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Research Article

A CLINICAL COMPARATIVE STUDY ON THE HEALING EFFICACY OF NANO SILVER AND BETADINE IN DIABETIC FOOT ULCERS

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ABSTRACT

Objective: The objective of the study was to study the efficacy of topical agents like betadine solution and nano silver solution/gel in the management of diabetic foot ulcer.

Materials: The study was a prospective, parallel-group, comparative trial. The patients were admitted with diabetic foot ulcer for a period of 2 years. A comparative study was done between both groups regarding the time of healing. Number of dressings and reduction of ulcer size was monitored. The number of patients included in our study was 60 out of which 30 were in test group with betadine solution and 30 were in another test group with nano silver solution.

Results: Age distribution, 25 patients are between 51 and 60 years of age. In sex distribution, males are affected more than females. In mode of onset, 68.75% of ulcers are traumatic in onset; plantar aspect and forefoot are most. Blood sugar levels between 200 and 300 mg% are in 38.33% of patients. Patients receiving insulin were 7l.66%, which helped in good glycemic control. Average duration of hospital stay is less with test Group l, that is, 30 patients stay. Percentage reduction of ulcer is between 91 and 99%, in 27 patients of test Group l While only six patients in test Group 2 had 91–99% reduction in ulcer size with p=0.00 and is highly significant, number of dressings required per patient are l0.225±2.957 in test group and are 21.65±3.847 in test Group 2, p=0.00 and significant.

Conclusions: Thus using nano silver dressings in the treatment of diabetic foot ulcers is found to be safe, effective, promoter of wound healing promote epithelization, and accelerates healing. Eliminates anaerobes and breaks microbial synergy more effectively than simple betadine dressing. Hence, nano silver gel proves to be more effective in the management of diabetic foot ulcer.

Keywords: Nano silver dressings, diabetic foot ulcers, wound healing.

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INTRODUCTION

Diabetes mellitus is a genetically based illness of lipid, protein, and carbohydrate metabolism linked to either a partial or total lack of insulin secretion. The number of patients afflicted with this disease and its complications has significantly increased in recent years. Diabetes mellitus is a condition that seems to affect people of all ages, from young children to the elderly. It is a disease that affects every organ and system in the body, most notably the kidney, blood vessels, eyes, and peripheral nerves. The high death toll each year is a result of its complications, which are most prevalent in the 40–60 age range. Due to factors such as neglect, poverty, and lack of education, the difficulties are more common among those with lower socioeconomic level. One of the main consequences of diabetes is diabetic foot: around 3–4% of people with diabetes mellitus now have deep infections or foot ulcers. 15% of people get foot ulcers at some point in their lives [1-3]. They result in lower extremity amputation if left untreated. Diabetic foot is the cause of 85% of non-traumatic lower extremity amputations. In India, the high prevalence of diabetes mellitus is 5% in urban areas and 1.5–1% in rural areas, meaning that 60 million people are at risk. This places an incredible burden on any effort to offer a structured diabetic foot care program.

METHODS

The study was a prospective, parallel-group, comparative trial in which patients were admitted with diabetic foot ulcer in S.V.R.R.G.G. Hospital, Tirupati from November 2011 to November 2013. The number of patients included in our study was 60 out of which 30 were in a test group with betadine solution and 30 were in another test group with nano silver solution.

Inclusion criteria

Patients aged more than 20 years with diabetic foot ulcers, ulcers of size <10×10 cm.

Exclusion criteria

Clinical signs of infection, cellulitis, X-ray showing osteomyelitis, Doppler showing gross atherosclerotic arterial changes and venous abnormalities such as varicosities, malnutrition, uncontrolled diabetes, and other clinically significant medical conditions that would impair wound healing like renal, hepatic, hematological, neurological, and immunological diseases.

Patients receiving corticosteroids, immunosuppressive agents, radiation, or chemotherapy within 1 month before entry into the study were also excluded from the study. Method of collection of data a detailed history was taken, including a history of the mode of onset, duration, and progress of ulcer, and information about diabetes status was obtained in the form of the duration of diabetes mellitus and medication. Ulcer examination was performed. All patients underwent the investigations as Hb, blood sugar levels, serum creatinine, urine ketone bodies, X-ray foot, Doppler (both arterial and venous). Ethical clearance was obtained from Ethical committee of our institution for this study.

For betadine dressing

If the ulcer contained slough, patients underwent debridement to have clean ulcer base. Following debridement, the base was cleaned once with wet gauze piece soaked in normal saline. Wet gauze piece in betadine solution was kept over the ulcer which was covered with gauze pad and roller bandage. For nano silver solution/gel dressings after cleaning the ulcer with help of normal saline, silver nano gel applied and the wound was closed with gauze pad and roller bandage. Dressings are changed according to need once or twice in the day if there is soakage of dressing. Patients are discharged from the hospital after significant reduction in ulcer size or in some cases after formation of granulation tissue and after applying partial thickness skin graft. Percentage reduction in the ulcer size was measured at the time of discharge using ulcer planimetry. Number of dressings required for each group and number of days of hospital stay were recorded. Patients are revaluated on the outpatient basis for 2 months.

RESULTS

Most of the patients fell in the age group between 50 and 60 years. The Mean±SD for test Group 1 is 49.325±11.25 and test Group 2 63.35±9.9.

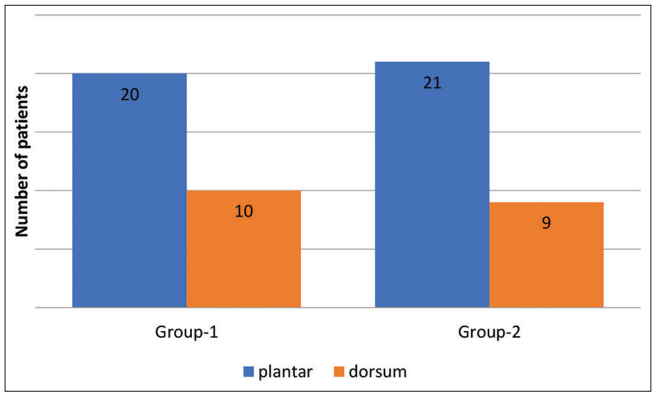

Fig. 1: Site of ulcer distribution

Age, gender, onset of diabetic foot ulcer, and site of ulcer distribution are statically similar between the two groups (Tables 1 and 2, Fig. 1).

Diabetic foot ulcers are more common in plantar aspect of foot due to increase of foot pressure.

DISCUSSION

Sixty patients were examined, and they were split into two test groups of 30 each at random. Every group was matched. The mean standard deviation for test Groups 1 and 2 in our study is 49.325±11.23 and 63.35±9.9089, respectively, with age comes a progressive increase in the occurrence of leg ulcers. During the age of five to six, diabetic foot ulcers are more common. As age of increases Prevalence is rises. The age distribution in our analysis matches the age distribution in the study that Harish *et al*. conducted [4].

There are a total of 39 (65%) males and 21 (35%) females in our study. Males were more likely than females (25%) to develop chronic leg ulcers in the study by Rao *et al*. [4]. A well-known government source, the NHDS, showed that hospital admissions and incidence of diabetic foot were greater in men [5]. Our study's sex distribution is comparable to that of Motat *et al*. [6]. Diabetes-related foot ulcers are more common in men than in women.

Every time we encountered a diabetic ulcer, trauma was consistently identified as the leading cause of the condition. The cause is readily apparent. The development of ulcers is triggered by neuropathy. In our study, trauma also caused 68.35% of the study participants to develop ulcers, with the remaining subjects developing ulcers on their own as a result of bullae rupture. It has been demonstrated in a study by Edmond *et al*. [5] that the planter and forefoot regions account for 93% of foot ulcers. The majority of diabetic foot ulcers are inevitably caused by changes in gait and are shoe-related. Wearing shoes that fit properly helps avoid them. Plantar foot ulcers are more prevalent in diabetic foot ulcers in our study.

Table 1: Demographic details in present study

Age in years	Group-1		Group-2	
	Number of patients	Percentages	Number of patients	Percentages
21–30	1	3	1	3
21–40	2	6.66	2	6.66
41–50	9	30	9	30
51–60	13	43.3	8	26.6
61–70	5	16.6	4	13.3
71–80	0	0	5	16.6
>80	0	0	1	3
Total	30	100	30	100
Mean±SD	49.32±11.23		63.35±9.9	
Sex distribution				
Male	19	63.3	20	66.6
Female	11	36.67	10	33.3
Onset of diabetic foot ulcer				
Traumatic	21	70	20	67.5
Spontaneously	9	30	10	32.5

Table 2: Blood sugar levels in present study

Blood sugar levels	Group-1		Group-2	
	Number of patients	Percentages	Number of patients	Percentages
<100	0	0	0	0
100–200	9	30	9	30
200–300	12	40	15	36.67
300–400	9	30	10	33.3

Mean±SD of Group 1 is 247.5±30.44 and Group 2 is 252.5±24.4 is statically similar

Table 3: Average duration of hospital stay present study

Period of stay (weeks)	Group-1 (Nano silver Dressings)		Group-2 (Betadine dressings)	
	Number of patients	Percentages	Number of patients	Percentages
1–2	7	23.3	0	0
2–3	10	33.3	0	0
3–4	13	43.3	0	0
4–5	0	0	8	26.6
5–6	0	0	22	73.3

Mean±SD is 2.9 weeks±0.84 weeks for Group 1 and for Group 2 Mean±SD is 5.4±0.5and p=00 and is highly significant
In test Group 1 43.3% of patients stay for 3–4 weeks whereas in test Group 2 73.3% of patients stay for 5–6 weeks

Table 4: Percentage reduction of ulcer size

Reduction of ulcer size	Group-1 (Nano silver Dressings)		Group-2 (Betadine dressings)	
	Number of patients	Percentages	Number of patients	Percentages
61–70	0	0	1	4.6
71–80	0	0	9	30
81–90	3	10%	14	45.3
91–99	27	90%	6	20

Mean±SD of Group 1 and Group 2 are 95.62±3.1 and 85.17±7.7 and p=0 and is highly significant. About 91–99% reduction in size of ulcer is seen in 27 out of 30 patients in Group 1 whereas Group 2 only 6 out of 30 show 91–99% reduction in size

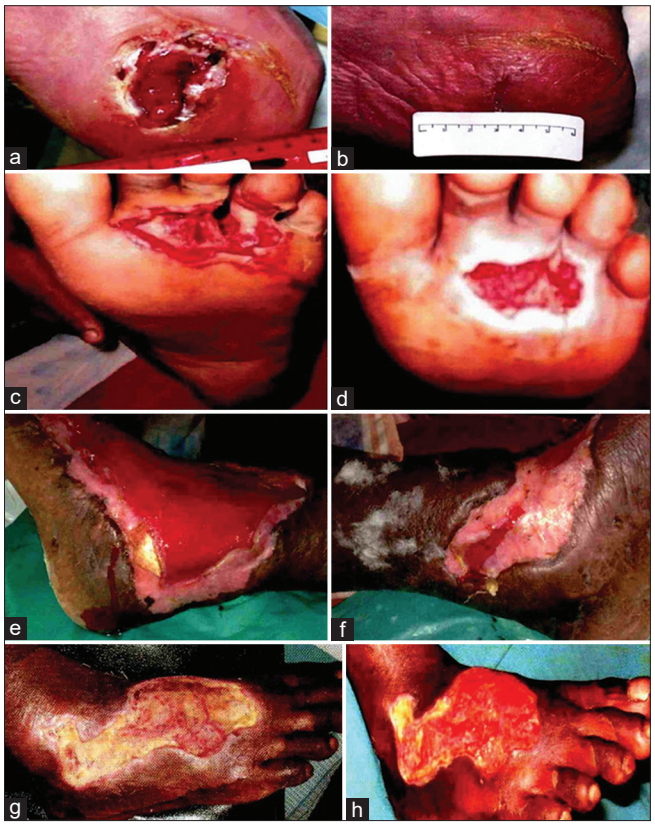

Fig. 2: Cases in present study. (a) After surgical debridement. (b) After application of nano sliver dressings. (c) After surgical debridement. (d) After application of nano sliver dressings. (e) After surgical debridement. (f) After application of betadine dressings. (g) After surgical debridement. (h) After application of betadine dressings

The test group's hospital stay lasted 2.921 0845 weeks in the current study, while test group 2's hospital stay was 5.4786±0.5007 weeks (Tables 3 and 4). The mean wound healing rates for the iodine and silver groups in a study by Miller *et al.* [7] were comparable, with the silver group showing a slightly higher healing rate (averages 52. 10, SD 51.89) than the iodine group (averages 1.69, SD 52.46). The length of hospital stay in our investigation is consistent with the findings of Miller *et al.*'s study [7].

The current study shows a noteworthy % reduction in ulcers of 95.625% with nano silver gel dressing and 85.175% with betadine dressing. p=0.00 (Fig. 2). A comparison of the number of wounds that healed for each treatment group was investigated for the segmentations of wound size and wound duration in the study by Miller *et al.* [7]. Similar results showed that the number of wounds healed overall for young (w2(1)50.07 p>005) and old (w2(1)50.17, p>0.05) wounds, as well as for little (w2(150.02 p>0.05} and big (w 2(1)50.02 p >0.05), did not differ between the treatment groups. Our study's percentage ulcer reduction is higher than that of the research done by Miller *et al.* [7]. Under circumstances provided silver dressings were more effective in comparison with the routine betadine dressings in healing the diabetic ulcers.

In comparison to the betadine dressing group, our study found that a much lower quantity of nano silver gel dressings was needed for each patient. The findings of Miller *et al.*'s study [7] indicated that the amount of time and dressings needed for ulcer healing in both situations using silver and betadine were comparable. The average number of dressings for chronic wounds with silver dressings was found in another RCT led by Munter KC and Beele [8]. The primary goal of the research was to determine that, in comparison to betadine dressings, nano silver dressings took a shorter time to heal and fewer treatments overall (Table 5).

Mean SD of test Group 1 and test Group 2 are 10.225±2.957 and 21.65 3.847 and result is in accordance with the results of study by Miller [7].

These results suggest that a silver antimicrobial can be considered as the first choice when attending clients with large and chronic leg ulcers or a history of protracted healing, even though both antimicrobials were ultimately comparable over a 6–7 week period. The usefulness of betadine and nanocrystalline silver, two widely used antimicrobials, was examined in this study. In terms of the total number of wounds treated and the overall rate of healing, both antimicrobials performed similarly [9,10]. Nevertheless, the use of silver compounds was linked to a faster rate of healing in the first 2 weeks of therapy and in larger, older wounds with higher exudate levels. This trial provides some

Table 5: Number of dressings required

Number of dressings	Group-1(Nano silver Dressings)		Group-2 (Betadine dressings)	
	Number of patients	Percentages	Number of patients	Percentages
1–5	1	3.3	0	0
6–10	16	53.3	0	0
11–15	12	40	0	0
16–20	1	3.3	12	40
21–25	0	0	14	46.6
26–30	0	0	4	13.34

Mean±SD of Group 1 and Group 2 are 10.22±2.9 and 21.65±3.8 and p=0 and is highly significant

insights as to circumstances in which one product may be preferred over the other.

CONCLUSIONS

Nano silver dressings are safe, effective, with a slight beneficial edge to the conventional dressing with solutions like betadine in terms of promoting less pain while changing the dressing, less number of dressings required and less duration of hospital stay. The above results indicate that nano silver dressings may be used as an adjunct in the management of diabetic foot ulcer and seems to be more efficient than conventional dressings in this regard.

CONFLICTS OF INTEREST

Nil.

FUNDING

Nil.

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