A NON-RANDOMISED CONTROLLED TRIAL STUDY OF THE EFFECT OF NANO SILVER PARTICLES AND CONVENTIONAL DRESSING ON THE HEALING OF CHRONIC ULCER

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ABSTRACT

BACKGROUND

Chronic ulcers are defined as those that show no tendency to heal after 1 month of appropriate treatment. They are a challenge to health care professionals and consume a great deal of healthcare resources around the globe. This article compares the effect of nano silver particles and conventional dressing with hydrogen peroxide, povidone-iodine and eusol on the healing of chronic ulcer.

The aim of this study was to compare the effect of Nano silver particles and conventional dressing on the healing of chronic ulcer prospectively.

MATERIALS AND METHODS

A non-randomised controlled trial study on 50 patients with chronic ulcer was conducted from Dec 2012 to Oct 2014 in the Department of General Surgery, JLN Medical College and associated group of hospitals, Ajmer. Chronic ulcer was defined as all wounds showing no/ minimal signs of healing over 4 weeks. Patients were divided into 2 groups, study and control group according to convenience. Control group was treated with conventional dressing using hydrogen peroxide, povidone-iodine and eusol. In the study group, the ulcer was treated by debridement and application of Nano silver particles on the ulcer. The healing response was classified as complete (100% healing), near complete (50% or more healing), partial (showing less than 50%) and no healing. Healing response was studied at 2, 6 and 10 weeks in both the groups.

RESULTS

The male-to-female ratio was 4: 1 in both the groups and the age distribution was between 21 - 70 years with 48% in the 31 - 50 years' age bracket in both the groups. In 66% cases, the chronicity was of 4 - 10 weeks with 70% ulcers falling in the foot and leg region in both the groups. In the study group where silver Nano particles were used in dressing a significant role in treatment response as complete healing was observed, as P value was < 0.05 at all stages of healing, i.e. at 2, 6 and 10 weeks. It also showed that as time progressed the response of Nano silver particles in healing increased with a P value at 2 weeks of .004 to a P value at 10 weeks of 0.0003. This shows the efficacy of Nano silver particles in the healing of ulcer.

CONCLUSION

Considering the observations of our study, we conclude that Nano silver particle is a useful topical agent for local application on all ulcers except malignant ulcers. The treatment with Nano silver as compared to conventional dressing is cost effective and helps reduce the morbidity related to amputation in diabetes and peripheral vascular disease.

KEYWORDS

Chronic Ulcer, Nano Silver Particles, Conventional Dressing.

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BACKGROUND

Ulcer is defined as break in the continuity of the covering epithelium, skin or mucous membrane. Chronic ulcers are those that fail to progress through an orderly and timely sequence of repair.¹ Chronic ulcer due to various causes is an important cause of morbidity and despite all advances made in the field of medicine the situation still persists.

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Delayed wound healing is generally a result of compromised wound physiology and typically occurs with venous stasis, diabetes, prolonged local pressure, malnourishment and peripheral vascular disease. Many drugs and methods for protecting the ulcer from infection, nutrient loss, relieving pain, hastening the healing of ulcer are available. Nano silver particles being one of them. Silver ions and its salts are well known for their potent antimicrobial agent. Nano silver has large ratio of surface, which dramatically increases the potential for silver ions to be accessed anywhere in body where larger silver particles cannot. Nano silver has potent antimicrobial, antifungal and antiviral activity.

Aims and Objectives

To compare the effect of Nano silver particles and conventional dressing on the healing of chronic ulcer prospectively at 2, 6 and 10 weeks.

MATERIALS AND METHODS**Study Design**

Non-Randomised Controlled Trial study.

Study Period

Dec. 2012 - Oct. 2014.

Sampling and Sample Size

All patients who attended the surgery OPD during the period from Dec. 2012 to Oct. 2014 with chronic ulcer defined as all wounds showing minimal or no healing over 4 weeks and who fulfilled the inclusion criteria were included in the study.

Both males and females above 20 years were included in the study. A total of 40 males and 10 females were included in the study. All patients with malignant ulcers, patients receiving corticosteroids, chemotherapy or radiotherapy were excluded from the study. Patients were divided into 2 groups- study and control group according to convenience and they matched for age, sex, duration, site and type of ulcer. The sample size 50 estimation was also done at conveniences. Control group was treated with conventional dressing using hydrogen peroxide, povidone-iodine and eusol. In the Study group, the ulcer was treated by debridement and application of Nano silver particles on the ulcer. The healing response classified as complete (100% healing), near complete (50% or more healing), partial (showing less than 50%) and no healing (by measuring area of ulcer). The healing response was studied at 1, 2, 6 and 10 weeks in both the groups.

Statistical Analysis

The healing response was analysed in Epi Info and chi-square test was done.

Complete healing by Nano silver particle is statistically significant, as P value is < 0.05 at all stages of study.

RESULTS

In the present comparative clinical study of 50 cases of chronic non-healing ulcer at JLN Medical College, Ajmer, who underwent treatment by nano silver particles or conventional dressing. Following results were obtained.

Sex	Study Group		Control Group	
	Nano Silver Particles		Conventional Dressing	
	Patients No's	Patients %	Patients No's	Patients %
Male	20	80	20	80
Female	05	20	05	20
Total	25	100	25	100

Table 1. Sex Distribution in Study and Control Group

Table 1 shows equal distribution of numbers of male and female in both the groups.

Age Groups (Years)	Study Group		Control Group	
	Nano Silver Particles		Conventional Dressing	
	No. of Patients	% Patients	No. of Patients	% Patients
21-30	05	20%	05	20%
31-40	06	24%	07	28%

41-50	07	28%	07	28%
51-60	04	16%	03	12%
61-70	03	12%	03	12%
Total	25	100%	25	100%

Table 2. Shows Age Distribution of Patients in both the Groups

Table 2 shows that maximum patients were in the age group of 31 - 60 years.

Duration Weeks	Study Group	Control Group
4-5	10	10
6-10	06	07
11-15	04	03
16-20	02	03
21-25	02	01
25-30	01	01
Total	25	25

Table 3. Duration of Ulcers

Table 3 shows that near equal distribution of duration of ulcer in both groups with 66% ulcers being in the duration of 4 - 10 weeks.

Site of Ulcer	Study Group	Control Group
Abdominal wall	01	01
Back	02	01
Chest	01	01
Foot	10	10
Fore arm	01	02
Gluteal region	01	02
Leg	08	07
Thigh	01	01
Total	25	25

Table 4. Site of Ulcers

Table 4 shows near equal distribution of site of ulcers in both groups. Overall 40% patients had ulcer foot, 30% had leg ulcers, 6% had ulcer back and 24% ulcers were present on other sites.

Type of Ulcer	Study Group	Control Group
Arterial	04	04
Diabetic	07	06
Infected	04	04
Venous	03	03
Postoperative	01	02
Traumatic	06	06
Total	25	25

Table 5. Type of Ulcers

Table 5 shows that the present study included different types of ulcers with 26% being diabetic ulcers with near equal distribution in both groups.

Healing Response	Nano Particles Dressing (Study Group)			Conventional Dressing (Control Group)			2 nd week		6 th week		10 th week	
	2 nd Week	6 th week	10 th week	2 nd week	6 th week	10 th week						
	No.	No.	No.	No.	No.	No.	Chi Square	P Value	Chi Square	P Value	Chi Square	P Value
Complete healing	8	15	20	1	6	8	6.64	0.004	6.65	0.0049	11.69	0.0003
Near complete	10	7	3	5	9	10	2.381	0.061	0.4386	0.2539	5.094	0.012
Partial healing	5	2	2	7	5	3	0.4386	0.2539	0	0.5	0.222	0.318
No healing	2	1	0	12	5	4	9.92	0.0008	3.03	0.04	4.384	0.018
Total	25	25	25	25	25	25						

Table 6. Healing Response

Table 6 shows that in the study group where silver Nano particles were used in dressing, a significant role in treatment response as complete healing was observed, as P value was < 0.05 at all stages of healing i.e. at 2, 6 and 10 weeks. It also shows that as time progresses the response of Nano silver particles increases (P value at 2 weeks is .004 and at 10 weeks it is 0.0003; this shows the efficacy of Nano silver particles in the healing of ulcer).

	Nano Silver Dressing (Study Group)		Conventional Dressing (Control Group)	
	No. of Patients	% of Patients	No. of Patients	% of Patients
Hypergranulation	0	0	2	8
Burning sensation	0	0	1	4
Hyperpigmentation	0	0	2	8
Itching	0	0	2	8
No side effects	25	100	18	72

Table 7. Side Effects

Table 7 showed no side effects in the silver Nano group. Hypergranulation in 8% patients, burning sensation in 4% patients, hyperpigmentation in 8% and itching in 8% patients was noted in the control group.

DISCUSSION

Nano silver shows potent antibacterial properties and is immensely useful in the medical field (Guzman et al 2012).² Studies have suggested that Nano silver can inhibit the gamma interferon and alpha tumour necrosis factor, which are involved in inflammation (Shin et al, 2007).³ The antimicrobial property of Nano silver shows enormous potential to be used as disinfectants (Brady et al, 2003).⁴ Silver dressings maintain moisture in wound environment and help in facilitation of autolytic debridement.⁵

In our study, we included ulcer of more than 4 weeks duration. In a similar study by VK Shukla et al⁶ (2004) done with placental extract in 70 patients, duration was more than 30 days. The chronicity of ulcer was considered after 30 days in our study. There were 40% patients of ulcer foot and 30% of leg ulcer in our study. In contrast in the study of VK Shukla,⁶ there were predominantly ulcer foot 61% and leg ulcers 19%. Ulcers of different aetiologies were selected in our study; 26% were diabetic ulcers in our study. In contrast in study by VK Shukla et al,⁶ maximum 34% were leprotic. After 1st week there was complete healing in 5 cases (20%), partial healing in 12 (20%) cases in Nano silver, whereas no ulcer showed complete healing in control group. In a study by Wright et al 2003⁷ on diabetic ulcers there were 17.75% patients in study groups showing complete healing, 48%

showing partial healing and 10% showing no healing after 1st week. In our study after 2 weeks treatment with Nano silver 32% showed complete healing, 40% near complete healing and 20% partial healing. There were 48% patients showing no healing response in the control group. In a similar study done by Lansdown⁸ in 2004 after 2 weeks treatment with Nano silver particles 30% patients showed complete healing, 42% showed near complete healing. After 10 weeks there was 80% complete healing, 12% near complete healing, 8% partial healing and 0% showed no healing response in study group as compared to 32% with signs of complete healing, 40% near complete healing, 12% partial healing and 16% showed no sign of healing in control group. There was a vast statistical difference between the 2 groups, as P value was < 0.05 at all stages of healing i.e. at 2, 6 and 10 weeks in the study group. In a similar study by Sibald et al⁹ in a study of 15 cases of venous ulcers with silver Nano particles, 76% showed complete healing, 14% showed near complete healing, 6% showed partial healing and 4% showed no healing at all after 10 weeks.

Limitation of the Study

Due to short duration of study, convenience sampling technique was followed. Thus, sampling size was also calculated by convenience. The results of the study cannot be generalised due to the potential bias resulting from the sampling technique and sample size estimation.

CONCLUSION

Considering the observations of our study, we conclude that Nano silver particles is a useful topical agent for local application on all ulcers except malignant ulcers. Complete healing by Nano silver particle is statistically significant, as P value is < 0.05 at all stages of study. Nano silver particle enhances the healing process as evident by early appearance of red granulation tissue, smaller lag period in healing and early completion of healing of ulcers without any adverse effect. The treatment with Nano silver as compared to conventional dressing is cost effective and helps reduce the morbidity related to amputation in diabetes and peripheral vascular disease.

REFERENCES

- [1] Nwomeh BC, Yager DR, Cohen IK. Physiology of the chronic wound. *Clin Plastic Surgery* 1998;25(3):341-56.
- [2] Guzman M, Dille J, Godet S. Synthesis and antibacterial activity of silver nanoparticles against gram-positive and gram-negative bacteria. *Nanomed* 2012;8(1):37-45.
- [3] Shin SH, Ye MK, Kim HS, et al. The effects of nanosilver on the proliferation and cytokine expression by peripheral blood mononuclear cells. *Int Immunopharmacol* 2007;7(13):1813-8.
- [4] Brady MJ, Lisay CM, Yurkovetskiy AV, et al. Persistent silver disinfectant for environmental control of pathogenic bacteria. *Am J Infect Control* 2003;31(4):208-14.
- [5] Woodward M. Silver dressings in wound healing: what is the evidence? *Primary Intention* 2005;13(4):53-60.
- [6] Shukla VK, Rasheed MA, Kumar M, et al. A trial to determine the role of placental extract in the treatment of chronic non-healing wounds. *J Wound Care* 2004;13(5):177-9.
- [7] Wright JB, Lam K, Olson ME, et al. Is antimicrobial efficacy sufficient? A question concerning the benefits of new dressings. *Wounds: A Compendium of Clinical Research and Practice* 2003;15:133-14.
- [8] Landsdown ABG. A review of the use of silver in wound care: facts and fallacies. *Br J Nurs* 2004;13(Suppl 6):S6-S19.
- [9] Sibbald RG, Contreras-Ruiz J, Coutts P, et al. 140 Open label pilot study of prolonged release nanocrystalline silver dressing (Acticoat 7): reduction of bacterial burden treatment in the treatment of chronic venous leg ulcers. *Wound Repair Regen* 2005;13(2):A28-A48.