e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(8); 1059-1065

Original Research Article

Comparative Assessment of the Efficacy of Collagen Dressing to Routinely Use Dressing Components Such as Normal Saline in the Treatment of Diabetic Foot Ulcers

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Received: 14-07-2022 / Revised: 16-08-2022 / Accepted: 30-08-2022

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Conflict of interest: Nil

Abstract

Aim: The current study compares the efficacy of collagen dressing to routinely use dressing components such as normal saline in the treatment of diabetic foot ulcers.

Material & Methods: This Prospective comparative study was conducted in department of surgery at Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, over a period of one year.

Results: Reduction in ulcer size was recorded on the day of admission, on the 7th day, 14th day and 28th day. In the normal saline-treated group, on the day of admission ulcer size reduction was found to be 18.53 ± 7.18 , on the 7th day was found to be 17.32 ± 8.19 , on the 14th day was found to be 15.18 ± 8.60 and at 28th day was found to be 13.55 ± 6.48 . In collagen treated group, on the day of admission ulcer size reduction was found to be 15.38 ± 7.29 , on the 7th day was found to be 14.26 ± 9.12 , on the 14th day was found to be 12.20 ± 7.11 and on 28th day was found to be 10.09 ± 5.38 .

Conclusion: Collagen dressing speeds wound healing in diabetic foot ulcer patients, lowering hospital stay and the necessity for split-thickness skin transplantation. Our research has led us to the conclusion that collagen dressings are superior to conventional dressings.

Keywords: Diabetic foot ulcer, Collagen, Normal saline-treated group, Collagen treated group

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Introduction

Diabetes mellitus (DM) presents a large social, financial, and health system burden globally; it is estimated to affect 700 million people by 2045 [1,2]. The morbidity and mortality in the diabetic population are mainly caused by the complications raised from the severe hyperglycemia. A common complication of DM is the slow or non-healing of wounds, particularly in the lower

extremity. It has been estimated that 15–25% of diabetes patients develop diabetic foot ulcer (DFU) in their lifetimes, among which approximately 85% will undergo amputation [3,4]. DFU is a type of non-healing chronic wound resulting from the interplay of several factors either directly or indirectly caused by the hyperglycemic condition. The abnormally high sugar level in the blood can result in poor blood circulation, prolonged inflammation,

signaling factors irregularities, and high susceptibility to infection [5]. Altogether, these factors not only disrupt the normal wound healing phases but also form a feedback cycle that will eventually worsen the existing condition.

A Diabetic foot ulcer (DFU) is a complicated wound that poses a challenge to conventional wound dressings, whereby it demands advanced therapies to address the specific requirements for wound treatment management.

With the cost of treating ulcers involving infections and amputations being up to USD 45,000, a breakthrough in DFU management could have a significant impact on the overall healthcare budget [6].

Conventionally, the wound is managed with debridement of necrotic tissue and contaminants from the wound bed [7].

Total contact cast (TCC) is a device providing mechanical support in treating DFU patients and it is currently the gold standard treatment [8-9]. It acts by redistributing the pressure in the plantar surface to the body mass as well as maintaining the subject's mobility, which prevents the breakdown of new skin [10]. TCC is also known to be an affordable ambulatory technique [11] to assist many diabetic patients. Although the use of TCC provides several benefits, it leads to immobilization and user's safety is a major concern, as it requires skillful clinicians to apply it efficiently. Nevertheless, there is a notable difficulty when inspecting the wounds due to the distinctive obstacles faced during removing the attached device [8-9].

In today's medical settings, numerous types of dressing materials containing collagen fibers, collagen membranes, collagen gels, or collagen sponges are employed. [12-13] Implanted collagen survival rates in animal experiments range from 80 to 100 percent due to its hemostatic effect and low antigenicity, and

the materials stay stable for several weeks following surgery with no inflammatory responses or foreign body reactions. Collagen has been effectively employed in biocompatible dressing materials for various wounds such as burns or ulcers, based on encouraging outcomes. [14]

e-ISSN: 0975-1556, p-ISSN: 2820-2643

The current study compares the efficacy of collagen dressing to routinely used dressing components such as normal saline in the treatment of diabetic foot ulcers.

Material & Methods:

This Prospective comparative study was conducted in department of surgery at Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, over a period of one year.

The research included 60 patients who had a clinical picture of a diabetic foot ulcer. Before enrolling in the trial, signed informed consent was obtained once the method of the study was explained. Ethical committee approval obtained before recruiting patients.

Inclusion criteria:

Patients with chronic foot ulcer were included in the study.

Exclusion criteria:

Critically ill patients, any evidence of underlying bone osteomyelitis and patients with malignancy were excluded from the study.

The patients were separated into two groups 30 patients in each group for analysis: group A (Collagen treated group) and group B (Normal saline-treated group).

Age, gender, length of hospital stays, ulcer size decrease in follow-up, percent reduction, percent granulation present, and percent epithelial tissue present were all observed and analyzed in both groups. Wound swabs were collected at the time of admission, then again on the 7th, 14th, and 28th days of therapy, and as needed. The damaged region was extensively cleansed

to remove external contamination and infected wounds were appropriately debrided before putting the dressing. Based on pus culture sensitivity reports, both groups received antibiotic therapy.

Results:

Out of the 60 patients in the study, 73% males and 37% females were present in the

normal saline-treated group and 65% males and 45% females were present in collagen treated group. In the above study, most of the patients (48%) were found to be in the age group of 51 to 60 year. The mean duration of stay in the hospital was found to be 35.3 days and 26.9 days in the normal saline-treated group and collagen treated group respectively (Table 1).

e-ISSN: 0975-1556, p-ISSN: 2820-2643

Table 1: Demographic data.

Variables	Normal saline group (%)	Collagen group (%)
Gender		
Males	73	65
Females	37	45
Age group (Years)		
<40	13	9
41-50	42	31
51-60	51	66
>61	13	11
Duration of hospital stay	35.3 days	26.9 days

Follow up on the 7th day, 14th day and 28th day was taken for percentages granulation present and percentages epithelial tissue present. The 0%, 100% and 100% granulation were observed on the 7th, 14th and 28th day in the normal saline-treated group while 82%, 100% and 100% granulation were observed on the

7th, 14th and 28th day in collagen treated group respectively. Similarly, 10%, 60% and 100% epithelial tissue were present on the 7th, 14th and 28th day in the normal saline-treated group while 54%, 100% and 100% granulation were observed on 7th, 14th and 28th day in collagen treated group respectively (Table 2).

Table 2: Percentage granulation and percentage epithelial tissue present in normal saline-treated group and collagen treated group.

Variables	Normal saline group (%)	Collagen group (%)	
Granulation present (%)			
Day 7	0	82	
Day 14	100	100	
Day 28	100	100	
Epithelial tissue present (%)			
Day 7	10	54	
Day 14	60	100	
Day 28	100	100	

Reduction in ulcer size was recorded on the day of admission, on the 7th day, 14th day and 28th day. In the normal saline-treated group, on the day of admission ulcer size reduction was found to be 18.53 ± 7.18 , on the 7th day was found to be 17.32 ± 8.19 , on the 14th day was found to

be 15.18 ± 8.60 and at 28th day was found to be 13.55 ± 6.48 . In collagen treated group, on the day of admission ulcer size reduction was found to be 15.38 ± 7.29 , on the 7th day was found to be 14.26 ± 9.12 , on the 14th day was found to be $12.20\pm$

7.11 and on 28th day was found to be

10.09 ± 5.38 (Figure 1).

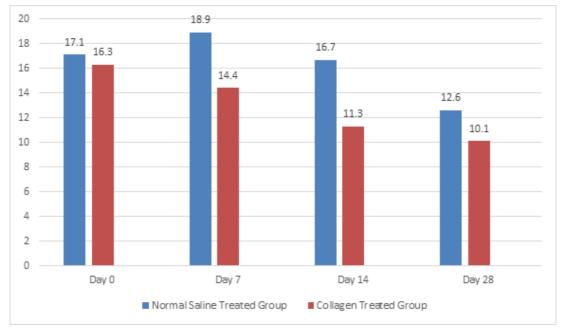


Figure 1: Ulcer size reduction in normal saline-treated group and collagen treated group.

On the 7th day, % reduction was found to be 5.1% in the normal saline-treated group and 16.4% in collagen treated group. On the 14th day, it was found to be 17.56% and 28.6% in the normal saline-treated group and collagen treated group

respectively. On the 28th day, 26.7% reduction was observed in the normal saline-treated group while 46.5% reduction was observed in collagen treated group (Figure 2).

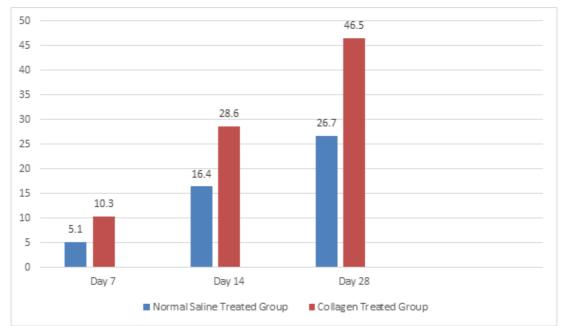


Figure 2: Percentage reduction in normal saline-treated group and collagen treated group.

Discussion:

Donaghue compared the efficacy of a collagen-alginate topical wound dressing

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with that of regular gauze moistened with normal saline in 75 patients diabetic foot ulcers. The mean percent reduction of the wound area was 80.6% in the collagenalginate dressing group and 61.1% in the gauze-dressing group. Complete healing was achieved in 48% of the collagenalginate dressing group and 36% of the gauze-dressing group. [15]

Though, the role of collagen in promoting wound healing is well established, [16-17] but it has not previously been tried extensively in the management of leg ulcers. The results of the present study are, therefore, encouraging. In addition, collagen dressing, unlike conventional dressing, is absorbed and does not have to be re-applied frequently. However, the ulcer should be debrided and cleaned before application. If there is evidence of infection, appropriate antibiotics should be administered.

Through electro spinning, cellulose acetate-collagen can be fabricated, and this fabricated biomaterial showed an abundance ofmesenchymal cell. proliferation on the scaffold indicating the capability to be used as wound dressing [18]. This positive outcome of in vivo study serves as the main reason for the electro spinning cellulose acetate being proposed to be used in wound dressing. Another study shows that the hybridization collagen or chondroitin sulfate incorporated with keratinocytes and sodium carboxymethyl cellulose incorporated with fibroblasts showed a compact stratified surface layer resembling epidermis. This indicates that the hybridisation of these scaffolds is a perfect biomaterial to be used as wound dressing [19] and hybridisation of cellulose and collagen enhances in vitro proliferation of Therefore, fibroblasts [20]. collagen presents an essential key factor in providing biological and structural integrity resembling native ECM. It is a complex system in which related substances undergoing continual

remodeling to regulate the activity of the cell and tissue function. Furthermore, collagen is known as surface-active and is capable of breaching the lipid-free interface [21] and, upon placing the collagen scaffold at the ulcerated region, more fibroblasts will be attracted to the wound region to accelerate the normal healing pathway [22]. Meanwhile, cellulose is capable of absorbing exudate from the injured tissue, retaining moisture microenvironment, and accelerating the granulation tissue formation [23].

e-ISSN: 0975-1556, p-ISSN: 2820-2643

In a comparable trial on 120 patients, Onkar et al gave collagen dressing to 60 patients with wounds of various etiologies whereas the other 60 patients received traditional dressing treatments. The Onkar et al trial was conducted over 8 weeks, and percentages of wounds treated with collagen dressing had more than 75% wound closure compared to 80% with traditional dressing (p=0.21). [24] Rao et compared collagen to traditional dressings in 100 patients with persistent foot ulcers caused by diabetes or burn injuries. The 75 of the 100 patients were treated with collagen dressing, while the others received standard dressing. The study found that collagen dressing had a significantly greater rate of wound healing than moistened gauze. The healing time for patients who received collagen dressing was 4.63±1.18 weeks, which was significantly less than the healing period for patients who received conventional dressing $(7.79\pm1.61 \text{ weeks})$? The study indicated that collagen dressing dependable and effective for the treatment of chronic foot ulcers, considerably reducing healing time, SSG demand, and follow-up time. [25-27]

Conclusion

Collagen dressing speeds wound healing in diabetic foot ulcer patients, lowering hospital stay and the necessity for splitthickness skin transplantation. Our research has led us to the conclusion that

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collagen dressings are superior to conventional dressings.

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