



AN OBSERVATIONAL STUDY TO ASSESS THE CLINICAL PROFILE AND OUTCOMES OF DIABETIC FOOT ULCER AT A TERTIARY CARE HOSPITAL IN JAIPUR

General Surgery

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ABSTRACT

Background: Diabetes mellitus (DM) is one of the main problems in health systems and a global public health threat that has increased dramatically over the past 2 decades [2, 3]. According to epidemiological studies, the number of patients with DM is estimated to be more than 360 million people by 2030 [4, 5]. DFU is considered as a major source of morbidity and a leading cause of hospitalization in patients with diabetes. In view of this, the present study was undertaken to address the demographics, clinical profile, and outcomes of diabetic foot ulcer at a tertiary care hospital in Jaipur. **Methods:** A hospital based prospective observational study **Observations:** The mean age of the study participants was found to be 56.33 + 12.637. 61.8% of the study participants were found to have pure neuropathic type of ulcer with 24.3% having neuro-ischemic type of ulcer. 13.9% of the study participants had pure ischemic type of ulcer. 37.5% of the study participants underwent wound debridement. 3.5% of the study participants underwent SSG, 59% of the study participants underwent amputations. The mean HbA1c of the study participants was found to be 8.951 + 1.6008. The mean duration of stay at hospital of the study participants was found to be 5.73 + 2.025. Mortality of the study population was 3.5%. **Conclusion:** Majority of the patients underwent multiple toe amputations, there was a significant statistical association between the Wagner's grade and the mode of intervention performed. Adequate glycaemic control, periodic screening for diabetic foot neuropathy, preventive foot care and education programs should be made available, particularly in primary and secondary health care settings to tackle the DFU disease which is a contributor to significant morbidity among diabetics.

KEYWORDS

diabetes mellitus, diabetic foot ulcer, tertiary care centre, wagners grading, hba1c, neuropathy.

INTRODUCTION

Diabetes is a serious, chronic disease that occurs either when the pancreas does not produce enough insulin, or when the body cannot effectively use the produced insulin. Raised blood glucose, a common effect of uncontrolled diabetes, may, over time, lead to serious damage to the heart, blood vessels, eyes, kidneys and nerves^[1]

Diabetic Foot Ulcer (DFU) is a common complication of DM and is a chronic condition that is usually the result of poor glycaemic control, underlying neuropathy, peripheral vascular disease, or poor foot care. DFU's are usually in the areas of the foot which encounters repetitive trauma and pressure sensations. The disease is typically chronic, and an interprofessional approach will have the best outcome^[6]. It is estimated that 15% of patients with diabetes will suffer from DFU during their lifetime and the prevalence of DFU ranges from 4%-27%^[7-9]. DFU has shown an increasing trend over previous decades^[10,11].

DFU is one of the common causes for osteomyelitis of the foot and amputation of lower extremities. Overall, the rate of lower limb amputation in patients with DM is 15 times higher than patients without diabetes. It is estimated that approximately 50%-70% of all lower limb amputations are due to DFU^[7].

Treatment of diabetic foot ulcer should be systematic for an optimal outcome. The primary management goals for DFU are to obtain wound closure as expeditiously as possible^[12,13]. The management of foot ulcer depends on the severity and vascularization of the wounded limbs. DFU requires appropriate wound care and antibiotic treatment for healing^[14].

MATERIAL AND METHODS

Study Area

The study was conducted in Department of Surgery, SMS Hospital, Jaipur (Raj.) after taking due permission from Institutional Ethics Committee.

Study Type And Design

Hospital Based Prospective Observational Study

Study Period

The duration of the study was from sept 2020-sept 2022

Study Population

Patients with diabetic foot ulcers admitted in Department of Surgery, SMS medical College and attached Hospital, Jaipur, Rajasthan after obtaining written informed consent.

Sample Size

Sample size was calculated at 95% confidence level and alpha error of 0.05 assuming 70% foot ulcers were Wegner's grade ≥ 3 as per reference seed Article "Tjokorda Gde Dalem Pemayun & Ridho M. Naibaho (2017) Clinical profile and outcome of diabetic foot ulcer, a view from tertiary care hospital in Semarang, Indonesia, Diabetic Foot & Ankle, 8:1, 1312974," DOI: 10.1080/2000625X.2017.1312974

At the absolute allowable error of 7.5 % minimum 144 cases of foot ulcers were required for the study.

Sampling Technique

Convenient sampling technique. Every case falling in inclusive criteria was included till the sample size was achieved.

Selection Criteria

The patient was included according to following inclusion and exclusion criteria.

Inclusion Criteria

- 1) Patients with diabetic foot ulcer admitted in surgery department.
- 2) Age > 18 years
- 3) Patients willing to participate.

Exclusion Criteria

- 1) Patients with coexisting varicose ulcers.
- 2) Ulcers associated with deep vein thrombosis.
- 3) Malignant ulcers.
- 4) Patients who are known case of vasculitis.

METHODOLOGY

Patients were selected according to selection criteria.

A written informed consent was taken from the participants.

A predesigned pro forma was filled and Clinical profile and Wagner's grading is documented.

Management and outcomes of diabetic foot ulcers was recorded and assessed.

Clinical follow up was at 2 weeks assessing the outcomes of ulcer.

Statistical Analysis

The collected data was collected tabulated and entered to a PC as

master sheet.

1. Quantitative variables were expressed as mean and SD.
2. Qualitative variables were expressed as frequency and percent.
3. Appropriate statistical tests were applied to obtain results.
4. A significance level of $p < 0.05$ was used in all tests.

Data Analysis

Statistical methods for analysis involved descriptive statistics such as mean, standard deviation and frequencies. The data was compiled in MS Excel, The data was presented in table and graph wherever applicable. The data was analyzed as per objectives. Inferences were drawn with help of appropriate tests of significance.

Ethical Implications

- Prior to commencement of the study, the research protocol was ethically reviewed.
- Approved by the Ethics Review Committee of SMS Medical College and Hospital, Jaipur.

OBSERVATION AND RESULTS

Table 1: Age Group Distribution

AGE GROUP	FREQUENCY	PERCENTAGE
25-35	12	8.3
36-45	21	14.6
46-55	30	20.8
56-65	47	32.6
66-75	31	21.5
>75	3	2.1
MEAN + SD	56.33 + 12.637	

32.6% of the study participants were of the age group between 56-65 years of age followed by 20.8% in the age group between 46-55 years of age. The mean age of the study participants was found to be 56.33 + 12.637.

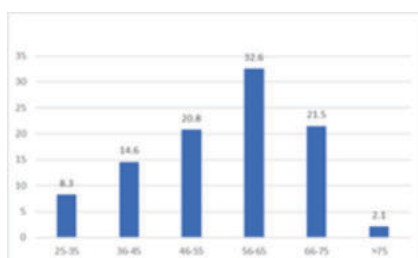


Figure 1: Age Group Distribution

Table 2: Gender Distribution

GENDER	FREQUENCY	PERCENTAGE
MALE	105	72.9
FEMALE	39	27.1

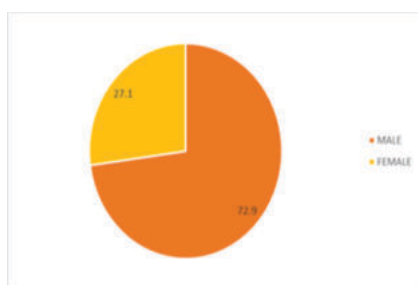


Figure 2: Gender Distribution

72.9% of the study participants were males with females contributing to 27.1% of the study participants.

Table 3: Wagner's Grading Distribution

WAGNER'S GRADING	FREQUENCY	PERCENTAGE
2 - Deeper, full thickness extension	2	1.4
3 - Deep abscess formation or osteomyelitis	81	56.3
4 - Partial Gangrene of forefoot	46	31.9
5 - Extensive Gangrene	15	10.4

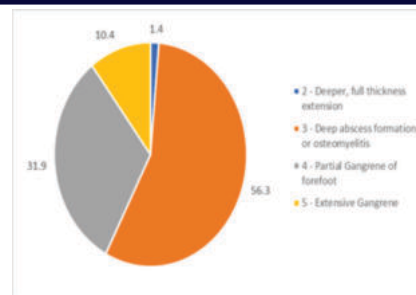


Figure 3: Wagner's Grading Distribution

56.3% of the study participants were found to have grade 3 DFU followed by 31.9% with grade 4 DFU. 10.4% of the study participants had grade 5 DFU with only 1.4% with grade 2 DFU.

Table 4: Distribution Of Type Of Ulcer

TYPE OF ULCER	FREQUENCY	PERCENTAGE
PURE ISCHEMIC	20	13.9
PURE NEUROPATHIC	89	61.8
NEUROISCHEMIC	35	24.3

61.8% of the study participants were found to have pure neuropathic type of ulcer with 24.3% having neuro-ischemic type of ulcer. 13.9% of the study participants had pure ischemic type of ulcer.

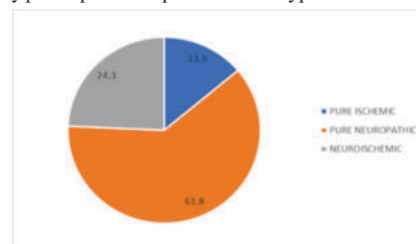


Figure 4: Distribution Of Type Of Ulcer

Table 5: Distribution Of Intervention

INTERVENTION		FREQUENCY	PERCENTAGE
DEBRIDEMENT		54	37.5
SSG		5	3.5
MINOR	SINGLE TOE 1	20	13.9
	S.TOE 2	7	4.9
	S.TOE 3	5	3.5
	S.TOE 4	9	6.3
	S.TOE 5	8	5.6
	MULTIPLE TOES	12	8.3
	FOOT AMPUTATION	5	3.5
MAJOR	BK	15	10.4
	AK	4	2.8



Figure 5: Distribution Of Intervention

37.5% of the study participants underwent wound debridement. 3.5% of the study participants underwent SSG. 13.9% of the study participants underwent single toe amputation. 8.3% of the study participants underwent multiple toe amputation. 10.4% of the study participants underwent below knee amputation. 2.8% of the study participants underwent above knee amputation.

Table 6: Distribution Of Culture Growth

CULTURE GROWTH	FREQUENCY	PERCENTAGE
NO GROWTH	41	28.5
ACINETOBACTER	4	2.8

CITROBACTER	10	6.9
E COLI	17	11.8
ENTEROCOCCUS	13	9.0
GRAM -VE NON-FERMENTING BACILLI	1	0.7
KLEBSIELLA	14	9.7
MRSA	13	9.0
PROTEUS	8	5.6
PSEUDOMONAS	16	11.1
STAPHYLOCOCCUS AUREUS	4	2.8
STREPTOCOCCUS	3	2.1

28.5% of the study participants did not have any growth on culture. The growth of organisms in the culture medium is seen in the following proportion of the study participants: E.coli (11.8%) > Pseudomonas (11.1%) > Klebsiella (9.7%) > MRSA (9%) > Enterococcus (9%) > Citrobacter (6.9%) > Proteus (5.6%) > Streptococcus (2.8%) > Staphylococcus (2.1%).

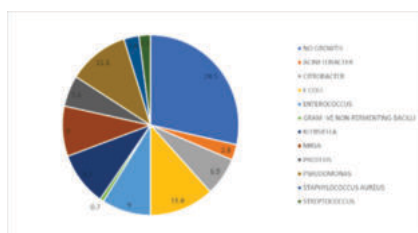


Figure 6: Distribution Of Culture Growth

Table 7: Initial And Follow-up Wound Size

WOUND SIZE	FREQUENCY	PERCENTAGE
INITIAL		
< 5 CMS	33	22.9
5-10 CMS	68	47.2
>10 CMS	43	29.9
FOLLOW-UP		
COMPLETE COVERAGE	8	5.6
2.5-5 CMS	86	57.2
5-10 CMS	33	22.9
>10 CMS	17	11.8

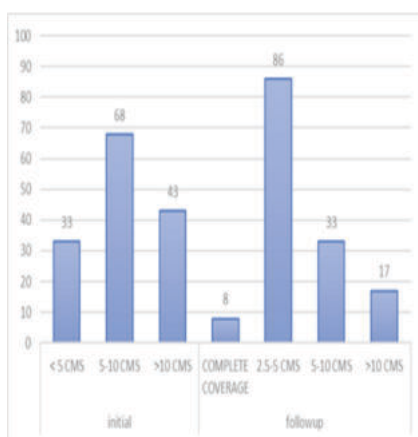


Figure 7: Initial And Follow-up Wound Size

47.2% of the study participants had initial wound size of 5-10 cms with 29.9% having wound size more than 10 cms. During follow-up, 5.6% of the study participants had complete coverage of the wound area, 90.3% of the study participants had wound size between 2.5-5cms.

Table 8: Glycemic Control Based On Hba1c

HBA1C CONTOL	FREQUENCY	PERCENTAGE
FAIR CONTROL (<7%)	56	38.9
GOOD CONTROL (7.1-8%)	3	2.1
POOR CONTROL (8.1-10%)	54	37.5
VERY POOR CONTROL (>10%)	31	21.5
MEAN + SD	8.951 + 1.6008	

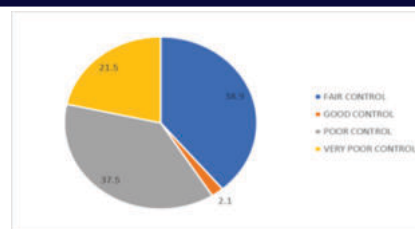


Figure 8: Glycemic Control Based On Hba1c

38.9% of the study participants had HbA1c values < 7%. 37.5% of the study participants had HbA1c values between 8.1-10% and 21.5% of the study participants had HbA1c values > 10%. The mean HbA1c of the study participants was found to be 8.951 + 1.6008.

Table 9: Association Of Intervention With Wagners Grading

INTERVENTION	GRADE	2	3	4	5	P Value
DEBRIDEMENT	COUNT	2	43	9	0	0.000
	%	3.7%	79.6%	16.7%	0.0%	
SSG	COUNT	0	4	1	0	0.0%
	%	0.0%	80.0%	20.0%	0.0%	
MINOR S.TOE 1	COUNT	0	14	6	0	0.0%
	%	0.0%	70.0%	30.0%	0.0%	
MINOR S.TOE 2	COUNT	0	2	5	0	0.0%
	%	0.0%	28.6%	71.4%	0.0%	
MINOR S.TOE 3	COUNT	0	4	1	0	0.0%
	%	0.0%	80.0%	20.0%	0.0%	
MINOR S.TOE 4	COUNT	0	3	5	1	11.1%
	%	0.0%	33.3%	55.6%	11.1%	
MINOR S.TOE 5	COUNT	0	3	5	0	0.0%
	%	0.0%	37.5%	62.5%	0.0%	
MINOR MULTIPLE TOES	COUNT	0	8	8	0	0.0%
	%	0.0%	50.0%	50.0%	0.0%	
MAJOR FOOT AMPUTATIONS	COUNT	0	2	3	0	0.0%
	%	0.0%	28.6%	37.5%	0.0%	
MAJOR BK	COUNT	0	0	6	10	62.5%
	%	0.0%	0.0%	37.5%	62.5%	
MAJOR AK	COUNT	0	0	0	4	100.0%
	%	0.0%	0.0%	0.0%	100.0%	

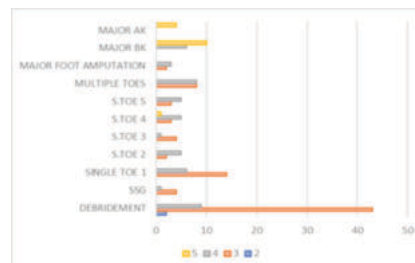


Figure 9: Association Of Intervention With Wagners Grading

100% of the study participants with grade 2 DFU underwent debridement. 79.6% and 16.7% of the study participants who underwent debridement were found to have grade 3 and 4 DFU, respectively. 70.0% and 30.0% of the study participants who underwent single toe amputation were found to have grade 3 and 4 DFU respectively. 50.0% each of the study participants who underwent multiple toe amputation were found to have grade 3 and 4 DFU, respectively. 28.6% and 37.5% of the study participants who underwent foot amputation were found to have grade 3 and 4 DFU, respectively. 37.5% and 62.5% of the study participants who underwent below knee amputation were found to have grade 4 and 5 DFU, respectively. 100% of the study participants who underwent above knee amputation were found to have grade 5 DFU. The association was found to be statistically significant between the modes of intervention and the Wagner's grade of the participants after applying chi square test.

Table 11: Association Of Wagners Grading With Hba1c

WAGNERS GRADING	N	HBA1C	P VALUE
		Mean	Std. Deviation

2	2	8.050	0.2121	0.000
3	81	8.365	1.0740	
4	46	9.172	1.6073	
5	15	11.560	1.3130	

The mean HbA1c values of the study participants with grades 2, 3, 4 and 5 were found to be 8.050±0.21, 8.365±1.07, 9.172±1.60 and 11.560±1.31 respectively. The association was found to be statistically significant between Wagner's grading and the HbA1c values of the study participants after using ANOVA test.

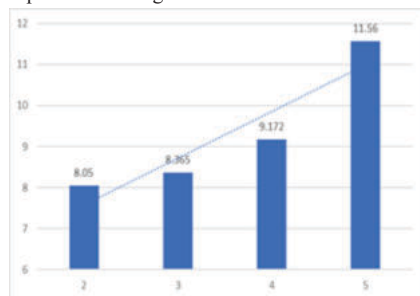


Figure 11: Association Of Wagners Grading With Hba1c

Table 12: Duration Of Stay At Hospital

DURATION OF STAY AT HOSPITAL	FREQUENCY	PERCENTAGE
1	1	.7
2	12	8.3
3	14	9.7
4	13	9.0
5	20	13.9
6	18	12.5
7	34	23.6
8	28	19.4
9	4	2.8
MEAN + SD	5.73 + 2.025	

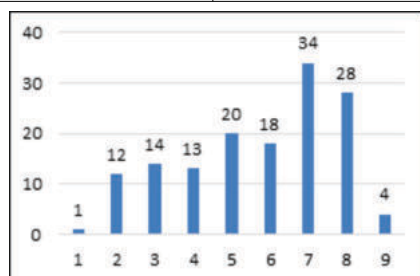


Figure 12: Duration Of Stay At Hospital

23.6% of the study participants had duration of stay at the hospital for 7 days with 19.4% of the study participants having duration of stay at the hospital of 8 days. The mean duration of stay at hospital of the study participants was found to be 5.73 + 2.025.

Table 13: Mortality Of The Study Participants

OUTCOME	FREQUENCY	PERCENTAGE
NO MORTALITY	139	96.5
DEATH	5	3.5

Figure 13: Mortality Of The Study Participants

96.5% of the study participants with diabetic foot ulcer recovered and 3.5% of the study participants died during the period of study.

CASE STUDY

The study included 144 Diabetic foot ulcer patients admitted under the Department of general surgery, S.M.S. Medical College & Associated Group of Hospitals, Jaipur to study the clinical profile and outcome of patients with diabetic foot ulcer.

In the present study, 32.6% of the study participants were of the age group between 56-65 years of age followed by 20.8% in the age group between 46-55 years of age. The mean age of the study participants was found to be 56.33 + 12.637. In a study done by Pourkazemi A et al. [15], the mean age of age of the study participants was found to be 55.4 ±

12.9 years of age, which is comparable with the findings of the present study. Also, in a study done by Sharma R et al. [16], the mean age of the study participants was found to be 54.08±10.33 years of age.. These findings are like the findings of the present study.

In the present study, 72.9% of the study participants were males with females contributing to 27.1% of the study participants. In a study done by Pemayun TGD et al. [17], Majority of the study participants were males. In a study done by Seth A et al. [18], 83.08% of the study participants were males. In a study done by Kavipriya S et al. [19], Majority of the study participants were males. These findings are similar to the findings of the present study.

In the present study, 56.3% of the study participants were found to have grade 3 DFU followed by 31.9% with grade 4 DFU. 10.4% of the study participants had grade 5 DFU with only 1.4% with grade 2 DFU. In a study done by Kavipriya S et al. [19], Out of 180, 73 patients were with Wagner grade ≥ 3. In a study done by Pemayun TGD et al. [17], 33% and 32.5% of the study participants had Wagner grade 3 and 4 respectively. These findings are like the findings of the present study. In a study done by Prakash V et al. [20], It was observed that majority of patients were in grade 2 (38%) and grade 3 (22%). The difference in the grades of ulcers can be attributed to the difference in the inclusion criteria.

In the present study, 61.8% of the study participants were found to have pure neuropathic type of ulcer with 24.3% having neuro-ischemic type of ulcer. 13.9% of the study participants had pure ischemic type of ulcer. In a study done by Prakash V et al. [20], 120 (43%) patients were found to have pure neuropathic, 31 (11%) patients were ischemic-type, while 84 (30%) were neuro-ischemic origin. These findings are like the findings of the present study.

In the present study, 28.5% of the study participants did not have any growth on culture. The growth of organisms in the culture medium is seen in the following proportion of the study participants: E. coli (11.8%) > Pseudomonas (11.1%) > Klebsiella (9.7%) > MRSA (9%) > Enterococcus (9%) > Citrobacter (6.9%) > Proteus (5.6%) > Streptococcus (2.8%) > Staphylococcus (2.1%). Diabetics with ulcers commonly experience infection with gram-positive organisms such as Staphylococcus aureus, Enterococcus, and gram-negative organisms like Pseudomonas aeruginosa, Escherichia coli, Klebsiella species, Proteus species, etc., and anaerobes [21]. Bhansal et al., [22] in his study concluded that 76 % of the microbes were gram-negative and 24 % were gram-positive. The predominance of gram-negative organisms has been noted in several studies [23,24]. However, certain studies [25] have established a higher proportion of gram-positive organisms. In a study done by Banu A et al [23], Staphylococcus aureus and Escherichia coli were the most isolated organisms (24.40%) followed by Pseudomonas aeruginosa (17.07 %). These findings are similar to the findings of the present study.

In the present study, 37.5% of the study participants underwent wound debridement. 3.5% of the study participants underwent SSG. 13.9% of the study participants underwent single toe amputation. 8.3% of the study participants underwent multiple toe amputation. 10.4% of the study participants underwent below knee amputation. 2.8% of the study participants underwent above knee amputation. 100% of the study participants with grade 2 DFU underwent debridement. 79.6% and 16.7% of the study participants who underwent debridement were found to have grade 3 and 4 DFU, respectively. 70.0% and 30.0% of the study participants who underwent single toe amputation were found to have grade 3 and 4 DFU, respectively. 50.0% each of the study participants who underwent multiple toe amputation were found to have grade 3 and 4 DFU, respectively. 28.6% and 37.5% of the study participants who underwent foot amputation were found to have grade 3 and 4 DFU, respectively. 37.5% and 62.5% of the study participants who underwent below knee amputation were found to have grade 4 and 5 DFU, respectively. 100% of the study participants who underwent above knee amputation were found to have grade 5 DFU. The association was found to be statistically significant between the modes of intervention and the Wagner's grading of the study participants.

In a study done by Kavipriya S et al. [19], the most common surgical techniques were debridement and abscess incision and drainage. The overall amputation rate was 30%. In a study done by Pemayun TGD et al. [17], The most common surgical procedures were debridement and abscess incision and drainage as majority of ulcers were in Wagner grade 3 and grade 4. The overall amputation rate was 36.3% (n = 98).

Multiple LEA (patients requiring further amputation due to progressions of the disease, such an initial digital and later requiring trans-metatarsal or major amputation) were performed in seven patients. Minor LEA was performed in 74 cases, wherein 67.2% of all amputations were performed at toe level. Major LEA was the outcome for 24 patients with four (4.1%) undergoing above-knee and 20 (20.4%) below-knee amputation. Patients with diabetes have increased risk of lower-extremity amputations and the main cause is diabetic peripheral arterial disease accelerated by the direct damage to the nerves and blood vessels by high blood glucose levels^[116]. These findings are like the findings of the present study.

In the present study, 47.2% of the study participants had initial wound size of 5-10 cms with 29.9% having wound size more than 10 cms. During follow-up, 5.6% of the study participants had complete coverage of the wound area, 90.3% of the study participants had wound size between 2.5-5cms. In a study done by Seth A et al.^[18], The mean baseline area of ulcer was 14.85 cm ± 23.12 cm, mean ulcer area at 1 month was 11.75 cm ± 22.68 cm, mean ulcer area at 2 months was 8.44 cm ± 22.05 cm and mean ulcer area at 3 months was 6.38 cm ± 21.19 cm. Percentage of ulcer healing at 1 month was 20.88%, at 2 months was 43.16%, and at 3 months was 57.04% which was significant at all-time points (P<0.001). These findings were similar to the findings of the present study.

In the present study, 38.9% of the study participants had HbA1c values < 7%. 37.5% of the study participants had HbA1c values between 8.1-10% and 21.5% of the study participants had HbA1c values > 10%. The mean HbA1c of the study participants was found to be 8.951 ± 1.6008. The mean HbA1c values of the study participants with grade 2, 3, 4 and 5 were found to be 8.050±0.21, 8.365±1.07, 9.172±1.60 and 11.560±1.31 respectively. The association was found to be statistically significant between Wagner's grading and the HbA1c values of the study participants. In a study done by Prakash V et al.^[20], 4% the study participants had HbA1c values < 7%. 24% of the study participants had HbA1c values between 8.1-10% and 60% of the study participants had HbA1c values > 10%. Regarding the relation between DFU an HbA1c, patients who achieved good glycaemic control, i.e. HbA1c ≤ 7%, had a 100% healing rate. Whereas the healing rate was only 52% among subjects whose HbA1c were still in higher grade (i.e., >7%) and the difference were statistically significant (p=0.007).

The current finding demonstrated that participants who had uncontrolled blood sugar having lesser success rate in treating DFU. Thus, degree of glycaemic control not only acts as a major risk factor for developing DFU but also plays a major role for its treatment success rate. Current study clearly shows that progression of major complications like DFU can be controlled if patients achieve optimal plasma glucose level.

Diabetic foot problems are one of the avoidable and treatable complications of diabetes, and the current situation should motivate us to do more in this area. Our goal should be to make excellent preventative foot care and education programs available, particularly in basic and secondary health care settings.

CONCLUSIONS

This study was conducted to assess the clinical profile and outcome of patients with diabetic foot ulcer admitted in Dept of Gen surgery, SMS medical college and hospital, Jaipur. nearly one third of the population was between the ages 56-65, majority of them were males with a Wagner's ulcer grade more than equal to 3, the mean HbA1c level being 8.95, there was a significant statistical association between the HbA1c values and the Wagner's grade of the ulcer, hospital stay duration was 5.73 days, gram negative organism were the predominant microorganisms among the wound cultures obtained, debridement, amputation, dressing, skin grafting were used to treat, majority of the patients underwent multiple toe amputations, there was a significant statistical association between the Wagner's grade and the mode of intervention performed, the study population had a mortality rate of 3.5%, adequate glycaemic control, periodic screening for diabetic foot neuropathy, preventive foot care and education programs should be made available, particularly in primary and secondary health care settings to tackle the DFU disease which is contributor to significant morbidity among diabetics.

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