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Clinical Study of Sterile Collagen Particles (Biofil) in the Management of Chronic Non Healing Ulcers

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Abstract
Introduction: *Patients who are suffering from non healing ulcers may lead into a significant problems and prolonged stress. Pain and discomfort are the main complaint of chronic non healing ulcer patients[1]. Pain may be mild or severe, pricking or burning which may exacerbate with frequent changing of dressings. Wound contracture and scar formation is the end result of any wound healing ulcers[2]. Collagen plays a very important role in the stage of wound healing process. Collagen particles are used in chronic non healing ulcer management. To evaluate their efficacy when compared with conventional method dressings this study was conducted by our department.*
Materials & Methods: *This study was a non- randomized, prospective type of study evaluated between December, 2014 to November, 2016 in Thanjavur Medical College and Hospital, Thanjavur, Tamilnadu, India. This is the comparative study between collagen particles dressing study group and conventional method dressing control group. Around a total of 104 patients with chronic non healing ulcers in various region and various types were taken in this study. Study group consisting of 52 patients and control group have 52 patients.*
Observation: *A significant increase in the wound healing rate percentage being 92.3% in the study group when compared to the control group percentage being 42.3% was seen. Collagen particles dressings found to be effective in the management of chronic non healing ulcer patients compared to the conventional method of betadine dressing. Collagen particles plays an important role by forming an early granulation tissue and scar formation and reduces the duration of the hospital stay.*
Keywords: *Collagen particles, conventional methods, healing, non-healing, amputation, betadine dressing.*

Objectives

To compare the efficacy of healing process in chronic non healing ulcer patients using collagen particles with those of conventional method dressings (betadine dressings).

Introduction of the Study

Wound, ulcer, and tissue damage results from many causes which may vary from surgical wounds, burns wounds, traumatic wounds, diabetic wounds etc. Wound may result following a contusion, hematoma, laceration or an abrasion. Sometimes spontaneous after blister formation. The skin continuation should be adequately maintained because it plays an important role in attaining homeostasis.

Certain ulcers are very difficult to handle like diabetic foot ulcers, chronic venous ulcers,

traumatic ulcers, arterial ulcers, pressure sore ulcers. An ideal dressing method should be economical to patients, very easy to use, adequately available dressing to cover the wound, good relief from pain, protecting wound from serious infections, increases the healing process, provides moisture environment, it should be elastic to wounds, non-allergic and adequate adhesion to the wound and promote epithelisation and granulation tissue & scar formation. Among numerous type of new dressing methods, biological wound dressing methods like collagen particles plays a crucial role in maintaining physiological interaction between wound bed and surface environment and bacteria which was impermeable to the wound surface. Collagen is the most abundant complex matrix protein in our human body which plays an important role in the end processing of wound healing[3,4]. It is very essential to create functional integrity of the wound because of the collagen deposition, maturation, and remodelling in the wound healing process. Collagen particle[5] dressing methods increases the efficacy of the wound healing process over conventional dressing methods like betadine dressings, which stimulates the collagen formation with higher efficacy. Collagen particles dressing methods have one more advantage when it was compared to conventional method dressings in the form of non-immunologic, non-pyrogenic, because of natural form & it is very easy to apply, non-allergic and relief from pain.

Dressings containing sterile collagen particles were used in the study and compared with conventional (betadine) dressings. The aim of our study was to evaluate the efficacy of collagen particles, with an objective to compare the rate of healing process using collagen particles with those of conventional methods.

Whether Split Skin Graft was ideally need or not, perception of pain perceived by the patients after applying the dressing methods and formation of granulation tissue and scar formation. This study was a non-randomized and prospective comparative study between use of collagen particles and betadine dressing group. It included 104 patients with 52 in each group, 52 patients were subjected to collagen particles dressing and 52 patients to betadine dressing. Comparison between these two groups was done with respect to parameters of wound area, number of debridements, number of dressings done and mode of healing. Institutional Ethical committee clearance was taken before starting the study and also consent from all participants. The study was conducted from December 2014 to November 2016, in Thanjavur Medical College and Hospital, Thanjavur, Tamilnadu, India. Patients were taken from all surgical unit wards and post operative wards in our hospital.

Inclusion Criteria: All non-healing ulcers were included like diabetic ulcers, venous ulcers, traumatic ulcers, pressure sores, amputation stump ulcers at least 6 weeks of duration. An area of at least 1cm^2.

Exclusion Criteria

1. Ulcers having exposed bone without granulation tissue.
2. Conditions which interferes the wound healing process are malignancy, connective tissues disorders, immune system disease.
3. Current medication with dialysis patients, patients on steroids, immunosuppressive drugs, radiation & chemotherapy.
4. Any known allergy to any of the dressing materials.
5. Patients who do not completed 12 weeks follow up and default.

Both the groups were treated with the respective dressing methods and the perception of pain and wound healing was assesed periodically, the amount of slough ,nature of granulation tissue and scar formation was assessed.

Limitations of the Study

The present study had the following limitations. First is that it was not a randomized study, so similarity among type of ulcers and size of ulcer was not maintained. Second, sample size was very

less where we included only 52 patients in each group. The study was conducted only for 12 weeks and the wound was studied only in two dimensions. Observer and patient were not blinded increasing the risk of bias. Wound volume measurement rather than area would have been a more accurate approach of judging results.

Observations

Out of 104 patients in this study, 7 patients were below 30 years, 13 patients were age between 31 to 40 years, 27 patients were age between 41 to 50 years, 21 patients were age between 51 to 60 years, 20 patients were age between 61 to 70 years, 16 patients were age above 71 years (Figure 1).Out of 104 patients in this study, about 87 patients are male patients, remaining 17 patients are female patients. Out of 104 patients in this study, 62 patients belonging to diabetic ulcer patients, percentage being 59.6%, 14 patients were arterial ulcer patients accounts for 13.5%, 13 patients were venous ulcer patients accounts for 12.5%, 8 patients were pressure ulcer patients accounts for 7.7%, 7 patients were traumatic ulcer patients accounts for 6.7% (Figure 2). Out of 104 patients in this study, 70 patients were healed both in study group and control group percentage being 67.3%. Out of 104 patients in this study, 34 patients were non healers in both study group and control group percentage being 32.7% for a duration of 12 weeks. Out of total patients in this study 5.8% ended up in amputation. Out of the 52 patients treated with collagen particles 48 had healing and only 4 were non healers whereas those treated with conventional method only 22 of the 52 patients had healing while remaining 30 were non healers.(Figure 3 and 4)

Figure1 Age Distribution

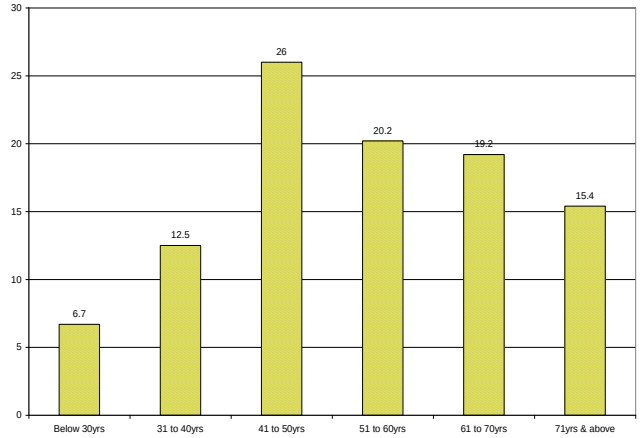


Figure 2 Ulcer Distribution

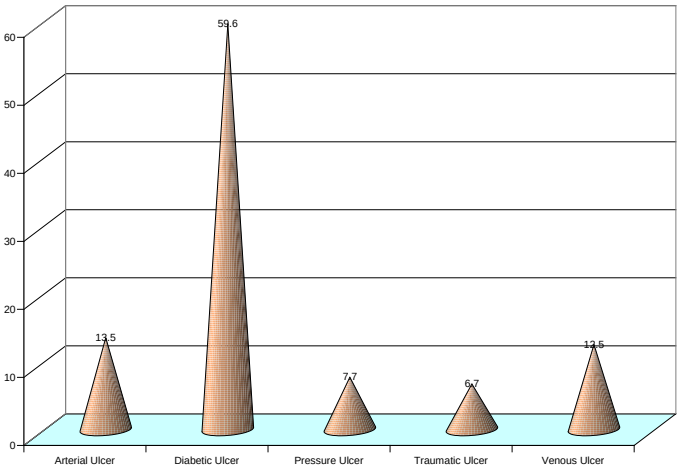


Figure 3 Chi- Square Test: Healing Distribution

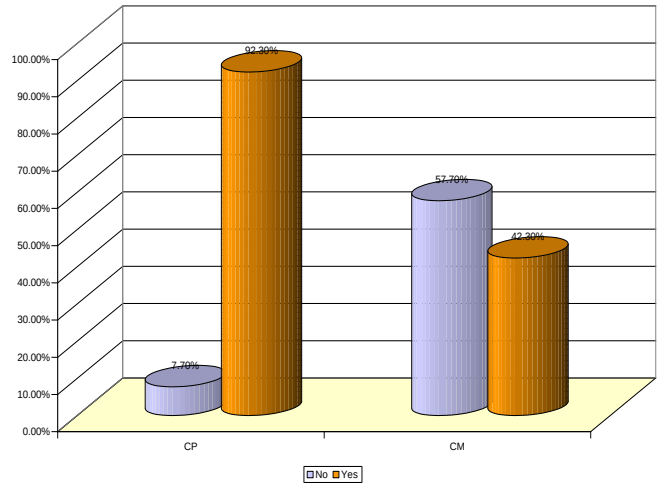
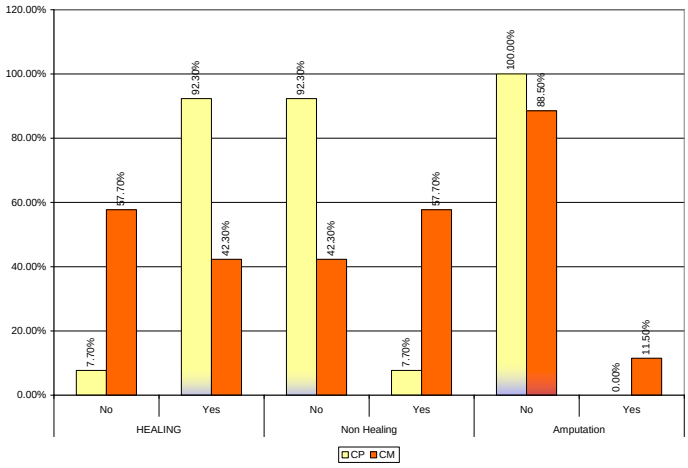


Figure 4 Efficacy of Collagen Particles (CP) Compare to Conventional Method (CM) Dressing



Discussion

Wound healing involves expression of various growth promoting factors which promotes cell differentiation, proliferation & migration, collagen deposition and formation of new connective tissue matrix[6]. Collagen particles are good biomaterial[7] for use of biomedical implantable devices & it can be used as a matrix for tissue regeneration outside of our body. Coming to advantages of collagen dressings over conventional dressings, frequency in change of dressing is reduced causing less discomfort for the patients, no case of allergic response to collagen particles has been reported in our study and application methodology is easier when compared to sugar dressings[8] or vacuum dressings[9] where a negative pressure system is required. Disadvantages are, this is not a cost effective treatment when used for bigger wounds, cannot be applied over infective wounds where debridements at initial setting are needed.

Present study is a prospective study regarding collagen particles dressing versus conventional dressing. The efficacy and wound healing capacity of both the methods were gauged using suitable statistical test. The study revealed some interesting results. The study constituted a total of 104 participants. The Age of the patients ranged from 27 to 92 years. Mean age was 54.81 ± 16.134 years in cases and 54.27 ± 15.575 years in controls. The difference in mean age between cases and controls was not statistically significant ($p>0.05$). Majority of the participants in the study were males in both the case and the control group. The difference in sex distribution of case and controls was not statistically significant ($p>0.05$). This could be because males are more prone to traumatic wounds and the prevalence of diabetes is also known to be higher in middle-aged males.

The study revealed that the participants presented with various wounds. However, post debridement wounds were the most common in both case and control group followed by post traumatic wound. Majority of the wounds were present in the lower limbs, followed by upper limb, chest, back and abdomen.

The wound duration in the cases and control groups were not found to be statistically significant ($p>0.05$). The mean duration of wound in cases was 16.90 ± 4.960 weeks and 15.56 ± 4.376 weeks in control group.

The percentage of wound healing was also compared between the cases and controls after 12 weeks. Though there was no statistically difference that was recorded between the groups based on the percentage of wound healing, the cases group recorded a higher percentage of wound healing compared to the control group. The case group in the study recorded 92.3% in wound healing compared to 42.3% in the control group. The study highlighted some important distinctions between the use of collagen particles in wound healing[10] and conventional methods

Conclusion

Collagen particles are effective in hastening the healing process by formation of early granulation tissue and wound contraction. The role of collagen in improving wound healing is by stimulating fibroblast activity[11]. So that, the number of debridements[12] and dressings required can be reduced; as supported by the present study. With the use of collagen granule dressings in comparison with the control group (betadine group) for the treatment of chronic non healing ulcers, the following conclusions were derived.

1) Collagen particles showed faster and better healing rates among the study group[13]
2) Area reduction was statistically significant in the study group
3) There was no adverse effects or reactions seen when collagen particles were applied over the wound.

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