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CLINICAL RESEARCH

Effect of the Adjuvant Treatment with Fire Moxibustion Therapy on Clinical Efficacy and Life Quality in Patients with Osteoporosis

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Keywords

Fire moxibustion therapy, Osteoporosis, Clinical efficacy, Waist pain, Life quality

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Abstract

Objective: To evaluate the clinical efficacy of adjuvant treatment with fire moxibustion therapy and the effects on lumbar pain, lumbar function and life quality in patients with osteoporosis (OP). **Methods:** A total of 140 patients with OP admitted to our hospital between January 2018 and October 2020 were recruited, and they were divided into control group and experimental group with random number table method (n=70 for each group). The patients in control group were treated with moxibustion, and those in experimental group were subjected to fire moxibustion therapy, in addition to the conventional therapy and nursing care. The visual analog scale (VAS), oswestry disability index (ODI) score, clinical efficacy and life quality of patients before and after treatment were compared. **Results:** After treatment, the VAS and ODI score of both groups were decreased yet the field of environmental, physical, social, psychological and total points were increased in all patients, and in patients of the experimental group, the VAS and ODI score was decreased yet the field of environmental, physical, social, psychological and total scores were increased in comparison with those in control group. **Conclusion:** Fire moxibustion therapy in the adjuvant treatment of patients with OP has shown significant efficacy, and it can relive the waist pain of patients, which helps improve the waist function and life quality of patients.

Introduction

Osteoporosis (OP) is a systemic skeletal disease which is characterized by the reduction on bone mass and the degradation on bone tissue microarchitecture, which results in the increased bone fragility and fracture susceptibility (1). Currently, Western medicine for patients with OP mainly relies on selective estrogen receptor modulators, diphosphonates, calcitonin, parathyroid hormone, fluoride, Vitamin D and calcium; however, due to the side effects of long-term or high dose on Western medicine, the efficacy remains dismay, and some patients may suffer from relapse (2). It has been presented that external treatments may play positive

roles in the treatment of OP in clinical practice, among which acupuncture is widely applied (3). Moxibustion is one of the acupuncture methods for traditional Chinese medicine (TCM), in which the moxibustion materials made of mugwort leaves are used to make heat and to stimulate the acupuncture points on the body surface so as to treat diseases. Fire moxibustion is an external TCM treatment method which uses the heat of alcohol combustion to promote the transdermal absorption of herbal medicines, thus eliciting the therapeutic effects. In our current study, the adjuvant treatment with fire moxibustion therapy is used to treat patients with OP, in addition to the conventional therapy of moxibustion, and its efficacies on patients' waist pain, waist function and life quality were reported, with the hope to provide a theoretic basis for the clinical treatment of OP.

Materials and methods

Ethics statement

Our hospital's Ethics Committee has carefully reviewed and approved the conduction of our study, and all patients or their legitimate guardians have signed the written informed consent for our study.

Subjects

140 patients with OP and admitted in our hospital from January 2018 and October 2020 were assigned to the control group and the experimental group based on the random number table method, and the former group consisted of 28 male and 42 female patients whose age ranges from 50 to 78 years (average age: 63.74 ± 6.37 years old) and who have a disease duration of 1 to 10 years (average duration: 4.74 ± 1.42 years). The experimental group was composed of 31 male and 39 female patients whose age ranges from 52 to 75 years (average age: 62.87 ± 6.79 years old) and who have a disease duration of 1 to 9 years (average duration: 4.42 ± 1.38 years).

There was no statistical significance between these two groups when it came to the basic data but the data were comparable. All patients enrolled complied to the criteria as listed.

Inclusion criteria: a) patients were conformed to the diagnostic criteria of OP according to the diagnostic criteria (4); b) patients had no contraindications to acupuncture and received fire moxibustion therapy.

Exclusion criteria: a) patients presented with low back pain caused by lumbar disc herniation, lumbar spinal stenosis and other diseases; b) patients with other bone metabolic diseases; c) patients with OP caused by trauma, other malignant tumors, combined diabetes, hyperparathyroidism, rheumatoid arthritis and other diseases; d) patients who had received anti-OP treatment prior to the enrollment.

Treatment regimen

All patients were given conventional therapy and care in which patients were given health education by nursing stuff and were told to relieve their tension, and were answered patients when they had questions. They were firstly informed about OP, including the damages, seriousness, and risk factors of the diseases, which were repeated and emphasized several times so as to raise the patients' awareness on OP. Patients were allowed to consult frequently and were given psychological guidance, along with the explanation concerning the significance on the cooperation with the medical stuffs to the remission of the disease, concerning the information on the impact of falling-down on OP and concerning the necessity of functional training, including Tai Chi practicing, neck swirling, leg swinging, fist clenching and chest holding. The training measures were selected in accordance with the tolerance, condition and recovery of each patient, and the training time and strength were monitored as well. Additionally, patients were encouraged to have Vitamin-rich and easily digestible meals with high protein and iron, and were given calcium supplementation (800 mg/day) and were told to avoid coffee, strong tea, and so on and to prohibit smoking and alcohol consuming for 4 weeks in total.

Then, for patients in the control group, they were subjected to moxibustion treatment. In detail, the primary acupuncture points were selected from Huangshu acupuncture point, Qihai acupuncture point and Guanyuan acupuncture point, and the secondary acupuncture point was taken from 2.5 inches from

both the left and right side of Qihai acupuncture point. Moxa strips (Jiangsu Kangmei Pharmaceutical Co., Ltd., Approval number: Z32020253, specifications: 25 g*10 sticks) were lit and patients were treated with fire moxibustion on the upper 3 cm of the skin tissue of the selected acupuncture points. The best effects were achieved when patients sensed both heat and humidity. 15 minutes were allowed for each acupuncture point, with one per day and 5 times for each week, and the treatment lasted for 4 weeks.

The patients in the experimental group were treated with fire moxibustion therapy where the patients were placed in a comfortable position, and the skin tissue of the osteoporotic area was exposed. The areas without fire moxibustion therapy in patients were covered with a quilt to prevent the patients from getting cold and to protect their privacy, while those with fire moxibustion therapy were covered with the towels which have been pre-dried on every side and the gauze blended with the Chinese herbal medicine, in which Shen Jin Cao (*Lycopodii Herba*), Tou Gu Cao (*Caulis Impatientis*), Guang Huo Xiang (*Pogostemonis Herba*) and Xiao Hui Xiang (*Foeniculi Fructus*) were used as the major ingredients. In detail, the areas with fire moxibustion therapy were sprayed with 95% ethanol, and the uniformity of spraying was maintained as well. The fire was then lit, and was put out when patients sensed both heat and humidity, followed by the repetition for 3 times in total. After the last therapy, the towels were placed on the areas with fire moxibustion therapy in patients, and patients were received massage. The removal of the towels and the wiping action over the patients' skin were conducted in a gentle manner, and patients were covered with the quilt and allowed to take 1 cup of warm water while being told of the precautions after fire moxibustion therapy by the nursing stuffs. The fire moxibustion therapy was conducted once per day and five times for every week, and the entire therapy lasted for 4 weeks.

Observational index

(I) Visual analog scale (VAS): The VAS scale was used to evaluate the degree of low back pain in patients of both groups (5). The total score varied from 0 to 10, and with 0 being no pain and 10 being severe pain, and higher score indicated the more severe low back pain. (II) Oswestry disability index (ODI): The ODI scale was employed to evaluate the lumbar function of patients in both groups, which included 9 aspects, including pain intensity, self-care, lifting, walking, sitting, sleep disturbance, social life and travel, with a total score of 45 (6). Total score of patients were calculated in the following formula: Total score= actual score/45 × 100%, and higher total score suggested the higher severity in patients' lumbar function. (III) clinical efficacy: the clinical efficacy in patients of these two groups was confirmed with the criteria in the Guiding Principles for Clinical Research on Novel Chinese Medicines and was listed as follows (7). Excellent effective: the clinical symptoms in patients disappeared, and bone density showed evident improvement. Effective: the clinical symptoms in patients basically disappeared, and bone density showed some improvement. Ineffective: the clinical symptoms in patients remained unchanged, and bone density didn't improve. Total effective rate was calculated by the formula: Total effective rate = cases of (Excellent effective + Effective)/total cases × 100%. (IV) life quality: the World Health Organization quality of life brief questionnaire (WHOQOL-BREF) was used to evaluate the life quality of patients in both groups (8). The scale includes four domains: environmental, physical, social, and psychological, and each domain contains 8, 7, 3, and 6 entries, respectively, with each entry scoring from 1 to 4, and the total score is 100, and the higher the total score is, the better the quality of life of the patients.

Statistical analysis

All data here were expressed as mean ± standard deviation (SD), and statistical significance was determined with both chi-square test and *t* test, which was suggested when *P*-value <0.05. All data here were analyzed using SPSS software (version 20.0, IBM Corporation, Endicott, NY, USA)

Results

Comparison on VAS and ODI scores

No significant difference was found in these two groups concerning VAS and ODI scores in patients before treatment (p>0.05; Table 1). After treatment, we confirmed that both VAS and ODI scores for patients were decreased, and patients in the experimental group exhibited lower VAS and ODI scores as compared to those in the control group (p<0.05; Table 1).

Comparison on the clinical efficacy

There was a statistical significance concerning clinical efficacy in the patients of these two groups, and the clinical efficacy in patients in the experimental group was evidently higher than the control group (p<0.05; Table 2).

Table 1 The comparison on the VAS and ODI scores (Point)

Group	Case	VAS		ODI	
		Before treatment	After treatment	Before treatment	After treatment
Experimental group	70	5.46±1.52	2.74±0.63*	54.74±8.56	28.64±6.38*
Control group	70	5.27±1.28	3.56±0.85*	56.22±9.37	35.77±7.20*
t		0.800	-6.484	-0.976	-6.201
P		0.425	0.000	0.331	0.000

*p<0.05, vs. Before treatment

Table 2 The comparison on the clinical efficacy [case (%)]

Group	Case	Excellent effective	Effective	Ineffective	Total effective rate
Experimental group	70	34（48.57）	30（42.86）	6（8.57）	64（91.43）
Control group	70	23（32.86）	31（44.29）	16（22.86）	54（77.14）
χ^2					5.393
P					0.020

Comparison on the life quality

Prior to the treatment, we reported no statistical significance concerning the scales for environmental, physical, social, and psychological domains and the total score for life quality (p>0.05; Table 3). After treatment, however, as compared to those before treatment, the scales for environmental, physical, social, and psychological domains and the total score for life quality in all patients were increased, among which patients in experimental group have been unveiled to score higher than those of control group (p<0.05; Table 3).

Discussion

OP mainly occurs in the elderly and includes both primary OP and secondary OP, and under normal conditions, during the process of bone tissue reconstruction, the bone resorption and bone formation are in a dynamic balance. The disturbance on the balance, that is, the bone resorption rate is higher than the bone formation rate, will result in bone loss and thus the onset of OP. According to the beliefs of TCM, OP belongs to the categories of “bone impotence”, “fatigue deficiency” and “bone paralysis” and is believed to be associated with the deficiency of Qi in the spleen, which results in insufficient production of water and grain and the loss of muscle and bone. As a result, the bones tend to lose nourishment and activity and leads to the onset of OP. Therefore, the treatment of OP should

Table 3 The comparison on life quality (point)

Group	Case	Environmental domain		Physical domain		Social domain		Psychological domain		Total score	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Experimental group	70	18.77±4.22	28.34±3.17*	16.74±3.83	24.36±3.52*	5.24±1.26	10.76±1.20*	13.64±3.42	20.38±3.22*	54.39±9.25	83.84±7.72*
Control group	70	19.56±3.76	25.64±4.84*	15.92±4.12	21.77±5.23*	5.50±1.34	8.64±2.15*	14.25±3.80	18.16±4.05*	55.23±10.77	74.21±8.28*
t		-1.169	3.904	1.220	3.437	-1.183	7.204	-0.998	3.590	-0.495	7.117
P		0.244	0.000	0.225	0.001	0.239	0.000	0.320	0.000	0.621	0.000

*$p<0.05$, vs. Before treatment

be based on the tonifying Qi, benefiting the essence, invigorating Qi, strengthening the spleen, activating the blood circulation and resolving blood stasis (9). Recent years have also witnessed the application of external treatment of Chinese medicine on the clinical treatment of OP. According to Zeng *et al*.'s report, Medicinal-cake-separated moxibustion was used to treat patients with OP, which showed improvement on both the clinical symptoms and bone density (10). Moxibustion is a commonly acupuncture method in TCM, which exerts its therapeutic effects using the heat generated via the burning of moxibustion materials. Additionally, it has been concluded that the herbal ironing therapy, that is, the hot application of herbal medicine to the lesion site, has also achieved some therapeutic effects in the treatment of OP, in which the herbal medicine can penetrate into the tissue under heat and can promote blood circulation, regulate Qi and meridians and activate collaterals (11). Fire moxibustion therapy is an external treatment strategy used in Chinese medicine, and its mechanism is similar to that of ironing therapy for Chinese medicine, where Chinese medicine has the capability to penetrate into the tissue under heat and to exert its therapeutic effects. In our study, patients control group were treated with moxibustion, and those in experimental group were subjected to fire moxibustion therapy, the results of which showed that the total effective rate in the experimental group was evidently higher than that in the control group, indicating that fire moxibustion therapy might be more effective in the treatment of OP.

Patients with OP are sometimes accompanied with the symptoms of lumbar pain, which leaves a serious adverse effect on their life quality. According to the results in our study, the VAS and ODI scores of patients in both groups presented a significant decrease after treatment yet the scores of various domains of life quality and total scores significantly was increased, and the degree of improvement in the experimental group was significantly higher than that in the control group, indicating that the adjuvant treatment with fire moxibustion therapy can effectively relieve the lumbar pain and improve their lumbar function and life quality in patients with OP. The herbal used for fire moxibustion therapy mainly consists of Shen Jin Cao (*Lycopodii Herba*), Tou Gu Cao (*Caulis Impatientis*), Guang Huo Xiang (*Pogostemonis Herba*) and Xiao Hui Xiang (*Foeniculi Fructus*), among which Shen Jin Cao (*Lycopodii Herba*) has the effects of dispelling dampness, relaxing tendons and activating blood circulation, Tou Gu Cao (*Caulis Impatientis*) is proved to have effects on muscle relaxation, blood circulation promotion, detoxification and pain relieving, Guang Huo Xiang (*Pogostemonis Herba*) is capable of dispelling heat, alleviating symptoms and preventing vomit in the stomach, and Xiao Hui Xiang (*Foeniculi Fructus*) is underlined to warm the kidney and liver, regulate Qi and relieve pain. The combination of all herbals can

warm the meridians and disperse cold, dispel wind and promote circulation and invigorate blood circulation and relieve pain. In addition, Shen Jin Cao (*Lycopodii Herba*) contains anthraquinones, which can help reduce the activity of Tartrated Resistant Acid Phosphatse (TRACP) and activity of Proteinase K in the tissue, decrease bone matrix degradation, reduce osteoclast synthesis, which further suppresses the bone resorption of osteoclasts and reduces the bone resorption of osteoclasts and reduces bone loss. The flavonoid in Guang Huo Xiang (*Pogostemonis Herba*) possesses regulatory effects on osteoprotegerin/Receptor activator of nuclear factor kappa B /Nuclear factor kappa B receptor activator ligand (OPG/RANK/RANKL) pathway to upregulate OPG expression while repressing RANKL expression, reducing both the number of osteoclasts and bone mineral loss, which elicits a protective effect on the bone. Also, by the coverage of the lesion with gauze moistened with the TCM, the temperature of fire moxibustion therapy can make those herbals penetrate into the affected area and strengthen the effects on activating blood circulation, dispelling dampness and harmonizing both Qi and blood. The active ingredients of the Chinese herbal and further infiltrate into the fascia, muscle, and other tissues under the heat of fire moxibustion therapy, which promotes the dilation of the surrounding capillaries, the circulation of both blood and lymph, the acceleration of tissue metabolism, and the enhancement on the absorption of edema and inflammatory products, while loosens the adhesion or contractures of tissues and eliminates the hematomas, thus alleviating the pain and restoring the normal function in patients with OP.

In a word, the adjuvant treatment fire moxibustion therapy has proven effective in treatment for patients with OP, which is associated with the reduction on the degree of lumbar pain, the amelioration on the patients' lumbar function and the improvement of patients' life quality.

Declaration of conflict-of-interest

The authors declare no conflict-of-interest.

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