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"AN OBSERVATIONAL STUDY ON SURGICAL CHARACTERISTICS, MANAGEMENT MODALITIES AND SHORT-TERM TREATMENT OUTCOMES OF DIABETIC FOOT ULCERS AT A TERTIARY HOSPITAL"

General Surgery

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are serious consequence of poorly controlled diabetes. DFUs are a therapeutic challenge in developing countries. This observational study aimed to analyse surgical characteristics, management modalities and short-term treatment outcomes of DFUs. **Methods:** This study was conducted on 155 patients. Data covering detailed history, management modalities and short-term outcomes were collected through an interviewer-administered structured questionnaire. **Results:** Mean age of patients is 58.32 ± 14.24 years, comprising 57.4% males. 54.8% patients belong in upper-lower class. 51.6% had diabetes for 5-10 years, 54.8% with very poor HbA1C > 10%. Ulcers involving the toes 34.8% and 82.6% ulcers were > 3 cm^2. Severe DFUs (Wagner grade 3-5) were seen in 75.4% of patients. Main intervention was surgical debridement. 37.4% suffered from SSI; revision amputation was done in 11.6% patients. Mean length of hospital stay 19 ± 12.1 days and mortality rate was 1.33%. **Conclusion:** Majority of patients had advanced DFUs. Larger prospective study should be done for proper management. Screening and proper evaluation can reduce complications.

KEYWORDS

INTRODUCTION:

Diabetic foot ulcer is defined by the International Consensus on the Diabetic Foot (IDF) as a full thickness break in the skin occurring on or below the ankle of either foot, directly resulting from diabetes or a complication of the disease [1]. The World Health Organization (WHO) defines diabetic foot as the lower limb of a diabetic patient that has potential risk of pathological consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurological abnormalities, various degree of peripheral vascular disease, and/or metabolic complications of diabetes. A lifetime risk, as high as 25%, exists for the emergence of a foot ulcer among diabetic patients [2]. The global prevalence of DFUs is estimated to be 6.3% [3].

Neuropathy appears to be the single-most important factor not only in developing diabetic foot but also in delaying the healing process. Patients having sensory loss appear to have seven times increased risk of developing foot ulcer. Origin of neuropathy remains unclear [4]. It may be due to insufficiency of intrinsic blood supply to peripheral nerves, may be autoimmune or microvascular ischemia caused by accumulates of advanced glycosylated end products [5,6]. Peripheral vascular disease is another important risk factor and is mainly due to widespread and often multisegmented atherosclerosis of large vessels of the leg. It is often bilateral and distal involving tibial and peroneal vessels below knee due to unknown reason [7].

Characteristics of a diabetic foot ulcer such as the anatomic location, wound depth, infection and ischemia of the foot lesion upon presentation, as well as glycaemic management, all have an impact on the outcome [8,9]. The grading of ulcer severity is critical in the care of DFU patients, and it has been reported to have higher impact on the final treatment success than the ulcer site [10].

Aim of the present study was to analyse the risk factors leading to complication in diabetic foot infection; to study surgical characteristics, management modalities and short-term outcomes of treatment of patients with DFUs; and to breach the information scarcity that exists about DFUs within the region.

MATERIAL AND METHODS:

Study Design and Study population:

This was a prospective hospital-based descriptive study in the surgical wards of KPC Medical College and Hospital, Kolkata. Our study population as per following inclusion and exclusion criteria:

Inclusion Criteria =>

i. All patients with Diabetic foot ulcers admitted under surgical ward of our hospital.
ii. All patients referred in surgical ward from other department's ward for treatment of DFUs.
iii. All patients (known Diabetic) admitted in surgical ward for other reason, but during hospital stay he/she developed DFUs.

Exclusion Criteria =>

i. All patients admitted with foot infections without DM.
ii. All patients admitted with gangrene foot of etiology other than infection of foot complicated by diabetes.
iii. All patients whose treatment could not be completed due to noncompliance.
iv. All patients with incidental diagnosis of diabetes on admission.
v. All patients who declined to give consent.
vi. All patients who did not continue his/her follow up visit.

Sample Size and Sampling:

During the period from January 2023 to January 2024, Seven hundred and ninety-three diabetic patients were admitted or referred in ward of the department of general surgery at KPC Medical College and Hospital, Kolkata. They were screened during this study period. One hundred sixty individuals satisfied the inclusion criteria and they were sensitized about the study. Out of 160, three patients declined to participate and two patients did not continue their follow up. Ultimately, a total of 155 DFU patients were enrolled in the study and it is depicted in the following figure.

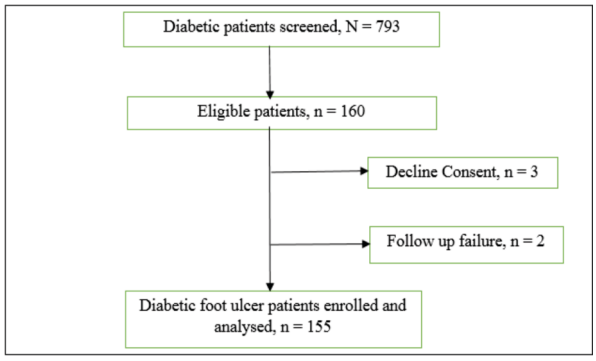

Figure: Participant Flow Chart

This sample size of 155 participants who were enrolled based on the inclusion criteria, through consecutive sampling. Written informed consent was obtained from each study participant before recruitment and participation in the study.

Data Collection and Study Definitions:
Data was collected using interviewer-administered structured questionnaire. The questionnaire was first prepared in English and then translated to Bengali and Hindi language. The research assistants were my junior residents and colleagues, who were trained about the data collection tool and study procedures.

The questionnaire collected socio-demographic informations including patient age, sex, level of education, occupation, marital status, area of residence. Medical factors such as body mass index, pre-existing medical conditions, length of time with diabetes mellitus and history of same problems with treatment history were also captured. Information from investigations including routine blood tests, HbA1c, presence of occlusive arterial disease as per Doppler ultrasonography and wound swab test for culture and sensitivity were recorded. The treatment modalities and short-term treatment outcomes were also captured in the tool.

Data Management and Analysis:
Data were entered into Redcap and exported to STATA version 15 for analysis. Patient's characteristics were described using summary statistics and presented in the form of means, median and standard deviation for continuous variables. For categorical variables, percentages and frequencies were generated. The distribution of DFU grades with regard to treatment modalities was expressed as proportions and presented in tables and bar charts.

RESULTS:
The collected data have been analysed and the respective outputs have been presented in the Tables 1-13 as in Appendix.

Socio-Demographic Characteristics of Study Participants:
Mean age of participated 155 patients was 58.32 ± 14.24 years. Majority were male 89 (57.4%). Most of patients had attained primary level of education 60 (38.7%). Majority of patients were married 83 (53.5%). Most of participants were from urban area 103 (66.5%) and majority of patients' socio-economic status belong in upper-lower class 85 (54.8%). Almost half of patients had family history of diabetes 77 (49.7%). Majority of patients were suffering from Dyslipidaemia 69 (44.5%). 90 (58.06%) patients had history of smoking and 63 (40.6%) patients had history of alcohol intake. These are presented in Tables 1 & 2.

As in Table 3, most of patients had history of onset of diabetes at the age group of 31-40 years 93 patients (60.0%) and duration of diabetes is 5-10 years in 80 (51.6%) patients. 122 (78.7%) participants had random blood sugar ≥ 200 mg/dl on admission and Severely uncontrolled HbA1c (> 10 %) was in 85 patients (54.8%). Most of the patients were diagnosed as Type 2 diabetes mellitus i.e. 153 (98.7%).

Hypertension was predominant comorbidities in 76 patients (49.03%) and 73 patients (47.09%) were suffering from moderate anaemia (8-10.9 gm/dl); 83 patients (53.5%) had thrombocytosis; median WBC was $13.4 \pm 8.2 \times 10^{9}$ / L. Body mass index of 60 participants (38.7%) was normal (18.5-24.9 kg/m²) and absence of ischaemic changes in lower limb was in 112 patients (72.3%). These are referred from the Tables 4,5, & 6.

Duration of DFUs was ≥ 4 weeks in 93 patients (60.0%). Most common anatomic location of DFUs was Toes, present in 54 patients (34.8%) and least common was above ankle, present in 5 patients (3.2%). Presented with new DFUs was 31 patients (20.0%) and 128 patients (82.6%) presented with large size ulcers (> 3 cm²). Ulcer severity scoring was done by Wagner Classification and 78 patients (50.32%) were presented with grade 4 (localised gangrene) (as in Tables 7 & 8).

There were 131 (84.5%) participants with clinically infected DFUs from whom wound swabs specimens were taken for culture analysis. *Pseudomonas spp.* Was most predominant microorganism, affecting 53 (40.5%) of the participants, followed by *Staphylococcus aureus*, *Klebsiella spp.*, other staphylococcus, *Proteus spp*., *E. coli* and *Citrobacter ferudii* being isolated in 31 (23.7%), 21 (16.03%), 13 (9.9%), 7 (5.3%), 5 (3.8%) and 1 (0.7%) of the patients respectively. The antibiotic susceptibility tests showed that the isolated organisms were more sensitive to Imipenem, effective in 49 (37.4%) patients and most resistant to Ciprofloxacin 37 (28.2%) patients. Pseudomonas was more susceptible to Imipenem and Amikacin at 70.3% and 61.9% respectively.

Doppler ultrasonography findings of our participants revealed that majority 57 (47.9%) had occlusion at Tibial artery followed by occlusion at Popliteal artery 23 (19.3%), Deep peroneal artery 15 (12.6%), Deep femoral artery 13 (10.9%) and Dorsalis pedis artery 11 (9.2%). These are in Tables 9 & 10.

As observed from the Tables 11, 12 & 13, the outcomes are described now. As per our study, all the patients with DFUs received antidiabetic medications and empirical antibiotic coverage. In 82 cases (52.9%) underwent surgical debridement of the ulcers, while 51 (32.9%) patients had lower extremity amputations (LEA) performed as initial surgical intervention after admission. Minor LEA were performed in 29 (18.7%), while 22 (14.19%) participants underwent major LEA. No revascularization surgeries were done during the study period.

The majority of minor LEA were toe disarticulations which were performed in 17 (33.3%) patients, while metatarsophalangeal amputations and trans metatarsal amputations constituted 9 (17.6%) and 3 (5.9%) patients, respectively. Below knee amputations constituted the most common type of major LEA among the participants, followed by knee disarticulations and above knee amputations, being performed in 14 (27.5%), 5 (9.8%) and 3 (5.9%) patients, respectively.

Following the initial surgery, 62 (40.0%) of the patients developed complications. 28 (45.2%) of these patients experienced surgical site infection. Wound dehiscence in 12 (19.4%) of participants, while recurrent gangrene and seroma/haematoma were seen in 11 (17.7%) and 7 (11.8%), respectively. 37 (23.9%) of the participants underwent revision surgery during the study period. The mean length of hospital stay is 19 ± 12.1 days. Only two (1.29%) participants died.

DISCUSSION:
Surgical Characteristics of DFUs:
Toes are most common location of DFUs among our participants (34.8%). This supports other research, which show that the forefoot is the most common site of foot ulcers in diabetic patients [11]. Ellis and Allies found that 59% of their patients had DFUs involving forefoot [12]. A possible explanation could be the presence of peripheral neuropathy, and development of foot deformities such as Charcot's foot which results in bone and toe deformities. These may result in abnormal distribution of foot pressures, which are more exerted on the forefoot and toes while walking.

Our study found that most of participants had newly occurring foot ulcers (80.0%), only 20.0% patients had recurring foot ulcers. An Egyptian retrospective study by Khalifa WA found 61.3% recurrence rates of DFUs [13], which is much higher than our study findings. These recurrences are linked to diabetic peripheral neuropathy, which causes loss of protective feeling in the foot.

As per our study 60.0% of the patients had the foot ulcer for at least 4 weeks, at time of presentation. Same finding is reported in a study by Pemayun T et. al. on DFU clinical profiles and outcomes [14]. Large size of ulcers (>3 cm²) in our study was 82.6%. This finding is almost same with study by Yasin M et. al. regarding baseline characteristics of infected DFUs, where 70.1% of the participants were reported to have ulcer ≥ 3 cm² [15]. Zubair M et. al. also reported that 64.9% of the patients had lesions ≥ 4 cm² [16].

Maximum patients had advanced diabetic foot ulcers, with 77.37% of the lesions falling into Wagner class 3 to 5. This is comparable to findings of studies by Cervantes-Garcia E et. al., Pemayun T et. al., Latif S et. al. where it was observed that majority of DFUs were more severe Wagner grade 3 and above in 93%, 78.2% and 70% of participants respectively [11,14,17]. But most of the patients in these studies were Wagner grade 3, which is contrary to our study, where most of patients were with Wagner grade 4 (50.32%).

Clinically infected ulcerations of 131 participants for which swab was taken for culture and sensitivity testing. In our study most predominant

bacteria was Pseudomonas spp. (40.5%), followed by Staphylococcus aureus (23.7%), Klebsiella spp. (16.03%), other Staphylococcus spp. (9.9%), Proteus spp. (5.3%), E. coli (3.8%) and Citrobacter ferudii (0.7%). Other studies have reported similar microbial isolations, but Staphylococcus aureus was the most frequently isolated bacteria in all those studies by Wahab WFA et. al., Anvarinejad M et. al., Mutonga DM et. al. and Macdonald KE et. al. [18 -21]. These differences in microbiological profile could be attributed to distinctions in sample collection methods, geographical regions, severity of infections and treatment therapies prior to presentation.

Our study also revealed that 119 (76.8%) patients whose doppler study detected lower extremity arterial occlusion. Peripheral arterial occlusive disease (PAOD) is up to 6 times more common in elderly diabetics than in non- diabetic elder patients as per study by Kabbani M et. al. [22]. DM is also linked to more severe PAD below knee arteries as described in study by Thiruvoipati T et. al. [23]. In our study Tibial artery (47.9%) was most occluded artery.

Treatment Modalities of Diabetic Foot Ulcers:

Medical interventions were antidiabetic medications, empiric antibiotic and blood transfusion. Initial surgical treatment included surgical debridement (82.0%). Lower extremity amputation was done as initial surgical intervention in 32.9% cases. Pemayun et. al also reported debridement as most performed surgical intervention for DFUs, as it was done in 87.2% of patients and LEA done in 36.3% of patients [14].

Short Term Outcomes of Treatment:

In our study participants 62 (40.0%) of patients developed some form of complications. 45.2% of patients among them developed SSI. This figure reveals higher occurrence than the study by Wukich et. al. who found SSI 9.5% among post-surgical intervention of DFUs [24].

As per present study 37 (23.9%) of patients underwent revision surgery. Revision amputation was most performed intervention (11.6%). Comparable findings were documented from Royal College of Surgeons of England, where revision surgery among DFUs was 31% [25]. Most recent studies revealed more higher frequency of revision surgery (40%) [26].

Two (1.29%) patients died during this study. Higher mortality rates among DFUs reported, i.e. 10.6% in a study by Thewjitcharoen Y et. al. [27].

During the study period we observed that the mean length of hospital stay for DFUs was 19 ± 12.1 days, comparable with Pemayun et. al. and Ozkara et. al.'s findings reporting an average of 17.8 days and 17.2 days, respectively [14,28].

CONCLUSION:

Our study highlights severity of diabetic foot ulcers is drastically increasing now a days (Wagner grade 3 to 5). Ulcer advancement has some relation with duration of diabetes, on average RBS level of patient, HbA1C level and delaying in seeking treatment with low level of basic education. We should use cautious about empiric antibiotic administration, as it is causing multidrug resistant microorganism infection. Somehow to establish relation between HbA1C level and variations in microbiological profile with its antibiotic sensitivity we need a larger prospective study. We have to do early identification of proper antibiotics and need to do early surgical debridement to avoid amputation.

RECOMMENDATIONS:

We recommend regular follow up of diabetic patients and adequate foot and toe nail care.

We recommend routine lower extremity doppler ultrasonography to assess peripheral arterial disease to avoid DFUs advancement.

We also recommend wound swabbing for culture and sensitivity testing for appropriate antibiotic coverage.

APPENDIX

Table.1: Sociodemographic Characteristics

Characteristics	Description	Number	Percentage
Age Group	<20 years	0	0%
	21 – 30 years	0	0%
	31 – 40 years	12	7.7%
	41 – 50 years	24	15.5%
	51 – 60 years	59	38.1%
	61 – 70 years	39	25.2%
	71 – 80 years	20	12.9%
	>80 years	01	0.6%
Mean ± SD years	58.32 ± 14.24 years		
Gender	Male	89	57.4%
	Female	66	42.5%
Level of Education	No formal education	40	25.8%
	Primary School	60	38.7%
	Secondary School	37	23.9%
	Tertiary School	18	11.6%
Marital Status	Single	42	27.1%
	Married	83	53.5%
	Divorced	12	7.7%
	Widow	18	11.6%
Socio-economic Status	Lower Class	42	27.1%
	Upper – lower Class	85	54.8%
	Lower – middle Class	14	9.03%
	Upper – middle Class	10	6.5%
	Upper Class	4	2.6%
Area of Residence	Urban	103	66.5%
	Rural	52	33.5%
Family History of	Diabetes	77	49.7%
	Dyslipidaemia	69	44.5%
	Obesity	40	25.8%

Table.2: Characteristics of Diabetic foot ulcer patients

Characteristics	Description	Number	Percentage
Personal History	Smoking	90	58.1%
	Alcohol	63	40.6%
Past Surgical History	Diabetic foot ulcer	49	31.6%
	Previous Surgery	37	23.9%

Table.3: History and Characteristics of Diabetes

Characteristics	Description	Number	Percentage
Age of Onset of Diabetes	<20 years	0	0%
	21 – 30 years	12	7.7%
	31 – 40 years	93	60%
	41 – 50 years	42	27.1%
	51 – 60 years	8	5.2%
	>60 years	0	0%
Diabetes Duration	<5 years	31	20%
	5 – 10 years	80	51.6%
	11 – 15 years	22	14.2%
	16 – 20 years	14	9.03%
	>20 years	8	5.2%
RBS level (mg/dl)	<200	33	21.3%
	≥200	122	78.7%
HbA1C level (mmol/ mol)	6 – 8	28	18.1%
	9 – 10	42	27.1%
	>10	85	54.8%
Type of Diabetes	Type 1 Diabetes	2	1.3%
	Known history	101	65.2%
	Type 2 Diabetes Newly Diagnosed	52	33.5%

Table.4: Other Important History

Description	Characteristics	Number	Percentage
Number of Visits to Clinic/ hospital	None	6	3.9%
	1 – 3 visits	90	58.1%
	4 – 9 visits	59	38.1%
Pre-existing Comorbidities	None	25	16.1%
	Hypertension	76	49.03%
	Cardiac disease	4	2.6%
	Renal disease	12	7.7%

	Eye disease	17	10.97%
	CNS disorder	1	0.6%
	Respiratory disease	20	12.9%
HIV Status	Negative	150	96.8%
	Positive	3	1.9%
	Unknown	2	1.3%
History of steroid intake		14	9.03%

Table.5: Investigation reports of DFU patients

Description	Characteristics	Number	Percentage
WBC (median ± SD)	13.4 ± 8.2 $^{*}10^{9}$ /L		
Haemoglobin (gm/dl)	Normal (≥12)	27	17.4%
	Mild Anemia (11-11.9)	42	27.09%
	Moderate Anemia (8-10.9)	73	47.09%
	Severe Anemia (<8)	13	8.4%
Platelet Count	Normal Platelets	62	40%
	Thrombocytosis	83	53.5%
	Thrombocytopenia	10	6.5%

Table.6: Other Characteristics related with DFUs

Description	Characteristics	Number	Percentage
Body mass Index (kg/m²)	Underweight (<18.5)	28	18.06%
	Normal (18.5 – 24.9)	60	38.7%
	Overweight (25 – 29.9)	42	27.1%
	Obese (≥30)	25	16.1%
Presence of Ischemia	Yes	43	27.7%
	No	112	72.3%

Table. 7: Surgical Characteristics of DFUs

Description	Characteristics	Number	Percentage
Duration of Ulcer	<4 weeks	62	40%
	≥4 weeks	93	60%
Anatomic Locations	Toes	54	34.8%
	Dorsum of foot	37	23.9%
	Plantar area of foot	28	18.06%
	Heel	13	8.4%
	Ankle	7	4.5%
	Whole foot	11	7.1%
	Above ankle	5	3.2%
Recurring Ulcer	Yes	31	20%
	No	124	80%

Table.8: Surgical Characteristics of DFUs

Description	Characteristics	Number	Percentage
Size of Ulcer	Medium (1 – 3 cm²)	27	17.4%
	Large (>3 cm²)	128	82.6%
Ulcer Severity (Wagner Grading System)	Grade I: (Superficial)	8	5.2%
	Grade II: (Deep involving tendon & Joints)	27	17.4%
	Grade III: (Deep ulcer with abscess/ Osteomyelitis)	30	19.4%
	Grade IV: (Localized Gangrene)	78	50.3%
	Grade V: (Entire foot with gangrene)	12	7.7%

Table.9: Characteristics of Micro-organisms

Micro-organisms	Number	Percentage
Pseudomonas spp.	53	40.5%
Staphylococcus aureus	31	23.7%
Staphylococcus spp. (other)	13	9.9%
Klebsiella spp.	21	16.03%
Proteus spp.	7	5.3%
Citrobacter ferudii	1	0.7%
Escherichia coli	5	3.8%

Table.10: Doppler ultrasonography –Peripheral arterial occlusion

Description	Number	Percentage
Dorsalis Pedis Artery	11	9.2%
Tibial Artery	57	47.9%
Deep Peroneal Artery	15	12.6%
Popliteal Artery	23	19.3%
Deep Femoral Artery	13	10.9%
None	36	23.2%

Table.11: Treatment Modalities according to Wagner Classification

Description	Characteristics	Wagner Classification (No. of patients)					Number & Percentage
		I	II	III	IV	V	
Antidiabetic Dugs	Insulin	10	12	22	30	53	127 (81.9%)
	OHA	16	12	0	0	0	28 (18.1%)
Antibiotics		4	7	25	51	68	155 (100%)
Blood Transfusion		1	3	8	11	12	35 (22.6%)
Surgical Debridement		7	12	28	35	0	82 (52.9%)
Dressing only/ Daily wound care		17	10	5	0	0	32 (20.7%)

Table.12: Surgical Characteristics for DFUs

Description	Characteristics	Wagner Classification (No. of patients)					Total number & Percentage
		I	II	III	IV	V	
Lower Extrimity Amputation	Minor LEA	2	0	3	5	19	29 (18.7%)
	Major LEA	0	0	2	20	0	22 (14.2%)
Minor LEA	Toe Disarticulation	17					33.3%
	MTP joint disarticulation	9					17.6%
	Trans metatarsal LEA	3					5.9%
Major LEA	Below Knee	14					27.5%
	Knee Disarticulation	5					9.8%
	Above Knee	3					5.9%

Table.13: Outcomes of DFUs

Description	Characteristics		Number	Percentage
Post-Operative Complications (n = 62) (40%)	SSI		28	45.2%
	Dehiscence		12	19.4%
	Phantom Limb		3	4.8%
	Stumo bone protrusion		1	1.6%
	Recurrent Gangrene		11	17.7%
	Seroma/ Haematoma		7	11.3%
Types of Revision Surgery (n = 37) (23.9%)	Debridement		12	7.7%
	Stump Refashioning		3	1.9%
	Haematoma evacuation		4	2.6%
	Revision Amputation (n = 18) (11.6%)	Toe disarticulation	9	5.8%
		Below Knee	6	3.9%
		Above Knee	3	1.9%
Length of Hospital Stays	19 ± 12.1 days			
Patients Outcome at 5 Weeks	Alive (n = 153) (98.7%)	Dis charged	82	52.9%
		Still Admitted	66	42.6%
		Lost to follow up	0	0%
	Dead		2	1.29%

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