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Original Article

Observation of the effects of two-stage irrigation therapy, combined with pedicled flaps, for treatment of infected tissue defects of the ankles and feet

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Abstract: Objective: The aim of this study was to compare the clinical efficacy of two-stage irrigation combined with pedicled flaps and dressing-debridement-dressing circulation for treatment of infected tissue defects of the ankle and foot. Methods: Clinical data of 86 patients with infected tissue defects of the ankle and foot were analyzed, retrospectively. Results: Differences in ankle circumferences, pre- and post-operative, in group A at the 1st, 3rd, and 5th month were significantly smaller than those in group B (all P<0.001), as were visual analog scale (VAS) scores at the same time points (all P<0.001). Verbal rating scale (VRS) scores in group A at the 1st, 3rd, and 5th month were also lower than those in group B (P=0.001). The number of bacteria in group A was less than group B on the 10th day after the operation, as well as 2 weeks before and 2 weeks after drainage tube removal (all P<0.001). Wound healing rates in group A were significantly higher than those in group B at 12 months after the operation (P<0.001). Average hospitalization times and number of dressing changes in group A were respectively shorter and fewer, compared with group B (P<0.001 and P=0.002, respectively). Conclusion: Two-stage irrigation combined with pedicled flaps could reduce local inflammation, edema, pain, and bacterial colonization, as well as facilitate wound healing, shorten hospitalization times, and reduce the average number of dressing changes.

Keywords: Irrigation, vacuum sealing drainage, infected tissue, flap

Introduction

Tissue infections caused by ankle and foot injuries are common. Therefore, effective treatment and repair of the wounds is of significant clinical concern [1, 2]. Microcirculation disturbance and local inflammatory edemas occur in the wounds after trauma. If not treated in time, the wound will be progressively aggravated within 48 hours, leading to occurrence of local and systemic infections [3, 4]. In severe cases, endotoxemia and even systemic inflammatory response syndrome may occur, resulting in multiple organ failure [5]. Therefore, it is vital to deal with wounds timely, healing them in the shortest time possible.

At present, clinical management of infected tissues in injured ankles and feet involves the following steps: removal of dirt and debris, protection of the wound, preventing infection, keeping the wound dry, reducing bacterial growth at the site, preventing further deepening of the wound, and accelerating wound healing [3, 6]. According to the extent of infection in the injured tissues, clinical treatment includes either local anesthetic debridement for mild infections or vacuum sealing drainage (VSD) for severe infections. Specifically, these treatments consist of dressing-debridement-dressing circulation and pedicled flaps, combined with VSD [7, 8]. Traditional treatment of foot and ankle infections can, however, aggravate the local infection in cases of extensively infected tissue area, incomplete debridement, and inadequate drainage. Two-stage irrigation, combined with pedicled flap treatment, was developed to accelerate wound healing and minimize tissue damage. In the first stage, the irrigation tube and the VSD is placed on the exposed area of deep tissue. The infected and necrotic tissue debris and the viscous pus is washed out, thus reducing the risk of VSD obstruction and maximizing its effects. In the second stage, the pedicled flap is selected for repair. Irrigation and drainage tubes are placed underneath this flap. Skin flap surgery and VSD technique can not only promote blood circulation in the wound site, but also improve the clearance of local infections [9]. VSD was first used in the early stage treatment of open fractures. It has been continuously improved over the years. It has been widely used to treat soft tissue, bone tissue, and chronic refractory wounds, as well as in skin and bone tissue transplantation and oral and maxillofacial surgery. However, the specific curative effects of VSD on infected foot and ankle tissues remain unclear.

The current study compared the clinical effects of two-stage irrigation, combined with pedicled flaps and the dressing-debridement-dressing approach, on local inflammatory reaction and wound healing in patients with infected tissue defects of the ankles and feet. This study aimed to further investigate the effects and underlying mechanisms.

Materials and methods

General data

Clinical data of 86 patients with infected tissue defects of the ankles and feet, admitted to Shanghai Fengxian District Hospital, from January 2014 to December 2017, were analyzed retrospectively.

Inclusion criteria: 1) Compliance with the diagnostic criteria of foot and ankle infection wounds, involving white skin edges with black necrotic tissue, less atrophic granulations, and possibility of bone, tendons, or muscle tissue exposure; 2) Aged between 18-80 years; and 3) No previous treatment.

Exclusion criteria: 1) Patients with serious heart, liver, lung, kidney, and other systemic diseases; 2) With systemic infections and serious complications; 3) Non-ankle and foot-infected wounds; and 4) Pregnant and lactating women.

Two-stage irrigation therapy, combined with pedicled flaps, was used to treat 21 patients (group A: 13 males and 8 females, with an average age of 43.20±1.20 years old). Dressing-debridement-dressing circulation was used to treat 65 patients (group B: 36 males and 29 females, with an average age of 45.40±5.60 years old). The wound agent was as follows: 1) Traffic accident injury: 6 cases in group A and 30 cases in group B; 2) Mangled injury: 4 cases in group A and 15 cases in group B; 3) Mechanical injury: 6 cases in group A and 10 cases in group B; and 4) Falling injury: 5 cases in group A and 10 cases in group B. All injury sites were in the ankles and feet, accompanied by local tissue infections.

Surgical methods

Group A: After admission, the patients underwent relevant pre-operative examinations. Those with life-threatening injuries were prioritized. Necrotic and contaminated tissues were removed by thorough debridement under spinal or general anesthesia. The wounds were rinsed with sterile saline and hydrogen peroxide and bleeding was stopped. The skin flap was designed according to wound size before the operation (flap area was 2-3 cm larger than wound area after debridement). According to the size and type of wound, appropriate VSD materials were selected. The irrigation tube was placed in the most seriously infected area. After making sure that the covered VSD dressing was in full contact with the wound, the skin was sutured intermittently with the VSD sponge. Biofilm was attached over the surface of the flap and the VSD drainage tube was connected to the vacuum device to detect any biofilm leakage. Pressure was then adjusted to 200-300 mmHg. Wound irrigation started on the day of the operation. Under aseptic conditions, 250 mL 0.9% sodium chloride was used to wash the drainage tube three times a day, with continuous vacuuming of the liquid. Irrigation speeds and times were adjusted according to drainage conditions. Irrigation continued for 7-10 days. Afterward, the VSD dressing was removed.

Group B: For debridement of the wound, a suitable subarachnoid or general anesthesia was first administered. Moreover, 3% hydrogen peroxide and chlorobenzene were used alternately to wash the wounds and remove necrotic tissue. After bleeding was stopped, wounds were dressed using gauze. They were then dipped in chlorobenzene solution. The wet dressing was changed. New dressing was then applied, according to the exudation of the affected area.

Table 1. Comparison of general data between the two groups of patients ($\overline{x}\pm$sd)

	Group A	Group B	χ^2/t	P
Male/female	13/8	36/29	0.786	0.624
Age (year)	43.20±1.23	45.40±5.61	1.780	0.079
Wound agent			3.418	0.332
Traffic accident injury	6	30		
Mangled injury	4	15		
Mechanical injury	6	10		
Falling injury	5	10		

Outcome measures

Pre- and post-operative ankle circumference and local pain scores: After admission of the patients, obvious visual infected tissues of ankle edema were measured with a meter ruler. The circumferences were calculated. Similar measurements were made at 1, 3, and 5 months after the operation. Differences between the pre- and post-operative ankle circumferences were then calculated.

In addition, patients estimated their own pain scores, according to the visual analog scale (VAS). This scale is divided into 0-10 points: 0 points indicating no pain, ≤3 points indicating slight but tolerable pain, 4-6 points indicating moderate tolerable pain which affects sleep, and 7-10 points indicating gradually intensifying and unbearable pain. Patients also graded their pain according to the verbal rating scale (VRS). This is a highly subjective scale but easy for the patient to understand. It divides the pain into 4 grades: grade 0 with no pain; grade I with mild, tolerable pain which does not affect daily life and sleep; grade II for moderate, obvious, and intolerable pain which requires painkillers and affects sleep; grade III with severe and unbearable pain, requiring painkillers and seriously affecting sleep and accompanied by autonomic nervous disorder or passive posture in some cases.

Quantitative detection of bacteria: Wound tissue specimens were collected from the same area ten days after surgery, as well as 2 weeks before and 2 weeks after drainage tube removal. The tissues were inoculated directly with cotton swabs on Luria-Bertani medium, then incubated at 37°C for 24 hours. Colony forming units (CFU) were calculated to compare bacterial infections in wounds.

Wound healing rates: The number of healed wounds were counted on the 14th day after treatment in both treatment groups. Criteria for wound healing were: wound closure with intact epidermis, absence of any exudate, no damage to the wound, such as rupturing, fluid flow after full-range of movement, and no discoloration.

Number of dressing changes and average hospitalization times: For both two groups, the number of dressing changes was counted. Wound healing was observed during dressing changes, according to the above standards. Hospitalization times were also recorded.

Statistical analysis

All data were analyzed using SPSS 13.0 statistical software. Measurement data are expressed as mean ± standard deviation ($\overline{x}\pm$sd) and were compared between groups by independent t-test. Count data are expressed as percentages (%) and were compared using χ^2 test. $P<0.05$ indicates statistical significance.

Results

Comparison of general data between the two groups of patients

There were no significant differences in age and injury types between the two groups. See **Table 1**.

Differences in ankle circumferences and local pain scores after the operation

The average differences in ankle circumferences in group A (35.41±2.64 cm, 32.72±2.21 cm, and 30.12±2.01 cm) were significantly lower than those in group B (38.42±2.31 cm, 36.51±2.07 cm, and 32.84±1.52 cm) for the same time points at 1, 3, and 5 months after the operation. In addition, VAS scores in group A were lower than those in group B at 1, 3, and 5 months after the operation (all $P<0.001$), as well as VRS scores ($P=0.001$). See **Tables 2-4** and **Figure 1**.

Comparison of quantitative detection of bacteria

Average CFUs obtained from group A ((52.10±8.32)*10^3, (34.22±6.43)*10^3, and (12.02±

5.35)*10^3, respectively) were less than those of group B ((73.10±8.55)*10^3, (45.03±5.52)*10^3, (25.05±5.23)*10^3, respectively) at 10 days after surgery, as well as 2 weeks before and 2 weeks after drainage removal. Differences were statistically significant (all P<0.001). See **Table 5** and **Figure 2**.

Wound healing rates

The wound healing rate was 80.95% (17/21) in group A, significantly higher than the 35.38% (23/65) in group B at the 12th month after the operation (P<0.001). See **Figure 3**.

Number of dressing changes and average hospitalization times

The average hospitalization time in group A (15.62±2.33 days) was significantly shorter than that in group B (23.44±4.52 days) (P<0.001). The number of dressing changes in group A (4.53±1.26 times) was also significantly fewer than that in group B (15.60±2.43 times) (P=0.002). See **Table 6** and **Figure 4**.

Table 2. Comparison of circumferences of ankles and feet between the two groups of patients ($\bar{x}$±sd)

	Group A	Group B	t	P
1 month after operation	35.41±2.64	38.42±2.31	5.789	<0.001
3 months after operation	32.72±2.21	36.51±2.07	7.289	<0.001
5 months after operation	30.12±2.01	32.84±1.52	5.230	<0.001

Table 3. Comparison of VAS scores between the two groups of patients ($\bar{x}$±sd)

	Group A	Group B	t	P
1 month after operation	7.31±1.10	8.91±1.15	5.599	<0.001
3 months after operation	5.42±0.52	6.72±0.95	5.972	<0.001
5 months after operation	3.21±1.21	4.32±0.56	5.769	<0.001

Note: VAS, visual analogue scale.

Table 4. Comparison of VRS scores between the two groups of patients ($\bar{x}$±sd)

	Group A				Group B				χ^2	P
	0	I	II	III	0	I	II	III	17.718	0.001
1 month after operation	2	8	10	1	0	23	34	8		
3 months after operation	5	7	9	0	4	30	26	5		
5 months after operation	12	7	2	0	15	35	13	2		

Note: VRS, verbal rating scale.

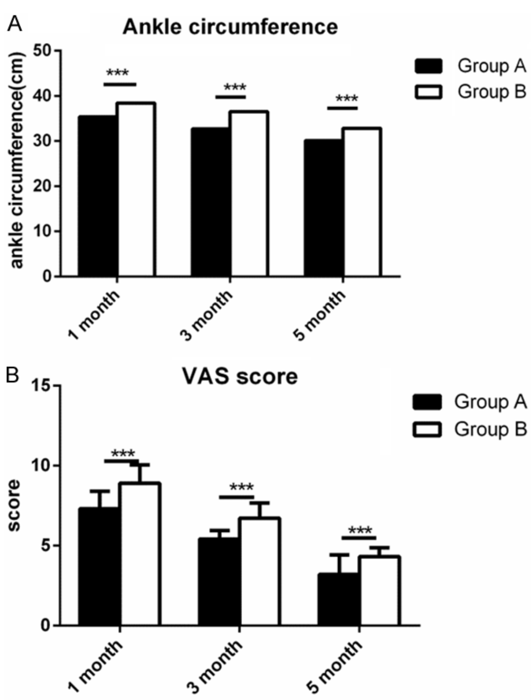

Figure 1. Comparison of ankle circumference and VAS between the two groups of patients. A: Differences in ankle circumference; B: VAS score. VAS, visual analogue scale. ***P<0.001.

Discussion

The anatomical structure of the foot and ankle joint is complex, bearing the weight of the body. Local soft tissue injuries with deep vascular and nerve tissue exposure due to traffic accidents and work-related injuries have increased annually, with a high incidence rate of 39% [10]. Exposed wounds in the deeper tissues can get infected and are often unable to heal on their own, thereby resulting in a protracted, difficult, and costly treatment. These factors make the disease a tough problem clinically [5, 11]. VSD can be used for treatment of most wounds lacking soft tissue coverage and deep drainage wounds. However, clinical coverage cannot replace the skin cover and is not a long-term solution. Flap transplantation is a common method for repairing such deep wounds [12, 13]. In recent years, the combination of VSD

Table 5. Comparison of quantitative detection of bacterial (CFU/cm^2) ($\bar{x}$±sd)

	Group A	Group B	t	P
10 days after operation (*10^3)	52.10±8.32	73.10±8.55	9.667	<0.001
2 weeks before drainage tube removal (*10^3)	34.22±6.43	45.03±5.52	7.313	<0.001
2 weeks after drainage tube removal (*10^3)	12.02±5.35	25.05±5.23	9.677	<0.001

Note: CFU, colony forming unit.

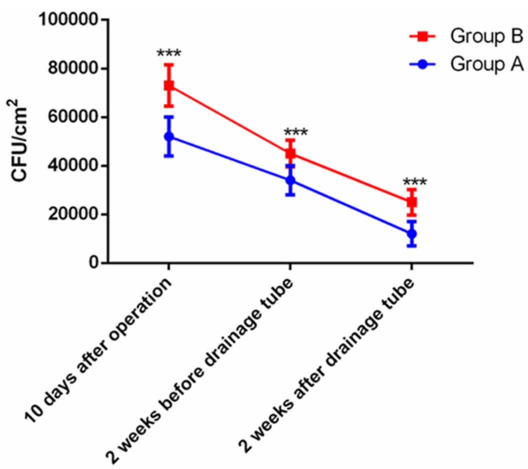

Figure 2. Comparison of quantitative detection of bacterial. CFU, colony forming units. ***P<0.001.

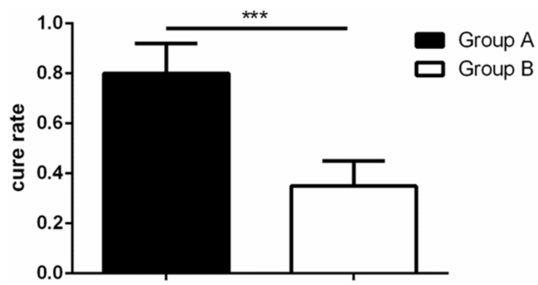

Figure 3. Comparison of cure rates at the 12th month after the operation. ***P<0.001.

technique and flap transplantation has been used for repairing injured and necrotic tissues. It has now become widely used in clinical practice [14]. Therefore, the above method is also advantageous in treating infected ankle and foot tissue injuries.

Drainage is the most basic surgical treatment for infections but has poor therapeutic effects on bone exposure and infected wounds [15, 16]. VSD uses a polymer foam material. Drainage tubes, adhesive membranes, and foam materials are non-toxic and non-immunogenic, as well as non-irritating to the injured and necrotic tissues. They are soft and elastic, porous and spongy, with good permeability and absorbability [17, 18]. Vacuum suction devices can actively drain and stimulate wound capillary proliferation and promote granulation tissue growth, accelerating tissue repair. This study found that the wound healing rate with VSD increased significantly 12 months after the operation.

The degree of local edema can be used to evaluate inflammation [19]. This study calculated the differences between pre- and post-operative ankle circumference, finding that VSD treatment significantly alleviated local inflammation, compared with simple dressing changes [20]. Sun et al. showed that VSD effectively covered the wounds, accelerated the exudation of the pus, and relieved the local edema, consistent with present results [21].

Extraction of the wound exudate, at any time, eliminates the culture medium of the bacteria and inhibits their proliferation, in addition to reducing the spread of infection and absorption of endotoxins [22]. This procedure has also greatly lowered the use of antibiotics, effectively preventing nosocomial cross infections and shortening hospitalization times. Direct culture of wound exudates collected from multiple sites and bacteria quantification is a good index for evaluating wound repair [23]. Hu et al. compared the VSD group and control group for the quantitative culture of the wound tissue exudates. They found that CFUs in the wound tissues were significantly lower in the VSD group, compared with the control group [24]. The current study also recorded fewer CFUs with the two-stage irrigation technique. VSD therapy can drain pus and necrotic tissue in the shortest time possible, restoring immune function, reducing bacterial load and toxin absorption, and preventing secondary infection of the wounds, systemic infection, endotoxemia, and systemic inflammatory response syndrome.

Table 6. Comparison of number of dressing changes and average hospitalization times between the two groups of patients ($\bar{x}$±sd)

	Group A	Group B	t	P
Hospitalization time (day)	15.62±2.33	23.44±4.52	7.588	<0.001
Number of dressing changes (time)	4.53±1.26	15.60±2.43	19.970	0.002

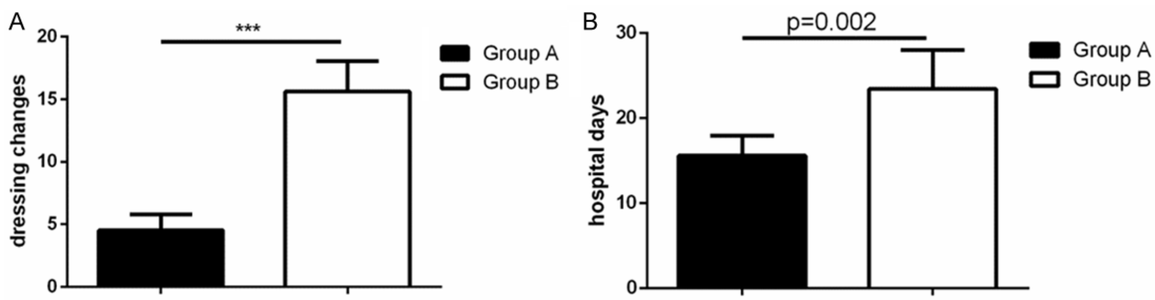

Figure 4. Comparison of number of dressing changes and average hospitalization times between the two groups of patients. ***P<0.001.

The purpose of two-stage irrigation therapy, combined with pedicled flaps, is to remove the necrotic and contaminated tissues, transforming infected wounds into relatively clean wounds. A suitable VSD was selected and applied for treatment. It was decided whether to apply VSD again according to the degree of granular tissue proliferation and infection control until the wound healing was ideal. Flap graft repair was then performed. The saphenous neurotrophic vascular flap is generally used, which has the advantages of convenient design, easy transposition, and simple coverage of fixed wounds. This flap has ample blood supply, with good venous return and high durability, since the major blood supply systems of the large saphenous vein, saphenous nerve, and saphenous artery are inter-connected. The operation is relatively simple to perform, as it does not require fiber surgery technology. The flaps are soft textured, moderately thick, and contain sensory nerves, resulting in good postoperative sensory recovery. The position of the flap is relatively concealed and does not cause significant tissue damage or affect the function of the donor site of flap. However, Fllomar et al. reported that sural neurotrophic blood supply flap resulted in complete or partial necrosis of the flap, marginal necrosis, venous congestion, flap edema, and infections [25]. These complications were not observed in this study during the short follow-up. However, to avoid these complications in the long-term, it is better to include small saphenous veins in the flap pedicles to ensure venous return, preventing the flap from swelling and necrotizing.

Two-stage irrigation therapy, combined with pedicled flap therapy, does not require daily dressing changes. Thus, it provides relief from pain and eases the workload of the nursing staff. It also alleviates psychological stress on the patients to a great extent. The main limitation of this study was the small sample size of only 86 patients. More clinical samples are necessary to confirm present findings that two-stage irrigation therapy, combined with pedicled flap therapy, can accelerate wound healing.

In conclusion, two-stage irrigation therapy, combined with pedicled flap therapy, can reduce local inflammation, edema and pain, bacterial colonization, average number of dressing changes, and hospitalization times. Therefore, this method contributes to healing of foot and ankle wounds.

Disclosure of conflict of interest

None.

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