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RESEARCH ARTICLE

Effectiveness of Topical Silver Colloid Nanoparticle Dressing in Comparison with Conventional Dressing for Acute Diabetic Foot Ulcer

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ABSTRACT

Introduction and Aim: Diabetic foot ulcer (DFU) is a major complication in diabetics and is associated with a high risk of amputation, morbidity and mortality. Topical silver nanoparticle dressings are increasingly being utilized for treatment of acute DFU's. The aim of the study is to compare the effect of topical silver colloid nanoparticle dressing wound in comparison to conventional dressing in acute DFU's. **Materials and Methods:** This is Tertiary care Hospital based comparative prospective observational study of 9 years. Patients with Acute DFU's were split into two groups with 400 in each. Group A includes conventional(control) dressing, Group B includes silver colloid nanoparticle dressing. A standard format was used for collection of data regarding DFU's and other necessary parameters. **Results:** The ulcer area significantly decreased in the silver colloid nanoparticle group compared to the conventional saline group. By the end of 4 weeks, Ulcers measuring less than 10cm^2 had 100% and 68.4% ulcers healing in silver colloid nanoparticle and conventional group respectively, whereas in ulcers measuring more than 10cm^2 to 25cm^2 had healing at 4 weeks 67.5% and 45.34% respectively. Patients with more than 25cm^2 had a protracted course about 8-12 weeks in respective groups but healing was comparatively better in silver nanoparticle group. **Conclusion:** Silver based nanoparticle dressings had a faster rate of wound healing in superficial acute DFU's with Meggitt Wagner's grade I and II. Patients in our trial group who received ionic silver-based dressings reached the end point sooner and either had an ulcer that healed spontaneously with regular dressing or was ready for SSG. We do not recommend silver dressing for acute DFU's with larger surface area in view of toxicity of silver ion. The use of silver ion dressing should be case based according to severity and clinical application.

Keywords: Diabetic foot ulcer; Silver colloid nanoparticle dressing; Conventional dressing; Wound healing

INTRODUCTION

Diabetic foot ulcers are chronic, non-healing lesions. DFUs are frequently observed as a consequence of diabetes, especially in those with inadequate blood glucose control or chronic diabetes. The status of diabetic foot ulcers is complicated[1]. Acute and chronic foot ulcers are the two varieties[2]. There are numerous types of dressings, such as polyurethane, foam, paraffin, and hydrocolloid dressings. Hydrocolloids are composed of a gel-like substance that comprises hydroactive particles, like sodium carboxymethyl cellulose or gelatin, which absorb fluid from wounds and keep them moist. The purpose of foam dressings is to keep the area comfortable while absorbing fluids from the wound. Paraffin dressings, sometimes referred to as paraffin gauze dressings, are a kind of wound dressing made of paraffin wax-impregnated fine mesh gauze. The thin, flexible, clear film or foam used to make these dressings is made of polyurethane[3–6].

Even though silver has a very low potential for toxin formation and only rarely leads to microbial resistance, in vitro studies have demonstrated the effectiveness of Silver based dressings in battling pathogenic germs, so the use of silver colloid in diabetic and venous ulcers acts as a very effective tool in wound management. With increasing surface area to volume ratios accompanied by decreased toxicity to the tissues, the advent of nanotechnology has enabled the development of nanoparticles that has a huge role in accelerated wound healing[7–9]. Overall, the utilization of nanocrystalline silver ion dressings in the treatment of diabetic foot ulcers offers a cost-effective approach that not

only improves patient outcomes but also eases the burden on healthcare resources[10].

Assessing and contrasting silver colloidal nanoparticle dressings with traditional dressings for the treatment of DFUs was the goal of the study. One of the most surprisingly simple therapeutic approaches is the application of topical medication to treat cutaneous infections[11]. Diabetes, severe skin damage (burns), excessive or prolonged bleeding (trauma), or even surgical incisions can result in both acute and chronic wounds[2]. Certain antiseptics are good at lowering the amount of germs and halting the spread of infection, but they can damage fibroblasts and healthy, viable cells[12]. Using silver-releasing dressings in addition to debridement is advised and advantageous when treating wounds that are susceptible to infection[13]. The development of nanotechnology has made it possible to produce micro silver particles with high surface-to-volume ratios. They become less harmful to human cells and, more significantly, more effective against bacteria as a result[14]. Silver-based dressings have been demonstrated to be effective against pathogenic germs in vitro, despite their minimal potential for harm and low tendency to develop microbial resistance[15]. AgNPs' biological activity is dependent on a number of variables, including their size distribution, shape, composition, dissolving rate, and surface chemistry[16]. Nanoparticles' physicochemical characteristics improve the bioavailability of therapeutic drugs following systemic and local delivery[17,18]; on the other hand, they can influence biological distribution, cellular absorption, penetration of biological barriers, and the ensuing therapeutic effects[19].

MATERIALS AND METHODS

The study involved approximately 800 patients who had provided their consent to participate. It was a hospital based comparative prospective observational study conducted at the Department of General Surgery in A J Institute of Medical Sciences and Research Centre, Mangalore, Karnataka, India. The study was conducted for a period of 9 years and was approved by the Institution Ethic committee. Simple random sampling was employed for individuals in the study. Eight hundred patients were divided equally into two groups, group A and group B, with 400 patients in each group. The first 400 patients received conventional wound dressing as per standard practice, belonging to group A. The next 400 patients received silver colloid nanoparticle wound dressing, belonging to group B. Daily dressing was done, Mean area of ulcer was noted before commencing of the study and after appropriate surgical debridement as in the case need be. After 7,14,21 and 28 days of silver colloid nanoparticle dressing, areas of ulcers are taken in cm square measurements using calipers/scale, compared with conventional dressing ulcers. The purpose of this division was to compare the outcomes of the two different groups. The patients were monitored for six months to a year in order to evaluate the efficacy of the individual dressings. Data was gathered and examined to assess aspects like wound healing, infection prevention, and DFU management in general.

Patient Criteria

The study included all DFU's patients of age 18 years and above with an area of at least 2cm2.These ulcers fell under Meggitt Wagner grade I and II, indicating relatively superficial ulcers with no significant infection or tissue involvement. The ulcer had a minimal duration of 25 to 30 days, and patients who are compliant with diabetic medication were included in the study. Some patients were excluded from the trial based on certain criteria. The following were the exclusion criteria: 1) Individuals with foot ulcers brought on by comorbid disorders or other underlying problems including paraplegia varicose veins, 2) Patients with diseases or circumstances that can hinder the healing of wounds, such as vasculitis, cancer, immune system problems, corticosteroid treatment, connective tissue disease, chemotherapy, immunosuppressive drugs, radiation therapy, uncontrolled diabetes, or osteomyelitis, 3) Patients with a history of allergic reactions or hypersensitivity to the material under study, colloidal silver gel, 4) A patient who is known to be hypersensitive to colloidal silver gel, 5) Patients refusing to consent to the dressing.

Statistical Analysis

Chi-square test was employed in the statistical analysis of the data and to test the difference in rate(percentage) between two modalities. The software used for data analysis was SPSS to find descriptive statistics, mean+/-, standard deviation, frequency, percentage.

RESULTS

In the present study, approximately 800 eligible patients were enrolled (Table 1). The study participants were divided into two groups, Group A are Conventional (Control) group and Group B are Silver colloid nanoparticle group (Table 2). Mean age of participants in conventional

Group and silver colloid nanoparticle group was 57.79 +/-12 and 58.65+/-16 respectively. Study included all patients who aged 18 years and above had an acute diabetic foot ulcer with an area of at least $2cm^2$. Patients with Meggitt Wagner grade I and II, indicating relatively superficial ulcers with involvement of skin and subcutaneous tissues without involvement of tendon or bones (Table 3). 26% of the patients were on OHA,52% patients were on Insulin and 22% patients were on both OHA and Insulin. Regular dressing was done up to 4 weeks in both groups, All the patients in the silver colloid nanoparticle group, ulcers measuring less than $10cm^2$, were completely healed, at the end of 4 weeks, where as in case of conventional group, (75)30% of patients still have residual ulcer at end of 4 weeks, and regular dressing

was continued, ulcers which are measuring more than $2cm^2$, at end of 4 weeks almost (48)30% and (75)50% of patients still have residual ulcer in silver colloid nanoparticle group and conventional group respectively. Out of 30% of patients with residual ulcers in silver colloid nanoparticle group, (32)20% of the patients went for Split thickness skin grafting and wound was healed within 2 weeks and (16)10% of the patients were not willing for skin grafting hence continued regular dressing and wound healed in 3 to 4 weeks. Out of (75)50% of patients with residual ulcer in conventional group (30)20% patients underwent for split thickness skin grafting and ulcer was healed in 3 weeks and in remaining (45)30% of patients regular dressing was continued as they were not willing for SSG's.

Table 1: Percentage incidence of patients included in the study

Gender	Conventional group (A)	Silver colloid nanoparticle group (B)	Total
Male	260(60%)	284(71%)	544
Female	140(40%)	116(29%)	256
Total	400(100%)	400(100%)	800

Table 2: Age distribution of patients included in the study

Age group	Conventional group	Silver colloid group	Total
21-30	56	50	106
31-40	90	96	186
41-50	100	104	204
51-60	80	74	154
>6o	74	76	150
Total	400	400	800

Table 3: Percentage distribution of patients included in the study according to Wagner's classification*

Wagner's grade	Frequency	Percentage
I	304	38%
II	496	62%
Total	800	100%

Conventional Dressing

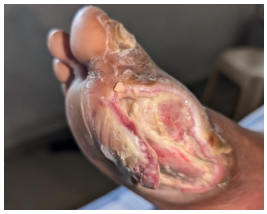

Fig. 1:

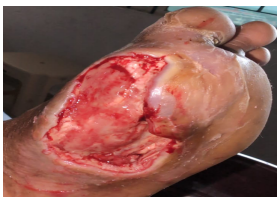

Fig. 2:

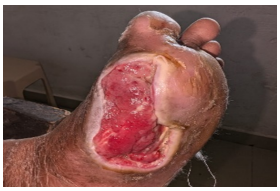

Fig. 3:

Silver Colloid Nanoparticle Dressing

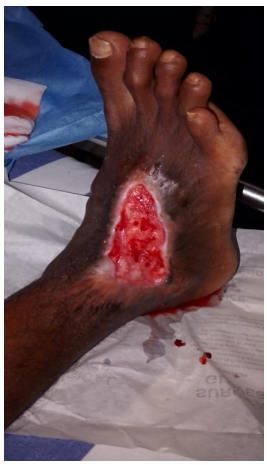

Fig. 4:

Table 4: Categorization of ulcers depending upon raw area involved

Serial number	Raw area of ulcer (cm^2)	Number of patients in conventional group	Number of patients in silver colloid nanoparticle group
1	<2.5	65(16,25%)	60(15%)
2	2.5 -7.5	110(27.5%)	96(22.5%)
3	7.5-10	55(13.75%)	84(21%)
4	10-15	63(15.75%)	60(15%)
5	15-25	60(15%)	46(11.5%)
6	>25	47(11.75%)	54(13.5)
Total		400(100%)	400100%)

Table 5: Percentage categorisation of study participant according to glycosylated haemoglobin (hba1c)

	Glycosylated haemoglobin (hba1c)	Number of patients in conventional group (400)	Number of patients in silver colloid group (400)
Well controlled	<7.0%	140(35%)	128(32%)
Moderately controlled	7-11%	132(33%)	152(38%)
Poorly controlled	>11%	128(32%)	120(30%)
Total number of patients		400(100%)	400(100%)

Table 6: Conventional group

Area of the raw (ulcer)	Number of cases at admission	Average size of ulcer in cm2	% of ulcer reduction on day 7	% of ulcer reduction on day 14	% of ulcer reduction on day 21	% of ulcer reduction on day 28	Total number (%) of patients remained not healed at the end of 1 month
<10 cm^2	250(62.5)	5.8+/-2.5 cm2	26(10.4%)	55(22%)	60(24%)	30(12%)	79(31.6%)
>10 cm^2	150(37.5)	19.21+/-2.6 cm2	14(9.33%)	17(11.33%)	23(15.33%)	14(9.33%)	82(54.66%)
Total number of patients in the study	400						

Table 7: Silver Colloid nanoparticle group

Area of the raw(ulcer)	Number of cases at admission	Average size of ulcer in cm^2	Ulcer on day 7	Ulcer on day 14	Ulcer on day 21	Ulcer on day 28	Total number (%) of ulcer remained unhealed at the end of 1 month
<10 cm^2	240(60%)	6.25+/-2.4 cm2	86(35.83%)	64(26.66%)	55(22.9%)	35(14.58%)	NIL
>10 cm^2	160(40%)	18.75+/-2.5cm2	22(13.75%)	25(15.62%)	39(24.37%)	22(13.75%)	52(32.5%)
Total number of patients in the study	400(100%)						

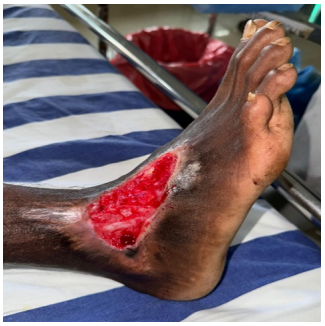

Fig. 5:

DISCUSSION

Acute or chronic wounds can be caused by surgical procedures, diabetes, burns, trauma, chronic pressure, or venous or arterial insufficiency. Additionally, antiseptic treatments may reduce the number of bacteria and stop an infection from spreading, but they may also be harmful to fibroblasts and other living cells. The effectiveness of silver-based dressings against pathogenic bacteria has been shown in vitro, despite the fact that silver has a very low potential for toxicity and rarely causes microbial resistance. For wounds that are susceptible to infection, it is therefore advantageous to employ silver-releasing dressings in conjunction with debridement.

According to reports, cytokines play a significant role in wound healing and scar reduction by modulating fibrinogen and reducing inflammation. Colloidal (nano) silver particles are also said to improve wound healing and lessen the appearance of scars. By safely eliminating the inflammatory cells, nano silver effectively reduces inflammation by inducing apoptosis particularly in the dermal inflammatory cells.

The Sharma et al. study showed a significant decrease in ulcers in the colloidal silver dressing group, with a 66% decrease on day seven (compared to the initial area of 100%). By contrast, on day seven, the group that received traditional dressings showed an 85.18% decrease. Additionally, although the conventional dressing group showed a reduction to 89.69% on day 14, the colloidal silver dressing group showed a significant reduction to 48% of the initial ulcer area. When using silver colloid dressing instead of traditional diabetic foot dressing, the wound's size shrank more quickly[9].

Gupta et al. claim that dressings containing nanocrystalline silver ions have become a cost-effective solution for diabetic foot ulcers. Tiny silver particles in these dressings cause the release of silver ions, which have antibacterial qualities. Nanocrystalline silver dressings can shorten hospital stays for diabetic foot ulcer patients, which will lessen the strain on the healthcare system. Diabetes foot ulcers can heal more quickly and provide better results for patients when infections are prevented and treated with the antimicrobial qualities of nanocrystalline silver ions. In general, using nanocrystalline silver ion dressings to treat diabetic foot ulcers is an economical method that not only enhances patient outcomes but also lessens the strain on medical resources[10].

CONCLUSSION

Nanoparticle based silver colloid dressings has a faster rate of wound healing in superficial acute Diabetic foot ulcers with Meggitt Wagner's grade I and II. Patients in our trial group who received ionic silver-based dressings reached the end point earlier and either had an ulcer that had spontaneously closed or was ready for a split-thickness skin graft at 4 weeks. Patients in the silver colloidal nanoparticle group required significantly fewer dressings, early recovery, less financial burden and lesser dressings as compared to patients in the conventional dressing group. Caution has to be exercised in patients with larger ulcers in view of toxicity and prolonged usage of any silver impregnated dressings in Diabetic foot ulcers.

Conflict of Interest

There is no conflict of interest.

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