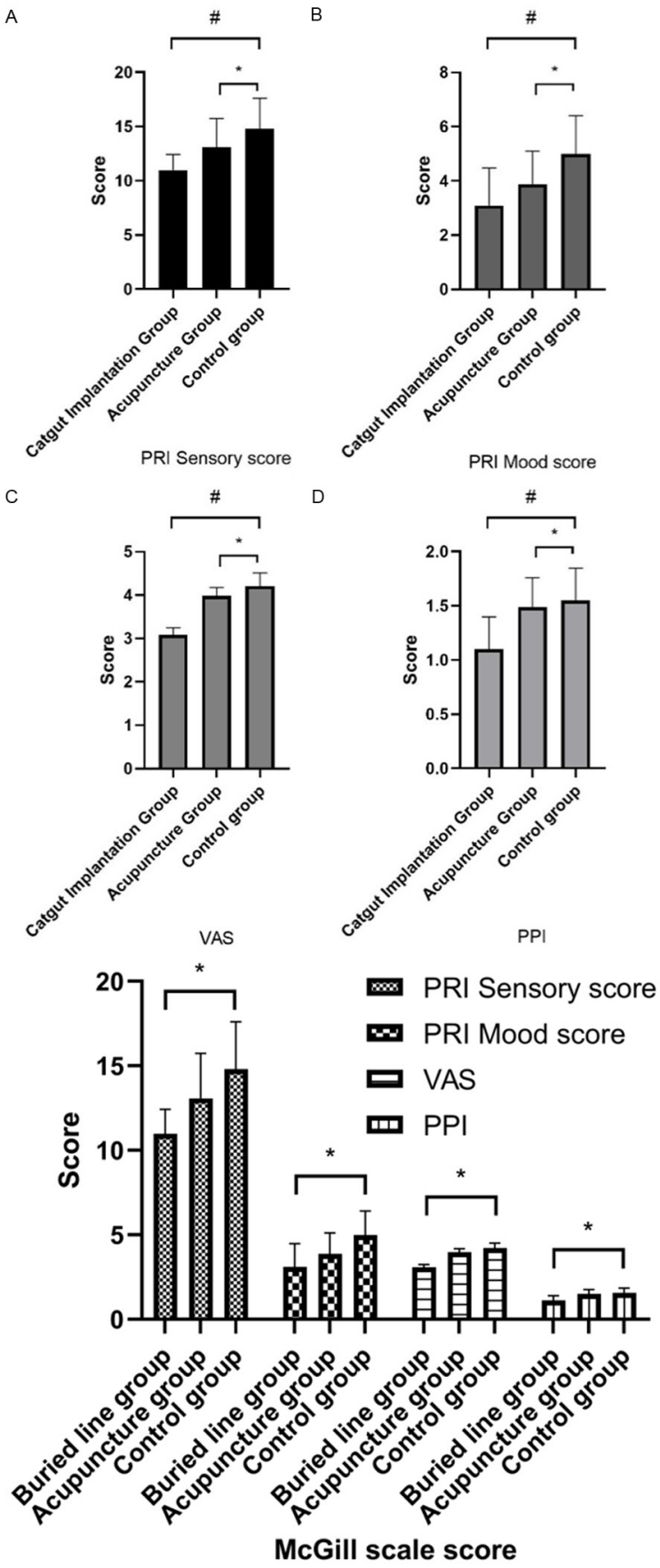

Figure 2. Comparison amongst the 3 groups for the scores of simplified McGill scale after treatment. (A) 20 d after treatment, the PRI sensory (A) and emotional (B) scores, VAS (C) and PPI (D) scores were lower in the CIG as compared with that of the CG ($P<0.05$). * and # indicate $P<0.05$ for comparison of the same index between groups.

slow development and poor prognosis, and attacks one heel in most of the cases or both sometime without trauma but with burning pain which will gradually intensify as the disease progresses, especially after climbing with weight or running and jumping [15, 16]. The clinical examination showed that patients may experience heel swelling and local pain on pressure, which may involve the foot arch in case of long-term standing, but there is no inflammation in the heel. Pain, swelling and local pain on pressure are typical clinical symptoms of the disease, and also important factors affecting the normal life of patients [17, 18].

According to modern medical research, calcaneodynia is associated with complex causes, such as spur, periostitis, etc. Although the causes are inconsistent, generally speaking, medical workers tend to believe that the disease is mostly due to the fact that as one becomes older, it is difficult for his/her tissues to bear the impact of weight for a long time, which results in inflammation induced pain and swelling [19]. It is also believed that the long-term laboring and walking will increase the load on the nodule, and lead to the fiber at the nodule stopping point in a process of fracture-repair-fracture-repair. In this process, the blood calcium salt

Table 4. Comparison amongst the 3 Groups for the Function Scores of AOFAS-AH before and after Treatment ($\bar{x} \pm s$)

Group	n	Before treatment	At 10 d	At 20 d
CIG	100	46.98±3.99	64.98±4.01	86.09±5.11*,#
AG	100	47.01±4.01	56.21±3.99	76.98±4.09*
CG	100	47.13±3.87	57.01±3.01	70.90±3.89*

Note: *P<0.05 vs conditions before treatment, and #P<0.05 vs the CG.

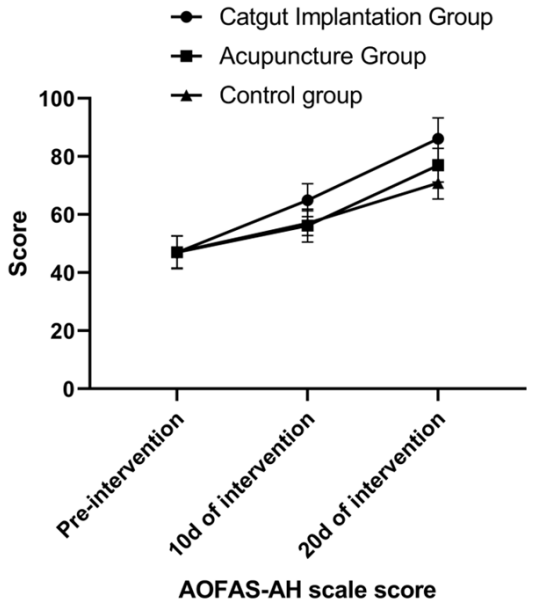

Figure 3. Comparison amongst the 3 groups for function scores of AOFAS-AH before and after treatment. Before treatment, the function scores of AOFAS-AH were similar in the 3 groups. At 20 d after treatment, the scores were obviously higher in the CIG as compared with the CG (P<0.05).

caused by the fiber fracture will deposit and ossify, stimulating the muscle fibers, and finally resulting in pain. Western medicine is more direct in the treatment of Calcaneodynia, including surgery, local closure, physiotherapy, and comprehensive therapy, etc. [20]. The surgery is mainly applicable to stubborn symptoms of calcaneodynia by reducing the tension of local fascia and tendon through removing the calcaneus nodule, bone spur and other tissues, and stopping pain by changing the stress through reconstructing the foot arch. Local closure follows the principle of stimulating the nerve endings to improve the excitability of the nerves, and then the pain threshold of the patients for the purpose of analgesia; physiotherapy is mainly based on the physical therapy to stimulate the patients' skin, accelerate the release of histamine to dilate the blood vessel wall, and promote the blood circulation, so as to alleviate the local inflammatory exudation and achieve the analgesic effect [21-23]. Clinical studies have found that although the above treatments are effective to a certain degree, they are also associated with significant side effects, and not complete treatment. Repeated closure will increase the possibility of rupture of aponeurosis, and recurrence rate after surgery.

In traditional Chinese medicine, Calcaneodynia has been studied in great detail, evidenced by records in the *Internal Canon of Medicine* that "with blood and *Qi* reducing, patients may experience swelling and painful heels", and in the *Golden Mirror of Medicine* that "the disease originates from the heel...due to stagnation of blood and *Qi*". In modern traditional Chinese medicine, Calcaneodynia is classified to the "injury of the tissues", "arthromyodynia" and "atrophic debility of bones", and closely associated with the kidney. Senior and weak individuals may experience blocked *Qi* and blood circulation, and stagnation of channels due to insufficient kidney essence, which finally lead to pain. As a traditional therapeutic tool in China, acupuncture is characterized by extensive application, simple operation, good economics and being safe. While regulating the *Qi* and blood in internal organs, functioning of meridians, and the *yin* and *yang*, this method can strengthen the bodies resistance to eliminate pathogenic factors by stimulating specific acupoints to achieve efficacy in a number of clinical diseases [24]. Catgut implantation at acupoints is a new discipline deriving from the modern development of theory of acupuncture. Compared with traditional acupuncture, it can give better play to the long-term acupoint stimulation effects and works better by dredging the channel and reducing stimulation [25]. With different groups, the efficacy of Catgut Implantation of acupoints selected at the Urinary Bladder Meridian and acupunture on patients with calcaneodynia, as well as the effects on ankle-foot function and pain intensity

Table 5. Comparison amongst the 3 Groups for Changes of Clinical Syndromes before and after Treatment ($\bar{x} \pm s$)

Score of Clinical Syndrome		CIG (n=100)	AG (n=100)	CG (n=100)
Pain	Before treatment	3.22±0.11	3.19±0.09	3.12±0.12
	After treatment	1.31±0.13*,#	1.59±0.18*	1.87±0.21*
	T	112.159	79.505	51.681
	P	<0.001	<0.001	<0.001
Swelling	Before treatment	1.98±0.04	2.01±0.03	1.99±0.05
	After treatment	0.21±0.03*,#	0.41±0.03*	0.59±0.04*
	T	354	377.124	218.643
	P	<0.001	<0.001	<0.001
Function	Before treatment	3.08±0.32	3.10±0.29	3.12±0.23
	After treatment	1.38±0.13*,#	1.49±0.21*	1.98±0.23*
	T	49.219	44.966	35.048
	P	<0.001	<0.001	<0.001

Note: compared with AG, *P<0.05, and compared with CG, #P<0.05.

were analyzed. The results showed that compared with the CG patients taking oral non-steroidal anti-inflammatory analgesics, the CIG had a higher effective rate (96.00%) and better scores of pain, swelling and function after catgut implantation of acupoints selected at the urinary bladder meridian. It has been pointed out that catgut implantation at the selected acupoints is a new way of acupoint stimulation with the energy generated by physical and chemical effects to relax channels and activate collaterals, unblock Qi and blood. In this study, it is held that, compared with the western treatments, acupoint selection at the ears is simpler and less painful. It can address both the symptoms and root cause by balancing the internal organs, and maintain collateral channels. Catgut implantation maintains and enhances the efficacy of acupuncture by retaining the needle at the acupoints. Its functions also include inducing acu-esthesia and waiting for *Qi* arrival, and its roles are coordinating internal organs, dredging channels, regulating the *Qi* and blood, reinforcing insufficiency and reducing excessiveness [26]. The urinary bladder meridian selected in this study belongs to the foot Tai Yang, and contains 67 acupoints responsible for diseases in head, eyes, back and lower extremities, and related tissues and organs. The kidney channel is responsible for the heel, while the kidney and bladder are exteriorly and interiorly associated through channels. According to the theory of "treating *yin* diseases by enhancing *yang*" in traditional Chinese medicine, pains and diseases on the kidney channel can be treated from the urinary bladder meridian, which embodies the theoretical idea of "overall treatment, and exterior and interior acupoint selection" in traditional Chinese medicine. Due to better intervention efficacy, patients in the CIG yielded higher VAS in the McGill scale, and function scores in the AOFAS-AH.

In conclusion, the catgut implantation at urinary bladder meridian has achieved significant efficacy in patients with Calcaneodynia, including obvious alleviation of pain and swelling, and improvement of joint functions. It deserves popularization in the clinic. Through the study compared the clinical efficacies of catgut implantation of acupoints selected at the urinary bladder meridian, acupuncture and oral administration of non-steroidal anti-inflammatory analgesics in treating patients with Calcaneodynia, the included sample size and intervention modes are limited, the analysis of study results is not comprehensive, and the results are not sufficiently representative. In the future, more samples shall be included for a more in-deep study to provide solid theoretical basis for the clinical treatment of patients with Calcaneodynia.

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Disclosure of conflict of interest

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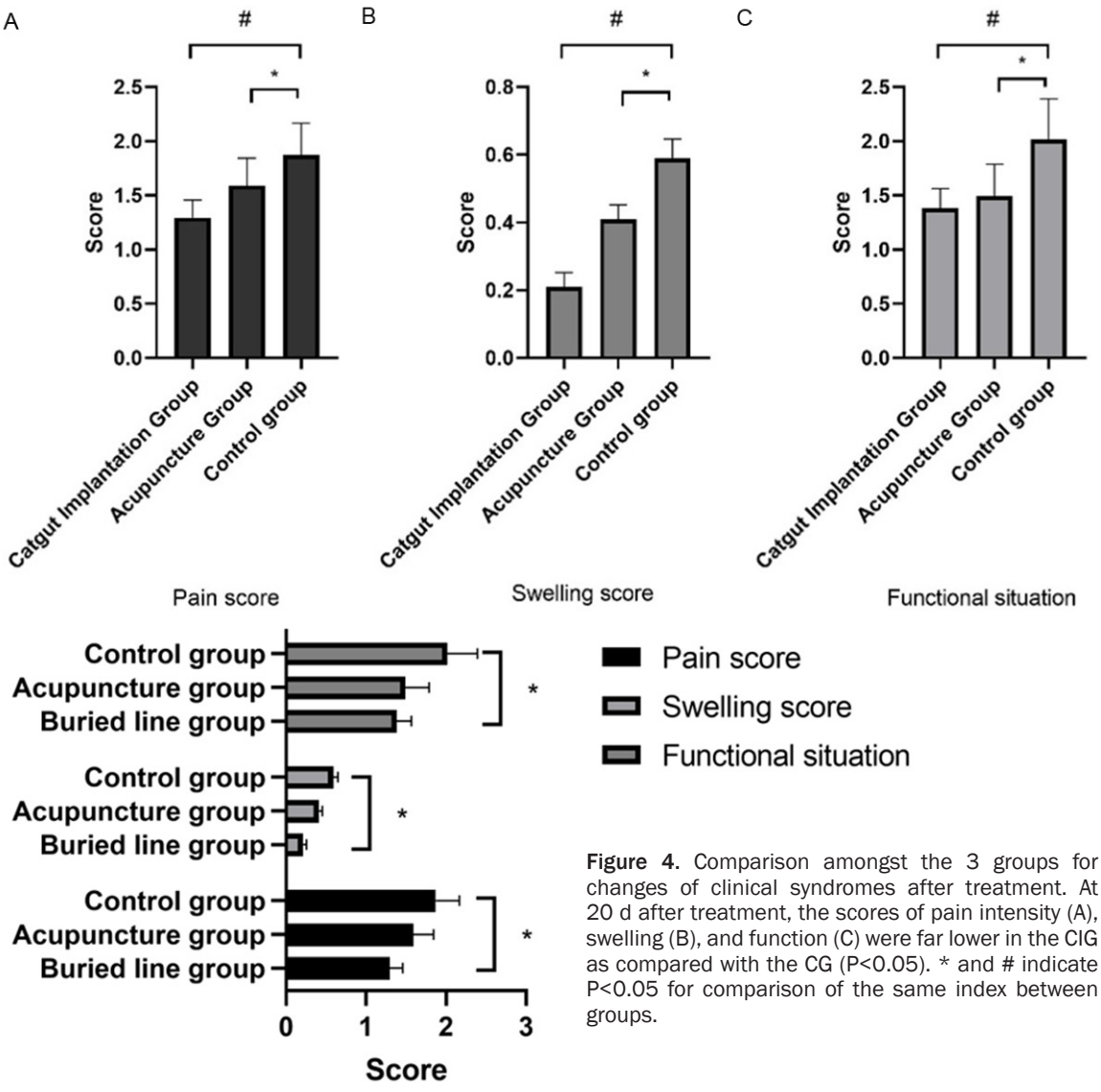

Figure 4. Comparison amongst the 3 groups for changes of clinical syndromes after treatment. At 20 d after treatment, the scores of pain intensity (A), swelling (B), and function (C) were far lower in the CIG as compared with the CG ($P<0.05$). * and # indicate $P<0.05$ for comparison of the same index between groups.

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