A Comparative Study of Collagen Based Dressings Versus Normal Saline Dressing in Healing Diabetic Foot Ulcer.

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Abstract: Diabetes is one of major global health problem. Of all known complications of diabetes, diabetic foot ulcers remain a major challenge to health sectors with increasing morbidity and mortality. According to WHO every 20 seconds a limb is being amputated as result of diabetes. Many researches is being done on management of diabetic foot ulcer. Biological dressing like collagen dressings are natural, non immunogenic, non pyrogenic, hypoallergenic and pain free. On topical application in wounds they create a physiological interface between the wound surface and environment. The present study is a comparative study between the collagen based dressing and normal saline dressing in healing diabetic foot ulcers with Wagner grading I & II in our hospital GMKMCH, Salem. Out of 50 patients studied over a period of 5 months from April 2019 to August 2019, collagen based dressing was proved superior to normal saline dressing in terms of wound healing and infection control in diabetic foot ulcers. Thorough surgical wound debridement followed by collagen based dressing with good glycemic control definitely a first line of management in treating diabetic foot ulcers.

Keywords: diabetic foot ulcers, Wagner grading I&II, collagen dressings.

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I. Introduction

Incidence and prevalence of diabetes and its complications are increasing all over the world. Among the diabetic complications, diabetic foot ulcers remains the frequent reason for hospitalization. About 15-25% of patients with diabetes develop diabetic foot ulcer during their life time. Diabetes is leading cause of non traumatic amputation of limbs and is a major global health problem. Over past 10 years many different dressing were introduced for treatment of diabetic foot ulcers. A study is needed to conclude a comprehensive mode of dressing in diabetic foot ulcers. Collagen based dressing are effective mode of treatment in healing diabetic foot ulcers. The present study is a comparative study between collagen based dressing and normal saline dressing in diabetic foot ulcers with wagner grade I & II at our institution GMKMCH, Salem.

II. Aims and Objectives

- > to compare the efficacy of collagen based dressing against normal saline dressing in diabetic foot ulcers in terms of wound healing and infection control
- > to compare the percentage decrease in ulcer size, periulcer edema and erythema, pus discharge and graded percentage increase in granulation and epithelisation.

III. Material and methods:

Study type - interventional

Study design - Prospective randomised comparative study

Study group – Over a period of 5 months from April 2019 to August 2019, 50 patients with Wagner grading I&II diabetic foot ulcers who had either Type 1 or Type 2 diabetes mellitus admitted in our General Surgery department at GMKMCH, Salem who fulfilled the inclusion and exclusion criteria were enrolled in our study.

Inclusion criteria:

- ➤ Both Male and female
- \triangleright Age between 20 70 years
- ➤ Both type 1 and type 2 diabetes
- Wagner grade I & II foot ulcers
- Patient giving consent for study

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Exclusion criteria:

- ➤ Wagner grade III,IV,V
- Wound swab negative ulcers
- Vascular occlusion
- > Osteomyelitis of foot
- > Patient not willing to give consent

Study method instituted:

From April 2019 to August 2019 a study was conducted to determine the efficacy of collagen based dressing against normal saline dressing in diabetic foot ulcers in terms of wound healing and infection control. All patients were treated by foot care team comprising of General surgeon, Diabetologist, Radiologist, Plastic surgeon, Microbiologist and staff nurse. Out of 50 patients, 25 cases were randomized into Group A and 25 were randomized into Group B. In Group A collagen based dressing were applied to diabetic foot ulcer and normal saline dressing was done for Group B patients.

Detailed clinical examination was performed. Both groups underwent debridement of necrotic tissues under sterile precautions and specific dressings were applied to each groups. Assessment of wound done during each dressing. Area of each wound was calculated weekly by calculating the longest vertical and horizontal dimensions of diabetic foot ulcers. Culture were taken and antibiotics were prescribed according to sensitivity. Bony involvement excluded with help of orthopedician and vascular compromise excluded with help of Doppler study. Glycemic management done with help of diabetologist. Both groups treated till complete healing of ulcer or until wound becomes fit for skin cover.

Statistical analysis of data from both groups obtained and results were tabulated. Students T test was used as statistical test to analyse the data obtained.

IV. Results and discussion:

Total of 50 patients with Wagner grading I & II were included in the study and 25 patients belonging to Group A were treated with collagen based dressings and 25 patients belonging to Group B were treated with normal saline dressing. Every time graded decrease in ulcer size , periulcer edema and erythema, graded increase in granulation tissue was observed, calculated , analysed and tabulated.

Table 1: Age Incidence:

Age group	No of cases	Percentage
21-30	3	6
31-40	12	24
41-50	18	36
51-60	10	20
61-70	7	14

Table 2: Sex Incidence:

Female cases	I	Male cases	
no of cases	percentage	no of cases	percentage
18	36	32	64

Table 3: ulcer size assessment:

	Percentage decrease in ulcer size	Percentage decrease in ulcer size	
Day	Collagen based dressing treated group	Normal saline dressing treated group	
1	Baseline	Baseline	
5	9	7	
8	15	10	
15	35	25	
21	40	32	
P = 20.2731 stude	nts t test		

Group A patients treated with collagen based dressings showed early decrease in ulcer size than Group B patients.

Table 4: Periulcer edema and erythema assessment:

	Percentage decrease in Periulcer edema and erythema	
Day	Collagen based dressing treated group	Normal saline dressing treated group
1	Baseline	Baseline
5	27	22
8	32	25
15	35	28
21	45	38
P = 21.2971 stu	idents t test	·

Group A patients treated with collagen based dressings showed early decrease in Periulcer edema and erythema than Group B patients.

Table 5: Time to lesion healing:

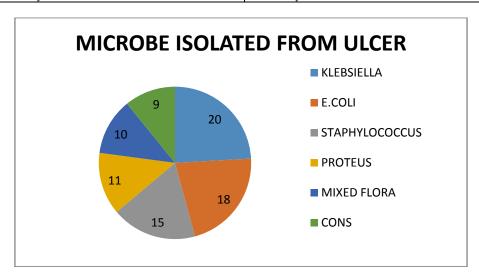
Collagen based dressing treated group	Normal saline dressing treated group
15+- 10 Days	28+-10 Days

Group A patients treated with collagen based dressings showed early lesion healing than Group B patients.

Table 6: Microbial culture and their outcome:

Time Taken For Nil Growth In Culture

Collagen based dressing treated group	Normal saline dressing treated group
7+- 4 Days	10+- 5 Days



It is evident from above chart that klebsiella is the most common organism causing infection among diabetic foot patients.

In the current study, the patient treated with collagen based dressing showed promising results in terms of early epithelisation, quick bacteria free ulcer bed, early granulation tissue formation, less time for healing, less hospital stay that saline dressing treated patients. No cases reported of allery and irritation to collagen dressings. In Wagner grade I and most of Wagner II grade patients there was complete epithelisation of ulcer without need for skin grafting in patients treated with collagen based dressings. Research studies available on collagen based dressing is very minimal.

Collagen is the main structural protein in the extracellular space in various connective tissues in the body. Collagen (kolla - glue, genes - producing) – three polypeptide chains that are rich in hydroxyproline amino acids (Glycine, Proline , Hydroxyproline & Arginine). Bioengineered collagens have wide spread application in the field of medicine and one such application is in treatment of chronic ulcers.

FUNCTIONS OF COLLAGEN IN WOUND HEALING:

- > Platelet Accumulation,
- > Inflammation,
- > Fibroblast Proliferation,
- Cell Contraction,

- Angiogenesis And Re-epithelialisation,
- ➤ Ultimately Leading To Scar Formation And Wound Remodelling

Of many sources of collagen - Bovine, Porcine, Marine, marine source based collagen are widely used because of high collagen content, eco friendly, less immunogenic, less inflammatory response.

USES OF COLLAGEN IN MEDICAL FIELD;

- Tendon, bone reinforcement, dental purposes
- Skin and wound healing, burns.
- Hernia repair
- * Reconstructive surgery, corneal graft, contact lenses
- Vascular grafts, dialysis membrane

V. Conclusion

Collagen based dressing are superior than normal conventional saline dressing in treatment of Diabetic foot ulcers in terms of early epithelisation, decrease in bacterial load and slough, speedy granulation tissue formation, early recovery and lower the need of amputations in diabetic foot ulcers.

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