# Research on the clinical efficacy of the combination of Chinese traditional medicine and Western medicine on the chronic traumatic tibial osteomyelitis

**Kai Huang, Bingyuan Lin, Qiaofeng Guo, Gouping Ma, Yiyang Liu, Lifeng Shen and Peijian Tong***

Department of Orthopedic, The First Affiliated Hospital of Zhejiang Chinese Medical University, No. 54, Mail Circuit, Shangcheng District, Hangzhou, Zhejiang, China

**Abstract**: The research investigation is carried to observe the clinical efficacy of the combination of Chinese traditional medicine (TCM) and Western medicine on the traumatic chronic tibial osteomyelitis (CO). A total of 80 patients who were admitted to this hospital between January 2012 and January 2017 were randomly divided into two groups, i.e. the control group and the observation group, with 40 patients in each group. In the control group, patients underwent the surgery to eliminate the lesion plus the antibiotics, while those in the observation group received the surgery, antibiotics administration and the wuwei xiaodu drink. In the observation group, patients had lowered erythrocyte sedimentation rate (ESR), white blood cells (WBC) and neutrophils in comparison with the control group ($p<0.05$). The total effectiveness rate of patients in the observation group was 92.5%, significantly higher than 80.0% in the control group ($p<0.05$). Combination of the TCM and Western medicine can mitigate the local lesion of traumatic CO and ameliorate the general status, with significant efficacy. Thus, it is worthy of being promoted in clinical practice.

**Keywords**: Tibia, chronic osteomyelitis, wuwei xiaodu drink, surgery.

## INTRODUCTION

Chronic osteomyelitis (CO) is mainly caused by the infection of purulent bacteria, with symptoms including hyperplasia, sclerosis or necrosis of bone tissues, sometimes concomitant with the abscess, cloaca or sinus tract; in addition, CO is a kind of chronic pyogenic infection, and also the common but stubborn disease (Schmidt-Rohlfing *et al*., 2012. Slyvka *et al*., 2010). Any inappropriate or delayed treatment against the CO will give rise to the traumatic chronic tibial osteomyelitis and current treatment in Western medicine focuses on the surgical elimination of lesions in combination with the antibiotics administration (Rao *et al*., 2011). Traditional Chinese medicine (TCM) has accumulated abundant clinical experience in treatment of CO, with promising efficacy, but there have been no systemic studies targeting the efficacy evaluation. To further explore the clinical efficacy of the combination of TCM and Western medicine on the chronic tibial osteomyelitis, we performed surgeries to eliminate the lesions and antibiotics administration plus the Wuwei Xiaodu drink to treat a total of 40 patients with tibial chronic osteomyelitis, and gained promising clinical efficacy.

## MATERIALS AND METHODS

### *General data*

A total of 80 patients who were admitted to this hospital for treatment between January 2012 and January 2017 were divided randomly into two group, the control group (n=40) and the observation group (n=40). Diagnoses of patients were made according to the Guidelines for the Diagnosis and Treatment of Diseases in Traditional Chinese Medicine (State Administration of Traditional Chinese Medicine, 1994) and *Practical Orthopedics* (Lu YP *et al*., 2003) and through the postoperative pathological examination.

Observation group: Among 40 patients, there were 34 males and 6 females, aged between 23 and 69 years old, and 19 patients had the lesion in the left tibia, and 21 in the right tibia; patients' disease courses ranged from 6 months to 6 years; there were 37 patients with sinus tract and 3 with soft tissue deficit concomitant with the bone exposure; 33 patients had the sequestrum. Besides, there were 28 patients with staphylococcal infections, 7 with *Pseudomonas aeruginosa* infections and 5 with *Staphylococcus epidermidis* infections.

Control group: Among 40 patients, there were 32 males and 8 females, aged between 19 and 66 years old, and 15 patients had the lesion in the left tibia, and 25 in the right tibia; patients' disease courses ranged from 6 months to 7 years; there were 35 patients with sinus tract and 4 with soft tissue deficit concomitant with the bone exposure; 30 patients had the sequestrum. Besides, there were 26 patients with staphylococcal infections, 5 with *Pseudomonas aeruginosa* infections and 9 with *Staphylococcus epidermidis* infections. Through the examination, we found that the differences in age, gender

**Corresponding author:* e-mail: oue030 @163.com

distribution, disease course, symptoms, vital signs and auxiliary examination showed no statistical significance ($p$>0.05), suggesting that data were comparable.

***Diagnostic criteria***

According to the diagnostic criteria in the Guidelines for the Diagnosis and Treatment of Diseases in Traditional Chinese Medicine (State Administration of Traditional Chinese Medicine,1994) and *Practical Orthopedics(*Lu YP *et al*., 2003) stipulated in 1994 by the State Administration of Traditional Chinese Medicine:

1) Acute onset history, or open injury history, or inducing factors, like wind-cold damp pathogens.
2) Local pains, pyogenic fluids in periosteum puncture, or ejection of the purulence, sinus tract or sequestrum.
3) Laboratory examination: anomaly in hemogram, increased white blood cells (WBC) or neutrophils, accelerated erythrocyte sedimentation rate (ESR), or pathogenic bacteria in culture of purulence.
4) X-ray image: bone destruction, periosteal reaction, or development of dead lumen or sequestrum.

***Inclusion criteria***

1) Patients conforming to the above diagnostic criteria, and volunteering to receive the treatment;
2) Patients aged between 10 and 70 years old;
3) Patients with good compliance, persisting in the treatment as required and cooperating with the treatment and questionnaire of physicians.

***Exclusion criteria***

1) Patients complicated with the severe damage to the heart, liver or kidney, or blood diseases that affected the observation;
2) Patients with the myelitis caused by the special pathogen, such as the bone tuberculosis;
3) Patients who did not accept the randomization, or the treatment plan;
4) Patients who were allergic to the TCM;
5) Patients who were not eligible to the inclusion criteria.

***Treatment methods***

*Observation group*

Local treatment: All patients underwent the contrast fistulography, and the sinus tract was enlarged to drain the purulence for purulent secretion culture and drug sensitivity test; lesions were eliminated regularly, followed by autoplastic transplantation of ilium and covering the traumatic plane using the adjacent flap, thereby thoroughly eliminate the sequestrum and inflammatory granuloma; during the operation, traumatic plane was rinsed using the normal saline to stop the bleeding; inside the lesions, the flushing tube and drainage tube were inserted and in the soft tissues surrounding the lesions, a silica gel drainage tube with lateral aperture and guided out through the other hole. Tubes were removed when patients met the following conditions: normal temperature for over 2 weeks, no turbid drainage liquid or inflammatory debris, drainage liquid less then 50 mL within 24 h, no evident swelling or pains in local wound, bacterial culture of the drainage fluid, hemogram or ESR showing no anomaly.

***General treatment***

TCM: Wuwei Xiaodu drink: honeysuckle, 30g; wild chrysanthemum flower, 30g; dandelion, 30g; Chinese violet, 15g; semiaquilegia root, 15g. At the 3rd day following operation, patients underwent the medication of Wuwei Xiaodu drink decocted in water, one dose per day, for consecutive four weeks. For any pains or immobility of affected limbs, concomitant with local swollen, no change in skin color, burning sensation, pressing pains of bone, or positive to the rapping, pallescence, Wuwei Xiaodu drink was supplemented with 15g of *Semen coicis*, 12g of pangolin and 12g of *Ligusticum wallichii*; for patients with excessive noxious heat, Wuwei Xiaodu drink was supplemented with 15g of *Semen coicis*, 12g of pangolin and 12g of *Ligusticum wallichii* (a Chinese herbal medicine plant mainly grown in Sichuan Province, which can promote blood circulation and promote qi circulation) for patients with deficiency of yang, Wuwei Xiaodu drink was supplemented with 10g of deer-horn glue, 15 g of the seed of Chinese dodder and 10g of monkshood; for patients with deficiency in yin, the drink was supplemented with 15g of *Carapax amydae* (Carapace of Chinese soft shelled turtle) cortex *Lycii radices, the root bark of the peony tree and radix rehmanniae* recen.

Anti-infection therapy: Based on the results of bacterial culture and drug sensitivity test, we selected the bacteria-sensitive antibiotics for anti-infection therapy. Supportive treatment: Vitamin was administrated if necessary; for patients with poor nutrition, immunity or deficiency of albumin, albumin could be infused intravenously before the operation; for patients with anemia, they could receive the perfusion of whole blood for several times. Control group: Patients in this group underwent the treatment strategy that was similar to those in the observation group in addition to the medication of Wuwei Xiaodu drink.

***Observation of efficacy***

*Evaluation of the short-term efficacy*

Visual Analogue Score (VAS)(Jie JH *et al*., 2011) was applied for the overall evaluation of the pains and exercise by patients, according to the following criteria: no pains, 0 point; mild but tolerable pains, 3 points or below; tolerable pains that could affect the sleep, 4 to 6 points; intolerable and strong pains, 7 to 10 pains. VAS scale was performed by patients within 5 to 10 min.

Measurement of the relative indexes: Tube-removing time was recorded; following 1 course of treatment, blood routine, C-reactive protein and hemogram were recorded

in the re-examination. Criteria for evaluation of efficacy: In this study, the evaluation criteria of the efficacy on the chronic osteomyelitis (suppurative osteomyelitis) were stipulated by the Guidelines for the Diagnosis and Treatment of Diseases in Traditional Chinese Medicine (State Administration of Traditional Chinese Medicine, 1994) in combination with the clinical condition, and divided into the four categories, failure, improvement, excellence and cure. The total effectiveness rate was the sum of the cure rate, excellence rate and improvement rate. A) Cure: Patients showed occlusion of sinus tract, or total cure of traumatic plane in the affected bones, or clear bones, without any residual sequestrum or periosteal reaction, or general or local symptoms, and had no recurrence within 1 year. B) Excellence: The sinus tract was almost closed, with cured traumatic plane and patients were almost free from the general or local symptoms, or vital signs; besides, secretion surrounding the lesion was reduced remarkably, without any residual sequestrum and the damaged bone tissues were under recovery. C) Improvement: Patients showed improvement in general or local symptoms, but no cure in the traumatic plane, with residual sinus tract, and stable lesions in X-ray image. D) Failure: Following one course of treatment, patients gained no improvement in the local or general symptoms, with progression in lesions in X-ray image. Evaluation of long-term efficacy: All patients underwent the long-term follow-up and regular re-examination.

***Ethical approval***

The research conducted by the Ethics Committee of the Institute met the requirements of relevant laws and ethics, and was discussed at the Hospital Medical Ethics Conference. All subjects had informed consent.

## STATISTICAL ANALYSIS

Statistical analysis was performed with the SPSS 13.0 software. Measurement data were presented in mean ± standard deviation. Comparison of the efficacy was performed with Ridit analysis. Comparisons before and after treatment were performed with the pairwise *t* test, and the intragroup comparison with the independent *t* test. $p<0.05$ suggested that the difference had statistical significance.

## RESULTS

***Short-term efficacy***

After treatment, the VAS scores in two groups were decreased remarkably in comparison with the scores before treatment ($p<0.05$); besides, difference in VAS scores of two groups showed no statistical significance ($p>0.05$); following the treatment, we found that the VAS score in the observation group was lower than that in the control group ($p<0.05$; table 1).

Following 2 weeks of treatment, we observed that WBC, CRP and neutrophils were declined into the normal range in the observation group, and the declines in the observation group were much more evident than those in the control group ($p<0.05$); besides, patients in the control group suffered from the longer tube-removing time than that in the observation group ($p<0.05$; table 2 and 3). Evaluation of efficacy: In the observation group, the total effectiveness rate was 92.5%, significantly higher than 80.0% in the control group ($p<0.05$; table 4).

***Long-term efficacy***

Following the operation, patients' follow-up period ranged from 1 year to 5 years with an average of 3.1 years. In the observation group, there were no patients with evident recurrence, while in the control group, there were 4 patients with recurrence.

## DISCUSSION

The chronic tibial osteomyelitis following the trauma is mainly characterized by the local swelling, emaciation, anemia, persistent or intermittent low-grade fever. Thus, indicators should be established through evaluating the improvement in the local pains or general discomfort. VAS, a widely recognized and simple pain evaluation scale, can accurately reflect the feeling of patients, and is considered as the most sensitive and reliable method to measure the pains or discomfort (Roland *et al*., 2008). In this study, we found that VAS scores after treatment in two groups were decreased significantly ($p<0.05$), suggesting that these two methods can ameliorate the local pains and systemic symptoms. Before treatment, difference in the VAS scores between two groups showed no statistical significance ($p>0.05$) and after the treatment, there was a statistically significant difference in comparison of the VAS scores between two groups ($p<0.05$). This suggested that on the basis of surgical elimination of lesions and the application of sensitive antibiotics, Wuwei Xiaodu drink can better ameliorate the pains and systemic discomfort.

Chronic tibial osteomyelitis is a kind of "suppurative osteomyelitis" in Chinese Medicine. According to "Orthodox Manual of External Medicine", suppurative osteomyelitis is caused by invasion of pathogenic cold into the bone, which could be prevented if our body is strong enough. Anyone who suffered from pathogenic cold is the one in poor health. Either they sleep outside during summer and autumn, invaded by cold-dampness, or they were covered with thin quilt after sexual intercourse, being susceptible to cold weather. Thus suppurative osteomyelitis would happen. In the view of "Orthodox Manual of External Medicine", most cases of suppurative osteomyelitis are caused by insufficiency of the body after disease, with remnant toxicity in the body, as well as intrusion of external evil into muscles and bones, thus leading to obstructive channels and Qi and blood stasis ( Xu YH *et al*., 1984). In some cases,

**Table 1**: Comparison of the VAS scores before and after treatment in two groups ($\bar{x} \pm s$)

| Group | n | Before treatment | After treatment |
|---|---|---|---|
| Observation group | 40 | 6.97±1.64 | 2.87 ±1. 44 * |
| Control group | 40 | 6.45±1.47※ | 3.68 ±1. 61 *※ |

Note: * $p$<0.05 in comparison of the VAS scores before and after treatment; ※ $p$>0.05 in comparison of the VAS scores before treatment, and in comparison of the VAS scores after treatment.

**Table 2**: Comparison of the efficacy indicators at the 4th week after treatment

| Group | n | WBC ($\times 10^9$) | ESR (mm/h) | CRP (mg/L) | Neutrophils (%) |
|---|---|---|---|---|---|
| Observation group | 40 | 5.9±1.78 * | 14.76±2.43 * | 2.74 ±0.78 * | 24.65±11.63 * |
| Control group | 40 | 4.62±2.67 | 6.27±3,24 | 1.76 ±0.47 | 16.27±10.76 |

**Table 3**: Comparison of the tube-removal time between two groups ($\bar{x} \pm s$)

| Group | n | Tube removal time |
|---|---|---|
| Observation group | 40 | 11.56±3.2 * |
| Control group | 40 | 15.47±4.6 |

**Table 4**: Comparison of the comprehensive efficacy between two groups [n (%)]

| Group | n | Cure | Excellence | Improvement | Failure | Total effectiveness rate (%) |
|---|---|---|---|---|---|---|
| Observation group | 40 | 12 | 17 | 8 | 3 | 92.5 * |
| Control group | 40 | 9 | 14 | 10 | 8 | 80.0 |

Note: * $p$<0.05 through the Ridit analysis of the efficacy in two groups.

suppurative osteomyelitis are caused by trauma injury of partial bones and subsequent infection of external evil, thus leading to obstruction of channels and Qi and blood. The treatment of suppurative osteomyelitis should be guided by the principle of removing heat toxin and dispelling stasis and endogenous dampness. According to "the Golden mirror of medicine", Wuwei Xiaoduyin is composed of honeysuckle, wild chrysanthemum, dandelion, Chinese violet and Gynura bicolor. In this prescription, honeysuckle and wild chrysanthemum could remove the evil of heat toxin and resolve stasis. Of those, honeysuckle could enter the channels of lung and stomach, removing the evil of heat toxin in middle and upper-jiao (The upper part of the stomach to the sublingual part, including the heart and lungs), while wild chrysanthemum could enter the channels of liver, exclusively removing the evil of heat toxin in the liver. With combination of these two, they could dispel heat toxin and stasis of qi leel (including lung, gallbladder, spleen, stomach, large intestine and other viscera scope and disease). On the other hand, dandelion and Chinese violet could also dispel the evil of heat toxin, which are the main medicines in the treatment of carbuncles, sores and boils. At the meantime, dandelion has diuretic effect and could relieve the evil of damp-heat in the lower-jiao (The part of the stomach from the lower mouth to the pelvis, including the kidney, small intestine, large intestine, bladder and other organs). Together with Chinese violet, they could dispel the evil of heat toxin and stasis of the blood-aspect. Gynura bicolor takes effect in tri-jiao (a unique noun in the theory of Tibetan Phenomenon of TCM, and the proper name of upper-jiao,middle-jiao and lower-jiao), removing the evil of damp-heat. With combined use of these five drugs, we could treat the upper, middle and lower-jiao at the same time. Meanwhile, Qi (the proper name of traditional Chinese medicine. The most basic material foundation of the human body) and blood are dredged, the evil of the upper, middle and lower-jiao and stasis are dispelled, and swelling is eliminated by diuretic effects. Therefore, for generations of Chinese Medicine, Wuwei Xiaoduyin is our *aureus*, hemolytic streptococcus, gaffkya tetragena first choice in the treatment of carbuncles, sores and boils caused by accumulation of heat toxin.

Modern pharmacologic studies (Li WL *et al*., 1998) have shown that the decoction of this prescription antagonizes the *Staphylococcus*, *Escherichia coli* and *Pseudomonas aeruginosa*. Additionally, scholars believed that Wuwei Xiaodu drink has the anti-bacterial effect and can be applied in the treatment of various diseases, including the infection diseases relating to the departments of gynecology, surgery or ophthalmology and otorhinolaryngology (Huang SX *et al*., 2002). The results of this study showed that on the basis of the surgical treatment, Wuwei Xiaodu drink worked better in ameliorating the hemogram, ESR and CRP in treatment of chronic tibial osteomyelitis, with promising efficacy and a low recurrence rate, and additionally, no severe toxic side-effect or allergies were found in treatment. Thus, Wuwei Xiaodu drink is worthy of being promoted in clinical practice.

## CONCLUSION

In summary, combination of the TCM and Western medicine shows evident clinical efficacy by mitigating the local lesion of traumatic CO and ameliorate the general status. Thus, it is worthy of being promoted in clinical practice.

## ACKNOWLEDGEMENTS

This study was done through Project (2016ZA005) with financial support No.81603644 of National Natural of Zhejiang Province Traditional Chinese Medicine Science and Technology, China

## REFERENCES

Huang SX and Tian DF (2002). Progress in the clinical application of Wuwei Xiaodu drink. *Hunan Guiding Journal of Traditional Chinese Medicine and Pharmacology*, **8**(9): 523-536.

Jie JH, Liu MZ and Cui LQ (2011). Changes of the VAS scores and WOMAC indexes in treatment of knee osteoarthritis using qingbi decoction. Hebei Journal of Traditional Chinese Medicine, **26**(1): 16.

Li WL, Liu J and Dong DY (1998). Mechanism of the Wuwei Xiaodu drink in treatment of the skin infection of bacteria. *Qinghai Medical Journal*, **28**(11): 3-5.

Lu YP, Xu ST and Ge BF *et al* (2003). Practical Orthopedics. Beijing: People's Military Doctor Press, p.1078.

Rao N, Ziran BH and Lipsky BA (2011). Treating osteomyelitis: antibiotics and surgery. *Plast. Reconstr. Surg*., **127**(Suppl1): 177S-187S.

Roland W, Moskowitz, Roy D, Alman and Mare C (2008). Hochberg, translated by Xie LM. Osteoarthritis [M]. People's Medical Publishing House, Beijing, China, p.262.

Schmidt-Rohlfing B, Lemmen SW and Pfeifer R *et al* (2012). Osteomyelitis in adults. Diagnostic principles and therapeutic strategies. *Unfallchirurg*, **115**(1): 55-66.

Slyvka RM. Chronic osteomyelitis of the lower extremities: Etiology, pathogenesis, principles of treatment. *Klin. Khir.*, **10**: 48-52.

State Administration of Traditional Chinese Medicine (1994). Guidelines for the Diagnosis and Treatment of Diseases in Traditional Chinese Medicine, p.141.

Xu YH (1984). Introduction of clinical cases of Wuwei Xiaodu drink. *Journal of Traditional Chinese Medicine*, **4**: 52-53.