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Analyzing diabetic foot ulcer through Amit Jain's classification: A descriptive study

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Abstract
Aim: The aim of this study is to analyse diabetic foot ulcer through the new focal Amit Jain's classification for diabetic foot ulcer and to predict the outcome associated with this classification.
Methods and materials: A descriptive retrospective analysis was done at 2 different centres. The study period was from January 2017 to December 2017. IEC approval was obtained for this study.
Results: A total of 54 patients were included in this study with 75.9% being males. Right foot was involved in 63% of patients. 53.7% of the patients had some associated comorbidity. Forefoot was the most common area affected with ulcers accounting for 88.8% of cases. 48.1% of the ulcers were less than 2 cm in size. Class 3 diabetic foot ulcers were the most common class of ulcer affecting 72.2% of the patients. Also, class 3 ulcers were significantly responsible for majority of amputation. 77.8% of the toe ulcers had amputation. 20.4% of diabetic foot ulcers had underlying osteomyelitis and 7.4% had peripheral arterial disease and they were significantly associated with amputation. There was no mortality in this study.
Conclusion: In this validation study, we observed that class 2 ulcers were common in females. Most amputations occurred in class 3 diabetic foot ulcers with no amputation occurring in class 1 diabetic foot ulcers. There was a significant association of male gender, size of ulcer, location of ulcer, presence of peripheral arterial disease and osteomyelitis with amputations. This is the first study to our knowledge that evaluates diabetic foot ulcers through the new Amit Jain's classification for diabetic foot ulcer.

Keywords: Diabetic foot, ulcers, amputation

Introduction

Diabetes mellitus is a chronic, debilitating non-communicable disease which is known to affect every vital organ in the human body [1-4]. The global prevalence of this condition continues to rise and it is projected to affect 439 million people by the year 2030 [1, 5].

Of all the known complications of diabetes, diabetic foot is the most distressing complication [4, 6]. Diabetic foot ulcers are a relatively common problem and they are known to contribute significantly to increased morbidity and mortality [7]. The lifetime risk for an ulcer in diabetics is 15% to 25% [4, 5].

Various classifications exist for diabetic foot ulcers like Wagner's Classification, University of Texas classification, PEDIS classification etc. [6-10]. Numerous studies have been done on them [8].

Amit Jain's classification for Diabetic foot ulcer is a new simple classification that was proposed in 2014 from Indian subcontinent [6, 11]. This classification divided diabetic foot ulcers into 3 classes namely simple, complex and complicated diabetic foot ulcers [Table 1].

Table 1: Showing Amit Jain's classification for diabetic foot ulcer

Class of diabetic foot ulcer	Description	Treatment guidelines
Class 1 Diabetic foot ulcer	Simple ulcers	Dressings and offloading
Class 2 Diabetic foot ulcer	Complex ulcers	Correction of intrinsic cause like bony deformities / revascularization (along with dressings and offloading)
Class 3 Diabetic foot ulcer	Complicated ulcers	Surgical debridement/ removal of affected bone (along with dressings and offloading)

This study aims to validate this new classification for diabetic foot ulcer and also to predict outcomes associated with this focal ulcer classification.

Methods and Materials

A descriptive retrospective analysis was done at two different centres namely Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital and in Surgical Unit I of Department of Surgery of Rajarajeswari Medical College, Bengaluru, India. Our centre caters to urban upper and middle class patients whereas other centre caters to rural and lower socioeconomic patients.

The following were inclusion and exclusion criteria's:

Inclusion Criteria

All patients with diabetic foot ulcers seen at Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital and patients in Surgical Unit '1' of Department of Surgery, Rajarajeswari Medical College.

Exclusion Criteria

1. Patients with incomplete data
2. Non diabetic patients with foot ulcer
3. Patients who refused treatment
4. Patients treated in other surgical unit
5. Healing ulcer following surgical debridement of abscess or cellulitis or other pathological lesions. Though, they can be categorised into class 1 ulcers, they were excluded from study in view of actual pathology being abscess or cellulitis and they are surgically caused wounds.

The study period was for one year from Jan 2017 to Dec 2017. The IEC approval was taken (RRMCH-IEC/25/2017-18)

Data analysis [12-15]

Data was analysed using statistical software SPSS 18.0 and R environment Ver.3.2.2. Microsoft word and excel were used for general graphs and tables. Both descriptive and inferential statistical analysis was carried out in this study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

The following assumption on data is made:

- Dependent variables should be normally distributed,
- Samples drawn from the population should be random
- Cases of the samples should be independent

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s test for homogeneity of variance has been performed to assess the homogeneity of variance.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher exact test was used when samples were very small.

Significant figures

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value: 0.01<P 0.05)

** Strongly significant (P value: P≤0.01).

Results

A total of 54 patients were included in this study that satisfied inclusion criteria. There were 41 males (75.9%) and 13 females (24.1%) [Figure 1].

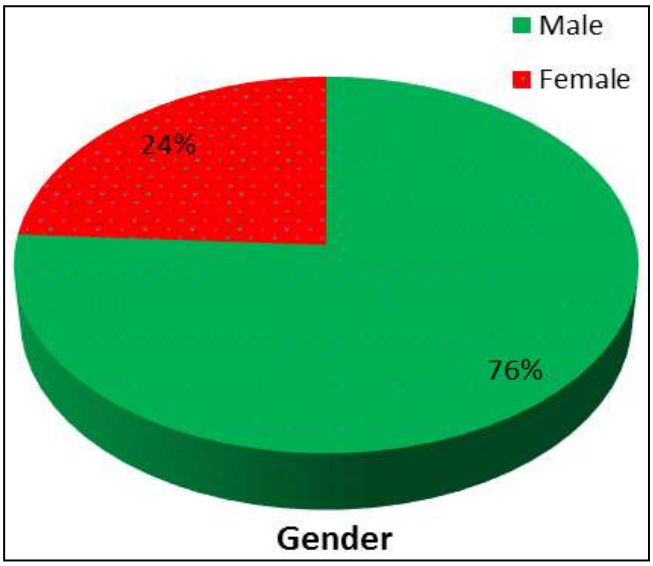

Fig 1: Showing distribution of gender

Majority of patients (59.2%) were between 51-70 years [Figure 2]. The average mean age was 58.76 ± 12.67 (mean ± S.D).

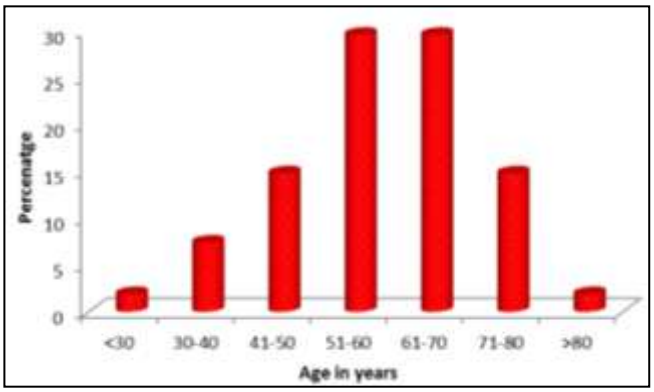

Fig 2: Showing age distribution of patients

Right foot was involved in 34 patients (63%), left foot was involved in 14 patients (25.9%) and 11.1% had bilateral involvement [Figure 3].

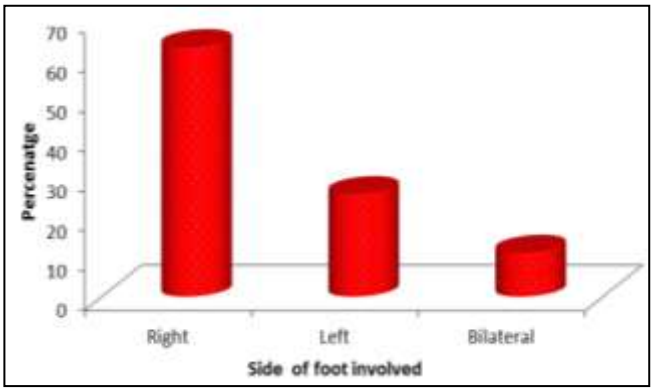

Fig 3: Showing side affected in the distribution of patients

Majority of patients (57.4%) had diabetes of duration 10-20 years. 9.3% had diabetes of more than 20 years [Table 2].

Table 2: Showing diabetes mellitus duration (yrs) in patients

DM Duration (yrs)	No. of patients	%
<10	18	33.3
10-20	31	57.4
>20	5	9.3
Total	54	100.0

Mean ± SD: 13.43±7.95

29 patients (53.7%) had associated co morbidities. Hypertension was commonest co morbidity affecting 48.1% of patient and 18.5% had Ischemic heart disease.

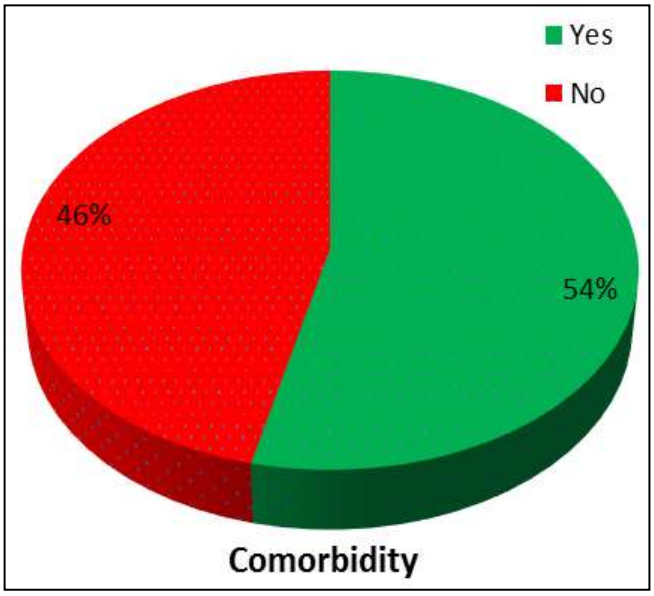

Fig 4: Showing co morbidity distribution

The most common site of ulcer was forefoot affecting 48 patients (88.8%) followed by hindfoot (9.3%). Midfoot was involved in 1.9% [Table 3].

Table 3: Showing area of the foot involved

Area Involved	No. of patients	%
Forefoot	48	88.9
Midfoot	1	1.9
Hindfoot	5	9.3
Total	54	100.0

The commonest class of ulcer was class 3 ulcer affecting 39 patients (72.2%) followed by class I ulcers (22.2%). Only 3 patients (5.6%) had class 2 ulcers [Table 4].

Table 4: Showing the distribution of cases according to the class of diabetic foot ulcer

Class of Ulcer	No. of patients	%
Class 1	12	22.2
Class 2	3	5.6
Class 3	39	72.2
Total	54	100.0

11 patients had underlying osteomyelitis (20.4%) and 4 patients had peripheral arterial disease (7.4%).

Majority of patients (48.1%) had ulcer of less than 2cm. 42.6% had ulcer of 2cm-4cm size. Around 5 patients (9.3%) had ulcer of more than 4cm in size [Table 5].

Table 5: Showing ulcer size distribution in patients

Size	No. of patients	%
Less than 2	26	48.1
2cm - 4 cm	23	42.6
> 4 cm	5	9.3
Total	54	100.0

Most common treatment modality was debridement which was done in 29 patients (53.7%) followed by toe amputation (24.1%). 3.7% of patient had major amputation [Table 6]. 7.4% of the patients had offloading as the primary treatment modality [along with dressings] and in 3.7% of patients dressing alone was treatment used. Overall 33.3% of patients had some form of amputation being done [Table 6].

Table 6: Showing treatment given

Treatment	No. of patients	%
Debridement	29	53.7
Toe amputation	13	24.1
Transmetatarsal amputation	3	5.6
BKA	2	3.7
Tenotomy	1	1.9
Primary offloading (With dressing)	4	7.4
Dressing alone	2	3.7
Total	54	100.0

There was significant association of gender with amputation. 94.4% males had amputation whereas only 5.6% of female had amputation done (P value=0.024*).There was no association of age, side, diabetes duration in relation to amputation. It was seen that 94.4% of class 3 ulcers had significant association with amputation whereas only 5.6% of class 2 ulcers had amputation (P=0.006 **) [Table 7].

Table 7: Showing Association of clinical variables according to amputation done of patients studied

Variables	Amputation Done		Total (n=54)	P value
	Yes (n=18)	No (n=36)		
Age in years				
<30	1(5.6%)	0(0%)	1(1.9%)	0.373
30-40	1(5.6%)	3(8.3%)	4(7.4%)	
41-50	1(5.6%)	7(19.4%)	8(14.8%)	
51-60	5(27.8%)	11(30.6%)	16(29.6%)	
61-70	8(44.4%)	8(22.2%)	16(29.6%)	
71-80	2(11.1%)	6(16.7%)	8(14.8%)	
>80	0(0%)	1(2.8%)	1(1.9%)	
Gender				
Male	17(94.4%)	24(66.7%)	41(75.9%)	0.024*
Female	1(5.6%)	12(33.3%)	13(24.1%)	
Side affected				

1	12(66.7%)	22(61.1%)	34(63%)	0.826
2	5(27.8%)	9(25%)	14(25.9%)	
3	1(5.6%)	5(13.9%)	6(11.1%)	
Class of Ulcer				
1	0(0%)	12(33.3%)	12(22.2%)	0.006**
2	1(5.6%)	2(5.6%)	3(5.6%)	
3	17(94.4%)	22(61.1%)	39(72.2%)	
DM Duration (yrs)				
<10	6(33.3%)	12(33.3%)	18(33.3%)	0.915
10-20	11(61.1%)	20(55.6%)	31(57.4%)	
>20	1(5.6%)	4(11.1%)	5(9.3%)	

It was noted that 94.4% of patient with forefoot ulcers had amputation [Table 8] wherein 77.8% of toes had amputation and was found to be significant (P=0.069*).

Table 8: Showing association of clinical variables according to amputation done in patients studied

Variables	Amputation Done		Total (n=54)	P value
	Yes (n=18)	No (n=36)		
Area Involved				
Forefoot	17(94.4%)	31(86.1%)	48(88.9%)	0.767
Midfoot	0(0%)	1(2.8%)	1(1.9%)	
Hindfoot	1(5.6%)	4(11.1%)	5(9.3%)	
Toes Involved				
Yes	14(77.8%)	16(44.4%)	30(55.6%)	0.020*
No	4(22.2%)	20(55.6%)	24(44.4%)	

Chi-Square/Fisher Exact Test

It was seen that presence of osteomyelitis was significantly associated with amputation (P value=0.029*).Also presence of peripheral vascular disease was associated with amputation significantly (P value =0.010**).There was no association of co morbidities like hypertension and ischemic heart disease in relation to amputation [Table 9].

Table 9: Showing Association of clinical variables according to amputation done in patients studied

Variables	Amputation Done		Total (n=54)	P value
	Yes (n=18)	No (n=36)		
Osteomyelitis				
Yes	7(38.9%)	4(11.1%)	11(20.4%)	0.029*
No	11(61.1%)	32(88.9%)	43(79.6%)	
Peripheral vascular disease				
Yes	4(22.2%)	0(0%)	4(7.4%)	0.010**
No	14(77.8%)	36(100%)	50(92.6%)	
Comorbidity				
Yes	9(50%)	20(55.6%)	29(53.7%)	0.700
No	9(50%)	16(44.4%)	25(46.3%)	
Hypertension				
Yes	7(38.9%)	19(52.8%)	26(48.1%)	0.336
No	11(61.1%)	17(47.2%)	28(51.9%)	
Ischemic heart disease				
Yes	4(22.2%)	6(16.7%)	10(18.5%)	0.715
No	14(77.8%)	30(83.3%)	44(81.5%)	

Chi-Square/Fisher Exact Test

It was seen that 87.2% of males had class 3 ulcers compared to 12.8% of females [Table 10]. All class 2 ulcers had female predominance (100%) suggesting strongly significant gender association with class of ulcer (p value=0.001**).

Table 10: showing gender distribution in relation to Class of Ulcer of patients studied

Gender	Class of Ulcer			Total
	Class 1	Class 2	Class 3	
Male	7(58.3%)	0(0%)	34(87.2%)	41(75.9%)
Female	5(41.7%)	3(100%)	5(12.8%)	13(24.1%)
Total	12(100%)	3(100%)	39(100%)	54(100%)

P=0.001**, Significant, Fisher Exact Test

There was no association with size of ulcer [Table 11] and diabetes duration in relation to class of ulcer [Table 12].

Table 11: Showing size distribution in relation to class of ulcer in patients studied

Size	Class of Ulcer			Total
	Class 1	Class 2	Class 3	
Less than 2	6(50%)	1(33.3%)	19(48.7%)	26(48.1%)
2cm - 4 cm	5(41.7%)	2(66.7%)	16(41%)	23(42.6%)
> 4 cm	1(8.3%)	0(0%)	4(10.3%)	5(9.3%)
Total	12(100%)	3(100%)	39(100%)	54(100%)

P=0.966, Not Significant, Fisher Exact Test

Table 12: Showing DM Duration of average distribution in relation to class of ulcer in patients

DM Duration of Average	Class of Ulcer			Total
	Class 1	Class 2	Class 3	
Less than 10 yrs	3(25%)	2(66.7%)	13(33.3%)	18(33.3%)
10 to 20 yrs	6(50%)	1(33.3%)	15(38.5%)	22(40.7%)
More than 20 yrs	3(25%)	0(0%)	11(28.2%)	14(25.9%)
Total	12(100%)	3(100%)	39(100%)	54(100%)

P=0.793, Not Significant, Fisher Exact Test

It was seen that 43.6% of class 3 ulcer had amputations [Table 13] whereas none in class I had any amputation suggesting significant association of class of ulcer with amputation (p =0.006**)

Table 13: Showing relation of overall amputation done and major amputation distribution in relation to class of ulcer in patients

	Class of Ulcer			Total (n=54)	P value
	Class 1 (n=12)	Class 2 (n=3)	Class 3 (n=39)		
Overall amputation Done					
Yes	0(0%)	1(33.3%)	17(43.6%)	18(33.3%)	0.006**
No	12(100%)	2(66.7%)	22(56.4%)	36(66.7%)	
Major Amputation					
Yes	0(0%)	0(0%)	2(5.1%)	2(3.7%)	1.000
No	12(100%)	3(100%)	37(94.9%)	52(96.3%)	

Chi-Square/Fisher Exact Test

There was no association of peripheral arterial disease or osteomyelitis with major amputations in this study. There was some significant association between size of ulcer in regards to major amputation (P=0.087^{+}) [Table 14]

Table 14: Showing amputation done/major Amputation distribution in relation to size of ulcer of patients studied

	Size			Total (n=54)	P value
	Less than 2 (n=26)	2cm-4cm (n=23)	>4cm (n=5)		
Amputation Done					
Yes	6(23.1%)	9(39.1%)	3(60%)	18(33.3%)	0.208
No	20(76.9%)	14(60.9%)	2(40%)	36(66.7%)	
Major Amputation					
Yes	0(0%)	1(4.3%)	1(20%)	2(3.7%)	0.087+
No	26(100%)	22(95.7%)	4(80%)	52(96.3%)	

Chi-Square/Fisher Exact Test

There was no association of co morbidity with class of ulcer.
There was no association of region of foot involved and class of ulcer. However, there was significant association between size of ulcer and region of foot involved. It was seen that 100% of cases with size less than 2cm involved forefoot in comparison to 60% of cases if ulcer of more than 4cm, 40% of over where ulcer was >4cm affected hind foot with hardly any ulcer of less than 2 cm affecting hind foot (P=0.016* significant association) [Table 15].

Table 15: showing area Involved distribution in relation to size of ulcer in patients studied

Area Involved	Size of ulcer			Total
	Less than 2	2cm-4cm	>4cm	
Forefoot	26(100%)	19(82.6%)	3(60%)	48(88.9%)
Midfoot	0(0%)	1(4.3%)	0(0%)	1(1.9%)
Hindfoot	0(0%)	3(13%)	2(40%)	5(9.3%)
Total	26(100%)	23(100%)	5(100%)	54(100%)

P=0.016*, Significant, Fisher Exact Test

Discussion

Understanding and managing diabetic foot ulcer is often complex and poses challenge to a surgeon in view of ulcer getting infected, becoming chronic and recurring which affects mental status of both patient and doctor [4, 16].
Studies have shown that 2% of diabetic patients will develop new foot ulcers every year [5]. Around 85% of amputations are related to diabetic foot ulcers [17]. Diabetic foot ulcers often are known to cause increased morbidity and mortality. Further, it is well recognized that diabetic foot ulcers are also hard to heal. [18]
It is seen that 60-80% of foot ulcers will heal and 10-15% of them will remain active [19].
Diabetic foot ulcers have been studied through various classifications and many of them attempt to encompass different characteristics like site of ulcer, depth, infection, ischemia, etc. [8]. These classifications have their own merits and demerits.
Amit Jain's classification for diabetic foot ulcer is a new focal ulcer classification that categorizes diabetic foot ulcers into 3 new simple types namely class I, class II and class III diabetic foot ulcers [6].
Class I ulcers are simple ulcers, wherein there is no underlying intrinsic causation like bony deformity or ischemia. Example here is a trophic ulcer [Figure 5].

Fig 5: Showing a trophic ulcer in forefoot region. This is Amit Jain's class 1 diabetic foot ulcer. As per Amit Jain's coding system, it is S1A1C1.

In class II ulcers, which are complex diabetic foot ulcers, there is an intrinsic cause of ulceration like bony deformity or ischemia. Examples are ischemic ulcer, charcot foot ulcer, ulcers due to toe deformities like claw toe, hammer toe, etc.
Class III ulcers, which are complicated ulcers, have underlying infection like cellulitis, abscess or osteomyelitis [Figure 6 & 7].

Fig 6: showing infected ulcer over right 2nd toe. This is class 3 diabetic foot ulcer. As per Amit Jain's coding system, it is S1A1C3.

Fig 7: Showing radiograph of the above patient (figure 6) having underneath osteomyelitis.

This newly proposed classification is a component of Amit Jain's system of practice which is now **"**The modern diabetic foot surgery" system [20, 21]. This ulcer classification is based on the author's "SCC concept" for diabetic foot (simple, complex, complicated) that is also used for offloading classification and classifying diabetic foot classifications [20, 22, 23].

The Amit Jain's classification for diabetic foot ulcers is easy, simple, practical, useful teaching tool, provides treatment guidelines, forms a common communicative tool and effectively addresses the triad of diabetic foot [6]. It is also precise enough to be useful in clinical practice.

Amit Jain further formed a coding system for diabetic foot ulcer which can be used similar to TNM staging system [11]. In this 'SAC' coding system, S stands for size, 'A' stands for anatomical area and 'C' stands for class of ulcer [11]. All these attempts were to form an improvised and standardized approach for Diabetic foot [11, 20].

Diabetic foot ulcers have various predictors either for healing or for amputation like wound size, wound duration, wound infection, previous amputation, anatomical area involved, presence of peripheral arterial disease, etc. [24]

Margolis *et al.* [25] Zimny *et al.* and Ince *et al.* [26] have noted relation of ulcer area to rate of healing [25, 26]. In their study, wound of less than 2cm^2 healed in 38.9% by 20 weeks compared to those >4cm^2 in whom only 22.4% had healed by 20 weeks [25]. There are studies which show that an ulcer is less likely to heal by 12 weeks if there is little reduction in wound area by first 4 weeks [27].

It is seen that diabetic foot ulcers are most commonly located in forefoot. In Smith *et al.* series [28], 79% of ulcers occurred in forefoot with 61% occurring in toes and 21% occurred at heel region. In Chalya *et al.* series [7]. 60.3% occurred in forefoot and 7.4% occurred in hindfoot. In our study, 88.8% had ulcers in forefoot region.

In Chalya *et al.* series [7], 7.4% had ulcers in both feet whereas in our study, 11.1% had bilateral involvement.

In Smith *et al.* series [28], it was seen that 36.2% had undergone some form of amputation due to ulcer. In Chalya *et al.* series [7], 56.7% underwent amputation. In our study, 33.3% had undergone some form of amputation. In this series, significant number of amputations occurred in males (94.4%, P=0.024*), class III ulcer had significant association with amputation (0.006**) and forefoot ulcer had more amputation wherein 77.8% of ulcer at toe had significant amputation (P=0.069*).

All (100%) cases of less than 2 cm size ulcer involved forefoot whereas 40% of cases in hindfoot had ulcer size of more than 4cm^2(p=0.016*). A total of 3.7% of patients had major amputation. There was significant association of size of ulcer in regards to major amputation in this study.

Messenger *et al.* observed a significant correlation between diabetic foot ulcer outcomes and presence of osteomyelitis. Their study had more than 20% of patients with osteomyelitis [29]. In our study, presence of osteomyelitis and peripheral arterial disease was associated with amputation significantly.

In Pemayun *et al.* series [5] there was high mortality (10.7%). In this study, there was no mortality. In Smith *et al.* series [28]. 9.5% of patient had mortality before ulcer healed (cohort study).

The main limitation in our study is that we did not have a long follow-up regarding healing of the ulcer and our sample size was small. We also did not assess the culture and sensitivity report as many were found missing.

Conclusion

This is the first study to our knowledge that evaluates diabetic foot ulcer through the new Amit Jain's classification for diabetic foot ulcer. A significant association of gender was seen with class of ulcer wherein males were more commonly affected with class 3 ulcers and 100% of class 2 ulcers were in females.

An association of amputation was found with classes of ulcer. Most amputation happened in class 3 diabetic foot ulcer. Male gender, size of ulcer, location of ulcer, presence of osteomyelitis and peripheral arterial disease had significant association with amputation in this study. Ulcers located at toes had more amputations. Further, 80% of major amputation occurred where ulcer was more than 4 cm whereas no major amputation occurred in ulcers less than 2 cm. There was also significant association of size of ulcer with region of foot involved wherein ulcers of less than 2 cm most commonly occurred in forefoot region.

This new classification is a simple, easy to understand, practical focal classification which addresses triad of diabetic foot effectively and provides treatment guidelines with prediction of ulcer outcomes. It is an excellent teaching tool and can form a common communicative tool with this classification getting incorporated into Amit Jain's coding system.

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