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"A COMPARATIVE STUDY OF AMORPHOUS HYDROGEL DRESSINGS WITH SILVER NANO PARTICLES VERSUS CONVENTIONAL DRESSING FOR TREATING DIABETIC FOOT ULCERS - A RANDOMIZED CONTROLLED TRIAL"

General Surgery

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ABSTRACT

The present study was aimed to find the effect of amorphous hydrogel dressings with silver nano particles versus conventional dressing on wound culture and slough in patients with diabetic foot ulcers. This two year randomized controlled trial was done in the Department of Surgery, J.J.M. Medical College, Davangere. A total of 60 patients with chronic diabetic foot ulcers from September 2015 to August 2017 were enrolled. Patients were divided into two groups of 30 each as group A (using hydrogel with silver nano particles) and group B (with povidone iodine).

KEYWORDS

Amorphous hydrogel dressings; Diabetic foot ulcer; Silver nano particles;

INTRODUCTION

With the advent of the twenty first century where advances in medical technology and literature has reached its pinnacle,where mankind has succeeded in deciphering the human genetic code, the issue of chronic wound management is still an enigmatic challenge.DIABETIC FOOT ULCERS is the most common cause of chronic wounds. Diabetic foot ulcers are the single biggest risk factor for nontraumatic foot amputations in persons with diabetes. The peculiar characteristics is the refusal of the diabetic foot ulcer to heal despite the best wound care management given. The false notion the wounds heal better if kept dry has given way to the newer concept of wound healing which allows chronic wounds to re-epithelialize much faster or develop granulation tissue much faster when treated with moist wound. Many techniques have been tried over the centuries to heal chronic leg ulcers.Although there exists no ideal wound dressing the management of chronic wounds especially diabetic foot ulcers has seen many new developments. The traditional moist dressings were initially supplemented with hydrocolloid dressings,gels,foams and other measures like hyperbaric oxygen, grwth factors, and various offloading therapies . Recent studies have shown that application of a subatmospheric pressure in a controlled manner to the wound site has got an important role in assisting wound healing. The present study was conducted to assess the efficacy of amorphous hydrogel dressings with silver nano particles versus conventional moist wound dressings can be used as a much better treatment option in the management of diabetic foot ulcer

METHODOLOGY

This two year randomized controlled trial was done in the Department of Surgery, J.J.M. Medical College, Davangere. A total of 60 patients with chronic diabetic foot ulcers from September 2015 to August 2017 were enrolled. Patients were divided into two groups of 30 each as group A (using hydrogel with silver nano particles) and group B (with povidone iodine).

Selection criteria

Inclusion

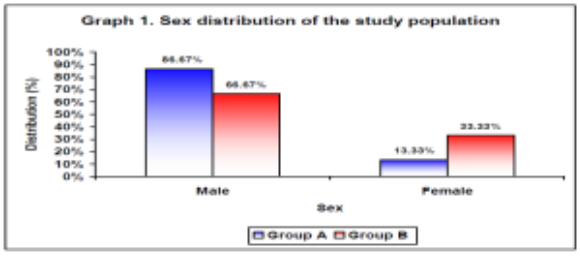
- Diabetic patients between the age group of 25 to 70 years.
- Patients having ulcers measuring more than one cms below ankle in dorsum of foot
- Patients with grade I and II ulcers based on Wegener"s classification.

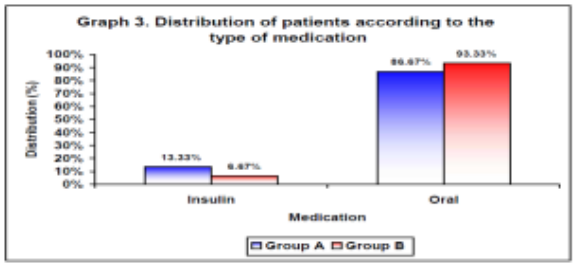
Exclusion

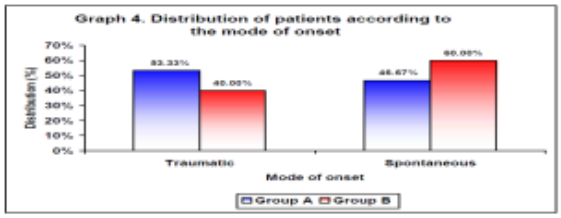
- Patients with grade III, IV and V ulcers of Wegener"s classification
- Patients with absent peripheral pulses, dorsal pedis artery, posterior tibial artery, anterior tibial artery.
- Patients who were not on regular follow-up.
- Patients not willing to participate in the study

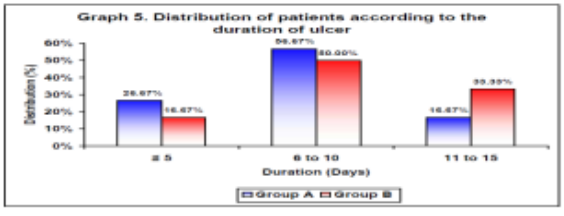
RESULTS

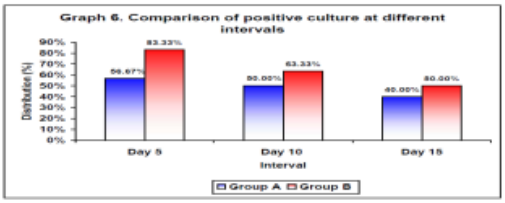
Most of the patients in group A (86.67%) and B (66.67%) were males (p=0.067). The mean age in group A was 60.23±9.27 years compared to 55.13±12.06 years in group B (p=0.072). The diabetic history, wound characteristics and culture in group A and B were comparable (p>0.050). On day five, maximum number of patients had negative wound culture in group A (43.33% vs 16.67%) compared to group B (p=0.024). The mean slough was comparable at all the intervals (p>0.050) in group A and B. Among the patients with group A, the mean reduction of Slough on day five (6.93±6.14% vs. 4.37±2.96%; p=0.045), dayten(15.22±7.40%vs9.10±7.00%;p=0.002)and day fifteen (21.57±8.71% vs. 15.90±8.11%; p=0.012) was significantly high compared to group B.

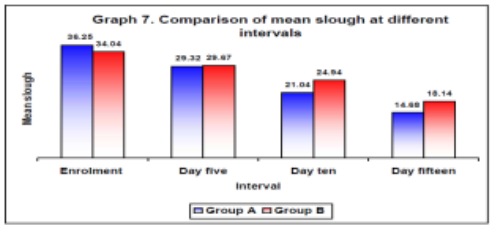


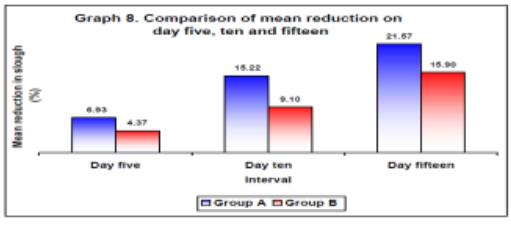












Diabetic foot ulcer on Fifteenth day by using silver nano particle

Diabetic foot ulcer on Fifteenth day by using silver nano particle

Diabetic foot ulcer on Fifteenth day by using conventional dressing

DISCUSSION:

Chronic wounds are injuries produced as a result of specific diseases such as diabetes. Healing of these wounds could take long time and there are chances of recurrence. For effective healing of wound, suitable material has to be used to cover the wound so as to prevent infection. To achieve the highest rate of healing and the best aesthetic repair of the wound, the design of a wound bandage, characteristics of the wound type, wound healing time, physical, mechanical, and chemical properties of the bandage are important aspects which must be taken into consideration.104

Historically, honey pastes, plant fibers, and animal fats were used as wound dressing materials. Nowadays, with new biopolymers and fabrication techniques, a wound dressing material is expected to have extraordinary properties which enhance the healing process of a wound.104

Amorphous hydrogel dressings consist of a crosslinked insoluble polymers (starch or carboxymethylcellulose) and water. They are designed to absorb wound exudate or rehydrate a wound depending on the wound moisture levels. Silver is a broad-spectrum antimicrobial agent which controls yeast, mould, and bacteria if provided in an appropriate proportion17 and has also anti-inflammatory properties.18 Silver NPs (Ag NPs) have unusual physical, chemical and biological properties.19-21

However nano-silver being a new generation of nanoproduct, data is lacking on effect of healing of chronic wound such as diabetic foot ulcers. This prompted us to find the efficacy of amorphous hydrogel dressings with silver nano particles versus conventional dressing for treating diabetic foot ulcers with special emphasis on wound culture and slough area.

This two year randomized controlled trial was done in the Department of Surgery, Bapuji and Chigateri General Hospitals attached to JJM Medical College, Davangere, from September 2015 to August 2017. A total of 60 patients who presented with diabetic foot ulcer measuring more than one cm. with slough, foul smelling discharge and minimal granulation tissue were studied. These patients were divided into two groups of 30 each to receive treatment with dressing and topical management using hydrogel with silver nano particles (Group A) and dressing and topical management using povidone iodine (Group B).
Several researchers105,106 have reported that diabetic foot ulcers mostly occur among males. Similar to these findings, in the present study males constituted 86.67% in group A and 66.67% in group B with male to female ratio of 6.5:1 in group A and 2:1 in group B. The male preponderance observed in the present study was consistent with an epidemiological study from Varanasi to determine risk factors for foot ulceration (71.13% of the patients males and 28.86% females). 107

In this study most of the patients who presented with diabetic foot ulcer were elderly. In group A 53.33% of the patients and in group B 50% of the patients were aged > 60 years. Though the mean age in group A was slightly high compared to group B (60.23 ± 9.27 years vs. 55.13 ± 12.06 years) but difference was statistically not significant (p=0.072). Similar to these findings several other reports have showed occurrence of diabetic foot ulcers mostly in middle aged patients. 108 A study107 from Varanasi to determine risk factors for foot ulceration reported mean age of the patients with diabetic foot ulcers as 55.25 years. Though there was male preponderance and most of the patient were elderly the distribution of demographic pattern of the study population in group A and B was comparable (p>0.050).

In this study, with regard to diabetic characteristics, majority of the patients in group A (86.67%) and in group B (93.33%) were on oral hypoglycaemic agents (p=0.335). The fasting blood sugar levels were slightly high in group A (259.30 ± 62.89 mg/dL) compared to group B (233.97 ± 81.31 mg/dL) but the difference was statistically not significant (p=0.183). These findings suggest that, the diabetic features in group A and group B were comparable.

In the present study pertaining to the ulcer characteristics, 53.33% of the patients in group A had traumatic mode of onset compared to 40% in group B (p=0.301). The duration of ulcer was in nearly half of the study population was between 6 to 10 days (group A 56.67% and group B 50%; p= 0.289). The other ulcer characteristics including site (p=0.796), shape (p=0.222), edge (p=0.490), floor (p=0.329),

surrounding skin (p=0.099), and necrotic tissue (p=0.438) were comparable in both the groups.

In the present study wound culture at enrolment was positive in all the patients in group A and B (100%). The commonest organism isolated was Proteus vulgaris in group A (33.33%) as well as group B (30%). Also the slough area in group A (36.25 ± 14.38) and group B (34.04 ± 14.38) was comparable (p=0.553).

Overall these findings suggest that, the demographic characteristics of the study population, history of diabetes, ulcer characteristic in patients with group A and B were comparable ruling out bias in the outcome. In the present study significantly higher number of patients had negative wound culture in group A (43.33%) compared to group B (16.67%) (p=0.024) on fifth day. Similar trend was noted on day 10 and 15, where the negative wound culture was noted in 50% and 60% of the patients in group A as against 36.67% and 50% in group B respectively but the difference was statistically not significant (p=0.297 and 0.436 respectively). Further the treatment was more effective in reducing wound culture with Proteus vulgaris followed by pseudomonas, Escherichia coli and MRSA. These findings suggest that dressing and topical management using hydrogel with silver nano particles resulted in effective management of wound though reduction in organisms. However this effect was limited to initial period only.

In this study, there was reduction in mean slough area from 36.25% ± 14.38% at enrolment to 14.68% ± 9.10% till day 15 in group A resulting in reduction of mean slough area of 21.57% ± 8.71%. Similar findings were noted in group B also that is, the mean slough area at enrolment was 34.04% ± 14.38% which reduced to 18.14% ± 7.40% and the reduction was noted as 15.90% ± 8.11%. Though there was considerable reduction in mean slough area in both the groups at different intervals, the mean reduction in slough area was significantly high in group A compared to group B. Among the patients with group A, the mean reduction of slough on day five (6.93% ± 6.14% vs. 4.37% ± 2.96%; p=0.045), day ten (15.22% ± 7.40% vs. 9.10% ± 7.00%; p=0.002) and day fifteen (21.57% ± 8.71% vs. 15.90% ± 8.11%; p=0.012) was significantly high compared to group B. These findings suggest that, dressing and topical management using hydrogel with silver nano particles favours wound healing as measured by slough area compared to dressing and topical management using povidone iodine. The early wound healing process observed in the present study can be explained by the combined mechanism of action with topical management using silver nano particles and amorphous hydrogel dressings. 93

Hydrogels consist of a matrix of insoluble polymers with up to 96% water content enabling them to provide water molecules to the wound surface and to maintain a moist environment at the wound bed. As the polymers are only partially hydrated, hydrogels have the ability to absorb a degree of wound exudate, the amount varying between different brands. They transmit moisture vapour and oxygen, but their bacterial and fluid permeability is dependent on the type of secondary dressing used.104,110

Hydrogels promote wound debridement by rehydration of non-viable tissue, thus facilitating the process of natural autolysis. Amorphous hydrogels are the most commonly used and are thick, viscous gels. Hydrogels are considered to be a standard form of management for sloughy or necrotic wounds. They are not indicated for wounds producing high levels of exudate or where there is evidence of gangrenous tissue, which should be kept dry to reduce the risk of infection.104,110

Silver on the surface of the dressing may come into contact with the wound where it exerts the antimicrobial action. Silver within the dressing structure acts on bacteria absorbed into the dressing with wound exudate, but is likely also to diffuse to some extent into the wound. In one part per million (1ppm) of silver ions or less, have been shown to be effective against bacteria. However, it is unclear how silver content and availability measured in experimental settings relate to wound healing performance. ilver ions are highly reactive and affect multiple sites within bacterial cells, ultimately causing bacterial cell death. They bind to bacterial cell membranes, causing disruption of the bacterial cell wall and cell leakage. Silver ions transported into the cell disrupt cell function by binding to proteins and interfering with energy production, enzyme function and cell replication. Silver ions are active against a broad range of bacteria, fungi and viruses, including many antibiotic-resistant bacteria, such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococci (VRE). 93

To date limited numbers of studies have assessed the role of silver nano particle in patients with diabetic foot ulcers.

Jude EB, et al.111 compared AQUACEL Ag (silver Hydrofiber) versus Algosteril (alginate) for 8 weeks or until healing (n=134) in patients with Non- ischaemic diabetic foot ulcers. Ulcer depth in the silver group reduced significantly more than in the control group (p=0.04). Overall improvement and less deterioration was greater in the silver group (p=0.058), and particularly in the subset using antibiotics (p=0.02). The mean time to healing was not significantly different between the two groups.

The VULCAN study102,103 randomised 213 patients with venous leg ulcers to receive either one of a number of silver-containing dressings or a clinician-selected non-antimicrobial control dressing. The main outcome measured was the rate of complete healing at 12 weeks. The study concluded that there was no statistically significant difference between the use of silver-containing dressings and the control dressings for the proportion of ulcers healed, time to healing or rates of recurrence. Overall the present study showed that treatment with dressing and topical management using hydrogel with silver nano particles in selected patients with diabetic foot ulcers results in favourable outcome through reduction in slough area and microorganisms.

CONCLUSION

Based on the results of this study it may be concluded that, diabetic foot ulcers treated with amorphous hydrogel dressings with silver nano particles are efficacious in terms of reduction in slough resulting in early wound healing compared to conventional dressing. However the reduction in microorganism resulted in patients who were treated with amorphous hydrogel dressings remains controversial as the reduction pattern was significant only during first five days. As it is a novel study and due to paucity of other study to compare, this study needs further research for the efficacious use in clinical application.

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