Estimation of percent wound area reduction over a period of four weeks among diabetic foot ulcers

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ABSTRACT

Foot ulcers are the most commonly experienced, fearful complications of diabetes which can frequently be life or limb-threatening. Several factors can lead to the occurrence of foot ulcers in diabetics. Prevention and proper management of DFUs are the prime most important in the care of patients with diabetes. It is essential to predict the wound healing time in managing the diabetic foot ulcers. The main objective of the study is to examine the reduction in wound area over four weeks in achieving more than 50% Percentage Area Reduction (PAR) as a clinical outcome. Two wound irrigation methods were used for irrigating the wounds. Assessment of the wound area was done and compared on achieving more than 50% reduction in ulcer area at the end of four weeks. The study used a descriptive comparative design with a control group. Diabetic Foot ulcer patients (N = 160) from a private hospital were randomly allocated into 80 in each group (Neem solution irrigation and Normal saline irrigation groups). In both groups Surface area of the wound was measured using a disposable wound ruler with standard calibrations at baseline and then at the end of each week till four weeks are completed. Data were analyzed in SPSS20 software while considering p < .05 as statistically significant. The mean Wound surface area of the Normal saline group was 18.41 at the end of the first week and 14.04 after four weeks verses 19.84. The above-quoted scores in the Neem solution irrigation group were 14.68 and 6.92, respectively, against 17.13 (p < .05). At the end of 4 weeks, the mean percent reduction in area from baseline of DFUs irrigated with Neem solution was 72.4% and with Normal saline was 48.7%. Ulcers irrigated with neem solution had a 28.7% greater mean reduction in area from baseline when compared with the normal saline control group at the end four weeks (p < .05).

INTRODUCTION

Diabetes causes a significant health issue and has reached alarming levels (Saeedi et al., 2019) and is becoming a common long-term condition worldwide. The International Diabetes Federation (IDF) in 2019 estimated that “approximately 463 million adults (20-79 years) were living with diabetes and by 2045 this will rise to 700” (Patterson et al., 2019). In 2045, the first countries “with the highest number of people with diabetes are expected to be China, India and Pakistan, with 147, 134 and 37 million, respectively” (Saeedi et al., 2019). It is estimated that “the annual population-based inci-
ence of a diabetic foot ulcer (DFU) ranges from 1.0% to 4.1%”. Foot ulcers are dreaded complications of diabetes, and recent studies have suggested that the risk of developing foot ulcer is as high as 25% (Singh, 2005). Particular “treatment of DFUs includes ‘conventional’ wound management procedures such as debridement, infection control, moist dressings, and offloading areas of high pressure or friction” (Rice et al., 2015). “Despite the efforts of conservative therapy, there will always be a percentage of ulcers that necessitate hospitalization” (Pemayun and Naibaho, 2017).

Foot problems stand as the main disturbing complication and are a common reason for hospital admission in diabetic patients (Jain et al., 2019). Several factors can lead to the occurrence of foot ulcers in diabetics. These factors not only increase the risk of foot ulcer and also cause delay or impairment in the wound healing. Due to excessive pressure which is caused by the Peripheral neuropathy on some points of the feet leads to impairment in peripheral vascular (ischemia) resulting in the susceptibility to ulceration. Besides, other “factors such as poor vision, limited joint movement, inadequate foot coverage and shoes can be susceptible to ulceration in diabetics” (Aalaa et al., 2012). “Early recognition of the etiological factors along with prompt management of diabetic foot ulcers is essential for a successful outcome” (Stephanie et al., 2007). The prevention of foot ulcers and adequately managing them becomes the priorities of care in diabetics.

“Foot problems in diabetics can frequently be life or limb-threatening, yet have not received the same level of attention as other diabetes complications” (Pemayun and Naibaho, 2017). “Predicting wound healing is an essential step in the management of DFUs. It is estimated that early detection and appropriate treatments may prevent up to 85% of amputations” (Wang et al., 2016). Around 85 percent of those are believed to be avoidable if appropriate (inter-professional team approach) medical attention, nursing intervention and proper patient education had been given at an earlier stage (El-Sedawy, 2016). Factors which delays healing in diabetic foot ulcer are ulcer size more than 3 cm², Peripheral vascular disease, previous history of ulcers. The other factors that may influence wound healing are generally useful for the development of strategy, also routine application as predictors of the outcome in patient management.”Modification of the modifiable factors, such as better control of diabetes, treatment of peripheral neuropathy, and early management of ulcers, may improve the outcome and facilitate healing” (Marzoq et al., 2019). “The degree of perfusion required for healing of a diabetic foot ulcer is affected by ulcer size, location, depth, infection, and nutritional status of the patient” (Woody, 2020). The local care of foot ulcer usually commences from taking full history with a complete physical examination. Local care for diabetic foot ulcers should begin with a complete history and physical examination. The patient ought to be followed, and wounds estimated routinely for about a month.

Through effective services, “nurses help to reduce the number of amputations and enable people with diabetes to maintain their quality of life and independence” (Amirmohseni and Nasiri, 2014). Nurses are well placed to undertake a leading role in wound management, especially while caring for people with diabetes. Identifying the problems by nurses and implementing immediate independent nursing interventions by using readily available medical agents that can be used safely by nurses to promote wound healing outcome and prevent foot amputations. The Principles of Wound management is based on treating infection, debridement, cleansing, maintaining moist in the wound bed and offloading. A nurse managing a diabetic foot ulcer adult patient includes assessing patient’s history, performing a physical examination, wound assessment, wound care, patient education and documentation. This cross-sectional study’s objective is to examine the clinical profile and achievement of >50% wound area reduction as a healing outcome in diabetic foot ulcers.

MATERIALS AND METHODS

Study Design

A cross-sectional comparative study was conducted among diabetic patients who attended the Diabetes Foot clinic at a speciality hospital, located in Guwahati city of Assam, India from Feb 2019–February 2020. The study compared neem solution wound irrigation with normal saline irrigation in the dressing of diabetic foot ulcers. The sample size was estimated based on the pilot study. Considering the value of $\alpha = .05$, with 80% power, the sample size of 80 were obtained per group. To increase the acceptability, 20% was added to the sample size. Participants were assigned randomly to two types of wound irrigation methods (experimental group and the control group). Patients with foot ulcers meeting the eligibility criteria, uncomplicated by infection or ischemia were included in the study.

Questionnaire

Diabetic Foot Ulcer was graded based on Wag-
Table 1: Comparison of demographic data between Groups

| cc | Control | Treatment | ChiSq | df | P-value |
|----|---------|-----------|-------|----|---------|
| Gender | Female | 12(15%) | 16(20%) | 0.69 | 1 | 0.405<sup>NS</sup> |
| | Male | 68(85%) | 64(80%) | | | |
| | Total | 80(100%) | 80(100%) | | | |
| Occupation | Employed | 58(72.5%) | 59(73.8%) | 0.03 | 1 | 0.858<sup>NS</sup> |
| | Unemployed | 22(27.5%) | 21(26.3%) | | | |
| | Total | 80(100%) | 80(100%) | | | |
| Diabetes | T2 | 80(100%) | 79(98.8%) | 1.01 | 1 | 0.316<sup>NS</sup> |
| | T1 | 0(0%) | 1(1.3%) | | | |
| | Total | 80(100%) | 80(100%) | | | |
| Medication | I | 60(75%) | 48(60%) | 7.18 | 3 | 0.066<sup>NS</sup> |
| | I+OHA | 10(12.5%) | 11(13.8%) | | | |
| | Nil | 1(1.3%) | 0(0%) | | | |
| | OHA | 9(11.3%) | 21(26.3%) | | | |
| | Total | 80(100%) | 80(100%) | | | |
| HbA1c | <=7% | 6(7.5%) | 7(8.8%) | 0.08 | 1 | 0.772<sup>NS</sup> |
| | >7% | 74(92.5%) | 73(91.3%) | | | |
| | Total | 80(100%) | 80(100%) | | | |
| Smoking | Betel | 0(0%) | 6(7.5%) | 11.01 | 2 | 0.004** |
| | N | 75(93.8%) | 74(92.5%) | | | |
| | Y | 5(6.3%) | 0(0%) | | | |
| | Total | 80(100%) | 80(100%) | | | |

<sup>NS</sup> Not Significant, **Highly Significant.

ner’s Scale, which is most generally used in grading: Grade 1—superficial ulceration; Grade 2—ulcer with deep infection, but without the involvement of the bone; Grade 3—ulcer with osteomyelitis; Grade 4—localized gangrene; Grade 5—gangrene of the whole foot. Clinical infection in the wound was graded based on the Infectious Diseases Society of America classification. The surface area of the wound was measured using a disposable wound ruler with standard calibrations. Participants were assessed for “peripheral neuropathy based on clinical signs and symptoms, in addition to the loss of vibration perception tested by using a 128-Hz tuning fork on the medial malleolus and the dorsal aspect of the big toe” (Kaya and Karaca, 2018). Participants’ HbA1c was measured by liquid chromatography method. Information on demography, history of DM and smoking were obtained.

Absence outcomes accurate and reproducible wound measurements have become increasingly important” (Margolis et al., 2002). In this study, wound researcher assessed by using The Pressure Ulcer scale for healing assessment on wound size, type of tissue on the wound bed and amount of exudate.

After completing the wound assessment by the researcher, the foot ulcer wound which required debridement was done by the surgeon as per the standard procedures. The wound was then irrigated with freshly prepared neem solution using a 10 ml syringe with 19 G needle in the experimental group. At the same time, the participants’ wound in the control group was irrigated by the normal saline. In both groups, the wound was subsequently dressed using the topical antibiotics (Biocollaz powder, Metrogyl-P and Metrogyl gel.) and the wound was dressed with any of the dressing (gel, foam,) as prescribed by the treating physician and covered with a dressing. The secondary dressing was applied to add either loft or cushion for comfort. For reduction of weight-bearing, a removable cast walker, diabetic shoe, walker cast, or a total contact cast was required for all participants. Patients returned to the foot clinic every 3-4 days for Wound Management

On the first day of the enrolment for the study, the 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. “With the ability to accurately predict...
### Table 2: Comparison on Percent Wound area reduction data between Groups

| Parameters          | Group  | Total  | Chi Sq | df  | P-value |
|---------------------|--------|--------|--------|-----|---------|
|                     | Control| Treatment|        |     |         |
| % Reduction Level   |        |         |        |     |         |
| ≤50%                | 23(44.2%) | 12(19.4%) | 35(30.7%) | 8.23 | 1       | .004** |
| >50%                | 29(55.8%) | 50(80.6%) | 79(69.3%) |     |         |       |
| Total               | 52(100%) | 62(100%) | 114(100%) |     |         |       |
| Age Group           |        |         |        |     |         |
| 20-40 Yrs           | 4(5%)  | 9(11.3%) | 13(8.1%) | 2.28 | 2       | 0.320 NS |
| 41-60 Yrs           | 51(63.8%) | 50(62.5%) | 101(63.1%) |     |         |       |
| 61-80 Yrs           | 25(31.3%) | 21(26.3%) | 46(28.8%) |     |         |       |
| Total               | 80(100%) | 80(100%) | 160(100%) |     |         |       |
| DM Duration         |        |         |        |     |         |
| < 5 Yrs             | 11(13.8%) | 15(18.8%) | 26(16.3%) | 1.88 | 3       | 0.597 NS |
| 5-15 Yrs            | 47(58.8%) | 48(60%) | 95(59.4%) |     |         |       |
| 15-25 Yrs           | 19(23.8%) | 16(20%) | 35(21.9%) |     |         |       |
| >25 Yrs             | 3(3.8%)  | 1(1.3%) | 4(2.5%) |     |         |       |
| Total               | 80(100%) | 80(100%) | 160(100%) |     |         |       |
| Ulcer Area          |        |         |        |     |         |
| 0-10 Sq Cm          | 32(40%) | 38(47.5%) | 70(43.8%) | 4.43 | 6       | 0.618 NS |
| 10.1-20 Sq Cm       | 23(28.8%) | 22(27.5%) | 45(28.1%) |     |         |       |
| 20.1-30 Sq Cm       | 15(18.8%) | 9(11.3%) | 24(15%) |     |         |       |
| 30.1-40 Sq Cm       | 2(2.5%) | 5(6.3%) | 7(4.4%) |     |         |       |
| 40.1-50 Sq Cm       | 2(2.5%) | 2(2.5%) | 4(2.5%) |     |         |       |
| 50.1-60 Sq Cm       | 1(1.3%) | 0(0%) | 1(0.6%) |     |         |       |
| > 60 Sq Cm          | 5(6.3%) | 4(5%) | 9(5.6%) |     |         |       |
| Total               | 80(100%) | 80(100%) | 160(100%) |     |         |       |
| HbA1c               |        |         |        |     |         |
| ≤7%                 | 6(7.5%) | 7(8.8%) | 13(8.1%) | 0.08 | 1       | 0.772 NS |
| >7%                 | 74(92.5%) | 73(91.3%) | 147(91.9%) |     |         |       |
| Total               | 80(100%) | 80(100%) | 160(100%) |     |         |       |

**Highly Significant, NS Not Significant
Table 3: Regression Coefficients on the effect of risk factors on wound healing

| Risk Factor         | B     | S.E.  | OR   | 95% CI  | Wald ChiSq | df | P-value |
|---------------------|-------|-------|------|---------|------------|----|---------|
| Age                 | -0.25 | 0.39  | 0.78 | 0.37-1.66 | 0.41       | 1  | 0.522   |
| DM Duration         | -0.09 | 0.33  | 0.91 | 0.48-1.74 | 0.08       | 1  | 0.775   |
| HBAc                | -0.54 | 0.89  | 0.59 | 0.1-3.37 | 0.36       | 1  | 0.549   |
| Peripheral Neuropathy| -0.56 | 0.46  | 0.57 | 0.23-1.41 | 1.48       | 1  | 0.223   |
| Ulcer Area          | -0.41 | 0.14  | 0.66 | 0.51-0.87 | 9.07       | 1  | 0.003** |
| Constant            | 3.88  | 2.12  | 48.36|         |            |    |         |

**Significant at P<.01.; NS Not Significant

wound dressing by the researcher.

Further wound debridement was done if required before application of the new dressing. During each visit made by the patient to the clinic, wound assessment was done, dressing of wound was changed, and the healing score was recorded. Patients were followed for up to 4 weeks. Additional data was obtained regarding adverse events that could be potentially related to the neem solution irrigation. Patients who failed to maintain their scheduled visits were excluded from the study. The primary outcome variables for this study was a healing process which was assessed at the end of each week from the initial assessment day the participant completed four weeks of assessment.

Ethical Aspects

Ethical committee approval was obtained for this study from the Marwari Hospital, registered with CDSCO, Government of India vide.Regd. No:ECR/487/Inst/AS/2013/RR-16. Permission was also obtained to conduct the study from the Sun Valley Hospital authorities. Informed written consent was obtained from the participants before completing the questionnaires. Identities of the Study participants were kept anonymous to maintain their confidentiality, and collected data were used only for the study.

Statistical Analysis

Statistical analysis was done by using SPSS-20 software, and p < 0.05 was considered statistically significant. Participants’ socio-demographic and clinical profile data are reported in frequency and percentages. The $\chi^2$ test was used to determine the association between two categorical variables, while logistic regression was utilized to estimate the odds ratio at 95% confidence interval. Multivariate analysis by logistic regression was done for testing the effect of each risk factor.

RESULTS AND DISCUSSION

Characteristics of Participants

In this study, 160 patients had participated, 80 patients in each group. Of them, females were 17.5% (28), while males were 82.5% (132). The mean age for participants was 50.36 (SD, 12.0) in females and 55.73 (SD, 9.71) years, most of the participants were employed 72.5% (116), while 27.5% (44) were unemployed. Majority of the participants (99%) had type 2 diabetes, 67.5% were on insulin, 18.8% on oral hypoglycemic drug, 13.1%. Among the study participants, only 3.1% (5) of them were smokers, while 3.8% (6) were betel nut users. There was no difference in any of the characteristics among the participants included, in this study between the two groups except for the smoking variable (Table 1). A maximum of 47.5% (76) of the subjects had either decreased vibration or absent sensation of vibration on their feet, 12.5% had Rest pain, and 3.1% intermittent claudication, which showed neuroathy symptoms of the subjects. "Prevalence of peripheral neuropathy was 47% when compared to 15–16% in other studies" (Nongmaithem et al., 2016).

Wound Percent Area Reduction (WPAR)

The Mean wound surface area was 19.20 cm$^2$ (Range 1–162 cm$^2$), while the Mean ulcer duration was 45.72 days (Range 4 days to 730 days) in both groups. In 13 participants from the Neem irrigation group and 2 participants from the Normal saline group, ulcers were healed before completion of 4 weeks. Results of 1st week and 4th week were compared kept limited to 160 participants (80 participants in
In this study, the researcher, in addition to a reduction in the wound area, studied other factors affecting wound healing process, such as duration of DM, peripheral neuropathy, age of wound, HbA1c level. Several studies have proposed their prediction model of time for wound healing, with only put concerns of the wound closure at the beginning (Pradanasoewondo et al., 2017). “Percent change in the ulcerarea following observation for four weeks can predict wound healing at 12 weeks, which can be utilized for early recognition of standard care response and the need for additional treatment” (Sheehan et al., 2006). Analysis of the present study data indicates that changes in wound area occur over four weeks and can predict wound healing over 12 weeks. Findings of a study have confirmed that “per cent reduction in wound size is an early predictor of treatment outcome and that protocols of care should be re-evaluated if >50% PAR is not achieved” (Warriner et al., 2011). Lavery et al. estimated that percentage of wound area reduction at one week of observation could predict healing at 16 weeks. However, the present study was limited to 4 weeks follow-up of patients.

Many other factors have been evaluated in the literature as early indicators of wound healing. However, “no factor has been consistently identified as an early predictor” (Sheehan et al., 2006) “The size, age and the grade of the wound are all predictors for the failure of a neuropathic foot ulcer to heal” (Margolis et al., 2002). This study has shown that only one factor out of 5 factors, i.e. Age, Duration of DM, HbA1C, peripheral neuropathy and Ulcer area was significantly correlated with wound healing. A Multivariate analysis using regression method was subsequently performed to the significant factors which were considered important for achieving more than 50% wound area reduction (Table ??). Ulcer area is statistically significant (p=0.003) with bigger wound size are less likely to achieve more than 50% PAR after four weeks (Odds Ratio=0.66). In acute foot ulcers, wound area and osteoprotegerin levels were positively correlated with healing. Despite what might be expected, subjects with the previous history of a wound with longer duration, as well as a history of captopril and simvastatin medications demonstrated slowed healing process. “Hemoglobin A1c (HbA1c), is an established marker to monitor blood glucose in diabetic patients, is found to have associated with ulcer healing” (Manjunath and Kumar, 2018). “The previous history of minor amputation, ulcer location, haemoglobin A1C, and the neutrophil-lymphocyte ratio is associated with outcomes of diabetic wound ulcers” (Vatankhah et al., 2016). Patients with Lower HbA1c have shorter healing duration (AlGoblan et al., 2016). While another study reported “elevated HbA1c was associated with slower and incomplete healing of foot ulcers in diabetic patients” (Manjunath and Kumar, 2018). Contradicting this report, the present study has found that HbA1c is not significantly correlated with wound healing. This is supported by research where Glycemic control was not significantly related to the healing process due to its long term effect (Pradanasoewondo et al., 2017). Another study has also failed to show any significant association between HbA1C and LEA (Ugwu et al., 2019). The present study was limited to participants having diabetic foot ulcers of Wagner grade 1 – 3, followed for only four weeks and may not be generalizable to patients with high-grade ulcers.

CONCLUSIONS

In conclusion, the present study showed that the percentage area of reduction is associated with wound healing of patients with diabetic foot, is a strong indicator of wound healing. It is unlikely an ulcer will heal in 12 weeks if there is little reduction in wound area during the initial four weeks of wound care. For the nursing practitioner who independently practices wound care management, achieving PAR of more than 50% is suggested as a reliable predictor of wound healing for patients with a diabetic foot with the potential for the development of strategies for the prevention of diabetic foot complications.

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