ISSN- O: 2458 - 868X, ISSN –P: 2458 - 8687

International Journal of Medical Science and Innovative Research (IJMSIR)

IJMSIR : A Medical Publication Hub

Available Online at: www.ijmsir.com

Volume – 3, Issue –1, January - 2018, Page No. : 161 - 165

A Study to Compare the Effect of Saline Dressing Verses Various Agents for Management of Diabetic Foot Ulcer

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Type of publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Introduction – the interplay between peripheral neuropathy, microvasculopathy, hyperglycemic and immunocompromised state of diabetes mellitus leads to diabetic foot ulcer. Various products are used in the management of diabetic foot ulcer, which if useful can help reduce significant morbidity to the patient. *Aim* – to study the age and sex incidence , duration of onset of diabetes and diabetic foot (DF) and to evaluate the outcome of various dressings in management of the ulcer. *Material and Methodology – Place of study* – Department of General Surgery, Stanley Medical College. *Duration* – may 2015 to may 2017. Divided into groups and received saline, povidone- iodine, metronidazole and eusol dressing. Prospective interventional study was conducted after institutional ethical committee clearance. *Results* – 66% males 34% females. Most between 41- 60 years of age. Use of various products did not offer any healing benefit when compared to normal saline dressing.

Keywords – diabetes mellitus, diabetic foot ulcer, betadine, povidone iodine, metronidazole, saline dressing, diabetic amputation.

Introduction - Diabetes is a major cause of morbidity and mortality in patients and present with diabetic foot ulcer complications . The prevalence of diabetes worldwide was estimated to be 2.8% in 2000 and is projected to be 4.4% in the year 2030, with the total number of people with diabetes expected to rise from 171 million in 2000 to 366 million in 2030.[1] Epidemiologic studies suggest that 2.5% of diabetic patients develop diabetic foot (DF) ulcers each year and 15% develop DF ulcers during their lifetime.[2]

DF is the main cause of nontraumatic lower extremity amputations[3] and precedes 85% of the cases.[4] DF lesions are a significant health and socioeconomic problems, having adverse effects on the quality of life and imposing a heavy economic burden on the patient and the State; it can lead to prolonged hospitalization and the need for rehabilitative and home care services.[5,6]

The development of a foot ulcer is traditionally considered to result from a combination of peripheral vascular disease, peripheral neuropathy and infection.[7] More recently, some factors have been identified that are believed to increase the risk of amputation in these patients.

Early recognition and management of risk factors for foot complications may prevent amputations, especially of the major type and prevent other adverse outcomes. Ethnic differences in amputation rates have been observed.[4,8,9] According to the genetic profile and cultural features of a given population, there may be differences in the risk factor pattern of the clinical complications of diabetes.

In the West, various reports are available on the risk factors for complications of diabetes; the aim of

identifying these risk factors being to develop strategies for avoiding the severely reduced quality of life following amputation.[9–13] In Iran, however, little data are available on the risk factors for amputation in DF.

AIM :

To study the age and sex incidence of diabetic patients , to study the duration between the onset of diabetes and the development of foot ulcer and to evaluate the outcome of various dressings in management of diabetic foot among the patients with diabetic foot ulcers admitted in Stanley Medical college from may 2015 to may 2017.

Materials And Methods:

A Prospective Interventional Study was conducted in Government Stanley Medical College from may 2015 to may 2017 . about 83 patients were included in the study and randomly allocated into four groups which respectively received saline, povidone-iodine, metronidazole and eusol dressing. Detailed history about the onset of diabetes, regularity of treatment and follow up were elucidated. Detailed history of present lesion – mode of onset, progression were recorded. Detailed general examination and local examination were carried out. All patients underwent daily surgical wound debridement and daily dressing.

Inclusion Criteria:

All patients were classified according to depth ischemia classification. Patients in grade – depth 0, 1, 2, 3 and ischemia A were included in the study. Appearance of healthy granulation tissue in the floor of the ulcer is taken as the end point of observation.

Brodsky Depth/Ischemia Classification [14]

DEPTH

GRADE	DEFINITION
0	At-risk foot with previous ulcer that may cause new ulcer
1	Superficial non-infected ulcer
2	Deep ulcer with tendon or joint exposed (+/- infection)
3	Extensive ulcer with bone exposed or deep abscess

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GRADE	DEFINITION
A	No ischemia
B	Ischemia, no gangrene
C	Partial forefoot gangrene
D	Total foot gangrene

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Observation And Results:

83 patients were included and 54 patients were males and 29 females. Initially 108 patients were included but during the course of stau in hospital they voluntarily or involuntarily withdrew form the study.

Table 1 – Age Incidence

Age group in years	Male	Female	Male %	Female %
20- 30	Nil	Nil	Nil	Nil
31- 40	5	1	9%	3%
41- 50	13	10	24%	34%
51- 60	22	12	40%	41%
61- 70	11	5	20%	19%
71- 80	3	1	7 %	3%
Total	54	29	100%	100%

Incidence in both male and female is maximum at 51- 60 yrs of age reflecting the gradual progression of disease

Family History:

This shows that 62% of the patients had positive family history.

Table 2 – duration of diabetes

Age in years	Male	Female	Total number of patients	Percentage
<1 yr	1	Nil	1	2%
1-5 yrs	5	2	7	8%
5-10 yrs	33	17	50	60%
>10 yrs	15	10	25	30%

Table 3 – treatment for diabetes

	Patient on OHA	Patient on Insulin	Total no. of patients	Percentage
Irregular	43	17	60	72%
Regular	15	8	23	28%

Physical activity status

22 % of the patients had sedentary lifestyle in this study

Table 4 – precipitating factor

	No. of patients	Percentage
Spontaneous	42	50%
Accidental injury	23	28%
Nail cutting	14	17%
Previous lesion	4	5%

Table 5 – grading of ulcer

Grade	Male	Female	Total	Percentage
1A	9	5	14	17%
2A	33	17	50	60%
3A	12	7	19	23%

Table 6 – study group data

Grading	Group A – saline dressing	Group B – povidone iodine dressing	Group C – metronidazole dressing	Group D – Eusol dressing
1A	3	4	3	4
2A	13	12	12	13
3A	5	4	6	4
TOTAL	21	20	21	21

Table 7- Time interval vs grade of lesion

	Time interval in days			
Grading	Group A	Group B	Group C	Group D
1A	18-24	21-25	17-21	20-24
2A	26-31	20-32	28-35	27-32
3A	41-52	46-53	39-48	43-54

Table 8- factors interfering with response

Factors	Total	Percentage
Grade of lesion	13	37%
Non – Compliance of Patients	11	31%
Uncontrolled Hypertension	4	11%
Hyperlipidemia	3	10%
Smoking	4	11%
Total	35	100%

Table 9- Test of significance saline vs povidone iodine

Test of significance is carried in accordance with chi-square test and test results are compared in accordance with the table of test of signifance.

Group	Responder	Non Responder	Total
A	11	10	21
B	15	5	20
Total	26	15	41

Chi – Square test = $\sum (O - E)^2 / E = 1.662$

P Value > 0.1 which implies the results are not significant

Table 10 –Saline vs Metronidazole

Group	Responder	Nonresponder	Total
A	11	10	21
C	13	8	21

TOTAL	24	18	42

Chi – Square test = $\sum (O – E)^2 / E = 0.41$

P Value > 0.1 which implies the results are not significant

Table 11 – Povidone iodine Vs Metronidazole

Group	Responder	Nonresponder	Total
A	15	5	20
C	13	8	21
TOTAL	28	13	41

Chi – Square test = $\sum (O – E)^2 / E = 0.80$

P Value > 0.1 which implies the results are not significant

Table 12 – Metronidazole vs Eusol

Group	Responder	Nonresponder	Total
C	13	8	21
D	9	12	21
TOTAL	22	20	42

Chi – Square test = $\sum (O – E)^2 / E = 1.43$

P Value > 0.1 which implies the results are not significant

Table 12 – Povidone Iodine vs Eusol

Group	Responder	Nonresponder	Total
B	15	5	20
D	9	12	21
TOTAL	24	17	41

Chi – Square test = $\sum (O – E)^2 / E = 2.99$

P Value > 0.05 which implies the results are not significant

Since the tests are not significant Null Hypothesis is proved in this Chi- Square test which shows one dressing is not superior when compared to others.

Discussion :

About 66% of the patients were male and 34% were female. Maximum numbers of patients were seen between the age group of 51- 60 years of age. In this group male and female percentage is more or less the same i.e., 51- 60 years the percentage of male is 40 and of female is 41.Longer duration of diabetes, poor glycemic control and physical stress had direct correlation with development of foot ulcer.

The Grade of the lesion, noncompliance of patients, uncontrolled hypertension, smoking and hyperlipidemia interfered with wound healing.This study clearly showed that usage of povidone iodine, eusol and metronidazole did not offer any healing benefit when compared to normal saline dressing. Hence a Multidisciplinary approach with holistic view forms the background for management of diabetic foot.

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