Topical Honey versus Alginate as Dressing for Management of Wagner Type 2 Diabetic Foot Ulcers

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Abstract: Diabetic foot problems, such as ulcerations, infections, and gangrene, are the most common cause of hospitalization among diabetic patients. Diabetic foot ulcers (DFUs), a leading cause of amputations, affect 15% of people with diabetes. Routine ulcer care, treatment of infections, amputations, and hospitalizations cost billions of dollars every year and place a tremendous burden on the health care system. Aim: to compare the effect of honey (Pedyphar[®] ointment) and alginate(Fibracol[®] gel) as dressing for management of Wagner Type 2 Diabetic Foot Ulcers. **Method** :random sample of forty diabetic patients (30 women and 10 men) divided into 2 groups, group A cared by honey (Pedyphar[®] ointment) and group B Alginate (Fibracol[®] gel) the study was performed in Assuit University Hospital during (September 2011 to March 2012). **Results**: the study showed that honey dressing had less time of healing 12 ± 3 weeks than alginate (Fibracol[®] gel) dressing 16 ± 4 weeks and there was statistical significant difference in relation to duration of healing.**Conclusion**: In our study we observed both dressing had good results in treating diabetic wounds but dressings soaked with topical honey had excellent result than alginate (Fibracol[®] gel). Honey dressing is a safe alternative dressing for Wagner grade II diabetic foot ulcers.

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Keys words: diabetic foot ulceration, honey dressing, Alginate (fibracol gel) dressing.

1. Introduction

Diabetic foot ulcers are significant complications of diabetes mellitus and often precede lower-extremity amputation. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. The etiology of diabetic foot ulcers usually has many components include peripheral sensory neuropathy, poor control blood glucose level, impaired vision, trauma, and deformity. Other factors in ulceration are ischemia, callus formation, obesity, Poor footwear that causes skin breakdown or inadequately protects the skin from high pressure and edema. The ulcers are susceptible to infection once the wound is present. Many of the risk factors for foot ulcer are also predisposing factors for amputation.⁽¹⁻⁵⁾

Wound dressings represent a part of the management of diabetic foot ulceration. Ideally, dressings should alleviate symptoms, provide wound protection, and encourage healing. Dressing choice should be guided l;l by the characteristics of the ulcer, the requirements of the patient, and costs so physician and nurse play important role in choosing suitable dressing for the patient. A dressing must be comfortable and acceptable for the patient and should help alleviate or at least, not worsen pain, especially during changing the dressing. Moreover, the dressing should also aid in the management of the infectionby itself. (6)

Alginate dressings, originally derived from seaweed, have been used for many years for a variety

of wounds.Alginate dressings maintain а physiologically moist microenvironment that promotes healing and the formation of granulation tissue. Alginates can be rinsed away with saline irrigation, so removal of the dressing does not interfere with healing granulation tissue. This makes dressing changes virtually painless. Alginate dressings are very useful for moderate to heavily exudating wounds ^(7,8). Alginate dressings ('SeaSorb[®]' or 'Fibracol[®]) are characterized by their gel-forming and absorbent nature and their ability to activate macrophages within the chronic wound bed. They generate a pro-inflammatory response which may initiate a resolving inflammation characteristic of healing wounds. They have been shown to induce more rapid wound healing when compared to gauze in one small trial and promote more granulation tissue formation in another.⁽⁹⁾

The use of honey as a therapeutic tool is often referred to as an 'alternative' medicine. However honey has been used for centuries as a medicine and is thought to be possibly the oldest known wound dressing. Honey is a supersaturated sugar solution which works primarily though an osmotic effect from its high sugar content. It also has the added benefit of producing hydrogen peroxide as it dilutes, enhancing its antimicrobial effect. It is known to reduce inflammation and wound pH levels, reduce exudate levels, edema, and create a moist wound environment. Medical grade honey is emerging as a product that has many benefits in aiding wound healing and is easy to use, both by the practitioner and the patient. It is also seen as a cost effective alternative to more extensive treatment modalities. With the widespread increase of diabetes and the constant development of antibiotic resistant bacteria, interest is growing in the use of alternative therapies such as honey to the treatment of infected wounds that are both effective and cost-effective.⁽¹⁰⁻¹²⁾

Aim of the study:

To compare the effect of honey (Pedyphar[®] ointment) andAlginate(Fibracol[®] gel) as dressing for management of Wagner Type 2 Diabetic Foot Ulcers.

Hypothesis:

Therate of healing in honey group is more rapid than alginate (Fibracol[®] gel) dressing.

Study design and population (material and method) Design:

Experimental comparative design used in this study **Setting:**

The study was carried out in the General Medicine and Vascular Surgery department of Assuit University Hospital duringSeptamber 2011 to March 2012).

Sample:

Random sample of forty patients (30 women and 10 men) diagnosed with diabetes mellitus and divided into 2 groups, group A cared by honey (Pedyphar[®] ointment) and group B Alginate (Fibracol[®] gel)&B).

The criteria for admission in the sample were: Ages between 30-65 years

Free from other associated disease as severe anemia, heart failure, chronic renal failure, peripheral arterial disease or foot oestomylitis

Data collection

Patients' consent for participation in the study was obtained before inclusion in the study and each patient was informed about the purpose of the study.

A pilot study was conducted on five patients with diabetic foot ulcer in order to evaluate applicability of the tools.

Patients who met the selection criteria were assigned randomly to one of the two dressing.

Three tools were used for the collection of data. The tools were developed by the researcher based on review of related medical and nursing literature (Basal A).⁽¹²⁾

Tool I:

This tool comprised of the following

Patient data which included patient's name, age, sex, level of education, occupation, marital status, and smoking habits.

Patient's medical history includes: duration of diabetes, types of treatment and complications of diabetes

Physical examination which includes vital signs, temperature and pulse of peripheral extremities (dorsalispedis or posterior tibial pulse), weight and height and body mass index (Kg/ m^2), and neurological reflex.

Clinical investigations: blood glucose level, hemoglobin, glucohemoglobin, albumen and renal function test, Doppler examination of leg , bacteriological culture of wound and sensitivity test to determine suitable antibiotic and X ray to exclude oestomylitis.

All patients in the two groups were managed identically in relation to medication i.e. antibiotic , vasodilators and tonic in addition to the drugs of diabetic and debridement of all non-viable tissues in and around the ulcer. The dressing of any type of the two dressing was changed daily by following the steps of each dressing technique

Tool II:

Tool II is an observational assessment of the ulcer characteristics or morphology. It included: site, size (was done by tracing the wound surface by using transparent paper and marking pen to measure the perimeter of the wound), grade or depth according to Wagner Grade Ulcer ⁽¹³⁾, types or color of tissue in the floor of ulcer, edges of ulcer, type and amount and odor of exudates, inflammatory responses, skin condition of the foot and pain during removal of dressing. Also evaluating healing level either complete, partial or no healing ⁽¹⁴⁾.

Tool III

This tool related to the steps that were followed by the researcher prior to the dressing for the two groups of patients with diabetic foot ulcer included:

The dressing procedures steps for all three dressing

- Maintain aseptic techniques principles
- Hand washing and gloving
- Removal of necrotic tissue and callus (debridement)
- Cleansing the wound and the area around the wound with normal saline.
- Dry the wound and the area around the by dry gauze
- Spread the ointment or gel on the dry gauze or dressing and placed on the wound and place other dressing to prevent oozing of gel or honey.
- As well as dressing was placed over the wound and wrapped with regular bandage.
- The researcher provided health teaching to the two studied groups during dressing procedure. The health teaching was started on the first day of the study and was emphasized almost at each time of dressing until patient's discharge from the study. The content of this teaching include: follow-up to the clinic when feeling of dull aching pain in the leg, fever and swelling, foot hygiene, nail care, proper foot wear, weight distribution and management of newly healed foot ulcer and follow-up therapeutic regimen.

Statistical analysis:

The collected data was organized, tabulated and statistically analyzed using SPSS software statistical

computer package version. Data was presents as number and percent. For quantitative datamean and standard deviation were calculated. Chi square was used as a test of significance. Significance was adopted at p<0.05 for interpretation of results of tests of significance.

3. Results

Regarding sociodemographic data, more than half of the studied patients were females in both groups (60% and 65% in group A and B respectively), mean of age were 39.28 ± 6.27 years in group A and 36.6 ± 9.34 years in group B. High percent of the patients in both group are married 65% and 60% respectively, 65% of patients in group A were overweight while 60% of patients in group B were normal weight. Majority of patients were nonsmokers in both groups. More than half (55%) had diabetes more 5 -10 years in group A while 70% in group B had diabetes since 10 to 15 years. 25% of the patients in group A and 45% in group B had previous ulcer (Table1).

In relation to wound characteristics majority of the patients (75%) in both group had single ulcer and 75% and 60 %respectively in group A and B had inflammation and exudate. Half of patients (50%) in group A had ulcer in the heel while 70% of patients in group B had ulcer in fore foot and there was statistical significance difference (Table2).

Regarding the size of the ulcer, 10 patient (50%) of patients in group A had ulcer size range 15-20 cm² while 8 (40%) of patients had ulcer size range 10-15 cm². There wasno statistical significance difference between two group in relation to size.

As regards the duration of healing, the mean duration was 12 ± 3 weeks in group A and 16 ± 4 weeks in group B which shows statistical significant difference between both groups (Table3).

Characteristics	GroupA No = 20 (100%)	Group B No = 20 (100%)	Chi- square X ²	Р
1- Sex			0.1	1.0
- Male	8 (40%)	7 (35%)		
- Female	12 (60%)	13 (65%)		
2- Mean of age	39.28±6.27	36.6± 9.34	1.1	0.29
3- Marital status:				
- Married	13 (65%)	12 (60%)	1.9	0.39
- Single	4 (20%)	7 (35%)		
- Divorce	3 (15%)	1 (5%)		
4- BMI	\$ 7	, <i>i</i>		
- Normal weight	3 (15%)	12 (60%)	9.0	0.01
- Over weight	13 (65%)	7 (35%)		
- Obese	4 (20%)	1 (5%)		
5- Smoking			0.28	0.60
- Yes	3 (15%)	1 (5%)		
- No	17 (85%)	19 (95%)		
6- Duration of known				
diagnosis of diabetes			1.64	0.20
- 5-10 years	11 (55%)	6 (30%)		
- 10-15	9 (45%)	14 (70%)		
7- Previous ulcer				
- Yes	5 (25%)	9 (45%)	0.99	0.32
- No	15 (75%)	11 (55%)		

 Table 1:Demographic data of the two groups

*Significant p< 0.05

Characteristics	Group A(honey) No = 20 (100%)	Group B (fibracogel)	Chi-square X ²	Р
		No = 20(100%)		
Number of foot ulcer			.000	1
- Single	15(75%)	15 (75%)		
- Multiple	5(25%)	5(25%)		
Presence of inflammation				
- yes	15(75%)	12(60%)	1.026	0.311
- No	5(25%)	8(40%)		
Presence of exudate				
- Yes	15(75%)	12(60%)	1.026	0.311
- No	5(25%)	8(40%)		
8- Sites of ulcer				
- Fore foot	5 (25%)	14 (70%)	14.4	0.001*
- Mid foot	5 (25%)	6 (30%)		
- Hind (heel)	10 (50%)	0		

Table 2: Characteristics of the wound of diabetic foot

Table 3:Changes in ulcer size and healing rate in both groups

Characteristics	Dressing by honey in Group A				Dressing by fibracol gel in Group B			
	No = 20				No = 20			
	Before	After 2	After 4	After	Before	After 2	After 4	After 6
	dressing	months	months	6 months	dressing	months	months	months
1- Size								
- Less 5 cm^2	0	2	3	1	2	5	5	4
$-5-10 \text{ cm}^2$	5	5	2	0	7	6	5	3
$-10-15 \text{ cm}^2$	5	5	2	0	8	6	3	1
$-15-20 \text{ cm}^2$	10	2	0	0	3	0	0	
- 0 (healed)	0	6	13	19	0	3	6	12
Chi square X ²	3.45			3.61				
$p^{=}$	0.412			0.396				
2-Result of dressing								
-Complete healing		6	7	6		3	3	6
-Partial healing								6
-Escape from study				1				2
3-Duration of healing	Mean= 12± 3 weeks			Mean= 16± 4 weeks				
t.	3.6							
Р	^p = 0.001 *							

4. Discussion:

The prevalence of diabetes mellitus is growing at epidemic proportions in the worldwide. Most alarming is the steady increase in type 2 diabetes, especially among young and obese people. Diabetic foot problems, such as ulcerations, infections, and gangrene, are the most common cause of hospitalization among diabetic patients. Diabetic foot ulcers (DFUs), a leading cause of amputations, affect 15% of people with diabetes. Routine ulcer care, treatment of infections, amputations, and hospitalizations cost billions of dollars every year and place a tremendous burden on the health care system.⁽¹⁵⁻¹⁹⁾

The ulcer dressing is an important aspect of diabetic foot management. The basic function of any

dressing is to protect the ulcer from mechanical trauma, to create a moist environment and prevent exposure to infections. The occlusive wound dressing reduces the bacterial load by absorption of the exudates and by preventing the bacterial contamination of the ulcer. This reduces the requirement for phagocytic and autolytic debridement and reduces the source for microbial growth.⁽¹⁸⁾

This study is conducted in order to compare the effect of honey (Pedyphar ointment) and Alginate (Fibracol gel) as dressing for management of Wagner Type 2 Diabetic Foot Ulcers.

In this study the mean of age of patients enrolled in this study and had diabetic foot ulcer were adult 39.28 ± 6.27 and $36.6\pm$ 9.34 in honey and Alginate(Fibracol gel) this may due to a lot of patient didn't know they had diabetes until they had complication and a lot of patient had type 1 diabetes.

This in contrast to **Basal**⁽¹²⁾where the highest percentage of patients in her study had foot ulcer were at the age of 60 years and more. Also **Boulton**⁽¹⁹⁾ reported that lower extremity ulcers are common among older adults due to the increased prevalence of chronic venous insufficiency, peripheral arterial disease, and diabetic neuropathy. Also diagnosed diabetes is most prevalent in middle-aged and elderly populations, with the highest rates occurring in persons aged 65 years and older

Majority of patients in the present study were nonsmokers in both groups this may related to majority of the patients were female. In contrast, other previous researches reported a relationship between smoking and foot ulcers. ⁽²⁰⁾

Wound dressings represent a part of the management of diabetic foot ulceration. Ideally, dressings should alleviate symptoms, provide wound protection, and encourage healing. All dressings require frequent change for wound inspection. Heavily exudating ulcers require frequent change to reduce maceration of surrounding skin. Dressing choice should be guided by the characteristics of the ulcer, the requirements of the patient, and costs⁽²¹⁾ in the present study both dressing honey and alginate (Fibracol gel) played important role in alleviate exudate, pain during change dressing and accelerate healing.

Hilton *et al.* ⁽²¹⁾ stated that in choosing a dressing for an infected diabetic footulcer, several factors have to be taken into account.Infected wounds tend to have a heavy exudate thatneeds to be controlled to prevent maceration of surroundingtissue. There may be considerable odor associated with infection that may be unpleasant and distressing for the patient and family. A dressing must becomfortable and acceptable for the patient and shouldhelp alleviate or, at the very least, not worsen pain, especially at dressing changes. Ideally, the dressingshould also aid in the management of the infectionitself.

We found in this study the effect of both dressing in healing of the diabetic foot ulcer in both group. By comparing the progress of healing and its duration for all the two groups of dressing, the finding revealed that the healing rate in the A group which managed by honey (Pedyphar ointment) were higher (19patients)or 95 % and 1 or 5% of patients only escape from the study with mean healing time was 12.60 ± 3 weeks) less than the other group(AliginateFibraco gel despite of the size of ulcer in honey group 50% of patients had size of ulcer 15-20 cm². This consistent with **Moghazyet al.**⁽²²⁾who stated that Honey is known, since antiquity, as an effective wound dressing. Emergence of resistant strains and the financial burden of modern dressings have revived honey as costeffective dressing particularly in developing countries. Its suitability for all stages of wound healing suggests its clinical effectiveness in diabetic foot wound infections.

Moreover the healing process takes place in spite of overweight and obesity of patients. This constant with **Basal**⁽¹²⁾ who mention that increase rate of healing in honey group Api care ointment were higher (86.7 % and 6.7% partial healing with mean healing time was 10.60 ± 4.48 weeks) than the two other groups(Betadine dressing and Dermagran dressing) and taken less time than them to develop complete healing. This may due to teaching and support to patients of all groups and thus higher compliance with the instructions about use of assistive devices as wheel chair, suitable shoes, cane to reduce weight bearing and frequent foot care, exercise, taking hypoglycemic agents and frequent evaluation of blood sugar level.

Also **Sahel, Dunford***et al.* **and Moore** *et al.***^{(23-²⁵⁾ stated that there are economical advantages to use honey as dressing. This is seen in direct cost savings when compared with conventional treatments. Other advantages on cost savings have been: use of antibiotics ceased, length of hospitalization is reduced (at least half). In addition, there are the savings in the costs of surgery where debridement and skin grafting become unnecessary when honey is used.**}

Alginate, or seaweed products are highly absorbent, pack into cavity wounds, provide hemostasis, and are traumatic at dressing change (but may require wetting). It is important to ensure that all dressing is removed from a cavity wound, because retained dressing may be a source for further infection. The dressings may have some bacteriostatic properties. Calcium alginate dressing inhibited growth of Staphylococcus aureus in vitro, with no increase in growth of Pseudomonas, Streptococcus pyogenes, or Bacteroidesfragilis.⁽²⁶⁾

Conclusion

In our study we observed both dressing had good results in treating diabetic wounds but dressings soaked with natural honey had excellent result than alginate (Fibracol gel). Honey dressing is a safe alternative dressing for Wagner grade II diabetic foot ulcers. It promotes healing and cost effective in the management of diabetic foot ulcer. The disability of diabetic foot patients was minimized by decreasing the rate of leg or foot amputations and thus enhancing the quality and productivity of individual life.

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