

Full Length Research paper

Clinical effect of chronic osteomyelitis treated by integrated Chinese-Western therapy

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Both Western and Chinese medicine have their own advantages in treating chronic osteomyelitis. In this study, we investigated the methods and clinical effect of chronic osteomyelitis treated by integrated Chinese-Western therapy. This is a prospective study. A total of 121 cases of chronic osteomyelitis (treated in the Military Training Medicine Institute hospital from January, 2002 to February, 2010) were divided into three groups, respectively treated with methods of traditional Chinese medicine, methods of Western medicine and integrated Chinese-Western therapy. All the patients were followed up and ranged from 8 to 56 months, with an average of 30 months. The total effective rate of the cases treated with methods of traditional Chinese medicine was 66.7%, cases treated with methods of western medicine was 54.8%, cases treated with integrated Chinese-Western therapy was 88.9%; the average period of hospitalization of cases treated with methods of traditional Chinese medicine was 59.3 days, cases treated with methods of western medicine was 74.6 days, cases treated with integrated Chinese-Western therapy was 43.7 days. There was a significant difference between the first two groups and the last one in terms of effective rate and average period of hospitalization. It is conspicuously effective to treat chronic osteomyelitis with integrated Chinese-Western therapy, which proved to be more powerful in improving recovery rate and reducing period of hospitalization than pure methods of traditional Chinese medicine or pure methods of Western medicine.

Key words: Chronic osteomyelitis, integrated Chinese-Western therapy.

INTRODUCTION

Chronic osteomyelitis is a kind of infection caused by the invasion of bone tissues by pyogenic bacteria through blood circulation or directly by traumas. This disease is characterized by hyperplasia, hardening and necrosis of bone tissues, resulting in dead bone, dead cavity, sinus tract, recurrent abscess and long period of treatment. As a persistent infectious disease difficult to cure, it has exerted seriously negative effect on people's wellbeing. The past few years have witnessed a gradual increase in the number of patients afflicted by this disease, due to the increase in traffic, factory and mine accidents, faulty application of antibiotic and so on (Xu et al., 2009; McKee et al., 2010; Lindfors et al., 2010). At present, there are quite a few methods to treat chronic osteomyelitis overseas, such as application of antibiotic, Chinese medicine, perfusion wash, interventional therapy and skin

flap transplantation, but assessment of the effect varies from person to person (Dinh et al., 2009; Zhang et al., 2010). To seek an effective method to treat chronic osteomyelitis, the author divided at random into three groups, the 121 cases received by Military Training Medicine Institute hospital from January, 2004 to February, 2010, treated respectively with methods of traditional Chinese medicine, Western medicine and integrated Chinese-Western therapy. The comparative study of the clinical effect is further discussed.

MATERIALS AND METHODS

Patients

Altogether 121 cases of chronic osteomyelitis were treated by Military Training Medicine Institute hospital from January, 2004 to February, 2010, of which 77 cases are male and 44 female. Their age ranges from 18 to 74, with the average 45.5. Sick time before treatment varies from 1 to 234 months, with the average 9.1 months. The injury causes are: 65 cases of traffic accident, 29

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Table 1. Sick time before treatment.

Group	N	Sick time before treatment (month)		
		Shortest	Longest	Average
Traditional Chinese medicine	27	3	194	11.6
Western medicine	31	1	183	8.3
Integrated Chinese-Western therapy	63	3	234	9.7
Total	121	1	234	9.1

Table 2. Age and gender.

Group	N	Average age (Year)	Gender	
			Male	Female
Traditional Chinese medicine	27	37.7	17	10
Western medicine	31	43.2	19	12
Integrated Chinese-Western therapy	63	49.5	41	22
Total	121	45.5	77	44

Table 3. Disease location.

Group	N	Disease location							
		Tibia	Femur	Humerus	Ulna	Radius	Pelvis	Phalanx	Skull
Traditional Chinese medicine	27	15	3	2	1	1	2	3	0
Western medicine	31	13	9	2	3	0	2	1	1
Integrated Chinese-Western therapy	63	31	13	11	2	1	1	4	0
Total	121	59	25	15	6	2	5	8	1

spontaneous, 8 bruise, 8 fall injury, 7 blast injury, and 4 machine injury. Disease location: 59 cases in tibia, 25 femur, 15 humerus, 6 ulna, 2 radius, 5 pelvis, 8 phalanx and 1 skull. Bone defect varies from 0 to 16.2 cm, and skin defect area varies from 0 cm² to 4 1×17 cm. Treatment before hospitalization: 32 cases with no external or internal fixation, 39 with external fixation, 31 with internal fixation, 13 with plaster fixation, and 6 with small splint fixation. Results of bacterial culture: 56 Gram-positive bacteria, 41 Gram-negative bacteria, 24 mixed infections; and the main species of infection bacteria are *Staphylococcus aureus* 32, *Streptococcus* 12, epidermis *Staphylococcus* 14, *coli* 19, *Aerugo pseudomonas* 12, *Escherichia coli* 3, other bacteria 20, with 9 cases having no bacteria cultured. (Tables 1, 2, 3, 4, 5 and 6)

Clinical manifestations and laboratory examinations

There is pain, pyorrhea and sinus tract in affected positions and some patients have a fever. Blood routine examination: white blood cells (WBC) of all patients increases, with normal or low hemoglobin, high ESR. X-ray examination: irregular thickening of bone shaft, irregular narrowing of medullary cavity, dissolved bone broken of varied size, dead bone and light penetration area inside bone.

Treatment

General treatment

A symptomatic supportive treatment with high-protein and high-

vitamin diet suggested was carried out after which nutritional support and symptomatic treatment was given to feeble patients. The original internal fixation was taken out, and then external fixation was given or a splint was used to fix the affected limb in cases of serious bone destruction or instable bone frame.

Group treatment

The 121 cases were divided into three groups according to their sequence of hospitalization, 27 treated with traditional Chinese medicine, 31 treated with Western medicine and 63 treated with integrated Chinese-Western therapy.

The group treated with traditional Chinese medicine were given oral Shenqi-Fuzheng-Tang (blended herbal medicine), and Guju-Yixiao-San (blended herbal medicine) for external application (these two herbal prescriptions are given by the patent of the author's hospital). The main ingredients of Guju-Yixiao-San are cortex phellodendri, hoelen, glycyrrhizae and dandelion. According to traditional Chinese medicine theory, this prescription aims to replenish liver and kidney, strengthen the healthy energy and clear the evil, dissolve blood stasis and detoxicate the affected position. This blended herbal medicine proved to be effective in resisting diseases and repairing tissue. The method of application involved putting the herbal medicine in a container and adding water in the ratio of 1:50, keeping the lotion boiled for up to 20 min, then cooling it down to 40 to 50°C, immersing the affected limb in it for 60 min with the temperature of the lotion maintained at 40°C or so. This is applied 3 times a day. Before immersion, the wound should be cleaned with sterile gauze to get rid of fluid and necrotic tissue

Table 4. Pathogenic bacteria.

Group	N	Pathogenic bacteria							No bacteria cultured
		<i>Staphylococcus aureus</i>	<i>Streptococcus</i>	<i>Epidermis staphylococcus</i>	Coli	<i>Aerugo pseudomonas</i>	<i>Escherichia coli</i>	Other bacteria	
Traditional Chinese medicine	27	2	5	2	1	4	2	6	5
Western medicine	31	9	3	5	4	1	0	7	2
Integrated Chinese-Western therapy	63	21	4	7	14	7	1	7	2
Total	121	32	12	14	19	12	3	20	9

Table 5. Cierny-Mader classification of 121 cases osteomyelitis.

Anatomic classification		Physiologic classification							
Type	Number	Type	Number	Type	Number	Type	Number	Type	Number
I	12	A	5	BL	3	BS	2	BL+BS	2
II	24	A	7	BL	13	BS	1	BL+BS	3
III	37	A	11	BL	16	BS	4	BL+BS	6
IV	48	A	6	BL	14	BS	9	BL+BS	19
Total	121		29		46		16		30

Source: Cierny et al. (1985).

Table 6. Representation of Cierny-Mader classification.

Bone involved (extent of bone involvement)		Physiologic class	
I	Medullary	A	Uncompromised
II	Superficially	BL	Soft tissues compromised locally
III	Localized(less than 5 cm, stable bone, healed fracture)	BS	Systemically compromised host
IV	Diffuse(greater than 5 cm, intercalary defect, non-union)	BL+BS	Local and systemical compromise

on the surface. After immersion, sterile gauze is rolled into a drainage strip and put in the wound to ensure unobstructed drainage. The wound is then covered with sterile gauze. Shenqi-Fuzheng-Tang, according to traditional Chinese medicine, aims to replenish the vital energy and blood, whose ingredients are ginseng, raw astragalus. This decoction is applied once a day.

For the group treated with western medicine, systemic

anti-infection treatment and dressing change for wounds is first given; at proper time, focal cleaning combined with perfusion wash is conducted. In the operation, dead bone, sinus tract, dead cavity and most inflammatory tissues is eliminated. Filling operation, skin flap and bone flap transplantations in case of large bone cavity, bone defect or skin defect in period I or II is conducted. Route dressing change and systemic sensitive antibiotics

according to the results of bacteria culture is applied. Continuous perfusion wash for 2 to 3 weeks is done - the washing fluid is saline solution plus sensitive antibiotics.

For the integrated Chinese-Western therapy, immersion treatment with Guju-Yixiao-San was applied and oral Shenqi-Fuzheng-Tang was taken by those who suffer skin defect, bone exposure or chronic skin ulcers. When infection is under control and wounds improve, focal

Table 7. Clinical effect and effective rate.

Group	N	Cured	Improved	Uncured	Total effective rate (%)
Traditional Chinese medicine	27	15	3	9	66.7
Western medicine	31	11	6	14	54.8
Integrated Chinese-Western therapy	63	49	7	7	88.9 ^{#*}

Chi-square test shows *P<0.05 manifests a significant difference compared with traditional Chinese medicine ($X^2=4.96$); #P<0.01 manifests a significant difference compared with western medicine ($X^2=13.88$).

Table 8. Shortest, longest and average hospitalization.

Group	N	Shortest hospitalization (day)	Longest hospitalization (day)	Average hospitalization (day)
Traditional Chinese medicine	27	31	118	59.3±22.0 ^{#&}
Western medicine	31	41	324	74.6±50.5 ^{*&}
Integrated Chinese-Western therapy	63	18	92	43.7±18.0 ^{^#}

One-way ANOVA Student-Newman-Keuls test shows $F=11.040$, $P<0.01$ - there is significant difference of average hospitalization between different groups. *P<0.05 manifests a significant difference compared with traditional Chinese medicine; #P<0.05 manifests a significant difference compared with western medicine; &P<0.05 manifests a significant difference compared with integrated Chinese-western therapy.

cleaning, eliminating dead bone, sinus tract, dead cavity and most inflammatory tissues was conducted. After the operation, if necessary, immersion with treatment with Guju-Yixiao-San was applied or perfusion wash with the herbal liquid, systemic sensitive antibiotics infusion and oral Shenqi-Fuzheng-Tang taken. To apply the perfusion wash, percolate the herbal liquid of Guju-Yixiao-San with six-layer sterile gauze, and keep the percolate for 48 h at 0°C, get the supernatant processed with asbestos filter. Wash the wound with 400 ml herbal liquid diluted with 500 ml saline. The daily dripping amounts to 3000 ml and keep perfusion wash for 2 to 3 weeks until there is no inflammatory reaction in the wound, the drainage fluid is clear and pathogen test is negative for 3 times running. After extubation, continue the immersion therapy to reinforce the treatment result.

The Criteria of Treatment Effect for Traditional Chinese Medicine issued by Traditional Chinese Medicine Administration on June 28, 1994 was used to evaluate the treatment effect. It was observed that the general symptoms and local edema pain disappeared, ulcers were healed, and X-ray indicates no dead bone. The general symptoms improved and edema pain was relieved, ulcers were not yet healed and the X-ray indicates dead cavity and dead bone. Although the general and local symptoms cannot be brought into control, X-ray indicates that the focus is deteriorating.

The study was approved by the institutional review board and the ethics committee of the hospital.

Statistical analysis

All statistical analyses were performed by using SPSS13.0 software; results were shown as mean ± standard deviation (SD). The statistical significance of differences in the mean value of hospitalization between different groups was determined by one-way ANOVA procedures and Student-Newman-Keuls test. The statistical significance of differences in the effective rate between different groups was determined by chi-square test. Data was considered statistically significant when $p<0.05$.

RESULTS

All the 121 cases were followed up, ranging from 8 to 56

months, with the average of 30 months. There was one case of amputation in both traditional Chinese medicine group and Western medicine group, and two cases of amputation in integrated Chinese-Western therapy group. Of the four cases, one undertook amputation by urgent demand of the patient and the family due to extensive skin ulcer on the right lower leg and ankle, and severe swelling of the lower limbs; the other three due to extensive ulcer on the right lower leg combined with canceration. All these amputation cases were deemed as uncured. Recurrence occurred to one case in the traditional Chinese medicine group and four cases in the Western medicine group, all of whom were cured after being hospitalized again. These recurrent cases were deemed as uncured. The treatment result and hospitalization of each group are as shown in Tables 7 and 8.

All statistical analyses were performed using SPSS 10.0 software. The results are shown as mean ± standard deviation (SD). The statistical significance of difference in the effective rate between different treatment groups was determined by chi-square test. SNK-q test was used to analyze the difference of average hospitalization between different treatment groups. Data were considered statistically significant when $P<0.05$.

The total effective rate of the cases treated with methods of traditional Chinese medicine was 66.7%, cases treated with methods of western medicine was 54.8%, cases treated with integrated Chinese-Western therapy was 88.9%; the average period of hospitalization of cases treated with methods of traditional Chinese medicine was 59.3 days, cases treated with methods of western medicine was 74.6 days, cases treated with integrated Chinese-Western therapy was 43.7 days. There was a significant difference between the first two groups and the last one in terms of effective rate and

average period of hospitalization.

Average hospitalization of patients treated with integrated Chinese-Western therapy is shorter than that treated with traditional Chinese medicine, and average hospitalization of patients treated with traditional Chinese medicine is shorter than that of treated with Western medicine.

DISCUSSION

Chronic osteomyelitis is an infection caused by the invasion of bone tissues by pyogenic bacteria through blood circulation or directly by traumas. Feeble physique, poor resistance against disease, strong toxicity of bacteria or untimely treatment after infection may result in bone destruction, dead bone, dead cavity, bone shell and sinus tract, and consequently contribute to chronic osteomyelitis.

In treatment of this disease, modern Western medicine relies heavily on large doses of antibiotics and operation to clear wounds and facilitate drainage and repair bone defect (Tlougan et al., 2009; Zeng et al., 2010; Tascini et al., 2009). This therapy emphasizes on thorough focal cleaning, removing dead bone and all the pathological scar tissues, eliminating dead cavity and improving local blood circulation so as to accelerate the recovery of bone and flab. The application of sensitive antibiotics is conducive to eliminating bacteria, enhancing the patient's resistance against diseases, dispelling inflammation, promoting blood circulation and the proliferation and differentiation of cells. The perfusion wash therapy has the dual role of sterilization and mechanical cleaning, which ensures a certain density of antibiotics inside the wound to inhibit and kill bacteria, at the same time takes advantage of the mechanical force of the fluid to clear surviving bacteria, blood clots, tissue debris and metalites accumulated in the process of tissue repairing.

However, the long course and recurrence of this disease often leads to dead cavity, dead bone and scar tissues in the focus, where the lack of blood supply makes the efficacy of antibiotics hard to reach. Furthermore, application of antibiotics for a long period is likely to produce tolerance in bacteria. All these have been attributed to the unsatisfactory effective rate and long course of treatment by means of pure Western medicine (Assmann et al., 2009).

The traditional Chinese medicine boasts a long history and rich experience in treating chronic osteomyelitis. Drawing on clinical practice, the author comes to the conclusion that an integrated Chinese-western therapy proves to be highly effective and can shorten the course of treatment compared with pure methods of western medicine or pure methods of traditional Chinese medicine. The oral application of Chinese medicine aims to adjust the function of all the organs, strengthen immunity from disease, reduce tolerance in bacteria, and side effects of Western drugs. External application of

Chinese medicine to the wound ensures centered efficacy of the drugs, and hence is helpful to clear dead tissues, drain pus and heal the wound. The integration of internal and external treatment changes passively waiting for an operation into actively strengthening the healthy energy and clearing the evil. Both the patient's immunity and local blood circulation are highly improved. Small-sized dead bones can be dispelled spontaneously or absorbed, while large-sized are cleared by operation. In short, the treatment course is shortened, healing rate increased and recurrence rate decreased. Before operation, take drug sensitivity test with secretion from the wound. Prescribe oral application of Chinese medicine under the condition of sufficient antibiotics. Clear the focus thoroughly as long as the infected focus is under control. Keep applying antibiotics and Chinese medicine internally as well as externally after operation. Early ambulation would improve microcirculation around the focus so as to prevent muscle and bone disuse atrophy.

Conclusion

Both Western and Chinese medicine have its own advantages in treating chronic osteomyelitis. But clinical practice has proved that an integrated Chinese-Western therapy is preferable to pure methods of Western medicine or pure methods of traditional Chinese medicine.

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