Section: General Surgery

Original Research Article

A PROSPECTIVE STUDY ON DIABETIC FOOT ULCER TO DETERMINE THE EFFECTS OF VARIOUS FACTORS ON ITS OUTCOME AND ROLE OF IONIC SILVER DRESSING IN ULCER HEALING

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ABSTRACT

Background: Aim: The aim of the present study was to understand the various aspects of diabetic foot ulcer, its etiology, progression and role of wound debridement and ionic silver dressing in ulcer healing.
Materials and Methods: The present study was conducted in the Department of General Surgery, Calcutta National Medical College & Hospital, Kolkata from January, 2019 to July, 2020. All the patients attending outdoor or admitted with diabetic foot gangrene in General Surgery Department of Calcutta National Medical College & Hospital, Kolkata.
Results: The proportion of the patients with age between 46-55 years (39.0%) was significantly higher. Only 4.0% of the patients were with age<35 years. The proportion of males 103(69.30%) was significantly higher than that of females 47(30.7%). 113 patients had been suffering from diabetes. Most of the patients (21.3%) had ulcer at dorsum followed by Great toe (20.0%). Most (56.0%) of the ulcers were in the Grade-II followed by Grade-III (34.7%). Only 1.3%, 2.7% and 5.3% were in the grade of V, I and IV respectively.116 patients had ulcer between 31-180 days. Most (90.7%) of the patients were with duration of DM more than 5 years. Most of the patients were having level of HbA1c between 9.1-12.0 (54.7%) followed by 7.0-9.0(41.3%). Only 1.3% had <7.0.
Conclusion: Silver ionic dressings are being commonly used for burns and other chronic wounds and its use can be extended to diabetic foot ulcers also. It is a cost effective option with better results.
Keywords: **D**iabetic foot ulcer, etiology, progression, role of wound debridement, ionic silver dressing, ulcer healing.

INTRODUCTION

Diabetes is a worldwide problem. India has the dubious distinction of becoming the diabetic capital of the world within the next few years: With its complications it is going to burden the resources of the country. A majority of diabetic patients develop foot ulcers in one point of time or other during the course of their illness. A significant number of such patients require long term hospital treatment and amputations. The etiopathogenesis of diabetic foot lesions are multifactorial. The skin of dorsum of the foot is thin and highly flexible, containing hair follicles, sweat glands land scanty sebaceous gland. Hairs are sparse and thin. The skin is less than 2 mm thick and few fibrous septa penetrate to deeper facial structures. The plantar skin is 5 mm thick especially over those points which bear weight viz. heel, ball of big toe and lateral margins of the sole. It has no hair follicles or sebaceous glands but glands are numerous. Hypodermis is not part of the skin but attaches the skin to underlying structures. Hypodermis is composed of loose areolar connective tissue most of which are composed of collagenous and elastic fibers running parallel to the surface of the skin, but some are continuous with the fibers of dermis. Often fat cells are deposited among these fibers. Hypodermis is well supplied with blood vessels and nerve endings. Tactile sensation is exceptionally good in the sole.[1]

Cutaneous nerves are arranged in the following way. The medial plantar nerve supplies the three and half digits of the foot. The lateral plantar nerve supplies one and half digits. The medial calcaneal branches of the posterior tibial nerve supply the skin under the heel. The motor and sensory components of the sciatic nerve supply the foot. The innervation to the sole is from the medial calcaneal branch of the tibial nerve. The dorsum of the toes is supplied by the digital branches of these nerves except the terminal phalanges which are supplied by the plantar nerves.[2] Patients with the diabetes have diminished ability to establish collateral circulation especially in arteries around knee Atherosclerotic vascular disease is more prevalent & accelerated with diabetes mellitus.[3] Enhanced non-enzymatic glycosylation of lipoprotein has been shown to impair the binding of glycosylated LDL to the LDL receptor. Glycosylated LDL enhances the formation of cholesteryl ester and accumulation human macrophages – formation of foam cells characteristic of the early atheromatous lesion.[4]

The management of diabetic patients with infected feet has to be individualized. Factors that have to be considered include manifestations of sepsis, the extent of tissue necrosis and gangrene. Also the vascularity to the involved limb, the extent and severity of the soft tissue infection, the presence and extent of bone involvement, the severity of the peripheral neuropathy, the presence and severity of foot deformity. The metabolic control of the diabetic state should be prompt and aggressive. If the glycemic status of the patient is not adequately controlled with oral drugs, insulin therapy should be initiated. With the availability of capillary blood glucose monitoring at the bedside, rapid correction of hyperglycaemia can be achieved.[5]

The aim of the present study was to understand the various aspects of diabetic foot ulcer, its etiology, progression and role of wound debridement and ionic silver dressing in ulcer healing.

MATERIALS AND METHODS

The present study was conducted in the Department of General Surgery, Calcutta National Medical College & Hospital, Kolkata from January, 2019 to July, 2020.All the patients attending outdoor or admitted with diabetic foot gangrene in General Surgery Department of Calcutta National Medical College & Hospital, Kolkata. 150 patients were included in the study.

Inclusion Criteria

1. All diabetic patients having a foot ulcer in attending outdoor or admitted in surgery ward of the department of General Surgery.

Exclusion Criteria

1. Diabetic foot problem without gangrene and need no surgical debridement.
2. Dry gangrene of foot in diabetic patients.
3. Known case of atherosclerotic gangrene of foot.
4. Other co-morbid conditions like renal failure and generalized debility which adversely affect wound healing.
5. Patients with allergic to silver ionic.

This study included 150 patients with diabetic foot gangrene admitted in Calcutta National Medical College & Hospital, Kolkata. Satisfying all the inclusion and exclusion criteria mentioned above and after the clearance of ethical committee patients were included in the study. A detailed history was taken from the patients. All patients underwent detailed clinical examination and relevant investigations were done. The wounds were thoroughly debrided. Initially, antibiotic was started empirically with broad spectrum antibiotics, having Gram +ve, Gram–ve and anaerobic coverage. Later, as per culture and sensitivity report antibiotic was changed, if necessary.

Debridement

Under anaesthesia surgical debridement of diabetic foot gangrene was done at operation theatre. Wound swab was taken and sent for culture and antibiotic sensitivity. Debridement was repeated, if found necessary

Dressing

Before applying dressing in all the four groups wound is cleaned with normal saline.

Ionic silver dressing is applied on the wounds. Transparent occlusive dressing is applied. Adequate hydration is ensured.

Dressing frequency

Daily dressing was done till the development of healthy granulation tissue, thereafter, dressing was done every alternate day.

Blood sugar control

As per the advice of the endocrinologist blood sugar control was done. X-ray of the foot was done for exclusion of any evidence of suspected osteomyelitis or to detect bony deformity. In some cases, Colour Doppler study was done to detect any evidence of ischemia.

Observation

Follow up in OPD and follow up at clinic twice a week for 1 week, once a week for next 2 weeks and then after 1 month,3 months and 6 months intervals.

Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analysed by SPSS 10.0.1and GraphPad Prism version 5. Data have been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. The median and the interquartile range have been stated for numerical variables that are not normally distributed. Student's independent sample's t- test was applied to compare normally distributed numerical variables between groups, Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t- distribution under the

null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a t value is determined, a p-value can be found using a table of values from Student's t- distribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis. $p<0.05$ was considered statistically significant.

RESULTS

Table 1: Baseline characteristics

Age Group (in years)	Number	%
26-35	6	4.0%
36-45	26	17.3%
46-55	74	49.3%
56-65	44	29.3%
Gender		
Male	103	69.3%
Female	47	30.7%
Detection of diabetes		
Known	113	75.33
Newly detected	37	24.67

The proportion of the patients with age between 46-55 years (39.0%) was significantly higher. Only 4.0% of the patients were with age<35 years. The proportion of males 103(69.30%) was significantly higher than that of females 47(30.7%). 113 patients had been suffering from diabetes.

Table 2: Distribution of site of ulcer, grade of ulcer (WAGNERS GRADING) and duration of ulcer

Site of ulcer	Number	%
Dorsum	31	21.30%
Great Toe	30	20.00%
Metatarsal Head	18	12.00%
Other Toes	18	12.00%
Heel	14	9.30%
Fore Foot	10	6.70%
Mid Foot	8	5.30%
Others	20	13.30%
Grade of ulcer		
I	4	2.7%
II	84	56.0%
III	52	34.7%
IV	8	5.3%
V	2	1.3%
Duration of ulcer		
≤30	24	16.0%
31-180	116	77.3%
>180	10	6.7%

Most of the patients (21.3%) had ulcer at dorsum followed by Great toe (20.0%). Most (56.0%) of the ulcers were in the Grade-II followed by Grade-III (34.7%). Only 1.3%, 2.7% and 5.3% were in the grade of V, I and IV respectively. 116 patients had ulcer between 31-180 days.

Table 3: Distribution of duration of diabetes mellitus and level of HbA1c

Duration of DM (in years)	Number	%
≤5	**14**	9.3%
6-10	**88**	58.7%
11-15	**26**	17.3%
16-20	**12**	8.0%
>20	**10**	6.7%
LevelofHbA1c		
<7.0	2	1.3%
7.0-9.0	62	41.3%
9.1-12.0	82	54.7%
>12	4	2.7%

Most (90.7%) of the patients were with duration of DM more than 5 years.Most of the patients were having level of HbA1c between 9.1-12.0 (54.7%) followed by 7.0-9.0(41.3%). Only 1.3% had <7.0.

Table 4: Distribution of type of Culture Sensitivity and findings of Doppler

Type of CS	Number	%
Mono	78	60.6%
Poly	51	39.4%
Total	131	100.0%
Findings of doppler		
Abnormal	28	18.7%
Normal	122	81.3%

Out of the total 150 cases CS was done, 66 (86.8%) cases out of which 60.6% and 39.4% of the CS were mono and poly respectively.

Table 5: Distribution of ABPI

ABPI	Right ABPI		Left ABPI	
	Number	%	Number	%
<0.30	0	0.0%	0	0.0%
0.30-0.70	5	6.9%	6	8.1%
0.71-0.90	7	9.7%	5	6.8%
≥1	60	83.3%	63	85.1%
Total	72	100.0%	74	100.0%

In most of the cases both right and left ABPI were ≥1. In 18.7% of the cases abnormal Doppler findings was found.

Table 6: Distribution of Treatment Modality

Treatment Modality	Number	%
Ionicsilver dressing	46	30.70%
Debridement-ionic dressing	56	37.33%
Debridement-ionic dressing-STSG	69	46.00%
Ionic silver-offloading	40	26.67%
Amputation--toe	13	2.60%
Amputation-Trans-metatarsal	2	1.30%
Amputation-Fore Foot	1	0.06%
Amputation–Belowknee	0	0.00%
Amputation-Midthigh	0	00.00%
Total	150	100.0%

In the present study maximum number of patient undergone combined debridement with ionic silver dressing and grafting (46%) followed by debridement and ionic dressing (37%) and ionic silver alone (22%).

Table 7: Distribution of status at different follow-up (outcome)

Status	At1st month		At3rdmonth		At6thmonth	
	Number	%	Number	%	Number	%
Healed	14	9.3	105	70	15	10
Complicated	8	5.3	0	0.0	0	0.0
Newulcer	0	0.0	2	1.3	7	4.6
Recurrence	0	0.0	2	1.3	5	3.3

Patients who were lost to follow-up were found as healed in the previous follow-up.

DISCUSSION

The present study has been conducted on 150 cases of diabetic foot gangrene admitted in the Department of General Surgery, Calcutta National Medical College & Hospital, Kolkata from January, 2019 to July, 2020.

The proportion of the patients with age between 46-55 years (39.0%) was significantly higher. Only 4.0% of the patients were with age<35 years. When compared with Wheellock Jr FC6, there is not much difference in youngest and oldest age group. The proportion of males 103(69.30%) was significantly higher than that of females 47(30.7%). Mayfield JA et al,[7] conducted study in which 53% were males. 113 patients had been suffering from diabetes. In this study 25% were newly detected diabetic patients as compared to a study by Siegel et al,[8] where 12% were newly detected.

In the present study maximum site of occurrence of ulcer over plantar aspect (66%) followed by dorsum (20%) and great toe (12%) respectively. 56% of the ulcers was Wagner Grade II. Study done by Sharada R et al8documented maximum occurrence over plantar aspect. Maximum type of ulcer in the study was Wagner grade II. In this study most of the patient's had HbA1c level above 7 as compared to the study by Ahmad NSet al,[9] which showed out of the total of 557 patients, 23.0% (n = 128) had HbA1c levels below 6.5%, which is classified as good glycemic control, whereas the mean (SD) HbA1c level for all 557 patients was 8.04% (2.04%).

In the present mean ABPI >1. In the present study, early disappearance of discharge and slough and early appearance of granulation tissue point towards

a quicker healing in diabetic foot ulcers using ionic silver dressing. The silver ions promote a faster wound contraction due to accelerated proliferation of fibroblasts. In the present study maximum number of patient undergone combined debridement with ionic silver dressing and grafting (46%) followed by debridement and ionic dressing (37%) and ionic silver alone (22%). Everett E and Mathioudakis N,[11] reviewed the rationale and guidelines for current standard of care practices and reviewed the evidence for the efficacy of adjuvant agents. The adjuvant therapies reviewed include the following categories: non-surgical debridement agents, dressings and topical agents, oxygen therapies, negative pressure wound therapy, acellular bioproducts, human growth factors, energy based therapies, and systemic therapies. Many of these agents have been found to be beneficial in improving wound healing rates, although a large proportion of the data are small randomized controlled trials with high risks of bias.
Highest incidence of healing is within 3 months (70%). 9.3% patient showed early healing within 1 month and late healing after 6 months are seen in 10% patients. Ulcers are more prone to get secondarily infected within 1 month (5.3%) which is attributed due to uncontrolled diabetes. New ulceration in another part developed in 9 patients mostly after 6 months (4.6%). Recurrence is seen after 6 months in3.3% patients despite therapy. 1.3% patients had to undergo amputation. Although Ndosi Met al,[12] showed that participants with a single ulcer on their index foot had a higher incidence of healing than those with multiple ulcers (hazard ratio 1.90, 95% CI 1.18 to 3.06).

CONCLUSION

The youngest patient in present study series of 150 patients studied was 38 years, and the oldest 81 years. The highest number of patients was seen in the age group of 46-55 years. The male to female ratio was approximately 2.1:1. 24% of the patients were newly diagnosed. Duration of the diabetes varies from 2 years to 23 years. About 60% had diabetes for 6-10 years. The ulcer was more common on the planter aspect than on dorsal aspect in the plantar aspect great toe was the commonest site. Most of the ulcer was Wagner grade II. Silver ionic dressings are being commonly used for burns and other chronic wounds and its use can be extended to diabetic foot ulcers also. It is a cost effective option with better results.

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