Original Research Article

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A prospective study to compare the effectiveness of saline dressing versus povidone iodine dressing in chronic diabetic wound healing: study from a tertiary hospital in south India

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ABSTRACT

Background: Saline dressings and povidone iodine dressings have been traditionally used for the management of chronic diabetic wounds

Methods: Subjects attending diabetic wound clinic and surgery outpatient department/ casualty of Government Medical College and Hospital, Kozhikode, Kerala, India were divided into two groups by consecutive sampling i.e., Povidone iodine and Saline dressing group. Regular occlusive dressing was done for 6 weeks of follow-up period.

Results: 3 out of 20 subjects in Saline treated group achieved complete healing by 6 weeks as compared to 1 out of 20 subjects in Povidone iodine treated group. There was a significant decrease in the wound surface area at 6^{th} week in Saline dressing group in comparison to the povidone iodine group at P = 0.03 (<0.05) level of significance.

Conclusions: Saline dressing is more effective in achieving healing in chronic diabetic wounds as compared to Povidone iodine dressing.

Keywords: Chronic diabetic wound healing, Diabetic foot ulcer, Occlusive dressing, Povidone iodine dressing, Saline dressing

INTRODUCTION

Diabetic foot ulcer (DFU) is the most costly and devastating complication of diabetes mellitus, which affect 15% of diabetic patients during their lifetime. To date, DFU is considered as a major source of morbidity and a leading cause of hospitalization in patients with diabetes. It is estimated that approximately 20% of hospital admissions among patients with DM are the result of DFU. Painful and lengthy hospitalization, multiple stages of surgery, disfigurement and disability, prolonged rehabilitation, loss of income and job and an enormous financial burden are some of the horrors looming over a chronic ulcer victim. Early effective wound management plays an important role in preventing

future complications and need for amputations. Hence emphasizing adequate and proper wound management for these patients. At our setup, these chronic diabetic wounds are managed by debridement and regular wound cleansing and dressing after thorough wash with betadine (povidone iodine), hydrogen peroxide and normal saline. The wound is then covered either with povidone iodine soaked gauge or simply with normal saline soaked gauge.

Our primary aim in this study was to compare the wound healing outcomes between the commonly used methods i.e. Normal saline dressing and povidone iodine dressing by giving occlusive dressing. Though povidone iodine dressing is widely used method presently, some studies have shown that iodine delays wound healing. Hence bringing out the differences in outcomes of these commonly used methods.

METHODS

A total of 40 patients (20 patients in each arm of Povidone Iodine dressing group and Saline dressing group) with complaints of chronic diabetic ulcers attending diabetic wound clinic and surgery outpatient department/ casualty of Government Medical College and Hospital, Kozhikode, Kerala, India were considered in this study. Study was undertaken after the approval from the Ethics Committee. Consecutive sampling was done satisfying the inclusion exclusion criteria till the sample size was attained in each group. Prospective cohort (comparative) study was done from March 2015-October 2016.

Inclusion criteria

A total of 40 subjects, age >18 years, with chronic diabetic wounds of duration >6 weeks were enrolled after informed written consent. Only clinically clean wounds without signs of acute inflammation, purulent discharge, or malodour were included. Patients presenting with infected wounds were initially treated with daily dressing - cleansing with normal saline and dressing with paraffin gauze along with surgical debridement and oral antibiotics based on bacterial wound culture report.

Pretherapy assessment

All patients were assessed by the consultant surgeon. Patients suffering from leg or foot ulcer were evaluated with Color Duplex Scan (Arterial/venous Doppler) to assess the arterial/venous insufficiency. An X-ray of the region was also carried out to rule out any underlying osteomyelitis. A wound bacterial culture swab was collected before inclusion in the study. The chronic wounds were adequately debrided surgically, thoroughly cleansed with sterile normal saline and covered with sterile paraffin gauze, cotton pads, and bandages.

Exclusion criteria

Patients who are not willing for the study; Postoperative wounds, Burns and other non-diabetic wounds, skin grafts donor sites; wound size >5cm in maximum diameter; known allergy to iodine or Tegaderm/opsite.

Methods of wound care

The subjects were divided into 2 groups by Consecutive Sampling - the povidone iodine dressing group and the Saline dressing group. Povidone iodine solution being used was the one available in hospital supply (betadine; Povidone-Iodine 5% w/v solution). After cleaning the wounds, the povidone iodine/saline soaked gauze was applied over the wounds and covered with a transparent sterile polyurethane semi-permeable sheet (opsite or

tegaderm) which served as an occlusive dressing. The wound dressings were changed regularly every 3-4 days for 6 weeks of follow-up period or till complete healing. Appropriate antibiotic coverage was given (Oral/IV). The observations of wound healing status were made at 2-week intervals at 2nd, 4th and 6th weeks, wherein the maximum dimensions of wound (length X breadth) in centimetres were recorded and wound surface area (cm²) were calculated for statistical comparison. The overall dressing comfort score was also subjectively analysed.

Outcome variable

The main outcome of interest was complete wound healing at the end of the sixth week. Secondary outcome was reduction in wound surface area measured in cm². The patient's overall dressing comfort was also monitored and subjectively analysed. Thus, the rate of wound healing was measured by reduction in the area/size of the chronic diabetic wound, and then the difference in the healing rates in each arm were compared.

Statistical analysis

Data was entered in Excel and the analysis was performed on SPSS software. Friedman test and Wilcoxan rank sum (Mann-Whitney) test were used to find out the differences between the two groups. A P value of <0.05 was accepted as significant.

RESULTS

A total of 40 subjects with 20 in each arm of povidone Iodine group and Saline group completed the follow-up period. None developed any reaction to povidone iodine and none were excluded or lost to follow up during the course of study.

Table 1: Gender distribution among subjects.

Gender	Frequency	Percentage
Male	30	75
Female	10	25
Total	40	100

Table 2: Educational status of the subjects.

	Frequency	Percentage
No formal education	1	2.5
Below SSLC	21	52.5
SSLC/Predegree	18	45
Total	40	100

Table 1 shows the gender distribution of the subjects studied. Among the total of 40 subjects, 30 (75%) were male and 10 (25%) were female. Table 2 show the level of education among the studied subjects. Out of 40 subjects, 1 (2.5%) had No formal education; 21 (52.5%)

had education below SSLC; and 18 (45%) had completed SSLC/Predegree. Table 3 show the distribution of occupation among the subjects. 8 (20%) were unemployed; 9 (22.5%) were homemakers (housewives); 16 (40%) earned daily wages (labourers) and 7 (17.5%) were professional/ self-employed.

Table 3: Occupation of the subjects.

	Frequency	Percentage
Not working	8	20
House wife	9	22.5
Daily wages	16	40
Professional/self employed	7	17.5
Total	40	100

Table 4: Age distribution of the subjects.

	Number of patients	Min	Max	Mean	SD
Age	40	39	72	58.30	8.407

Table 5: Comparison of baseline characteristics of povidone iodine and saline dressing groups.

Characteristics	Povidone iodine dressing group (n=20)	Saline dressing group (n=20)
Age (years)	Mean - 58.25	Mean - 58.35
Gender	Male 16 (80%)	14(70%)
Gender	Female 4 (20%)	6(30%)
Smoking	12 (60%)	9(45%)
Alcohol	12 (60%)	9(45%)
Hemoglobin gm%	Mean - 12.21	Mean - 11.51
Serum albumin (g/dl)	Mean - 3.07	Mean - 3.06
Duration of diabetes (years)	Mean - 10.90	Mean - 12.95
Duration of chronic wounds (months)	Mean - 5.94	Mean - 7.79
Types		
Venous ulcer	3 (15%)	2 (10%)
Arterial ulcer	4 (20%)	3 (15%)
Pressure sore	5 (25%)	6 (30%)
Traumatic ulcer	8 (40%)	9 (45%)
Site		
Leg	3 (15%)	1 (5%)
Ankle	2 (10%)	5 (25%)
Foot dorsum	6 (30%)	4 (20%)
Foot sole	6 (30%)	9 (45%)
Thigh	3 (15%)	0
Forearm	0	1 (5%)

The data for categorical variables are given in numbers with percentages in brackets.

Table 4 shows overall age distribution and Table 6 shows the baseline characteristics of povidone iodine and saline dressing groups. The overall mean age was 58.30 (SD=8.407), with a mean age of 58.25 in povidone iodine group and 58.35 in Saline dressing group. There was a male preponderance in both the groups. (80% males in povidone iodine group and 70% males in saline group). 60% in povidone iodine group and 45% in saline group had a habit of smoking and alcohol. Among the blood investigations done, haemoglobin and serum albumin were taken into consideration for statistical analysis. Mean Hb in povidone iodine group was 12.21g% and in saline group was 11.51. Mean S. Albumin value in povidone iodine group was 3.07g/dl and Saline group was 3.06g/dl. Mean duration of diabetes was 10.90 years in povidone iodine group and 12.95 years in Saline group. Mean duration of existence of chronic wounds was 5.94 months in povidone iodine group and 7.79 months in saline group. Both the groups were comparable in terms of demographic characteristics, duration, aetiology, and location of wounds. Similarly, both groups were comparable in terms of concomitant disease, previous medical and surgical therapy.

Table 6: Comparison between outcomes of povidone iodine dressing group and saline dressing group in terms of Surface area reduction of wounds.

	Surface area in povidone iodine dressing group (sq.cm)	Surface area in saline dressing group (sq.cm)	P value
Baseline assessment	11.29	9.21	0.18*
After 2 weeks	10.59	7.83	0.09*
After 4 weeks	9.74	7.04	0.05*
After 6 weeks	8.86	5.52	0.03*

^{*}using Mann-Whitney Test

The etiological types in Povidone iodine group were: Venous ulcer - 15%, arterial ulcer - 20%, pressure sore -25%, traumatic ulcer - 40%; while in saline group were: venous ulcer - 10%, arterial ulcer - 15%, pressure sore -30%, traumatic ulcer - 45%. Hence, overall etiological types in descending order were Traumatic ulcer > Pressure sore > Arterial ulcer > Venous ulcer. Sites of diabetic wounds in Povidone iodine group were: leg -15%, ankle - 10%, foot dorsum - 30%, foot sole - 30%, thigh - 15%, forearm - 0%; while in saline group were: leg - 5%, ankle - 25%, foot dorsum - 20%, foot sole -45%, thigh - 0%, forearm - 5%. Hence, overall sites of wounds in descending order were foot sole > foot dorsum > ankle > leg > thigh > forearm. Majority of subjects had a wound of traumatic aetiology, mostly located on the foot and ankle.

Table 5 shows the comparison between the outcomes of Povidone Iodine dressing group and Saline dressing group in terms of Surface are reduction of wounds. The mean surface area of wound in Povidone iodine group was: baseline - 11.29sq.cm, 2nd week - 10.59sq.cm, 4th week - 9.74sq.cm, 6th week - 8.86sq.cm; While in Saline group was: baseline - 9.21sq.cm, 2nd week - 7.83sq.cm, 4th week - 7.04sq.cm, 6th week - 5.52sq.cm. The two groups were comparable in terms of wound surface area at baseline (i.e. at 0 week). After 6 weeks, the mean reduction in surface area of wound is more in the saline dressing group compared with the povidone iodine dressing group and the results are statistically significant at a P value of < 0.05 (P = 0.03).

Proportion of complete healing at 6 weeks

Wounds completely healed in 15% (3 subjects) of saline dressing group and 5% (1 subject) of the povidone iodine dressing group.

During dressing, it was observed that few patients with povidone iodine dressing experienced some discomfort with the dressing, while Saline dressing group had no such complaints. It may be inferred that Saline dressing is more comfortable compared to povidone iodine dressing. Since this is a subjective parameter, this inference is solely based on the observations made during dressing and the reviews given by the subjects throughout the follow up. Pain scores were not considered as almost all the wounds were painless due to diabetic neuropathy.

DISCUSSION

According to a study of prevalence of DFU and associated risk factors in diabetic patients by Shailesh K et al males were affected more than females, mean age of 55.25 years, more common in rural areas compared to urban areas, average duration of diabetes 11.50 years, etiological factors were unknown in most of the subjects, followed by minor trauma, mostly located below ankle over plantar aspect, owing to sensory neuropathy as the prominent risk factor.³ This study shows male predominance, mean age 58.30 years, mean duration of diabetes of 11.92 years, with most wounds located below ankle (foot sole) and traumatic and pressure sores being the commonest etiologies. This study is thus comparable to the study by Shailesh et al.

Various types of non-adherent or Saline-soaked gauze dressings are often regarded as standard treatment for diabetic ulcers and have usually been used as the control arm in studies of dressings. These dressings are designed to be atraumatic and to provide a moist wound environment. These simple, relatively inexpensive dressings are not designed specifically for managing infection but can be safely used in conjunction with antibiotic treatments.^{4,5} Normal saline dressings act in part as an osmotic dressing. Meanwhile there are also studies portraying the potential issues with the use of

Saline dressings, such as patient discomfort, prolonged inflammation, localized hypothermia, infection risk etc.^{6,9}

In the present study, the routine dressings have been modified as "moist occlusive" dressings. Occlusion of a wound cavity with the help of a semi permeable membrane retains the moisture of wound exudates and serves as a moisture-retentive dressing. The western world, most wound clinics do not recommend the use of povidone iodine application on clean wounds. However, in India many physicians and nurses frequently use povidone iodine even in clean wounds. The present study demonstrates that the rate of wound healing with povidone iodine and Tegaderm/ Opsite was slower than that achieved by the saline-treated group.

For instance, the cost of commercially available povidone-iodine 10% Solution (100ml) is around Rs.100, while that of a Normal Saline (100ml) is around Rs.15. Hence saline dressing is more cost-effective compared to povidone-iodine dressing.

CONCLUSION

Saline dressing is more effective as compared to povidone iodine dressing in achieving complete healing, reducing wound surface area, and increasing comfort in subjects with chronic diabetic wounds. Furthermore, saline dressing is more cost-effective compared to povidone iodine dressing.

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Ethical approval: The study was approved by the

institutional ethics committee

REFERENCES

- 1. Yazdanpanah L, Nasiri M, Adarvishi S. Literature review on the management of diabetic foot ulcer. World J Diabetes. 2015;6(1):37-53.
- Ramachandran A, Snehalatha C, Shetty AS, Nanditha A. Trends in prevalence of diabetes in Asian countries. World J Diabetes. 2012;3(6):110-7.
- 3. Shahi SK, Kumar A, Kumar S, Singh SK. Prevalence of diabetic foot ulcer and associated risk factors in diabetic patients from North India. Age. 2012;47(8):55-26.
- 4. Hilton JR, Williams DT, Beuker B, Miller DR, Harding KG. Wound dressings in diabetic foot disease. Clinical Infect Dis. 2004;39(2):100-3.
- 5. Jeffcoate WJ, Price P, Harding KG. Wound healing and treatments for people with diabetic foot ulcers. Diabetes Research Reviews. 2004;20(1):78-89.
- 6. Ryan M. The issues surrounding the continued use of saline soaked gauze dressings. Wound practice and research. J Australian Wound Management Association. 2008;16(2):16.
- Atiyeh BS, Amm CA, Musa KA, Sawwaf A, Dham R. The effect of moist and moist exposed dressings on healing and barrier function restoration of partial

- thickness wounds. European J Plastic Surg. 2003;26(1):5-11.
- 8. Singh A, Halder S, Chumber S, Misra MC, Sharma LK, Srivastava A, et al. Meta-analysis of randomized controlled trials on hydrocolloid occlusive dressing versus conventional gauze dressing in the healing of chronic wounds. Asian J Surg. 2004;27(4):326-32.
- 9. Damour O, Hua SZ, Lasne F, Villain M, Rousselle P, Collombel C. Cytotoxicity evaluation of

antiseptics and antibiotics on cultured human fibroblasts and keratinocytes. Burns. 1992;18(6):479-85.

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