

Comparative Analysis of Dressing Methods on Wound Healing in Diabetic Leg Ulcers at tertiary hospital

Shridhar Hosamani ¹, Nagaraja.N ², Nutan. B.V ^{3*}

¹Assistant Professor, Dept of General Surgery, SSIMS and RC, Davangere Karnataka India

²Assistant Professor, Department of General Surgery India

³Assistant Professor, Department of General Surgery SSIMS and RC, Davangere, Karnataka India

***Corresponding Author and reprint request to:** Dr. NUTAN. B.V, Assistant Professor, Department of General Surgery SSIMS and RC, Davangere, Karnataka, India

ABSTRACT

Background: An ideal wound dressing should be able to provide a moist wound environment, protect from secondary infection, provide optimal exudate management and promote tissue regeneration. **Objective:** To assess wound healing in diabetic Leg ulcers with the two methodologies of dressings considered in this study **Methods:** This prospective study was conducted among patients admitted in the Department of Surgery at ESICMC & PGIMSR, Bengaluru, between January 2019 and June 2020 were source of data. 106 patients were included in this study, with 53 patients each in foam dressing and saline dressing groups.. **Results:** There was no significant statistical differences in the reduction of slough and exudate(p-value 0.864), and appearance of granulation tissue(p-value 0.623) . The mean surface area reduction in polyurethane foam group was 0.49cm²/week, whereas in saline group was 0.35cm²/week. 66 out of 106 ulcers showed complete closure at 12th week.

Conclusions: The two methodologies of dressings applied in this study thus help in assessing wound healing rates, with improved healing and increased proportion of complete closure of ulcers seen in foam dressing group compared to conventional

saline dressings.

Keywords: Dressing Methods, Wound Healing, Diabetic Leg Ulcers,

Introduction

Ulcers and their management are fundamental in the practice of surgery. The prevalence of leg ulceration is approximately 3% to 5% in the older population aged 65 years and more.¹

The words quoted by Luodon and published in 1805² very much summarize leg ulcer management, -“ulcers on the leg form a very extensive and important class of disease, the treatment of such cases is generally looked upon as an inferior branch of practice, an unpleasant and inglorious task where much labour must be bestowed and little honour gained.”²

By definition, chronic wounds are wounds that have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity over a period of three months.³

In the United States, it is estimated that 2 to 3 million patients per year are at a risk of developing diabetic ulcers.³ These ulcers pose a significant challenge to health care professionals and an immense burden on the health care system and the economy. They also result in reduced quality of life and social isolation among patients.

Their origin is multifactorial and hence proper diagnosis of arterial, venous and neuropathic ulcers is essential if further compromise of the lower limb is to be avoided.

Ulcers may appear similar, but upon closer inspection it becomes apparent that they are completely different entities.

Not only are lower limb ulcers of different etiologies but also ulcers have specific anatomic locations which by itself gives rise to special problems in their management.

The presence of diabetes mellitus impairs wound healing. In diabetic ulcers, there will be tissue ischemia and infection due to large vessel occlusion and end organ angiopathy. Also sensory neuropathy leads to repeated trauma and unrelieved wound pressure. The thickened capillary basement membrane decreases perfusion in the microenvironment, and elevated perivascular localization of albumin suggests increased capillary leak.³

VEGF upregulation in patients with diabetes is also impaired. Hypoxia is normally a potent upregulator of VEGF, but in diabetic patients VEGF expression is not upregulated in response to hypoxia.

Diabetics are susceptible to infection because of an attenuated inflammatory response, impaired chemotaxis and inefficient bacterial killing. Collagen degradation is increased, with impaired collagen deposition. Also collagen is brittle secondary to glycation. Collagen glycation diminishes focal adhesion formation between fibroblast and matrix resulting in decreased fibroblast migration.

Hyperglycemia also induces increased production of inflammatory molecules- TNF- α , IL-1, and interfere in collagen synthesis. High glucose exposure also results in changes in the cellular morphology, decreased proliferation, and abnormal

differentiation of keratinocytes. Altered leucocyte infiltration and wound fluid IL-6 characterize the late inflammatory phases of wound healing.

There is abnormal expression of growth factors and rapid degradation in wound fluids, as a result of increased insulin degrading enzyme activity. Insulin degrading enzyme activity is positively correlated with HbA1c levels. There is increasing evidence that the resident cells in chronic wounds undergo phenotypic changes that render them senescent and impair their capacity for proliferation and movement.

Two critical points while selecting an appropriate wound dressing are absorption and occlusion. Studies have demonstrated that the rate of epithelialization under a moist occlusive dressing is twice as that of wound left uncovered and dry.

Materials and Methods:

This prospective study was conducted among patients admitted in the Department of Surgery at ESICMC & PGIMSR, Rajajinagar, Bengaluru, between January 2019 and June 2020. Ethical clearance was taken from institutional ethical committee. The cases were taken up for study on admission and after obtaining Informed written consent. Duration of study was January 2019 to June 2020

Inclusion criteria:

1. Diabetics between age 18 and 60 years
2. Diabetic footulcers
3. Wagner's grade 1 or 2
4. Wound surface area more than 4cm² but less than 20 cm²

5. Palpable Dorsalis pedis artery/ Anterior tibial artery/ Posterior tibial artery

Exclusion criteria:

1. Wagner's grade 3 or 4
2. Osteomyelitis of underlying bone
3. Exposed underlying bone
4. HbA1c more than 7.5

Patients satisfying the above criteria were enrolled in the study after taking informed written consent. All the patients were evaluated with thorough history, clinical examination and investigations.

Methodology:

Data was collected using a pro-forma meeting the objectives of the study. Detailed history, clinical examination and necessary investigations were undertaken. The purpose of the study was explained to the patient and informed written consent was obtained.

Two groups were divided and current standard of practice were followed including serial debridement, control of infection using appropriate antibiotics as per wound swab & pus culture and sensitivity report, glycemic control with insulin, and adequate pain relief in both groups as per IWGDF (International Working Group on Diabetic Foot) Guidelines 2019.⁵⁸

In saline dressing group, saline soaked gauze dressing was applied over ulcer and dressing was changed on daily basis, sometimes twice daily, depending on soakage, for 2 weeks and alternate day dressing was done thereafter.

In foam dressing group, polyurethane foam dressing was applied over the ulcer and dressing was changed once in 2 days for 2 weeks and biweekly dressing was done thereafter.

Wound size was assessed using serial photographs and sterile paper scales. Granulation tissue formation, reduction in slough and exudate, and pain, reduction in wound surface area, time taken to heal were assessed.

Dressings were done till the patients were discharged. Patients were discharged from the hospital after significant reduction in ulcer size and formation of healthy granulation tissue. Later patients were instructed to follow upon OPD basis. Patients were followed up for 12 weeks, weekly till 8 weeks and fortnightly till 12 weeks and data was collected.

Sample size Estimation:

G Raymanet al⁴, in their study “Sustained silver releasing foam dressing in the treatment of diabetic foot ulcers” investigated clinical performance and safety of a sustained silver releasing foam dressing, contreet foam in the treatment of diabetic foot ulcers. The relative ulcer area was reduced by a mean of 56% or by 56% in average in 4 weeks. ContreetFoam showed good exudate management properties and was considered easy to use. Hence there is difference of mean percentage of 56% for reduction of the wound size after application of non-adhesive foam dressing.

Hence, sample size was calculated using G*power software, version 3.1.9.2 as: power of study = 80%, relative precision of +/- 5%, CI = 95% and attrition of 5%, the sample size calculated was 106, 53 in polyurethane foam dressing and 53 in saline dressing.

106 patients were included in this study after taking informed written consent.

All these patients were allotted either groups, with 53 patients each in foam dressing

	Group	Total		
--	--------------	--------------	--	--

group and 53 patients in saline dressing group using computer based randomization and study was carried out.

Statistical analysis:

The data was analysed using Statistical Package for Social Science (SPSS) software version 21. The data was analysed for descriptive statistics like frequency, percentage, mean and standard deviation. Chi Square Test was used to assess the statistical significant difference. A p-value was taken as significant when <0.05 .

Results:

TABLE 1: AGE DISTRIBUTION OF STUDY PARTICIPANTS

			Normal Saline	Polyurethane Foam		Chi Square	p-value
Age	<50Years	Count	31	18	49	14.745	0.009
		% of Total	29.2%	17.0%	46.2%		
	≥50 Years	Count	22	35	57		
		% of Total	20.8%	33.0%	53.8%		
Total		Count	53	53	106		
		% of Total	50.0%	50.0%	100.0%		

Out of 106 patients, 49 patients were aged less than 50 years, and 57 patients were aged more than 50 years. The incidence of diabetic foot ulcers is more in elderly patients, with significant p-value 0.009.

TABLE 2: GENDER DISTRIBUTION OF STUDY PARTICIPANTS

		Group		Chi square	p-value
		Normal Saline	Polyurethane Foam		
Female	Count	11	23	15.74	<0.001
	% of Total	10.3%	21.5%		
Male	Count	42	30		
	% of Total	39.7%	28.5%		
Total		Count	53		
		% of Total	50.0%		

Out of 106 patients, 34 were females and 72 were males. Incidence is more in males. With statistically significant p-value <0.001.

			Group		Total	Chi-square	p-value
			Normal Saline	Polyurethane Foam			
Type of diabetes	IDDM	Count	13	15	28	4.745	0.475
		% of Total	12.3%	14.2%	26.4%		
	NIDDM	Count	40	38	78		
		% of Total	37.7%	35.8%	73.6%		
Total		Count	53	53	106		
		% of Total	50.0%	50.0%	100.0%		

O
u
t

of 106 patients, 28 patients had IDDM, and 78 patients had NIDDM, with no statistically significant difference i.e, p- value 0.475.

TABLE 4: WAGNER'S GRADING OF ULCERS

			Group		Total	Chi square	p-value
			Normal Saline	Polyurethane Foam			
Wagner classification	Grade 1	Count	12	11	23	1.470	0.574
		% of Total	11.3%	10.4%	21.7%		
	Grade 2	Count	41	42	83		
		% of Total	38.7%	39.6%	78.3%		
Total		Count	53	53	106		
		% of Total	50.0%	50.0%	100.0%		

Out of 106 patients, 23 patients had Grade 1 ulcers and 83 patients had Grade 2 ulcers, with no statistically significant difference. P-value 0.574

TABLE 5: PAIN DISTRIBUTION

			Group			Chi square	p-value
			Normal Saline	Polyurethane Foam	Total		
Exudate Discharge	Dry to low	Count	41	44	85	1.751	0.864
		% of Total	38.3%	41.5%	80.2%		
	Moderate to high	Count	12	09	21		
		% of Total	11.7%	8.5%	19.8%		
Total		Count	53	53	106		
		% of Total	50.0%	50.0%	100.0%		

Out of 106 patients 93 patients had mild pain, 13 patients had moderate pain, with p-value 0.874. Adequate analgesia provided in both groups during the study.

Out of 106 patients, 85 patients had dry to low exudate, 21 patients had moderate to high exudate, with no statistically significant difference with p-value 0.864.

Discussion:

The incidence of diabetes across the globe is high. There is also a rapid rise of diabetes across the world. 80% of the people with diabetes are from low and middle income nation.⁵ This increase is believed to be due to increase in aging and growing populations, urbanization, family history, obesity, poor diet and sedentary lifestyles. In 2003, it is estimated that approximately 194 million people worldwide, or 5.1% in the age group 20-79, have diabetes.⁵⁹ This estimate is expected to increase to about 333 million or 6.3% in the adult population, by 2025.⁵

The prevalence of foot ulcers among people with diabetes is 4% to 10%, the annual population based incidence is 1% to 4.1%, and the lifetime incidence may be

as high as 25%. These ulcers frequently get infected, cause great morbidity, engender considerable financial costs, and are usually the first step leading to lower extremity amputation.⁶ Those who develop a diabetic foot ulcer are at a greater risk of premature death, myocardial infarction and fatal stroke than those without a history of ulceration. Annual incidence of amputation ranges between 0.25% to 1.8%.⁷ It is not only the financial costs to societies but equally as important are the costs to the patients that have a foot ulcer. Patients with diabetic foot ulcers are more likely to have depression.⁸ Their quality of life is poorer.⁹ People with a history of foot ulcers have a 40% greater mortality rate than those with diabetes alone.¹⁰ Mortality following amputation is similar to the presence of a foot and is around 50% at 5 years.¹¹ It is a pivotal event in a person's life.

The risk factors for development of diabetic foot ulcers are neuropathy, peripheral vascular disease, foot deformity, present or previous diabetic foot ulcer, age, gender, social isolation, retinopathy and renal disease.¹²

In our study, out of 106 patients, 53 patients were included in foam dressing group and 53 patients in saline dressing group. The mean age of the patients was 51+/- 8.481 years in foam dressing group, and 48.17+/- 8.187 years in saline dressing group. 46% of patients were aged less than 50 years, and 54% were aged more than 50 years overall (p-value 0.009). This is showing an increased incidence of diabetic ulcers with age. In foam dressing group 23 patients were females and 30 patients were males. Whereas in saline dressing group 11 were females and 42 were males. 31.8% of patients were females, and 68.2% were males overall (p-value <0.001). This male predominance is probably due to the reason that in our society males

work outdoors mostly and will be barefoot while working, thus are more prone to trauma. Besides, a lot of males smoke cigarette which impedes blood supply by increasing vasospasm, blood viscosity and hypercoagulability, thus predisposing to ischemic foot ulceration.

In our study, 28 patients had type 1 diabetes mellitus, and 78 patients had type 2 diabetes mellitus, corresponding to 26.4% and 73.4% respectively (p-value 0.475). Incidence of Type 2 diabetes mellitus is increasing rapidly, also it is the most common type of diabetes mellitus.⁵⁹ The mean duration of diabetes was 9.92 \pm 5.47 years in foam dressing group and 11.15 \pm 5.74 years in saline dressing group (p-value 0.34). The mean duration of ulcer was 10.85 \pm 7.69 months in foam dressing group and 8.11 \pm 8.30 months in saline dressing group (p-value 0.069). The mean HbA1c levels were 6.72 \pm 0.32 in foam dressing group and 6.66 \pm 0.32 in saline dressing group (p-value 0.71).

In our study, MeggitWagner's classification was used to assess the severity of diabetic ulcers. 23 patients had grade 1 ulcer and 83 patients had grade 2 ulcer (p-value 0.574). The limitations of this classification system is that it does not include PAD and infection, yet it is widely accepted classification system because of its simplicity and also it is well established. Other classification systems have come up over years such as University of Texas, SINBAD, PEDIS etc.,. University of Texas system includes infection and ischemia and is better classification than Wagner. SINBAD and PEDIS being other classification systems which are also being used.

In our study, 21 patients out of 106 had moderate to high exudative discharge from the ulcer and 85 patients had dry to low exudate (p-value 0.864). All ulcers required

serial debridements under local anaesthesia and IV antibiotics were administered as per culture sensitivity reports. 77 patients had ulcer over dorsal aspect of foot and 29 patients had ulcer over plantar aspect of foot (p-value <0.001). Diabetic foot ulcers are more common in the plantar aspect of foot. Dorsal aspect ulcers being the more predominant ulcers in our study.

Conclusion:

Wound closure is the ultimate aim in diabetic ulcers and early intervention will promote this to occur. The two methodologies of dressings applied in this study thus help in assessing wound healing rates, with improved healing and increased proportion of complete closure of ulcers seen in foam dressing group compared to conventional saline dressings.

Polyurethane foam dressing are an excellent alternative to saline dressings because of the following reasons:

- Prevention of tissue dehydration and cell death
- Increased breakdown of dead tissue on the wound surface
- Interaction growth factors on their target cells
- Accelerated angiogenesis
- Significant reduction in wound pain
- Less risk of infection
- Less scar tissue is formed resulting in better cosmetic appearance
- Removal of dressing is less traumatic and less painful
- Optimal wound healing environment
- Improved quality of life for the patient

References

1. Mekkes JR, Loots MA, Van Der Wal AC, Bos JD. Causes, investigation and treatment of leg ulceration. *Br J Dermatol.* 2003 Mar;148(3):388-401. doi: 10.1046/j.1365-2133.2003.05222.x. PMID: 12653729.
2. Thekdi PI, Bathla V, Koradi P, Jhala D, Patel D. A study on newer dressing materials versus conventional dressing materials in ulcer healing. *International Surgery Journal.* 2016 Dec 13;3(1):108-12.
3. Townsend CM, Beauchamp RD, Evers BM, Mattox KL. *Sabiston textbook of surgery E-book.* Elsevier Health Sciences; 2016 Apr 22.
4. Rahman GA, Adigun JA, Fadeyi A. Epidemiology, etiology and treatment of chronic leg ulcer: experience with sixty patients. *Annals of African Medicine.* 2010;9(1).
5. Atlas D. International diabetes federation. *IDF Diabetes Atlas, 7th edn.* Brussels, Belgium: International Diabetes Federation. 2015.
6. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *Jama.* 2005 Jan 12;293(2):217-28.
7. Hunt DL. Diabetes: foot ulcers and amputations. *BMJ clinical evidence.* 2011;2011.
8. Jeffcoate WJ, Harding KG. Diabetic foot ulcers. *The lancet.* 2003 May 3;361(9368):1545-51.
9. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. *The Lancet.* 2005 Nov 12;366(9498):1719-24.
10. Iversen MM, Tell GS, Riise T, Hanestad BR, Østbye T, Graue M, Midthjell K. History of foot ulcer increases mortality among individuals with diabetes: ten-year follow-up of the Nord-Trøndelag Health Study, Norway. *Diabetes care.* 2009 Dec 1;32(12):2193-9.

11. Young MJ, McCardle JE, Randall LE, Barclay JI. Improved survival of diabetic foot ulcer patients 1995–2008: possible impact of aggressive cardiovascular risk management. *Diabetes Care*. 2008 Nov 1;31(11):2143-7.
12. Abbott CA, Carrington AL, Ashe H, Bath S, Every LC, Griffiths J, Hann AW, Hussein A, Jackson N, Johnson KE, Ryder CH. The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort. *Diabetic medicine*. 2002 May;19(5):377-84.