

A Comparative Study Between Conventional And Nanosilver Dressings In Patients With Diabetic Ulcer

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Abstract: A patient of diabetes mellitus is exposed to a number of complications of which Diabetic foot is a common condition. The surgeon is usually facing the problem of "Life and Leg". With proper understanding of the disease and the new concepts in the management of Diabetic foot, it has been possible to save many limbs and lives. The aim of this study is to evaluate the effectiveness of Nano crystalline silver dressings in the management of diabetic foot ulcer. A prospective study of 54 cases of Diabetic foot ulcers belonging to Wagner's Grades 1 and 2, admitted and treated (from Sept 2015 to Sept 2017) in Siddhartha Medical College / Government General Hospital, Vijayawada, AP, India was done. They were randomly sorted into 2 groups and comparative study was done between conventional and Nano silver dressings. Nano silver dressings in the treatment of diabetic foot ulcers were found to be safe, effective, promote wound healing and epithelization, eliminate anaerobes and break microbial synergy more effectively than conventional dressing.

Keywords: Diabetic foot, Nanosilver dressings, Wagner's grading, Nano crystalline technology

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I. Introduction

Diabetes is an "iceberg" disease. At present India is having second highest number of people with diabetes mellitus next to china and accounts for almost 1/6 of the diabetic patients in the world.¹ Diabetic foot ulcer occurs in about 20% of all patients with diabetes and precedes 85% of all lower limb amputations.² Relative risk of leg amputation is 40 times higher among persons with diabetes than with non-diabetics.³ Early recognition and proper therapy of diabetic foot lesion may save the foot and leg. There continues to be great interest and research put into the treatment and prevention of diabetic foot. Conventionally, Normal Saline and Betadine solution are used in the management of diabetic foot ulcers. Now-a-days Silver dressings are being utilised for diabetic foot management. Silver has antiseptic, antimicrobial, anti-inflammatory properties and is a broad-spectrum antibiotic.⁴ Nano-technology makes it possible to expand the surface area of silver particles markedly to nano scale, thus increasing their contact with bacteria or fungi, and vastly improving its bactericidal and fungicidal effectiveness. Free silver cations have a potent antimicrobial effect which destroys microorganisms immediately by blocking the cellular respiration and disrupting the function of microbial cell membranes. They also bind and denature the bacterial DNA and RNA, thus inhibiting cell replication. It is non-cytotoxic, non-irritating and non-staining. Such an environment facilitates and enhances wound healing.

1.1 Wagner – Meggits Classification Of Diabetic Foot Lesions: ⁵

Grade 0 : At risk foot, no obvious ulcer but thick callus, prominent metatarsal heads, claw toes or any bony abnormality.

Grade I : Superficial ulcer not clinically infected.

Grade II : Deeper ulcer often infected but no bone involvement.

Grade III : Deep ulcer, abscess formation or bony involvement.

Grade IV : Localized Gangrene.

Grade V : Gangrene of the whole foot.

II. Aims And Objectives

The aim of study is to evaluate the effectiveness of nano crystalline silver over conventional dressings in the management of diabetic foot ulcer. The objectives of the current study are to compare the following between nanosilver crystalline dressings and conventional dressings: 1. Average duration of hospital stay, 2. Percentage reduction in ulcer size, 3. Number of dressings required.

III. Materials And Methods

This study is based on a prospective study of 54 cases admitted and treated (from Sept 2015 to Sept 2017) in Siddhartha Medical College / Government General Hospital, Vijayawada.

3.1 Inclusion Criteria

1. Diabetic patients in the age group of 30-75 years admitted in general surgery ward with complaints of diabetic foot ulcer.
2. Wagner's Grade 1 and 2 Lesions with ulcer size less than 7 cms. in its largest dimension.

3.2 Exclusion Criteria

1. Wagner's 3, 4 and 5 lesions and patients with arterial, venous and malignant ulcers were not included in the study.
2. Other clinically significant medical conditions that would impair wound healing like renal, hepatic, hematological, neurological, and immunological diseases.

IV. Methodology

The age, sex and other demographic details of patients, mode of onset, mode of presentation were noted. Detailed history of the current illness was noted and previous history of wounds, gangrene or ulcers were noted. Wagner's classification was applied and Patients with Grade 1 and 2 lesions were selected for the study. Any associated arterial or venous disorders associated with diabetes are noted. Patients were evaluated with General physical and local examination and systemic examination based on history and clinical findings. All necessary investigations were performed. Patients with Grade I and Grade II lesions (n = 54) were randomly sorted into 2 groups and a comparative study was done between conventional and Nano silver dressings in following aspects: 1. Average duration of hospital stay, 2. Percentage reduction of ulcer size, 3.No. of dressings required. For Conventional Dressing: If ulcer contained slough, patients underwent debridement to have clean ulcer base. Following debridement, 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 was applied and the wound closed with gauze pad and roller bandage. Dressings are changed according to the 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 Planometry. Number of dressings required for each group and number of days of hospital stay were recorded. Patients are re-evaluated on the outpatient basis for 2 months.

V. Results And Observations

In this study, the age incidence is found to be ranging from 30 – 75 years. Maximum number of patients are in the range of 51 – 60 years (37%). The Male to Female ratio is 3 : 2. Most of the cases presented following some kind of trauma (80%). However, 20% of the patients presented spontaneously without any history of trauma. 68% were found to have peripheral neuropathy.

Table 1: Average Duration of Hospital stay in Nanosilver and Conventional dressings

Period Of Stay (In Weeks)	Nanosilver Dressings		Conventional Dressings	
	No. Of Patients	%	No. Of Patients	%
1 To 2	6	22	0	0
2 To 3	9	33	2	7
3 To 4	11	41	5	18
4 To 5	1	4	8	30
> 5	0	0	12	45
Total	27	100	27	100

Table 2: Mean and SD of Period of Hospital Stay in Nanosilver and Conventional dressings

	N	Mean (in weeks)	Mean (in days)	SD	T Value	P value
Nano Silver Dressings	27	2.759	19.313	6.013	7.3313	<0.0001
Conventional Dressings	27	4.833	33.831	8.351		

Table 3: Comparison of % Reduction of Ulcer size between Nanosilver and conventional dressings

% Reduction Of Ulcer Size	Nanosilver Dressings		Conventional Dressings	
	No. Of Patients	%	No. Of Patients	%
61 - 70 %	0	0	1	4
71 - 80 %	0	0	4	15
81 - 90 %	7	26	15	55
91 - 99 %	20	74	7	26
Total	27	100	27	100

Table 4: Mean and SD of % Reduction of Ulcer size in Nanosilver and Conventional dressings

% Reduction of Ulcer	N	Mean	SD	T Value	P value
Nano Silver Dressings	27	92.41	4.47	4.1538	<0.0001
Conventional Dressings	27	85.37	7.59		

Table 5: Number of dressings required in Nanosilver and conventional dressings

No. Of Dressings	Nanosilver Dressings		Conventional Dressings	
	No. Of Patients	%	No. Of Patients	%
1-5	1	4	0	0
6-10	9	33	0	0
11-15	12	45	1	4
16-20	5	18	11	41
21-25	0	0	13	48
26-30	0	0	2	7
Total	27	100	27	100

Table 6: Mean and SD of Number of dressings required in Nano silver and Conventional dressings

No. of Dressings required	N	Mean	SD	T value	P value
Nano Silver Dressings	27	11.389	4.003	8.9006	<0.0001
Conventional Dressings	27	20.463	3.469		

VI. Discussion

Foot disease is a common complication in diabetes that can have tragic consequences. A high proportion of foot complications in diabetes are due to factors such as diabetic peripheral neuropathy, angiopathy, hyperglycemia and infection working alone or together. Wagner’s classification of diabetic foot provides an objective grading for elucidation of association and comparison of risk factors including patient’s awareness for the prevention of diabetic foot. In the present study, comparative study was done between conventional and nanosilver dressings in patients with Wagner’s grade 1 and 2 lesions which yielded following results

6.1 Duration of Hospital Stay

In the present study, duration of hospital stay in conventional dressing group is 33.8 ± 8.3 days, whereas in the nanosilver dressings group is 19.3 ± 6 days. ($p < 0.0001$). This is in accordance with the results of study by Ramanaiah et al⁶ and Charne N Miller at al.⁷

Table 7: Comparison of duration of Hospital Stay among various studies

	Present Study	Ramanaiah et al. ⁶
Conventional dressings	33.8	36.19
Nano silver dressings	19.3	20.54

In a study conducted by Charne N Miller at al⁷, the mean wound healing rates were similar for the silver and iodine groups with silver recording a marginally higher healing rate (average 52.10; SD 51.89) compared with iodine (average 51.69; SD 52.46).

6.2 Percentage Reduction of Ulcer

In the present study, % reduction of ulcer with nanosilver gel dressings is 92.41 % and with conventional dressings is 85.37 %, which is significant. ($p < 0.0001$).

Table 8: Comparison of % Reduction of Ulcer among various studies

	Present Study	Ramanaiah et al. ⁶
Conventional dressings	85.37	84.69
Nano silver dressings	92.41	94.81

In both the studies, it can be seen that silver dressings were more effective in comparison with the routine conventional dressings in healing the diabetic ulcers. In the study by Charne N Miller et al⁷, a comparison of the number of wounds that healed within each treatment group was explored for the wound duration and wound size segmentations. In similar findings, there was no difference between the treatment groups in the number of wounds healed overall for young [$w_2(1) 50.07, p > 0.05$] and old wounds [$w_2(1) 50.17, p > 0.05$] as well as for small [$w_2(1) 50.10, p > 0.05$] and big wounds [$w_2(1) 50.02, p > 0.05$]. In our study, Percentage Reduction of Ulcer is more than that of the study conducted by Charne N Miller et al.⁷

6.3 Number of Dressings

In our study, number of dressings required per patient is significantly less in nanosilver gel dressings group.

Table 9: Comparison of number of dressings among various studies

	Present Study	Ramanaiah et al. ⁶
Conventional dressings	20.463	17.54
Nanosilver dressings	7.389	10.92

In the study by Charne N Miller et al⁷, it was concluded by the results that the time taken and number of dressings taken for healing of ulcers in both cases with silver and betadine were similar. In another RCT conducted by Munter KC, Beele H⁸, the number of dressings for chronic wounds with silver dressings were on an average 18.

VII. Conclusion

1. In the present study, diabetic foot is more common in the age group of 51 – 60 years. Male individuals are more prone as they are usually working outdoor and are exposed to trauma.
2. Diabetic foot is more prevalent in rural population than urban due to their habit of barefoot walking.
3. Nano silver dressings in the treatment of diabetic foot ulcers are found to be safe, effective, promoter of wound healing, promotes epithelization, accelerates healing, eliminates anaerobes and breaks microbial synergy more effectively than conventional dressing. Hence Nano silver has proven to be more effective in the management of diabetic foot ulcers.

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