

Efficacy of Aloe Vera Cream for Healing Diabetic Foot Ulcers

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Abstract

Background : To compare the efficacy of aloe vera cream with normal saline dressings for infected diabetic leg ulcers.

Methods: In this randomized controlled trial 60 patients with infected ulcers on lower limbs were assigned into 2 groups by random sample collection using lottery method. Patients in Group A received aloe vera dressings and patients in Group B received saline soaked dressings daily and were advised to revisit after 8 days. Wound was assessed on the very first visit and then on the 8th day. Patients were assessed with reference to duration of diabetes, grade of ulcer, body mass index and efficacy of treatment.

Results: Out of 60 patients, majority were females (53.33%). The efficacy of AVC (aloe vera) dressing was significantly higher than that of NSD (normal saline dressing). i.e. 100% vs 53.3%. (p-value = 0.000) Similar trend was observed for age, gender, BMI, Grade of ulcer and duration of diabetes (p = < 0.05) except for patients with 11-15 years of diabetes & obesity.

Conclusion: Efficacy of Aloe vera is higher as compared to that of NSD for treating diabetic foot ulcers. Added advantage of Aloe vera is its cost effectiveness and minimal side effects.

Key words: Aloe vera, normal saline, infected diabetic leg ulcers

Introduction

Diabetic foot ulcers (DFU) are the most significant complication of diabetes and affect 15-20% of patients with diabetes.^{1,2} Neuropathy, peripheral vascular disease, deformities of foot related to trauma or motor neuropathy, osteomyelitis and infection are major threats related to diabetic foot ulcers. More than 50% of non-traumatic lower limb amputations are related to DFU infections and 85% of all lower limb amputations in diabetic patients are preceded by an ulcer.³

Many products like tissue extracts, vitamins and minerals and a variety of herbal products have been

reported to improve and hasten the healing effects.⁴ Various studies have illustrated the effectiveness of local application of aloe vera for the management of infected chronic ulcers. Aloe vera contains analgesic, antiseptic, anti-inflammatory and antimicrobial properties thus helping in wound healing.⁵ It does not contain any side effects and does not lead to resistance to any drug. It is also cheap and easily available.⁴ Recent studies have suggested that aloe vera also holds anti-fungal, anti-neoplastic and immune-modulatory properties. A great number of active ingredients have been discerned in aloe vera including vitamins, minerals, sugars, anthraquinones or phenolic compounds, enzymes, lignin, saponins, sterols, amino acids and salicylic acid which make aloe vera highly efficacious in wound healing.⁶

A study conducted by Banu et al showed that growth of bacteria decreased from 100% to 6.7% in aloe vera dressing group by day 11 with P < 0.001.⁴ In another study, it was found that the results of wound healing were 0.00±0.00 in aloe vera group and 0.6±1.3 in the saline dressings group.⁷

Patients and Methods

A randomized controlled trial was conducted in Surgery Unit-I of Holy Family Hospital, Rawalpindi, from January to June 2016 after approval from Institutional Research Forum of Rawalpindi medical college (RMC). All patients (n=60) between ages 18-65 years, with controlled diabetes mellitus (HbA1c<6), and having an infected diabetic ulcer of Grade I-II were enrolled. Grading was done according to Wagner Grading System. Patients with uncontrolled diabetes mellitus, severe infection and deep ulcers with exposed bones, and those requiring extensive debridement and limb amputations were excluded. Patients were assigned into two groups using lottery method. Thirty patients were allocated in each group A and group B. The wound was assessed on the first visit and then a follow up was advised on the 8th day in OPD for wound evaluation. The status of the wound was recorded and compared with the condition on the first visit. Chi square test was applied to compare the frequency of treatment efficacy between two groups.

Effect modifiers like age, gender, BMI, grades of ulcer, duration of DM were controlled by stratification. Post stratification chi square test was applied using 5% significance level. P value of < 0.05 was considered statistically significant.

Results

Out of the 60 patients included in our study, 28 patients were females and 32 were males. Mean duration of diabetes was 4.67 years (Table 1).

Table 1: Descriptive statistics

Treatment group		AVC Group (n = 30)	NSD Group (n = 30)
Age (years)	Mean	46.30	47.40
	SD	9.667	10.241
BMI	Mean	24.09	24.37
	SD	2.90	3.07
Duration of DM (years)	Mean	4.67	5.73
	SD	4.365	4.697

In AVC group, 50% patients had Grade I diabetic ulcer. On the other hand, there were 16 (53.3%) patients with Grade I and 14 (46.7%) with grade II diabetic ulcer in NSD group. All patients in group A and 16 patients in group B showed improvement in wound condition (Table 2). This difference in treatment efficacy was statistically significant (P = 0.000). The efficacy of Aloe vera dressing was significantly higher than that of normal saline dressing in all age groups. Similar trend was also observed for gender (Male [AVC: 100 % vs. NSD: 56.3 %, p-value = 0.008] & Female [AVC: 100 % vs. NSD: 50 %, p-value = 0.001]). Stratification according to BMI, ulcer grade and duration of diabetes show significant improvement in AVC group (Table-3).

Table 2: Treatment Efficacy (wound condition on 8th day in both groups)

Wound condition on 8 th day			
Treatment Group	Improved with formation of granulation tissue	No improvement with no granulation tissue	p- Value
AVC(n=30)	30 (100 %)	0 (0 %)	0.000
NSD(n= 30)	16 (53.3 %)	14 (46.7 %)	

Table 3: Treatment efficacy stratified for BMI, Ulcer grade & DM duration in both groups

Variable	Treatment groups				P-value	
	AVC group(n = 30)		NSD group(n = 30)			
	Improvement	No improvement	Improvement	No improvement		
BMI	Normal weight	12 (100%)	0	7 (63.6%)	4 (36.4%)	0.02
	Over weight	14 (100%)	0	7 (46.7%)	8 (53.3%)	
	Obese	4 (100%)	0	2 (50%)	2 (50%)	
Grade of ulcer	I	15 (100%)	0	8 (53.3%)	8 (53.3%)	0.00
	II	15 (100%)	0	7 (46.7%)	7 (46.7%)	
Duration of diabetes (years)						0.00
	1-5	20 (100%)	0	9(52.8%)	8 (47.2%)	
	6-10	6 (100%)	0	3 (42.9%)	4 (57.1%)	
	11-15	4 (100%)	0	4(66.7%)	2 (33.3%)	

Discussion

Diabetic foot ulcer is one of the most disabling complication of diabetes. The prevalence of diabetic foot is 4-10% in diabetic patients and most commonly effect elderly population. A great number of foot ulcers heal (60-80%), while 10-15% of them remain active, and 5-24% of them eventually lead to limb amputation within a period of 6-18 months after the first evaluation. Studies have shown that 40-70% of all nontraumatic amputations of the lower extremity occur in patients with diabetes.⁸

Various herbal medicines have successfully been used for thousands of years to treat different dermatological conditions. Honey and aloe vera are among the most popular natural products currently used in wound care in various parts of the world. The wound healing properties of honey are well known in modern medical practice.^{9,10} Aloe vera has strong analgesic and anti-inflammatory properties due to its inhibitory action on thromboxane A2 and B2, prostaglandin 2A and bradykinin. Various studies have shown that aloe vera also promotes healing of radiation-damaged skin and decubitus ulcers.¹¹

Aloe vera is a plant from the lily family which has recently been the subject of various medical researches. Aloe vera is well known as a medicinal plant and has been used for various medical purposes for a long time.¹²

Mansour et al concluded that use of mouthwash containing aloe vera was effective in healing of wounds of oral cavity and also reduces the

inflammation compared to the control group.¹³ Aloe vera's gel has also been reported to be efficacious in healing of the first and second degree burn wounds.¹⁴ The topical application of aloe vera gel has been recommended for accelerating the healing process of various wounds, such as burns, inflammations, and cutaneous infections. Based on these it can be inferred that aloe vera gel is a suitable and economical dressing for a variety of wounds.¹⁵

In our study, it was observed that effectiveness of Aloe vera dressing was significantly higher than that of Normal saline dressing i.e. 100% vs 53.3% with a P = 0.000). This difference was also significant among all age groups as well. The same trend was observed for both genders. Ulcer grade (Grade - I & Grade - II) & duration of diabetes (1-5 years & 6-10 years) also showed a statistically significant value as well.

In a study conducted by bashir et al, aloe vera gel showed 100% activity against gram negative isolates and 75.3% against tested gram-positive isolates. The aloe vera gel also promotes wound healing.¹⁶

Banu et al compared the efficacy of aloe vera with topical antibiotics for the management of infected leg ulcers. The study inferred that growth of bacteria in the aloe vera group decreased significantly with P < 0.001. There was no decrease in the bacterial growth in control group on cultures taken on 11th day.⁴

Soltani B studied the role of aloe vera in wound healing. He found that the score of wound healing was 0.00±0.00 in aloe vera group and 0.6±1.3 in the control (saline dressings) group with a p-value of 0.003.⁶ These results are in accordance with the findings of our study, showing the effectiveness of aloe vera in healing of diabetic leg ulcers. An Indiana pilot study conducted in 2015, studied the role of Aloe Vera Gel Dressing in diabetic foot ulcer, chronic wounds of traumatic and burns origin. Majority of the cases (87.7%) healed in 14-21 days. Rest of 12.3% cases did not show any resolution.¹⁷

Aloe Vera can stimulate the intercellular communication at level of gap junctions. It also stimulates proliferation of human type II diabetic skin fibroblast cells.^{18, 19} Viswanathan V showed that cream prepared by using herbal formulation was found to be efficacious as well as safe in treating diabetic foot ulcers like the standard wound cream for example silver sulphadiazine cream. This polyherbal formulation also contains 4.85 % aloe vera.¹

Conclusion

Efficacy of Aloe Vera is superior as compared to that of normal saline dressings in managing diabetic foot

ulcers. Additional benefits of Aloe Vera include its cost effectiveness and minimal side effects.

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