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Research Article

THE ROLE OF HONEY IN THE DIABETIC FOOT ULCER TREATMENT-CROSS SECTION ANALYTICAL STUDY IN SOUTH INDIA

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ABSTRACT

Honey, a natural product is used for Ulcer management since time immemorial and found to have both antibacterial and antimicrobial property with low pH which hinders the process of progression of pathogens in the ulcer. This study is conducted to evaluate the efficacy of the standardized preparation of honey in the Diabetic foot ulcer and its acceptance, suitability and cost expenditure. The ulcer healing, pain during the process, personal satisfaction and cost involved are compared with the conventional dressing methods. This prospective study was carried out in department of surgery diabetic foot ward for a period of 6 months from January 2017 to June 2017 with 100 patient divided into two groups. Both the groups underwent surgical debridement ulcer bed preparation, diabetic control and applied with honey in experimental group and control group with povidone-iodine/Hydrogen peroxide dressing. In our study we could observe in Honey dressing groups 87% wound healing compared to 65% is povidone-iodine dressing and only two patients went for amputation in honey dressing and much-improved pain factor. Mean pain score for the honey dressing groups were 1.24, however, the pain score in the conventional dressings group was 2.72 which was statically significant. Our study concludes the beneficial effects of honey dressing in Diabetic foot ulcer.

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INTRODUCTION

Diabetic foot ulcer results due to the impaired diabetic metabolism comprehensively affecting all the three sets of neurons- sensory, motor and autonomic and affecting micro and macro blood circulations. The pressure changes resulting out of neuropathic and vascular changes enhance growth of pathogens, ischemic necrosis and develop foot ulcer. If appropriate and adequate multidisciplinary care is not given, the foot ulcer will lead onto amputation.

Diabetes has reached global epidemic proportions with India becoming capital of Diabetes. Increase in the Life expectancy, life style habits, prevalence of junk foods, sedentary life style and myths on foot care all leads to increased derangement of Diabetic metabolism and foot care problems. 15% of all diabetic foot ulcers will lead onto amputation and 80% amputations taking place are due to Diabetic foot ulcer.

In India there is 74 million people with a prevalence rate of 8.8% are suffering from Diabetic Mellitus constituting 15% world Diabetic population. It is expected to rise to 99.7 million by the year 2014. In India also prevalence is more on the Urban

than the rural India. China leads in having higher number of Diabetic patients with 128.3 million people⁽¹⁾. Type II Diabetes is the most common cause. However, there are more than 1 million children globally affected with Diabetic Mellitus Type I. Almost 45000 foots are amputated due to diabetes mellitus foot ulcer. Bare foot walking, illiteracy, low socio economic statelate presentation, native treatments, ignorance and lack of affordability all constitute the rise in the foot ulcer complications. ⁽²⁻³⁾

Diabetic Ulcer foot infection are commonly polymicrobial and Methicillinresistant microorganisms commonly staphylococcus aureus group, pseudomonas and anaerobic pathogens like bacteriods, peptococuscauses mixed infections⁽⁴⁾. Antibiotic resistance is more common.

From ancient time onwards natural honey is used for wound healing. However there is limited evidence and statistical inputs on the medical healing property of honey in Diabetic foot ulcers⁽⁵⁾ Anthropological evidences show, Egyptians had used honey way back in 5000 years ago. It is used extensively in Ayurvedic medicine since 2500BC. The antibacterial activity proved in vitro studies and other clinical study data show the

application of honey impairs the pathogens in the ulcer. Honey has anti-inflammatory activity and stimulates immune responses in the Ulcer. ⁽⁶⁾Honey is a saturated or supersaturated solution of sugar having more affinity and interaction with the molecules of water. The pH of honey is very low and range from 3.2 to 4.5. This acidity nature of honey impairs the growth of microorganisms in Ulcers. ⁽⁷⁾

Honey increases hydrogen peroxide production from the enzyme glucose oxidase at 1:1000 concentrations. Through the amount of hydrogen peroxide is less than the conventional peroxide dressing but it is enough to prevent bacterial culture without annihilating the granulation tissues. In honey dressing the odour emanating from the Ulcers are decreased as natural honey provides bacteria with glucose and fructose as an alternative to the aminoacids from dead cells and serum. (8) The malodour producing compounds such as ammonia, amines and sulphar are replaced by lactic acids. Evidences shows the healing property of honey are due to its property to activate monocytes providing the moisture environment to the wounds thereby enacting fibroblast migration, epithelization, reducing scaring and hypertrophy. (9)

The wax content in the honey acts like a physical barrier to external pathogens. The wax content of the honey also forms a semi solid medium offering better wound contact thereby preventing the development of Biofilms.

Honey reduces the pain and promotes granulation tissue formation. Honey has hygroscopic property which reduces edema. It debrides the slough and stimulate angiogenesis. (10) Honey also has antifungal properties. It is also proved the Honey is active against many antibiotic resistant bacterias. (11) Honey is locally available and cheaper comparing to other dressing materials available for Ulcer Management. This study is intended to make a comparative evaluation of its antimicrobial properties, wound healing effect and psychosomatic wellness among the patients undergoing the dressings for Diabetic foot ulcer.

Aims and Objectives of Study

To evaluate the efficacy and feasibility of natural honey dressings in diabetic foot ulcers, comparing with conventional wound dressings.

MATERIALS AND METHODS

This is a prospective randomized case controlled analytical study carried out in a teaching hospital in South India Department of Surgery Diabetic foot ward from 2017 1st January to 30th June in 100 patients. Patients are randomized into two groups

- 1. Control Group 50 patients
- 2. Experimental group 50 patients

Inclusion Criteria

- Patient with diagnosis of Diabetic Foot Ulcer with Wagner grade 1 - 2
- Age 25-75 both sex
- Blood sugar is on control with medication
- Ulcer size 2-10 cm.

Exclusion Criteria

- Patient with active systematic infection or comorbities
- Ulcer size more than 10 cm
- Immuno compromised individuals
- Patient having diabetic foot ulcer of Wagner grade more than 3
- Patient not willing to give consent
- Pregnancy
- Malignancy
- Chronic alcoholic and smokers

Procedure: All the patients were admitted in the Diabetic foot ward. The patients were randomized into two groups. After getting consent and explaining the procedures to the patient the routine biochemical investigations to assure the Diabetic status, Co-morbidities, vascularity of the limbs were analyzed. Demographic details obtained.

All patients wound assessment done using Bates Jenson wound assessment scale and pain using visual analogue scale. Through surgical debridement of wounds done and washed with saline. Wound swab taken for culture and sensitive. Completed haemostatis of wound obtained. In control group the wound is applied with Hydrogen peroxide solution and followed by Povidone ointment.

In experimental group the saline washed wound is applied with natural Agmark standardized Honey in sufficient quantity and absorbable gauze dressing done. The dressing procedure is done daily and wound assessment done on 1, 15, 30th and 60th day or complete healing of wound whichever is earlier.

Bates Jenson wound Assessment Scale

Standardisation Bates Jenson wound assessment scale (1990) was used to assess the wound status. The toll has a check list with 13 items. The items include wound size, depths, edges, undermining, necrotic tissues type, amount, exudate type and amount, skin color surrounding the wound, peripheral tissue indurations, granulation tissue and epithelization. The maximum score was 65 and the maximum score from Day 1, 15^{th} , 30^{th} and 60^{th} ...⁽¹²⁾

Ethical consideration

Formal ethical approval for the study was obtained from the college ethical Board. Both written and oral information in local language were given to the participants of the study. Demography and study data were collected with consent. Participants in the study were given option to withdraw from the study at any time.

Observation and Finding

Demographic pattern

Table 1 Demographic profile of patients in both groups.

Sl. No	Demographio Variable		Dressing p - 50		nal dressing ıp 50	Chi Square	P - Value
	v ai iabie	Frequency	Percentag	ge Frequency	Percentage	Value	value
	Age in Years						
	31-40	2	4.00	5	10.00		
1	41-50	6	32.00	14	28.00	3.829	
	51-60	18	36.00	17	34.00	3.829	0.281
	Above 60	14	28.00	14	28.00		
	Sex						
2	Male	25	50.0	26	52.0	0.180	0.671
	Female	25	50.0	24	48.0	0.160	0.071
3	Occupation						
3	Status	19	38	21	42		

Unemployed	23	56	15	30	13.406 0.004
Unskilled	8	16	13	26	
Skilled	0	0	1	2	
Professional					

Age and Sex were of equal number in each number with no statistical difference. There is significant difference with occupational status with the p value < 0.004.

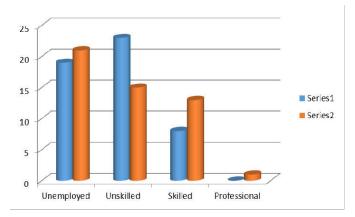


Fig 1 Occupation profile of people in both group

Body Mass Index

The body mass index of all the patients involved in the study is calculated and tabulated (Table 2). There is no significant difference.

Table 2 Body Mass Index of all patients in both Groups

Sl. Body Mass		Honey 1	<u>., g </u>			Р.	
No.	Index	Frequency	Percentage	Frequency	Percentage	Square Value	Value
1.	Underweight	2	4	3	6		
2.	Normal	12	24	13	26	2.610	0.106
3.	Overweight	27	54	23	56	2.010	0.100
4.	Obesity	9	18	11	22		

Wound Healing Status

The wounds are managed as per the procedure and both group had daily dressings. Wounds are asses using Bates Jenson wound Assessment Scale on day 1/16/30th. The complete healing of wounds was assessed as on 30th day are observed. The mean and SD values are tabulated in table 3. In the honey group 87 % healing of the wounds seen .However it was only 65 percentages in the povidone_iodine group.

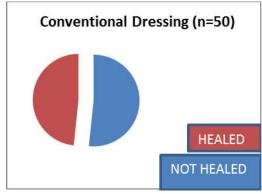
Table 3 Wound healing mean and SD values in both group.

Wound Healing -	Day 30 th		- T value	P Value	
would nearing -	Mean	SD	- i value	r value	
Honey Dressing (n=50)	19.39	4.88			
Conventional Dressing (n=50)	15.88	3.81	5.05	0.0001	

There is significant difference between the two groups on the mean and SD values wound healing observed P-value <0.0001. Honey dressing had significant advantage over the conventional dressing.



Fig 2 Diabetic foot ulcer after 4 weeks of honey dressing



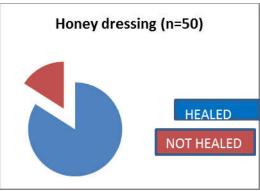


Fig 3 Diabetic foot ulcer after 4 weeks of honey vs conventional dressing

Frequency and percentage of distribution wound colonization of patients with diabetic foot ulcer

The amount of colonization/discharge in the ulcers on the day 1 and day 16 th were measured and values tabulated in Table 4. There was significant reduction in the wound colonization and discharge from the ulcers on the patients having honey dressing. There was no difference on the day 1 but subsequent to treatment, the honey group had a favorable impact.

Table 4 The wound colonization in both groups.

Group	Wound	Day	Day 1		Day 16	
	Infection					
	Confluent	24	48	7	6	
Honey	Semi confluent	13	26	9	18	
Dressing	Scanty	15	30	15	30	
(n=50)	Sterile	0	0	23	56	
Conventional	Confluent	29	58	6	12	
Dressing	Semi confluent	10	20	10	20	
(n=50)	Scanty	11	22	16	32	
	Sterile	0	0	18	36	

Pain Score

The pain experienced by the patients during the process of dressing and subsequently was assessed using the standardized visual analogue scale. In the honey dressing group there was statically significant reduction in the pain score and patient satisfaction and compliance were good. The mean and SD values of pain score on the 16th day are tabulated in table 5.

Table 5 Pain score mean and SD values in both groups on Day 16th

Level of Pain -	Day 16th		– +value	P	
Level of Fain	Mean	an SD +valt		Value	
Honey dressing (n=50)	1.24	0.889	11.171	0.000	
Conventional Dressing (n=50)	2.72	0.986	11.151		

Since the p value is less than 0.01, it shows there is significant level of reduction in the pain score in patient undergoing dressing with honey. (13)

Correlation of wound infection, pain and wound healing

As per the data observed the variable of pain, colonization and wound healing were correlated between two groups the R value calculated and tabulated in Table 6.

Table 6 Correlation of wound infection, pain and wound healing

Group	Variable	R value	
	Wound infection verses pain	0.064	
Honey Dressing	Pain verses wound healing	0.069	
group n=50	Wound healing vs wound infection	0.761	
C	Wound infection versus pain	0.163	
Conventional	Pain verses wound healing	0.098	
Dressing group n=50	Wound healing vs wound infection	0.811	

In all three events, there are significant improvements in the group with Honey dressing

Prevalence of Bacterial pathogen in Diabetic foot ulcer

Prevalence of microorganism in both the group of patients was assessed using swab culture. The poly microbial nature of infections notedhowever there is no difference in both the groups. Staphylococcus aureus infections were common in both the group with 69% followed by Klebsiella infection 21%.

Table 7 Bacterial culture reports.

Sl.	Microbial organism	Honey Dressing		Conventional Dressing	
No.	Mici obiai oi ganisiii	Frequency	Percentage	Frequency	Percentage
1	StaphylococusAureas	34	68	35	70
2	Klebsiella	10	20	11	22
3	Ecoli	3	6	2	4
4	Psuedomonas	5	10	7	14
5	Staphalbus	2	4	2	4

DISCUSSION

Mean level of wound infection, wound healing and pain score are much better in Honey dressing compared to conventional dressing. (14) Honey has antibacterial properties against Pseudomonas infections and prevents the formation of biofilm. (15-16) Several studies have shown that honey had the ability to provide a protective physical barrier preventing cross infection and optimal milieu for wound healing. (17-18)

Mohan Pc *et al* has stated in their study honey has a debriding effect by its osmotic action which causes an outflow of lymph, lifting debris from the wound bed, removes the molodour by imbibing use of dead particles for nutrition, stimulate tissue regeneration, decrease pain and edema. Our study also saw the same impact. (19)

Fakoor *et al* stated even in antibiotic resistance bacterial infected wounds dressing with honey shown palpable enhancement of wound healing⁽²⁰⁾ in fracture wounds and Subramanium *et al* have shown effect of honey in burns.⁽²¹⁾ Honey preparations in standardized forms are necessary for wound dressing free of antibacterial. Often the local preparation honey may not be sterile. Hence we have used Agmark branded honey tested for purity and free of antimicrobials for our study. Hamouri SK in his study in Jordan has demonstrated healing properties of honey. In our study also there is statistically significant improvement in wound healing.⁽²²⁾

Hydrogen peroxide concentration in honey is around one mmole/litre in contract in routine antiseptic preparation Hydrogen peroxide solution it is 1000 mmole/litre in the standard 3% solution, which will be harmful to the newly generating granulation tissue. Acidic pH of the honey hinders bacterial growth.

Honey provides economical advantage as it is cost effective and need of surgical debridement and amputation are less. Honey is also readily available in all parts of the country. No toxic effects are reported in any studies conducted so far in literature.

CONCLUSION

Honey dressing following standardized wound care protocols significantly reduce pain, enhance healing rate, cost effective and minimize infections. It is ready available, no toxic effect has been reported, has antimicrobial character and protects wounded by farming physical barrier. Hence our study recommends use of honey dressing for Diabetic foot ulcer.

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