



Research Paper

Topical Use of Honey in Diabetic Foot Ulcer: A comparative analysis at a rural tertiary care hospital

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Abstract

Background: Honey dressings are also a cost-effective method of wound care as compare to other topical wound care therapies. **Aim:** We compared the topical effect of honey dressing to silver colloidal dressings in diabetic foot ulcer patients. **Methods:** This prospective randomized clinical trial included 60 adults of any race and either sex between age 18-60 years, ulcer duration of at least 1 month, willing and able to perform dressing changes daily at home, adequate nutrition (albumin >2.0 g/dL), target wound could not be on heel or over a Charcot deformity, and haemodynamically stable. They were divided in two groups: Treatment modality group – Dressing with Commercial grade food industry processed honey. Control group – Dressing with Silverex and Megaheal. Wound assessment was done based on Bates-Jensen Wound Assessment Tool. The patients were followed-up at week-2, 4 and 6. **Results:** A total of 68 patients were randomized to receive topical commercial grade honey (group 1) or silver colloidal preparation (group 2). Out of 68 patients, 5 patients were lost to follow-up and 3 patients were amputated. These 8 patients were excluded from final analysis. Our study observed a significant improvement in necrosis tissue type at 6-weeks in group 1 in comparison to group-2 ($P=0.013$). We also observed a significant improvement in necrosis tissue amount at 6-weeks in group 1 in comparison to group-2 ($P=0.038$). **Conclusion:** Topical honey is more effective than standard treatment in diabetic foot ulcer.

Key words: Diabetic foot ulcer, topical honey, necrosis

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I. Introduction

Diabetes mellitus (DM) is a chronic and progressive endocrine disorder that primarily results in hyperglycaemia (excess glucose in the blood). It is considered as one of the major health problems with increasing prevalence worldwide was 2.8% in 2000 (171 million) and is estimated to increase (4.4%) by 2030 (366 million).^{1,2}

Approximately 25% of diabetic patients have a higher reported lifetime risk of developing foot complications and foot ulceration is the most common with an estimated annual incidence from 25 to 80%.⁵ Most of the foot ulceration ultimately turns into diabetic gangrene especially if left untreated which contribute to approximately 80% of lower limb amputations.

Main pillars of treatment for DFU today include: local wound care with surgical debridement, dressings promoting a moist wound environment, wound off-loading, vascular assessment, treatment of active infection, and glycaemic control.⁶ Treatment of DFU is intensive, protracted and associated with high costs. Due to these reasons, various treatment approaches have been tried and tested keeping in view cost effectiveness and patient compliance also.

Many topical and systemic agents have been used either solely or in combination but most of them have been eliminated because of resistance. With increasing trend towards the abuse of antibiotic therapy many

of the diabetic wound infections are increasingly caused by drug-resistant organisms and they show resistance to commonly used antibiotics, ultimately leading to increased costs, morbidity, and mortality.⁷

Honey is produced by honey bees after collecting and processing nectar from various plants. It is well-known for its high nutritional and prophylactic medicinal value. Honey is also known to have role in wound healing since very long time. It has been used as a wound care product for treating venous leg ulcers, burns, chronic leg ulcers, pressure ulcers etc.⁸

Honey dressings are also a cost-effective method of wound care as compare to other topical wound care therapies.¹⁰ A lot of studies have been done evaluating role of honey in wound healing.

In the present study, we compared the topical effect of honey dressing to silver colloidal dressings in diabetic foot ulcer patients.

Patients and Methods

This prospective randomized clinical trial was conducted over the period of one year. Department of Surgery, Dr. RPGMC, Kangra at Tanda, Himachal Pradesh. The study was conducted after getting approval from Protocol Review Committee of Dr RPGMC Tanda and obtaining informed consent.

Sixty Adults of any race and either sex between age 18-60 years, ulcer duration of at least 1 month, willing and able to perform dressing changes daily at home, adequate nutrition (albumin >2.0 g/dL), target wound could not be on heel or over a Charcot deformity, and haemodynamically stable patients were included. Patients having any skin diseases, multiple comorbidities associated with diabetes, known allergy to honey, acute or chronic osteomyelitis, epilepsy, neurological or psychiatric disorders, bleeding or coagulation disorders, and refusal to participate were excluded.

Randomization was done on basis of patient attending the surgical OPD, having DFU selected after doing a computer-based randomization. They were divided in two groups: Treatment modality group – Dressing with Commercial grade food industry processed honey. Control group – Dressing with Silverex and Megaheal.

Wound assessment

Wound assessment was done based on standardized wound assessment tool (Bates-Jensen Wound Assessment Tool).

Data Collection

The data were collected based on the above-mentioned assessment tool and also size of the wound was taken on a two weekly interval starting from week 0 and then week-2, 4 and 6. The patients were followed-up on basis of inpatient department and after discharge were followed on OPD visits. They were contacted telephonically at the scheduled time of their OPD visit.

Statistical Analysis

Data were recorded into Microsoft® Excel 2019 and exported into SPSS v21.0 (IBM, USA) for statistical analysis. Categorical data were expressed as frequency and percentage, and compared using Chi square test. Quantitative data were expressed as mean and standard deviation. P value <0.05 was considered significant.

II. Results

A total of 68 patients were randomized to receive topical commercial grade honey (group 1) or silver colloidal preparation (group 2). Out of 68 patients, 5 patients were lost to follow-up and 3 patients were amputated. These 8 patients were excluded from final analysis. In our study, mean age of the patients in group 1 was not significantly different with group 2 (56.90±8.71 years vs. 52.20±11.67 years; P=0.082). In group 1, 19 patients were males while in group 2, 24 patients were females. We observed that sex-based distribution was not significantly different between bot groups (P=0.252). In our study, 23% patients in group 1 (n=7) and 17% patients in group 2 (n=5) had duration of diabetes ≥10 years. We also observed that duration of diabetes was comparable between both groups (P=0.747). In our study, 70% patients (n=21) in group 1 and 63% (n=19) in group 2 had duration of diabetic ulcer ≥1 month. We also observed that duration of diabetic ulcer was not significantly different between group 1 and group 2 (P=0.584). In our study, proportion of patients with smoking was 77% in group 1 (n=23) and 73% in group 2 (n=22). Proportion of patients with smoking was not significantly different between group 1 and group 2 (P=0.766). In group 1, the most common sites were left foot dorsal (n=11) and left foot plantar (n=11) while in group 2, the most common sites were left foot dorsal (n=9) and right foot dorsal (n=6).

Effect of treatment on wound edges

Our study observed a non-significant difference between group 1 in terms of wound edges at week-0 (P=0.982), week-4 (P=0.828), and week-6 (P=0.959).

Comparative effect of treatment on margins' undermining

Our study observed a non-significant difference between group 1 in terms of wound margins' undermining at week-0 (P=0.753), week-4 (P=0.774), and week-6 (P=0.537).

Comparative effect of treatment on necrosis tissue type

Our study observed a non-significant difference between group 1 in terms of necrosis tissue type at week-0 (P=0.954) and week-4 (P=0.616). However, there was a significant improvement in necrosis tissue type at 6-weeks in group 1 in comparison to group-2 (P=0.013).

Comparative effect of treatment on necrosis tissue amount

Our study observed a non-significant difference between group 1 in terms of necrosis tissue amount at week-0 (P=0.867) and week-4 (P=0.830). However, there was a significant improvement in necrosis tissue amount at 6-weeks in group 1 in comparison to group-2 (P=0.038).

III. Discussion

Desirable characteristics for wound dressings must incorporate the principles of wound healing. A moist wound environment has been recognized as optimal for healing. Dressings have since been engineered to maintain this environment while also controlling the growth of microorganisms, allowing gaseous exchange, and thermally insulating the wound, which allows atraumatic removal. These dressings must also accommodate practical issues such as allowing observation of the wound and providing mechanical protection and conformability; of course, dressings must also be cost effective.

Among several different alternative therapies, honey is an effective choice because it provides rapid wound healing along with cost-effectiveness. Although honey has been used as an alternative medicine for wound healing since ancient times, the application of honey to diabetic wounds has only recently been revived.

In our study, mean age of the patients with diabetic foot ulcer was 54.55 years. In the study by Seth et al, a mean age of 58.49 ± 11.04 years was reported. Maximum number of the patients in our study were in age-group of 55-64 years. It may be because that Diabetes Mellitus type II is classically seen in elderly patients, though recent reports have shown it to affect adolescent population too. Our findings are in concordance with Seth et al.⁴⁸ Previous studies by Gadepalli et al and Ramakant et al have also reported similar findings.^{49,50}

Approximately 72% of our patients were males. It has been reported that gender make the difference in the prevalence of DM. Women and men with DM may differ in the way they face the disease and the way they adhere to the care necessary to keep the disease under control. Men, for example, care less for their feet, resulting in a higher proportion of amputations among them. On the other hand, women have higher difficulty in maintaining glycemic and lipid control due to the difficulty of change in lifestyle, especially the adoption of an eating plan and regular physical activity. The other reason could be as women have a lower risk than men for foot ulceration, because of the result of less severe neuropathy, increased joint mobility, and lower foot pressures. Seth et al reported male preponderance with 83%.⁴⁸

In our study, mean duration of diabetes was 6.21 years. In a study by Sahi et al, the mean duration of diabetes was higher in DFU cases (11.5 ± 5.74 years) than patients having no sign of DFUs (7.59 ± 4.86 years, $p = 0.00$).⁵¹ Seth et al reported in their study that the mean duration of diabetes mellitus in their patients was 12.03 ± 6.96 years. In our study, mean duration of diabetic ulcer was 1.49 months.⁴⁸

In our study, the most common site of diabetic ulcer was left foot dorsal (n=20), left foot plantar (n=15), right foot dorsal (n=9), right foot plantar and right foot involving great toe (n=4 each), left foot involving great toe (n=3), and right foot involving little finger (n=2). In the study by Pilla et al, left side was found to be affected in 48 cases while the right side was found to be affected in 52 cases.⁵²

In our study, there was no significant effect of topical honey on wound edges, undermining up to 6 weeks. However, use of topical honey significantly improved necrotic tissue type, amount, exudate type, and amount of exudate. Shukrimi et al compared Povidine-Iodine solution with topical honey and reported that ulcer healing was not significantly different in both study groups.⁵³ Surahio et al reported that use of honey significantly reduced rate of amputation and improve wound healing when used for wound dressing in chronic diabetic foot ulcers.⁴⁰ Makhdoom et al (2009) found that by the end of the trial period, all the DFUs yielded various bacterial infections, but despite the presence of bacteria in the ulcers, healing progressed unhindered, demonstrating the ability of honey to suppress the bacteria (bacteriostatic) from inhibiting wound healing. Since ulcers were not balanced at the baseline, one could not determine whether the honey dressings eradicated some bacteria (bactericidal).⁵⁴ Two studies (Hammouri, 2004; Jeffery, 2008) did not report any irritation with the honey dressings, as was found with the povidone iodine and hydrogen peroxide group (n=14). There was, therefore, a comparatively low chance of honey causing irritation (P=0.0003).^{55,56}

References

Table 1: Demographic characteristics

	Group 1	Group 2	P value
Age (Years)	56.90±8.71	52.20±11.67	0.082
Male:Female	19:11	24:6	0.252
Duration of diabetes (Years)			0.747
<10	23	25	
≥10	7	5	
Duration of diabetic ulcer			0.584
<1 month	9	11	
≥1 month	21	19	
Smokers	23	22	0.766
Site of ulcer			
Left foot dorsal	11	9	
Left foot involving great toe	0	3	
Left foot plantar	11	4	
Left foot toes	2	1	
Right foot dorsal	3	6	
Right foot involving great toe	0	4	
Right Foot involving little finger	2	0	
Right foot plantar	1	3	

TABLE 2: COMPARATIVE EFFECT OF TREATMENT ON WOUND EDGES

Edges		Group 1	Group 2	P value
Week-0	1	2	3	0.982
	2	4	4	
	3	10	9	
	4	7	6	
	5	7	8	
Week 4	1	3	4	0.828
	2	6	7	
	3	10	11	
	4	10	8	
	5	1	0	
Week 6	1	5	6	0.959
	2	10	9	
	3	10	11	
	4	5	4	
	5	0	0	

TABLE 3: COMPARATIVE EFFECT OF TREATMENT ON WOUND MARGINS' UNDERMINING

Undermining		Group 1	Group 2	P value
Week-0	1	6	8	0.753
	2	9	10	
	3	7	8	
	4	5	3	
	5	3	1	
Week 4	1	9	9	0.774
	2	12	11	
	3	8	7	
	4	1	3	
	5	0	0	
Week 6	1	8	8	0.537
	2	16	12	
	3	6	9	
	4	0	1	
	5	0	0	

TABLE 4: COMPARATIVE EFFECT OF TREATMENT ON NECROSIS TISSUE TYPE

Necrotic tissue type		Group 1	Group 2	P value
Week-0	1	0	0	0.954
	2	5	6	
	3	17	15	
	4	4	5	
	5	4	4	
Week 4	1	2	1	0.616
	2	14	10	
	3	10	13	
	4	4	6	
	5	0	0	
Week 6	1	4	3	0.013
	2	22	12	
	3	4	10	
	4	0	5	
	5	0	0	

TABLE 5: COMPARATIVE EFFECT OF TREATMENT ON NECROSIS TISSUE AMOUNT

Necrotic tissue amount		Group 1	Group 2	P value
Week-0	1	0	0	0.867
	2	5	4	
	3	6	7	
	4	8	7	
	5	11	15	
Week 4	1	3	2	0.830
	2	7	5	
	3	9	10	
	4	7	6	
	5	4	7	
Week 6	1	8	3	0.038
	2	14	10	
	3	8	10	
	4	0	6	
	5	0	1	