

Dressing Methodology for Diabetic Foot Ulcers

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Abstract:

Introduction: Diabetic foot ulcer is a one of the most widespread complications encountered by physicians and Nurses following dressing methodology. **Aims and Objectives:** This study was done for evaluating the effect and efficacy of neem irrigation on wound healing outcome among patients with diabetic foot ulcers. **Materials and Methods:** A total of 22 patients were recruited in Sun Valley Hospital, Guwahati, India. The design of study was randomized single blinded 2 arm study. Out of 22 patients 11 were recruited in standard or active control arm under saline irrigation while 11 of them were recruited in treatment arm under neem irrigation. The follow up of standardized wound healing records were maintained till 4th week from baseline. The Statistical analysis was done by independent 't' test at base line as four subsequent weeks. Paired 't' test was applied in each arm to investigate effect and efficacy of neem irrigation on wound healing outcome. The standardized effect size was also estimated by Cohen D to evaluate the efficacy. **Results:** The Pre score and week 1 score difference in control group (0.18 ± 0.40) was insignificant, $p=.167$, $D=0.45$ while the same in treatment group (1.10 ± 0.99) was significant, $p=.007$, $D=1.11$. The week 1 score and week 2 score disparity in control group (0.33 ± 0.50) was insignificant, $p=.081$, $D=0.67$ whereas the same in treatment group (0.56 ± 1.01) was insignificant, $p=.139$, $D=0.55$. Week 2 score and week -3 score variation in control group (1.00 ± 1.22) was significant, $p=.04$, $D=0.82$ while the same in treatment group (2.33 ± 1.86) was significant, $p=.028$, $D=1.25$. **Conclusion:** The treatment effect and efficacy of neem irrigation on wound healing among patients with diabetic foot ulcers was statistically non inferior in the pilot study and it hopes that it may prove statistical superiority when it is replicated in future which is in pipeline.

Key words: Diabetic Foot Ulcers, Neem Irrigation, Wound Healing Outcome

Introduction

Diabetic Foot Ulcer is considered as a major source of morbidity and a leading cause of hospitalization in patients with diabetes and is also reported as a common complication in Type 2 diabetes mellitus patients (Tesfamichael G. Mariam, Abebaw Alemayehu, Eleni Tesfaye, et al., 2017). The average risk of foot ulcer development in people with diabetes is estimated to be 15%. (Yazdanpanah, 2018). It is estimated that approximately 20% of hospital admissions among patients with DM are the result of DFU (Saseedharan, S., Sahu, M., Chaddha, R., Pathrose, E., Bal, A., Bhalekar, P., Krishnan, P. (2018)). Due to the emergence of multi-resistant organisms and a decrease in newer antibiotics, wound care professionals have revisited the ancient healing methods by using traditional and alternative medicine in wound management (Ploderer, 2018). Numerous case reports in the literature describe wound treatment with various substances such as sugar, honey, neem, iodine etc (Pereira, 2017). As a primary care giver and as a wound care practitioner a nurse has a tremendous opportunity to re-examine the old method of treatments and apply in the current environment.

This pilot study was a randomized, controlled, single blind trial designed to compare the safety and efficacy of neem irrigation and saline irrigation on the wound healing outcomes in patients with diabetic foot ulcer. Data was collected during the period January to June 2019.

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The study took place at Sun Valley hospital, Guwahati and was approved by the Ethical Committee at Marwari Hospital, registered with CDSCO, Government of India vide.Regd. No:ECR/487/Inst/AS/2013/RR-16. Patients were randomly assigned to the conventional care (saline irrigation) and neem irrigation. Experimental group contained 11 patients and control group contained 11 patients. All patients whose ulcers healed or who reached at least 4 weeks actively enrolled in the study without early withdrawal were included in the analysis.

Methods

Patient Assessment

On the first day of the enrolment for the study, patient's baseline data related to socio-demographical and physiological variable were obtained including the wound assessment. Wagner classification was followed for grading the ulcer wounds. Pre intervention wound assessment was done using The Pressure Ulcer scale for healing (PUSH) on the wound size, type of tissue on the wound bed and amount of exudate.

The wound which required debridement was done by the surgeon according to standard procedures. The wound was irrigated with freshly prepared neem solution using a 10 ml syringe with 19 G needle in the experimental group, by the normal saline in the control group and was subsequently dressed using the topical antibiotics (Biocollaz powder, Metrogyl-P and Metrogyl gel). The wound was then dressed with any of the dressing (gel, foam,) as prescribed by the treating physician and covered with a dressing. A secondary dressing was allowed to add either loft or cushion. Off-loading using a removable cast walker, diabetic shoe, surgical shoe, walker cast, or a total contact cast was required for all treatment arms. Subsequently, patients returned every 3-4 days for wound dressing by the nurse. Further wound debridement was done if required before application of new dressing.

Every time the patient visited, wound assessment was done when the dressing of wound was changed and healing score was recorded. Patients were followed for up to a period of 4 weeks. Surface area of the wound was measured using a disposable wound ruler with standard calibrations. Digital photographs at a fixed distance from the wound were obtained. Qualitative assessment of tissue content was done by the investigator and the tissue types was described as necrotic, fibrotic, granulation, epithelialized and scoring was done accordingly. Additional data was obtained regarding adverse events that could be potentially related to the neem irrigation. Patients who failed to maintain their scheduled visits were excluded from the study. Outcome variables for this study were assessed at the end of each week from the initial assessment day till 28th day or completion of 4 weeks.

Patient Population

Patient demographics, were collected during the initial visit as shown in Table 1.

Table 1. Demographic Information and Clinical Characteristics of Participants (N=22)

Characteristics	Sub Group	Control (n=11)	Experimental (n=11)	Total
Demography				
Age (Mean \pm SD)		53.82 \pm 6.68	52.64 \pm 9.51	53.23 \pm 8.04
Gender	F	1 (9.1%)	2 (18.2%)	3(13.6%)
	M	10 (90.9%)	9 (81.8%)	19(86.4%)
Edu.	Graduate	4(36.4%)	2(18.2%)	6(27.3%)
	Higher Sec	1(9.1%)	2(18.2%)	3(13.6%)
	illiterate	0(0%)	1(9.1%)	1(4.5%)
	Secondary Education	5(45.5%)	6(54.5%)	11(50%)
	Upper primary	1(9.1%)	0(0%)	1(4.5%)
Occupation	Farming	0(0%)	3(27.3%)	3(13.6%)
	Business	2(18.2%)	0(0%)	2(9.1%)
	House wife	1(9.1%)	2(18.2%)	3(13.6%)
	Retd	0(0%)	1(9.1%)	1(4.5%)
	Service	8(72.7%)	5(45.5%)	13(59.1%)
Family	Joint	4(36.4%)	5(45.5%)	9(40.9%)
	Nuclear	7(63.6%)	6(54.5%)	13(59.1%)
Smoking habit	Present	1 (9.1%)	0 (0%)	1 (4.5%)
	Not present	10 (90.9%)	11 (100%)	21 (95.45 %)
Other characteristics				
HbA1C	Mean \pm SD	11.87 \pm 4.5	14.10 \pm 4.40	12.55 \pm 4.12
Age of wound Days	Mean \pm SD	73.73 \pm 11.115	90.91 \pm 212.29	82.32 \pm 162.51
Ulcer grade	Gr I	0(0%)	1(9.1 %)	1(4.5%)
	Gr II	6(54.5%)	8(72.7 %)	14(63.6%)
	Gr III	5(45.5%)	2(18.2 %)	7(31.8%)

The inclusion criteria included (1) Patients over the age of 20 years who have diabetes and a foot ulcer of any duration. **(2)** Wounds with an area of at least 1 cm² (greatest length greatest width). **(3)** Patients with foot ulcers which are uncomplicated by clinical signs of infection or ischemia. **(4)** Patients who have the support of caretakers to adhere to non-weight bearing practices. **(5)** Who are hemodynamic ally stable **(6)** Patients who are to follow the language and understand .**The exclusion criteria included (1)** Diabetic foot ulcers of grade 4 or 5 as per Wagner classification. **(2)** Foot ulcers which are complicated by infection or ischemia. **(3)** Clinical features of Drug Abuse / Alcoholism. **(4)** Significant cognitive or mental illness. **(5)** Presence of High Fever or Systemic infections. **(6)** Have any active symptomatic illness. **(7)** Treatment on immunosuppressive drugs.

Results

After screening, the eligible participants were randomly allocated to treatment arms. The age of the participants of the present study ranged from 35 to 68 years. Findings of the present study showed that the majority of participants (87 %) were males and rest of them were females. In the present study 50 %of participants had secondary education, 13.6%had higher secondary education and 27.3% had college education. The mean baseline ulcer size was 17.9 cm² in experimental group and 20.5cm²in control group with no observed statistical differences in the wound score .As they had completed the endpoint at the end of 4 weeks, the data for both group patients were included who have completed 4 weeks assessment. Hypothesis testing was performed using *t* tests at 2-sided *a* of .05. Sample sizes were chosen to give a power of at least 0.8 for significant differences between the saline irrigation and neem irrigation arms.

The average pre intervention wound score in control group (12.82 \pm 2.09, n=11) was statistically at par with experimental group (11.36 \pm 2.11, n=11), *p*=.120, *D*=0.67.

The same in case of week 1 follow up shown that control group (12.64 ± 2.01 , $n=11$) was significantly higher than that of experimental group (10.30 ± 2.87 , $n=10$), $p=.042$, $D=0.87$. The week 2 follow up also shown significant reduction in case of treatment group (9.90 ± 2.73 , $n=10$) compared to control (12.56 ± 2.19 , $n=9$), $p=.033$, $D=0.96$. The week 3 follow up also revealed that control group (11.56 ± 2.60 , $n=9$) was statistically non-significant yet higher than that of treatment group (8.33 ± 4.08 , $n=6$), $p=.083$, $D=0.91$. The week 4 observation also shown that average wound score in control group (10.75 ± 3.20 , $n=4$) was statistically insignificant with treatment (14.00 , $n=1$), $p=.431$

The Pre intervention wound score and week 1 wound score difference in control group (0.18 ± 0.40) was insignificant, $p=.167$, $D=0.45$ while the same in treatment group (1.10 ± 0.99) was significant, $p=.007$, $D=1.11$. The week 1 score and week 2 score disparity in control group (0.33 ± 0.50) was insignificant, $p=.081$, $D=0.67$ whereas the same in treatment group (0.56 ± 1.01) was insignificant, $p=.139$, $D=0.55$. Week 2 score and week 3 score variation in control group (1.00 ± 1.22) was significant, $p=.04$, $D=0.82$ while the same in treatment group (2.33 ± 1.86) was significant, $p=.028$, $D=1.25$.

Outcome Measures

The primary outcome of this study would be DFU healing at a faster rate with $\geq 50\%$ reduction in wound size restoration of functional integrity. Secondary outcome would be that prediction of wound healing at 4 weeks that will help to take necessary action to prevent amputation or other mortality. Constant monitoring and management of Clients with DFU will prevent evolving of potential chronic higher grade DFU, reduce consumable resources and have economic benefits.

Discussion

Majority of diabetic foot ulcer patients' studies by Mariam (2017), Younis et al (2018) has revealed that DFU is commonly seen in Type 2 Diabetes patients as a complication. It was found that the mean age of the study participants' was 53 years suggesting that productive years of life were lost by diabetic foot patients warranting the health care professionals on the measures for prevention of foot complications. Study findings showed that 82% were employed and 18% were unemployed. Temporary or permanent unemployment status may result due to DFU affecting economic status of the patient and family.

Patients with chronic wounds require prolonged periods of dressings and this can cause a significant financial burden to the health-care system. Neemleaves have been extensively used because of their availability throughout the year and the ease of extracting the compounds. The constituents of neem leaves have been demonstrated to exhibit immunomodulatory, anti-inflammatory, and hyperglycaemic, antiulcer, antimalarial, antifungal, antibacterial, and antiviral, antioxidant, ant mutagenic and ant carcinogenic properties (Rahmani, 2018). In the present study, it is observed that use of neem irrigation is comparatively better than the use of saline irrigation. This study showed that use of neem irrigation can be a better option for chronic non healing wounds. Ulcer healing scores revealed that it promoted healing effect on the diabetic ulcer wounds.

Limitations:

The study was limited to only patients with diabetic foot ulcers of grade 1, 2, and 3. It is possible that the improvement seen in the ulcers was solely related to conventional therapy. However, when comparing the outcome obtained with 4 weeks of neem irrigation, to the conventional saline irrigation method for Diabetic foot ulcer the results are very promising.

Conclusion:

The results presented here indicate that neem irrigation is an appropriate clinical option in the wound management of DFUs with significant increase in healing rates and rate of percentage of wound closure as compared with conventional saline irrigation options.

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