

Original Article

Efficacies of different diameters of fire needle therapy on stage II and III pressure ulcer: a comparative study

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Abstract: Objective: To compare the therapeutic efficacy of fire needle with different diameters in the treatment of grade II and III pressure ulcers. Methods: Forty-five patients were randomized into three groups: a fine-needle (0.5 × 40 mm), intermediate-needle (0.65 × 50 mm), and thick-needle group (0.8 × 50 mm), with 15 patients in each group. All patients were treated with conventional nursing, debridement, and fire needle therapy. The participants were treated once a week for 3 weeks, resulting in a total of three treatments. Using the DESIGN-R bedsore evaluation scale before and after treatment, we evaluated pressure ulcer depth, size, and granulation score. Results: The efficiency in the fine-, intermediate- and thick-needle treatment groups were 80.0%, 93.3%, and 86.7%, respectively, and there was no significant difference among the groups ($P > 0.05$). Compared with baseline, the pressure ulcer depth, size, and granulation scores were decreased after fire needle therapy in all three groups ($P < 0.001$, $P < 0.05$, and $P < 0.05$, respectively). The intermediate fire needle significantly reduced the depth of the pressure ulcer and granulation tissue score more than the fine fire needle and the thick fire needle ($P < 0.05$ in both cases), but the three groups did not differ significantly in terms of the effect on wound area ($P > 0.05$). Conclusion: Different diameters of fire needle can be used to treat grade II and III pressure ulcers, and intermediate fire needles can reduce pressure ulcer depth and granulation tissue score more effectively than fine and thick needles.

Keywords: Pressure ulcer, fire needle, DESIGN-R, clinical research

Introduction

Pressure ulcers are localized lesions on the skin or subcutaneous tissue that are caused by pressure, combined scissors force, or friction. They often occur in the sacral and caudal regions, heel, acromion, hip joint, ankle joint, etc. [1]. Patients with restricted mobility and poor health are often particularly vulnerable to pressure ulcers [2], and the lesions cause pain and discomfort in these patients [3, 4]. In addition, pressure ulcer treatment is associated with considerable costs for society [5, 6].

Early and effective treatment of pressure ulcers improves prognosis. In clinical practice, pressure ulcers are prevented by intensive care, but there is a lack of good treatment [7]. In this regard, several studies have reported that fire needle therapy—a traditional form of acupuncture—can promote wound healing in cases of pressure ulcers [8-10]. The fire needles used in

this technique can have various diameters, but no high-quality trials have been conducted to determine whether different diameter fire needles have different efficacies in the treatment of pressure ulcers. Therefore, the present trial compared the effects of different fire needle thicknesses in this regard.

Materials and methods

Design

This was a triple-blind, multicenter, randomized controlled trial involving three patient groups: a fine-needle group, an intermediate-needle group, and a thick-needle group. After signing the informed consent form, participants were randomly allocated to each group (**Figure 1**).

Participants

We recruited out-patient and in-patient study subjects who were to be treated in the acu-

Curative effect of fire needle therapy on pressure ulcer

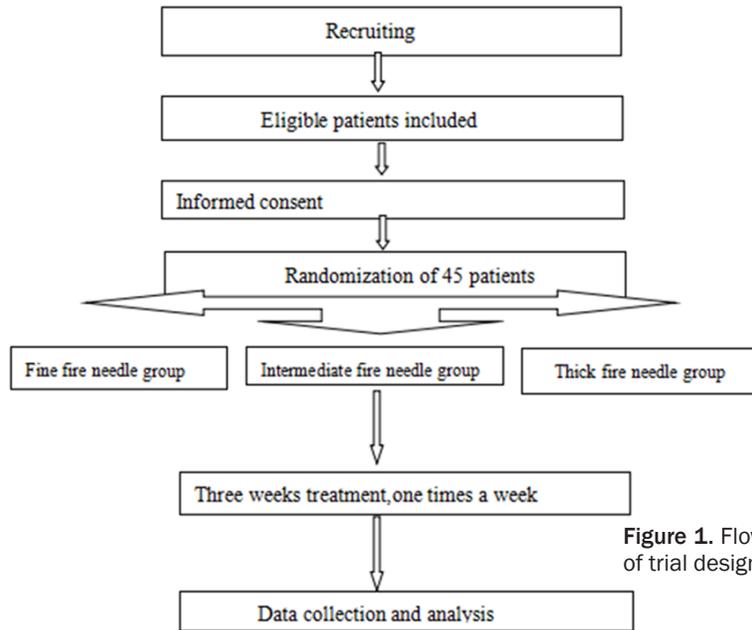


Figure 1. Flow of trial design.

puncture and physiotherapy room of the First People's Hospital in Jining, Shandong Province, China between June 2015 and June 2017. To qualify for inclusion, patients had to be between 18 and 75 years old and to have suffered one or more skin ulcers lasting for more than 1 month. Furthermore, the lesions had to meet the 2007 national pressure ulcer expert guidance grade II-III diagnostic criteria [8]: Grade II pressure ulcers are characterized by (1) purple color, induration, pain, blisters, and skin loss, manifesting as superficial open ulcers that appear dry, (2) pink color without infection, which may represent complete rupture of the lesion, or (3) blisters; Grade III pressure ulcers involve epidermal damage and full-thickness skin tissue loss that exposes subcutaneous fat, but not bone, tendon, or muscle. The basal part of the ulcer is pale white, but the depth of tissue loss is not clear.

Potential participants were excluded if they (1) had a mental illness, (2) could not co-operate with examination and treatment, (3) had arrhythmia or atrial fibrillation, or (4) had active osteomyelitis. Eligible participants were excluded if they (1) did not conform to the inclusion criteria, (2) had a serious adverse reaction and could not continue treatment, (3) were treated in violation of regulations, and (4) were impossible to judge curative effect. The DESIGN-R assessment of progression toward healing is shown in **Figure 2**.

Using a random number table, 45 patients were divided into three groups, with 15 patients in each group. There was no statistical difference in gender, age, or disease course between the groups ($P > 0.05$) (**Table 1**).

Intervention

Groups: The three groups of patients were treated in the same way (fire needle). The only difference was the diameter of fire needle. The specifications were as follows: fine fire needle- 0.5×40 mm, intermediate fire needle- 0.65×50 mm, thick fire needle- 0.8×50 mm.

Treatment methods

Basic treatment: Patients were given routine decompression and anti-infection nursing. Their bed sheets were kept clean and urine was cleaned up promptly. Their nutritional intake was improved to include vitamins and trace elements.

Debridement: Before treatment, hydrogen peroxide solution was used to wash the pressure ulcer and ensure an aseptic operation. Pus and secretions were cleaned up and the ulcerated tissues were eliminated. Next, 0.9% normal saline solution was used to rinse and expose the full wound.

The fire operation: At first, an iodophor was used to disinfect the ulcer and the skin around the wound. The ulcer was then irrigated using saline. The clinician then heated about 1.0 cm of the needle tip until it was red-white and penetrated it quickly into the wound, ideally to the base of the ulcer. The speed of penetration was rapid and the needle was not left in the wound. The procedure was carried out along the edge of the ulcer, and an interval of 0.5-1.0 cm was left between the insertion points. The size of the ulcers determined the number of needle insertions that were used. The participants were treated once a week for 3 weeks for a total of three treatments. Subsequently, the effect was assessed.

Curative effect of fire needle therapy on pressure ulcer

DESIGN-R assessment of progression towards healing

Chart number: _____
 Name of patient: _____ Date: / / / / / /

Depth: this should be measured at the deepest point of the wound. If the wound becomes shallower, the decreased depth should be reflected in the assessment										
d	0	No particular skin lesion and no redness	D	3	Lesion extends into the subcutaneous tissue					
	1	Persistent redness		4	Lesion extends to muscle, tendon and bone					
	2	Lesion extends into dermis		5	Lesion extends into the articular or body cavity					
				U	It is impossible to measure the depth					
Exudate: amount										
e	0	None	E	6	Heavy: requires dressing change more than twice a day					
	1	Slight: does not require daily dressing change								
	3	Moderate: requires daily dressing change								
Size: the area of a skin injury (length × width). Longest measurement in the wound is length; width is longest measurement perpendicular to that axis										
s	0	None	S	15	100 cm ² or larger					
	3	Smaller than 4 cm ²								
	6	4 cm ² or larger, but smaller than 16 cm ²								
	8	16 cm ² or larger, but smaller than 36 cm ²								
	9	36 cm ² or larger, but smaller than 64 cm ²								
	12	64 cm ² or larger, but smaller than 100 cm ²								
Inflammation/Infection:										
i	0	None	I	3	Clear signs of local infection (eg, inflammation, pus and foul smell)					
	1	Signs of inflammation (fever, redness, swelling, and pain around the wound)		9	Systemic impact, such as fever					
Granulation tissue: percentage of healthy granulation										
g	0	Granulation cannot be assessed because the wound is healed or too shallow	G	4	Healthy granulation tissue occupies 10% or more, but less than 50%					
	1	Healthy granulation tissue occupies 90% or more		5	Healthy granulation tissue occupies less than 10%					
	3	Healthy granulation tissue occupies 50% or more, but less than 90%		6	No healthy granulation tissue exists					
Necrotic tissue: when necrotic and non-necrotic tissues are mixed, the dominating condition should be used for assessment										
n	0	None	N	3	Soft necrotic tissue exists					
				6	Hard and thick necrotic tissue is attached to the wound					
Pocket: the area obtained by subtracting the ulcer from the entire affected area, including the pocket										
p	0	None	P	6	Smaller than 4 cm ²					
				9	4 cm ² or larger, but smaller than 16 cm ²					
				12	16 cm ² or larger, but smaller than 36 cm ²					
				24	36 cm ² or larger					
Region [sacrum, ischium, trochanter, calcaneum, heel, other region]				Total						

Figure 2. DESIGN-R assessment of progression toward healing.

Table 1. General data comparison of three groups of patients with class II~III degree pressure ulcer

Group	Number	Gender (Number)		Age	Course of disease
		Male	Female		
Fine fire needle group	15	8	7	52.46 ± 12.86	1.48 ± 0.53
Intermediate fire needle group	15	9	6	51.24 ± 14.17	1.45 ± 0.56
Thick fire needle group	15	6	9	52.35 ± 13.83	1.53 ± 0.45

Observation of curative effect

Observation index: The effects of the procedure were evaluated using the Japanese DESIGN-R bedsore evaluation scale [9], which considers depth, exudation, lesion area, infection, inflammation, granulation tissue, necrotic tissue, blisters, and other aspects. Each ulcer was given a grade between 3 and 7, and the total score ranged from 0 to 28, with higher scores indicating more serious pressure ulcers. In the present study, we mainly used DESIGN-R

scale, depth, scope, and wound granulation tissue as the evaluation index.

The standard for curative effect evaluation: We used the standard of diagnosis and treatment published by the State Administration of Traditional Chinese Medicine [9], which identifies “cured” lesions when brown erythema has subsided or festering wounds have healed and “improved” lesions when erythema has not completely faded, or when ulcerated wound carriage has been shed, new tis-

Curative effect of fire needle therapy on pressure ulcer

Table 2. Comparison of the clinical efficacy of three groups of patients with pressure ulcer in class II~III degree

Group	Number	Cure rate (%)	Improvement rate (%)	The failure rate (%)	Total efficiency (%)
Fine needle group	15	6	6	3	80.0
Intermediate needle group	15	10	4	1	93.3
Thick fire needle group	15	8	5	2	86.7

sue has grown, and the wound has gradually reduced.

Statistical analysis

All data were processed using SPSS ver. 17.0 statistical software. The data are expressed in terms of mean \pm SD. A paired t-test was used before and after treatment, and one-way ANOVA was used to compare among the groups. The effective rate was compared using the Chi-square test. *P*-values < 0.05 were considered statistically significant.

Results

General data comparison in three groups of patients with second-degree pressure ulcers

As shown in **Table 1**, the general data did not differ significantly among the three groups of patients (*P* > 0.05).

Comparison of clinical efficacy among the three groups

As shown in **Table 2**, the three groups of patients with grade II-III pressure ulcers differ significantly in terms of total efficiency (*P* < 0.05).

Changes in pressure ulcer depth after treatment in the three groups

As shown in **Table 3**, before treatment, the three groups did not differ significantly in terms of granulation tissue depth, scope, or ulcer grade (*P* > 0.05). After treatment, the scope and depth of the wound granulation tissue were significantly improved in all groups (*P* < 0.01 in all cases), suggesting that fire needle therapy can promote recovery of pressure ulcers.

The intermediate fire needle reduced the depth and granulation tissue score of the pressure ulcers significantly more than the fine and thick needles (*P* < 0.05 in both cases), but there was

no significant difference in wound area among the three groups (*P* > 0.05), suggesting that the intermediate fire needle is more effective than the fine and thick needles at reducing depth and promoting improvement in granulation tissue growth.

Discussion

Pressure ulcers are common in bedridden or wheelchair-bound patients [11, 12]. External factors are the most important mechanical contributors to this condition: when direct pressure that exceeds the normal capillary pressure (4.27 kPa) is sustained for a long period of time, pressure ulcers can form in the caudal region, trochanter, external ankle, heel bone, etc. and most ulcer parts are hidden [13, 14], so pressure ulcers are often long-lasting and difficult to treat. In addition, they are easily infected and so cause various complications [15]. Therefore, early and effective treatment of pressure ulcers is the key to the prevention and treatment of this disease [16]. At present, pressure ulcers are mainly treated by nursing staff [17, 18], and the prevention measures used include wound disinfection, air cushion beds [19, 20], and guidance-based practice. However, there is still a lack of effective prevention methods.

Recently, several papers have reported that acupuncture, fire needle therapy, and other methods [21, 22] can effectively improve pressure ulcers and promote recovery. These studies have found that the thickness of fire needles affects the outcome of fire needle therapy. However, to date, no researchers have investigated these reports.

Fire needle therapy is a combination of acupuncture and moxibustion: conferring the mechanical stimulation of acupuncture and the burning of moxibustion [23]. Fire needle therapy involves pricking diseased tissue, causing mild local burning and inducing a stress response. This in turn improves local blood cir-

Curative effect of fire needle therapy on pressure ulcer

Table 3. Depth, range, and granulation score were compared among three groups (Score, $\bar{x} \pm SD$)

Group	Number	Depth of pressure ulcer				Pressure ulcer range				Granulation tissue score			
		Before treatment	After treatment	t	P.	Before treatment	After treatment	t	P.	Before treatment	After treatment	t/P.	
Fine	15	3.26 ± 0.79	0.62 ± 0.68	7.5	0.0005	4.46 ± 2.99	1.78 ± 1.89*	4.5	0.04	2.40 ± 1.05	0.73 ± 0.79*	3.5	0.029
Intermediate	15	3.20 ± 0.86	0.33 ± 0.48*	8.5	0.0003	4.26 ± 2.98	0.80 ± 1.37*	9	0.0008	2.32 ± 0.98	0.31 ± 0.56*	3.9	0.035
Thick	15	3.13 ± 0.74	0.73 ± 0.64	6.5	0.00013	4.53 ± 2.64	2.00 ± 1.85	3.8	0.03	2.46 ± 1.10	0.82 ± 0.68	3.25	0.027
F		0.025	13.56			0.017	14.23			0.32	12.65		
P		0.86	0.0009			0.96	0.00038			0.87	< 0.01045		

Note: *, compare with fine or thick needle group, P < 0.05.

Curative effect of fire needle therapy on pressure ulcer

ulation and increases the local immune response [24, 25]. New tissue then supersedes the old, reducing local inflammation and promoting tissue recovery. In the present study, we observed that all three kinds of needle effectively improved the symptoms of pressure ulcers. However, total efficiency was higher in the intermediate fire needle group than in the other two groups.

The DESIGN-R bedsore evaluation scale was published in 2002 by the academic committee of the Japan Society of bedsores. It is commonly used to score pressure ulcers [26]. Evaluation can be carried out once a week using this scale. In the present study, we assessed wound depth, range, and growth of granulation tissue as the main indexes to compare the effects of different fire needle thicknesses on pressure ulcers. The results suggest that the intermediate fire needle improves wound depth and inhibit the growth of granulation tissue significantly better than the fine and thick needles. However, the impact on the scope of the wound was similar among all three groups.

We believe that, although all three needles can treat grade II-III pressure ulcers, the intermediate fire needle is more effective than the fine fire needle and causes less tissue damage than the thick fire needle, which may inhibit the growth of granulation tissue and affect wound recovery. The results of this experiment indicate that there is no direct correlation between the effectiveness of fire needle treatment in the treatment of pressure ulcers and the thickness of fire needle. However, the intermediate fire needle was more effective at improving the ulcer depth and promoting granulation tissue growth. However, as the sample size of the present study was small, further studies involving more participants would have greater clinical value.

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Disclosure of conflict of interest

None.

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Curative effect of fire needle therapy on pressure ulcer

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