DOI: 10.7860/JCDR/2018/36691.11590

Original Article

Surgery Section

Comparative Study of Nanocrystalline Silver Ion Dressings with Normal Saline Dressings in Diabetic Foot Ulcers

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ABSTRACT

Introduction: Diabetic foot is a broad spectrum term which includes infection, ulceration and foot gangrene. Proper assessment of wound along with an aggressive multidisciplinary approach can reduce the risk of limb amputation. Wound dressings play an important role in diabetic foot care management. Nanocrystalline silver ion dressing is a newer modality that has been in consideration for the treatment of diabetic wounds.

Aim: To analyse the effect of nanocrystalline silver ion dressings and its comparison with standard normal saline dressings in diabetic foot ulcers.

Materials and Methods: This was a prospective study conducted in the Department of Surgery, Dayanand Medical College and Hospital, Ludhiana from January 2016 to June 2017. A total of 30 diabetic patients were included in the study and were equally divided into – Study group and Control group randomly. The study group received nanocrystalline silver ion dressings while the controls received daily dressings with normal saline soaked gauges. Data regarding presence of wound discharge, type of discharge, granulation tissue, changes in the size of wound and presence of slough was recorded and analysed (Chi-square tests).

Results: Study group showed better outcomes with 10 Patients (66.7%) being complete responders as compared to control group where 5 patients (33.3%) were complete responders. The wound discharge shifted from purulent to serous, faster in the study group. Granulation tissue formation and slough assessment was significantly better in study group.

Conclusion: Nanocrystalline silver ion dressings is a cost effective option in diabetic foot ulcer management. It decreases the period of hospitalization and reduces the burden on the health care system.

Keywords: Diabetes, Dressings, Foot, Silver, Wound

INTRODUCTION

The prevalence of diabetes is increasing rapidly with more than 62 million cases in India [1,2]. Long-term effects of diabetes include retinopathy, nephropathy and neuropathy. Diabetic foot is a blanket term for foot disorders such as infection, ulceration or destruction of deep tissues due to peripheral neuropathy and ischemia from peripheral vascular disease [3]. The diabetic foot ulcers take time to heal and require great care. Offloading and debridement of the wound expedites the healing process, however in wounds of advanced grade and stage vascular repair or amputation might be required. At least 40% of these amputations can be prevented with a team approach to wound care [4]. The selection of wound dressings plays a pivotal role in diabetic wound care management. An ideal dressing should be cheap, easy to use, non adherent, non allergic, maintain a moist wound environment, absorb excessive exudates, allow gaseous exchange, control wound odour, provide thermal insulation and mechanical protection, prevent wound contamination and lower the risk of infections [5]. Numerous dressings are available like Saline, hydrogels, hydrocolloid, foam, alginate, Paraffin (Tulle), Polyurethane, silver impregnated dressings. Saline dressings are inexpensive and provide an atraumatic moist environment but the maintenance of the moist environment is a problem with these dressings. Hydrogel dressings provide adequate hydration and analgesic effect for dry wounds with necrotic eschar [6,7]. Hydrocolloid dressings provide more consistent moisture retention, absorb low to moderate level of exudates and retain growth factors which promote granulation [6,7]. Foam and alginate dressings are highly absorbent and can aid in decreasing the risk for maceration in wounds with heavy exudates [6,7]. Paraffin dressings offer the advantage of low adherence with lesser trauma during dressing removal [7]. Polyurethane dressings are transparent and enable proper wound monitoring [7]. Hyperbaric oxygen therapy, vaccum assisted devices and culture skin substitutes are other wound therapies that have been advocated [6,7]. Silver dressings using silver nitrate or silver sulfadiazine have the limitation of rapid inactivation of silver by the wound fluid, which is compensated by frequent replacement but it results in excess of silver being delivered to the wound.

Nanocrystalline silver ion dressing is an effective antimicrobial barrier composed of an absorbent inner core that maintains a moist environment optimal for wound healing and outer layers of silver coated polyethylene nets which prevent wound contamination and exhibit bactericidal effect [8]. Waterproof top film with visible strike through indicates when dressing change is required. To achieve a broad spectrum bactericidal effect, silver ions concentration must be atleast 30-40 mg/l. Nanocrystalline silver ion dressings provides concentration of silver at 70-100 mg/l which is bactericidal and kills over 150 types of pathogens. It releases as much as 30 times silver ions which allows dressing changes to be reduced from once or twice daily to every second or third day [9]. A continuous equilibrium of aqueous silver is maintained for over 48 hours and silver is released at good concentration levels even when water volume is doubled at 24 hours. Nanocrystalline silver ion dressings have been in use for burns and chronic wounds [8,10-13], but the literature on their use in diabetic wounds is limited.

So, the present study was conducted to study the effect of nanocrystalline silver ion dressings and its comparison with standard normal saline dressings in diabetic foot ulcers.

MATERIALS AND METHODS

This was a prospective observational study conducted in the Department of Surgery, Dayanand Medical College and Hospital, Ludhiana, from January 2016 to June 2017 after obtaining approval

from the institutional ethics committee (ECR/715/Inst/PB/2015). All diabetic foot ulcer patients aged between 18-75 years and diagnosed with Diabetes mellitus according to criteria laid down by the American Diabetes Association Criteria [14] were included in the study. While the patients with age <18 years or >75 years, having septicemia, osteomyelitis, triple vessel disease, wounds resulting from arterial or venous insufficiency and patients on corticosteroids, immunosuppressive drugs or chemotherapy were excluded from the study.

All diabetic foot ulcer patients attending the surgery clinic during the study period, fulfilling the above mentioned criteria and who consented to be a part of the study were included. A total of 30 patients attending the clinic agreed to be a part of the study. These were equally divided into two groups (15 each) -Group A the Study group and Group B the Control group. Simple randomization was used and patients were alternately assigned to these groups i.e., the first patient assigned to group A and the second one to group B. Both the groups underwent initial wound debridement to remove necrotic tissue. However, wounds in Study group were treated with nanocrystalline silver ion dressings which were changed every 2-3 days while in the control group Normal saline soaked gauges were used which were changed daily. Ulcers were treated until the wound got closed spontaneously or the wound showed healthy granulation and was in a position to be grafted or secondarily sutured or until completion of the 56 days (8 weeks) of assessment whichever was earlier. Each patient received supportive and conventional care of the wound throughout the study. Blood sugar was controlled by insulin and oral hypoglycaemics and strict euglycemia was planned. All patients were administered broad spectrum systemic antibiotics. Wounds were assessed for:

a) Presence of wound discharge
b) Type of wound discharge (purulent/serous)
c) Granulation tissue
d) Changes in the size of wound (largest transverse diameter and largest vertical diameter also including the depth)
e) Presence of slough (percentage of total surface area).

Depending on the findings at the end of the study period the patients were categorized into the undermentioned categories [15].

1. Complete Responders: Complete healing of lower limb ulcers
2. Partial Responders: A 50% or greater reduction in the product of the two longest perpendicular diameters from baseline.
3. Non-complete responders: Less than 50% reduction in the product of the two longest perpendicular diameters from baseline.
4. Non-responders: No reduction or increase in ulcer area over base line.

Age Group	Study	Control	Total	Chi square value	p- value
31-40	2 (13.3%)	1(6.7%)	3	5.905	0.116
41-50	6 (40%)	1(6.7%)	7		
51-60	3 (20%)	7(46.7%)	10		
> 60	4 (26.7%)	6 (40%)	10		
Total	15 (100%)	15(100%)	30		
Sex				1.677	0.195
Female	5(33.3%)	2(13.3%)	7		
Male	10 (66.7%)	13(86.7%)	23		
Total	15 (100%)	15 (100%)	30		

[Table/Fig-1]: Age and sex distribution of patients in study and control group.

STATISTICAL ANALYSIS

The data so obtained were analysed by using Chi-square test. A p-value was calculated and a p-value < 0.05 was considered statistically significant. All statistical calculations were done using SPSS (Statistical Package for the Social Science) 21 version statistical program for Microsoft Windows.

RESULTS

The mean age of study group was 54.47 years, whereas in control group the mean age was 59.93 years. Age and sex distribution was comparable in both groups and statistically non significant (p>0.05) [Table/Fig-1].

The Mean Fasting Blood Sugar (FBS) in study group was 280.40 mg/dl and Mean FBS in control Group was 296.27 mg/dl. Mean Initial ulcer size in study group was 50.67 cm square and in control group was 54.93 cm square. Both Mean FBS and Mean Ulcer size were comparable in both groups and were statistically non significant.

Initially it was observed that all the patients in study and control group had discharge from the wound. [Table/Fig-2] compares the wound discharge in both the groups at two and eight weeks and the results were statistically significant (p<0.05).

According to type of wound discharge, it was observed that initially purulent discharge was present in both the groups. There was gradual shift from purulent to serous discharge in both the groups with rate of conversion being faster in study group; at the end of 8 weeks in study group there was one patient with serous discharge and 1 patient with purulent discharge whereas there were 4 patients with serous discharge and three patients with purulent discharge in control group.

The granulation tissue and slough assessment for both the groups shows early appearance of granulation tissue (at two weeks) in the study group (p<0.05 at two weeks) [Table/Fig-3] and a rapid decrease in slough [Table/Fig-4] in the study group.

Wound Discharge	Initial		2 weeks		chi-square value	p-value	8 weeks		chi -square value	p- value
	Study	Control	Study	Control			Study	Control		
Present	15	15	8	10	0.556	0.001	2	7	3.968	0.046
Absent	0	0	7	5			13	8		
Total	15	15	15	15			15	15		
	30		30				30			

[Table/Fig-2]: Presence of wound discharge in study and control group.

Granulation tissue	Initial		2 weeks		chi square value	p- value	8 weeks		chi square value	p- value
	Study	Control	Study	Control			Study	Control		
Absent	15	15	2	8	5.4	0.020	1	3	1.154	0.283
Present	-	-	13	7			14	12		
Total	15	15	15	15			15	15		
	30		30				30			

[Table/Fig-3]: Granulation tissue in study and control group.

Slough Tissue	Initial		2 weeks		Chi square value	p- value	8 weeks		Chi square value	p- value
	Study	Control	Study	Control			Study	Control		
Absent	-		8	6			13	8		
Present	15	15	7	9	0.536	0.0002	2	7	3.968	0.046
Total	15	15	15	15			15	15		
	30		30				30			

[Table/Fig-4]: Presence of slough in study and control group.

Type of wound closure	Study group		Control group		To-tal	Chi square value	p-value
Not closed	2	13.3% %	8	53.3 %	10	8.933	0.063
Spontaneous	7	46.7 %	3	20 %	10		
Secondary Suture (SS)	1	6.7 %	3	20 %	4		
Split Thickness Skin Graft (STSG)	5	33.3 %	1	6.7 %	6		
Total	15	100 %	15	100 %	30		

[Table/Fig-5]: Type of wound closure.

Study Outcome	Study group		Control group		To-tal	Chi square value	p-value
Complete Responders (CR)	10	66.7%	5	33.3%	15	3.833	0.280
Non Complete Responders (NCR)	0	0	1	6.7%	1		
Non Responders (NR)	2	13.3%	4	26.7%	6		
Partial Responders (PR)	3	20%	5	33.3%	8		
Total	15	100%	15	100%	30		

[Table/Fig-6]: Remarks.

Mean Initial ulcer size in study group was 55.67 cm square and in control group was 54.93 cm square. At the end of 8 weeks the mean ulcer size in the study population was 9.23 cm square and 18.31 cm square in the control group. The type of wound closure and the clinical outcomes for both groups are detailed in [Table/Fig-5,6] respectively.

Non closure was observed in 2 patients in study group as compared to 8 in control group. Only 1 out of 2 patients in the study group underwent Below Knee Amputation where as in control Group with 3 out of 8 patients underwent Below Knee Amputation.

DISCUSSION

Diabetes has a wide spectrum of complications which can be attributed to persistent hyperglycaemia but, it is not the only one, as it cannot explain presence or absence of complications of diabetes, despite good glycaemic control. Long standing diabetes increases the risk of developing foot ulcers [15]. The chronic pain and disability impose a big threat to patient's quality of life along with the financial burden due to prolonged treatment. More than 70% required surgical intervention and in more than 40% there is a toe or foot amputation [16].

An aggressive approach to the wound management can save the limb in many cases. Patient education, good glycaemic control, offloading, debridement, infection control and adequate perfusion are mandatory in the management of diabetic foot ulcerations. Selection of an appropriate dressing with timely replacement can expedite the healing. Various modes of treatment and wound dressings are used but still treatment failure rate is very high and many patients still end up with limb amputations.

Nanotechnology using silver ions offers greater antimicrobial property. The smaller silver particles produced are lesser toxic to human tissue cells due to increased surface area to volume ratios [17,18]. The early disappearance of discharge and slough and the early appearance of granulation tissue point towards a quicker healing in diabetic foot ulcers in study groups using nanocrystalline silver as compared to conventional normal saline soaked dressings. The results drawn could be attributed to the potent and rapid antibacterial activity of nanocrystalline silver as shown by Wright J et al., Yin H et al., Voight D et al., [12,19,20].

The most common mode of wound closure in the study group was spontaneous closure, which was in concordance with Lee PY et al., [21]. The silver ions promote a faster wound contraction due to accelerated proliferation and differentiation of fibroblasts into myofibroblasts [21]. This was followed by Split Thickness Skin Graft. The failure rates were low in the study group as only in 2 patient wound did not closed and only 1 patient underwent below knee amputation. However failure rates were high in control group with wound not getting closed in 8 patients and 3 patients undergoing below knee amputation. It was observed that in study group 10 patients out of 15 (66.7%) were complete responders as compared to 5 (33.3%) patients in control group which was in concordance with the study of Wright JB et al., [22]. Sharma R et al., recorded a higher percentage of complete responders (84.6%) which could be attributed to the longer duration of treatment in their study (12 weeks), however they also supported the fact that nanocrstalline silver ions accelerate healing of wounds [23]. The percentage decrease in wound area after 8 weeks of dressing in the study and control group was 83.42% and 66.66% which was comparable to the results of Sharma et al., (85.63% and 68.63% respectively) [23].

LIMITATION

The study results shows that the nanocrytalline silver ion dressings have a role in promoting early healing of diabetic foot ulcers. But the sample size that we could incorporate for our study was small, so to confirm our results future studies in large cohorts are required.

CONCLUSION

Nanocrystalline dressings are being commonly used for burns and other chronic wounds and its use can be extended to Diabetic foot ulcers also. It is a cost effective option with better results as compared to the conventional saline dressings in diabetic foot ulcer management.

ACKNOWLEDGEMENTS

The authors especially thank all the medical and non medical staff of the department and hospital for their sincere work and cordial cooperation with this project.

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FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **Apr 07, 2018**
Date of Peer Review: **Apr 19, 2018**
Date of Acceptance: **May 11, 2018**
Date of Publishing: **Jun 01, 2018**