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Effect of Bismuth Subgallate/Borneol Combined with Autologous Platelet-Rich Gel in the Treatment of Patients with Diabetic Foot Ulcers

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Abstract

Objective: To explore the effect of Bismuth Subgallate/Borneol (SuileTM BSB) healing dressing combined with autologous platelet-rich gel (APG) in the treatment of diabetic foot ulcer (DFU). Methods: A total of 120 patients with DFU hospitalized in the Changsha Central Hospital from August 2020 to September 2021 were selected and randomly divided into an experimental group (BSB + APG, n = 60) and a control group (BSB, n = 60) according to random number table method. The total therapeutic effect, healing time, hospital stay, level indexes of various inflammatory factors before and after treatment and ulcer area were observed in the two groups. Results: The total effect of the control group was worse than that of the experimental group, and the data between the two groups were significant (P < 0.05). The healing time and hospital stay in the control group were longer than those in the experimental group, and the data between the two groups were significant after comparison (P < 0.05). Before treatment, there was no significant difference in the levels of inflammatory factors between the two groups (P > 0.05); after treatment, the levels of inflammatory factors including WBC, CRP, IL-6 and TNF- α in the control group were higher than those in the experimental group, and there was significant difference between the two groups (P < 0.05). Before treatment, there was no significant difference in ulcer area between the two groups (P > 0.05); after 14 days of treatment, the ulcer area in the control group was larger than that in the experimental group, and the data between the two groups were significant (P < 0.05). **Conclusion:** BSB combined with APG can achieve better therapeutic effect, reduce the inflammatory reaction of patients, and promote wound healing in the treatment of patients with diabetic foot ulcer.

Keywords

Bismuth Subgallate/Borneol, Autologous Platelet-Rich Gel, Diabetic Foot Ulcer, Wound Healing

1. Introduction

Diabetic foot ulcer is a very common and serious chronic complication in diabetic patients, which is caused by diabetic peripheral neuropathy, vascular disease, mechanical injury and infection, followed by ulcer formation and (or) deep tissue destruction. Its incidence rate is as high as 34%, and it is often difficult to heal, which brings a heavy burden to individuals, families and society [1]. Bismuth Subgallate/Borneol (SuileTM BSB) is a patented product dedicated to wound healing, which not only has a better effect on wound bacteriostasis and reducing wound infection, but also can promote the formation of granulation tissue in patients and shorten the healing time of patients [2], but its healing effect is not satisfactory for diabetic foot ulcers that have formed sinus or deep. In recent years, autologous platelet-rich gel (APG) has been widely used in the treatment of diabetic foot ulcers, which can promote wound healing by evenly smearing or injecting it into the sinus tract. At present, there is no clinical experiment on the effect of combined use of the two at home and abroad. In this paper, 120 patients with diabetic foot ulcer who came to the hospital from August 2020 to September 2021 were selected as the research object, and the effect of BSB combined with APG in the treatment of diabetic foot ulcer was analyzed.

2. Data and Methods

2.1. General Information

A total of 120 patients with DFU hospitalized in the Changsha Central Hospital from August 2020 to September 2021 were selected as the subjects. Sample size of 126 was rounded off to 120 DFU patients (60 patients in each group) was calculated with 95% confidence interval, power of study 84%, P1 = 20% and P2 = 15% using WHO calculator.10. Inclusion criteria: patients were younger than 70 years old; all patients were in line with the diagnostic criteria of diabetic foot ulcer; all patients voluntarily participated in the experimental and signed the informed consent. Exclusion criteria: patients with tuberculosis, tumor, severe liver and kidney dysfunction and cardiovascular and cerebrovascular diseases; patients with low treatment compliance and unable to carry out the test according to the requirements. Patients within the experimental were randomized into a control group (n = 60) and a experimental group (n = 60) according to random number table method. There were 41 male patients and 19 female

patients in the control group, with the age ranging from 46 to 70 years old, with a mean of (61.23 \pm 2.33) years old, and the course of disease ranging from 3 to 9 years, with a mean of (5.49 \pm 1.14) years. There were 37 male patients and 23 female patients in the experimental group, with the age ranging from 44 to 70 years old, with a mean of (60.86 \pm 2.56) years, and the course of disease ranging from 4 to 9 years, with a mean of (5.87 \pm 1.36) years. The age, gender, course of disease, BMI, FPG, HbAlc and other clinical data of the patients in the two groups were not statistically significant after comparison (P > 0.05), which can be explored.

2.2. Method

After admission, patients in the two groups need to implement active anti-infection, control their blood sugar and blood lipid indicators, effectively deal with diabetic complications and complications, strengthen nutritional nerves, improve microcirculation, and enhance the nutritional status of patients. Standardized debridement, drainage, dressing replacement and negative pressure suction were carried out to ensure the cleanliness of the wound [3]. On the basis of the above measures, the patients in the control group were treated with BSB. The specific method was to cut the dressing according to the size of the wound of the patient, take out BSB and cover it around the wound and at the sunken position of the patient. After ensuring that the dressing was effectively attached to the wound, sterile gauze was used to cover, wrap and fix it. The patient's dressing was changed regularly every day. The time of dressing change was adjusted according to the patient's secretion. The patients in the experimental group were treated with Suile™ BSB healing dressing combined with autologous platelet-rich gel. The main methods were as follows: 1) Preparation of platelet-rich plasma: based on the size of the wound and sinus tract, the peripheral venous blood was collected and the ratio of blood volume to wound size was determined to be 10:1. The whole blood was collected by secondary centrifugation at a speed of 1323 r/min. The centrifugal radius is 8 cm, the centrifugal time is 4 minutes, the upper plasma and the white membrane layer and the upper layer of the red blood cells which are about 1 mm close to the boundary are sucked by a pasteurized tube and transferred to another centrifugal tube, the secondary centrifugation is carried out, the rotating speed is 2646 r/min, the centrifugal radius is 8 cm, after 6 minutes of centrifugation, a platelet deposition layer can be obtained, Take a pasteurized tube to suck and remove most of the plasma in the upper part. The rest must be based on the use of the required plasma and blood cell components. After standing for half an hour, shake the centrifuge tube to obtain PRP. A total of five preparations are required. 2) Preparation of APG: After treating the wound surface, 1 mL of 10% calcium gluconate was added to 2000 u thrombin freeze-dried powder to prepare thrombin-calcium agent, and then PRP and thrombin-calcium agent were mixed in a ratio of 10:1 to prepare APG. The prepared APG is evenly coated on the wound surface of the patient or injected into the sinus tract by a platelet gel injector. After the coagulation of platelet gel, the surface was covered with vaseline gauze, covered with sterile gauze and bandaged and fixed, and the dressing was changed every 3 days. After the granulation tissue of the wound was formed, BSB was added to cover the periphery and depression of the wound, and the dressing was changed every 3 to 5 days [4].

2.3. Observation Index

The total effect, healing time, hospital stay, inflammatory factor levels and ulcer area were compared between the two groups. 1) Total effect of treatment: After treatment, the ulcer surface of the patient is completely healed, the repair is good, and there is no infection, which is considered as significant effect; after treatment, the ulcer surface of the patient is healed well, and the healing area is more than 30%, which is considered as effective; after treatment, if the healing area is less than 30% or aggravated, it is considered as ineffective; 2) The total effective rate of the treatment was the markedly effective rate plus the effective rate [5]. The main inflammatory factors in the two groups were WBC, CRP, IL-6 and TNF- α

2.4. Statistical Treatment

The data analysis software in this experimental is SPSS 25.0 statistical software, the expression method of enumeration data is rate, the test method is χ^2 test, the expression method of measurement data is mean \pm standard deviation, the test method is t-test, P < 0.05 data comparison is meaningful.

3. Results

3.1. Comparison of the Total Treatment Effect of the Two Groups of Patients

The total treatment effect of the control group was worse than that of the experimental group, and the data between the groups were significant after comparison (P < 0.05). The main contents of the data are shown in **Table 1** below.

3.2. Comparison of Healing Time and Hospitalization Time between the Two Groups

The healing time and hospitalization time of the control group were longer than

Table 1. Comparison of total treatment effect between the two groups [cases (%)].

Group	Number of cases	Valid		Not valid	Total effective rate	
control group	60	32 (53.33)	19 (31.67)	9 (15.00)	51 (85.00)	
experimental Group	60	38 (63.33)	21 (35.00)	1 (1.67)	59 (98.33)	
t	-	-	-	-	5.982	
P	-	-	-	-	0.019	

those of the experimental group, and the data between the groups were significant after comparison (P < 0.05). The main contents of the data are shown in **Table 2** below.

3.3. Comparison of Levels of Inflammatory Factors before and after Treatment between the Two Groups

Before treatment, the levels of inflammatory factors in the two groups were not statistically significant after comparison (P > 0.05); after treatment, the levels of inflammatory factors including WBC, CRP, IL-6 and TNF- α in the control group were higher than those in the experimental group, and the data between the groups were significant after comparison (P < 0.05). See **Table 3** below for main data.

3.4. Comparison of Ulcer Area between the Two Groups before and after Treatment

Before treatment, there was no significant difference in the ulcer area between the two groups (P > 0.05); after 14 days of treatment, the ulcer area in the control group was larger than that in the experimental group, and the data between the two groups were significant (P < 0.05). See **Table 4** below for the main contents of the data.

4. Discussion

Wound healing of diabetic foot ulcer includes acute inflammation, cell proliferation and regeneration of epidermis and other tissues, which is a dynamic process.

Table 2. Comparison of healing time and hospitalization time between the two groups (X \pm s, hours).

Group	Number of cases	Ulcer healing time	Length of stay
control group	60	48.57 ± 3.21	50.16 ± 4.95
experimental Group	60	38.77 ± 3.24	46.43 ± 5.22
t	-	3.644	3.016
P	-	0.000	0.000

Table 3. Comparison of blood biochemical indexes before and after treatment in the two groups $(X \pm s)$.

Niverh	Number	WBC (×10 ⁹ /L)		CRP(mg/L)		IL-6 (pg/mL)		$TNF-\alpha (pg/mL)$	
Group	Group of cases	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
control group	60	27.45 ± 5.16	10.29 ± 0.57	8.62 ± 2.25	6.47 ± 1.38	44.13 ± 2.88	21.07 ± 1.98	25.25 ± 5.43	17.46 ± 3.19
experimental Group	60	27.11 ± 6.27	8.93 ± 0.43	8.65 ± 2.24	5.01 ± 1.63	44.04 ± 2.65	12.43 ± 1.28	25.39 ± 4.85	14.88 ± 2.31
t	-	0.324	3.054	0.073	3.195	0.178	3.886	0.149	3.374
P	-	0.746	0.000	0.942	0.000	0.859	0.000	0.882	0.000

Table 4. Comparison of ulcer area of patients in the two groups before and after treatment $(X \pm s, points)$

Group	Number of cases	Before treatment	After 14 days of treatment	
control group	60	2.48 ± 0.25	1.44 ± 0.36	
experimental Group	60	2.58 ± 0.54	0.43 ± 0.21	
t	-	1.302	4.408	
P	-	0.196	0.000	

Elderly patients are prone to other diseases, such as coronary heart disease and hypertension, as well as poor blood sugar control and malnutrition, which make the wound unhealed for a long time [6]. Autologous platelet-rich gel is rich in anti-inflammatory cytokines such as fibrin, platelets and white blood cells, which can promote wound healing. At present, this technology is also widely used in the treatment of oral, dermatology, cosmetic surgery, cardiothoracic surgery and other fields [7]. The main ingredient of SuileTM BSB wound healing dressing is borneol, which is a relatively safe and effective healing dressing, and can greatly promote the healing of ulcer wounds. Its mechanism of action is to significantly inhibit wound bacteria, reduce wound infection, promote fibroblast proliferation and granulation tissue growth, and shorten the wound healing time [8]. However, for patients with diabetic foot ulcers that have formed sinus tracts or are relatively deep, a single way to promote healing is often less effective. At present, there is no clinical experimental on the effect of combined use of these two methods at home and abroad. In this experimental, patients with diabetic foot ulcer were divided into control group and experimental group, and the treatment methods were BSB alone and BSB combined with APG, respectively. The total effect, healing time, hospitalization time, inflammatory factor levels before and after treatment and ulcer area were compared between the two groups. The overall treatment effect of the control group was worse than that of the experimental group, and the data between the groups were significant after comparison (P < 0.05). The healing time and hospital stay in the control group were longer than those in the experimental group, and the data between the two groups were significant after comparison (P < 0.05). After treatment, the levels of inflammatory factors including WBC, CRP, IL-6 and TNF- α in the control group were higher than those in the experimental group, and the data between the two groups were significant (P < 0.05). After 14 days of treatment, the ulcer area of the control group was higher than that of the experimental group, and the data between groups were significant after comparison (P < 0.05). It can be seen that the use of SuileTM BSB healing dressing combined with autologous platelet-rich gel technology in the treatment of diabetic foot ulcer wound healing can achieve synergistic bacteriostatic effect, reduce inflammatory reaction, promote granulation tissue formation, and accelerate wound healing.

In a word, in the treatment of patients with diabetic foot ulcer, the application

of BSB combined with APG can achieve better therapeutic effect, reduce the inflammatory reaction of patients, and promote the healing of ulcer wounds, which is worthy of promotion.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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