

Original Research Article

Risk factors in the development and Progression of diabetic ulcers and their Outcome in a tertiary care hospital

Punyapu Sridhar^{1*},A.Sashidhar Rao²,Karthik³,G.Satyanarayana⁴,Samiuddin⁵

¹*Senior Consultant Surgeon, Department of General Surgery, Kamineni Hospital, LB Nagar, Hyderabad, Telangana, India*

² *Assistant Professor, Department of General Surgery, Kamineni Academy of Medical Sciences and Research Center, Hyderabad, India*

³*Assistant Professor, Department of General Surgery, Kamineni Academy of Medical Sciences and Research Center, Hyderabad, India*

⁴*Dean, Kamineni Academy of Medical Sciences and Research Center, Hyderabad, India*

⁵*Junior Resident, Department of General Surgery, Kamineni Hospital, LB Nagar, Hyderabad, India*

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Abstract

Introduction: There is an increase in the number of diabetic patients now a days and the lifetime risk of a patient with diabetes developing a foot ulcer is very high. Early diagnosis and presentation to hospital for prompt treatment of diabetic foot ulcer is capable of reducing the significant morbidity and mortality. Early detection of peripheral neuropathy, patient's education regarding foot care and customized footwear is crucial in reducing risk of any injury that can lead to ulcer formation. **Material and Methods:** A hospital based prospective observational study was conducted on diabetic patients in kamineni Hospitals, L B Nagar, Hyderabad during a period of 2 year from July 2018 to June 2020. The influence of various risk factors in development and progression of diabetic ulcer and their influence on outcome was studied. **Results:** 150 patients with diabetes ranging in age from 21 years to 95 years were studied. Most of the patients in our study come from low and medium socioeconomic status. Mean duration of diabetes is 4.9 years. History of trauma was absent in 101 patients (67.3%). Majority of the patients in the study population were having poor glycaemic control. In this study 41 patients (27.3%) were diagnosed to have PVD and neuropathy was seen in 54 patients (36%) whereas 96 patients (64%) had no signs of neuropathy. Patients were followed for a period of 3 months and found that 98 patients (65.3%) diabetic ulcers healed, 34 patient's ulcers were chronic non healing ,10 patients underwent disarticulation of single or multiple toes, 6 patients underwent major surgery-below knee amputation and 2 patients needs split skin grafting. **Conclusion:** Diabetic foot ulcer outcomes can be predicted by several factors, some of which are modifiable. Modification for the modifiable factors, such as better glycaemic control, treatment of peripheral neuropathy, and early management of ulcers, may improve the outcome and facilitate healing.

Keywords: Diabetic foot ulcers, Glycaemic control, Peripheral neuropathy, Peripheral Vascular Disease.

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Introduction

Diabetes is a metabolic disease characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action or both, and has a population prevalence of about 10-15%. According to the International Diabetes Federation, India is the epicentre of diabetes mellitus and it was found that in 2017 India had the second-largest populace of 73 million diabetic patients, after China. And the figure is expected to be just double 134 million by 2045[1]. Individuals with diabetes are more susceptible to develop any of the associated microvascular or macrovascular complications[2]. It has been estimated that the lifetime risk of a patient with diabetes developing a foot ulcer may be as high as 25%[3,4]. Diabetic foot ulcers (DFUs) are associated with significant morbidity and mortality, and most of them are preventable long-term complications of diabetes. Early diagnosis and presentation to hospital for prompt treatment of

diabetic foot ulcer is capable of reducing the significant morbidity and mortality associated with this condition. Early detection of peripheral neuropathy, patient's education regarding footcare and customized footwear is crucial in reducing risk of any injury that can lead to ulcer formation. It has also been estimated that up to 85% of all amputations in diabetes are preceded by diabetic foot ulcers [5,6]. Various risk factors like peripheral neuropathy, peripheral vascular disease, previous history of ulcers and amputations and foot deformities etc., lead to the development of foot ulcers and subsequent infection and amputation. This study is hence conducted to identify the various known risk factors for development and progression of foot ulcerations in diabetics and their outcome. Early recognition of diabetic patients with at-risk feet will help in initiating preventive measures including patient education regarding foot care and thereby decrease the morbidity and mortality as well as the emotional and economic consequences associated with diabetic foot ulcers.

Aims and objectives

Aim: To study the influence of various risk factors in development and progression of diabetic ulcer and their influence on outcome.

*Correspondence

Dr. Punyapu Sridhar

Senior Consultant Surgeon, Department of General Surgery,
Kamineni Hospital, LB Nagar, Hyderabad, Telangana, India
E-mail: punyapusridhar123@gmail.com

Objectives: To observe association of the age, sex, socio-economic background, BMI, addictions and glycaemic control of the patients presenting with diabetic ulcers over lower limbs.

To observe the various risk factors like peripheral arterial disease, peripheral neuropathy, previous history of ulcers, foot care and their association with final outcome.

Methodology

This is an observational study on diabetic patients in Kamineni Hospitals, L B Nagar, Hyderabad during a period of 2 years from July 2018 to June 2020. Patients attending the general surgery Clinic as well as those admitted to the hospital were included in the study.

Study Design: Prospective observational study

Study Sample: Sample size was calculated by using the single proportion formula

$$Z^2 p (1-p)$$

$$n = \frac{Z^2 p (1-p)}{d^2}$$

n – Sample size

z- 1.96

p – Expected prevalence of proportion (25%)

d – Precision (5%, d = 0.05)

Study period: Patients attending the general surgery clinic as well as those admitted to the hospital during a period of 2 years from July 2018 to June 2020. A total of 150 patients were enrolled in the study after fulfilling inclusion and exclusion criteria. Informed consent was obtained from all subjects after the procedures involved were fully explained.

Inclusion criteria: Patients with diabetic ulcers on the lower limbs were included.

All inpatient and outpatient cases who attended for regular follow up were included.

Patients above 18 years were included.

Exclusion Criteria: Patients with ulcers over lower limbs with causes other than diabetes.

Patients with diabetic ulcers on other anatomical areas.

Patients who lost for regular followup.

Patients who developed other systemic complications.

A pre-tested pre-structured proforma was used to record history details, including duration of diabetes, smoking history, type of footwear used, previous foot ulceration or amputation, mode of treatment and symptoms of neuropathy and vasculopathy.

A thorough physical examination including the examination of the feet was done.

Evidence of peripheral sensory neuropathy in the feet was established using a 10gm/ 5.07 Semmes – Weinstein monofilament at four plantar sites (great toe and base of 1st, 3rd and 5th metatarsal heads).

Each filament was placed against the plantar surface of the foot in a perpendicular fashion so that it bent with a constant force, with the 10gm filament. With eyes closed, the patients were required to elicit a yes/no response to monofilament pressure and correctly identify the site of contact. Insensitivity to 10g monofilament at any one site on either foot indicated loss of protective sensation. Evidence of peripheral vascular disease was assessed using ankle - brachial index (ABI) and palpation of pedal pulses (dorsalis pedis and posterior tibial arteries).

Systolic BP at ankle

Ankle Brachial Index = -----

Systolic BP at elbow

The patient was placed in recumbent position for 5 minutes. Then the systolic blood pressure in both arms is measured using a sphygmomanometer and inflatable cuff tied above the elbow. The higher of the two values is used for the brachial portion of the index.

The systolic blood pressure in the ankles is then measured using the dorsalis pedis and posterior tibial arteries with the inflatable cuff placed just above the ankle. A Doppler probe is used and the pressure at which the acoustic pulse signal returns after deflating the cuff is noted. The higher of the ankle systolic pressure value is used for calculating the ankle portion of the index. An ABI of 0.9 or less is taken as evidence of PVD. Lower limb arteries of the affected limb are evaluated with arterial Doppler of that limb. Blood samples were taken for estimation of glycosylated haemoglobin (HbA1c) and glycaemic control was evaluated as good control (HbA1c = 7.5%), fair control (HbA1c between 7.6% - 9.0%) and poor control (HbA1c = 9.1%). Wound swabs and tissue were collected from diabetic ulcers and sent for culture and sensitivity testing. Isolates from the cultures were collected and growth of organism was noted. The final outcome was taken on the condition of the ulcer at a follow up of 3 months period. The data was collected on Microsoft excel analysis tool pack. The collected data was then analysed using with SPSS software version 21. The statistical method used was chi-square test and P < 0.05 was considered significant.

Results

Demographic details: 150 patients with diabetes ranging in age from 21 years to 95 years comprised the study group. Most patients were in the age spectrum of 51-90 years (mean age is 60.5 years) and highest incidence is in the 6th decade of age is seen.

In our study, Male: female ratio is 2.5:1 (108 men, 42 women), there is male preponderance. Most of the patients in our study come from low and medium socio-economic status. High Socioeconomic status was 16%, Medium Socioeconomic status was 46.7%, Low Socioeconomic status was 37.3%. The duration of diabetes in our study population ranged from 0 year to more than 15 years. Mean duration is 4.9 years. Most of the patients were in the duration spectrum of 0-10 years. 0 - 5 Years was (108) 72.0%, 6 - 10 Years was (26) 17.3%, 6 - 10 Years (26) 17.3%, More than 15 Years was (1) 0.7%. In our study, history of trauma was present in 49 patients (32.7%), history of trauma was absent in 101 patients (67.3%). Amongst our study group, smokers are 61 persons (40.7%) and non-smokers are 89 persons (59.3%). 44 patients (29.3%) were obese among the study population and 106 patients (70.7%) were non-obese. In our study population 27 patients (18%) had a significant past history of diabetic foot infections, ulcers and amputations, majority patients 123 (82%) were experiencing the ulcers first time.

Degree of glycemic control: The HbA1c values in the study population ranged from 7.3% to 11.1%. The mean HbA1c is 9.08%. Majority of the patients in the study population were having poor glycaemic control as evidenced by HbA1c = 9.08%. Fair glycaemic control as evidenced by HbA1c between 7.6% - 9.0% was seen in 35 (23.3%) study subjects. Good glycaemic control (HbA1c < 7.5%) was observed only in 4 (2.7%) study subjects.

PVD in study population: In our study 41 patients (27.3%) were diagnosed to have PVD and remaining 109 patients (72.7%) has no PVD.

Neuropathy: In our study neuropathy was seen in 54 patients (36%) whereas 96 patients (64%) had no signs of neuropathy.

Type of footwear used by the study population: In our study, 4 people (2.7%) had history of bare foot walking, 126 people (84%) used normal footwear and 20 people (13.3%) used specialised footwear.

Final outcome in study population: In our study, patients were followed for a period of 3 months and found that 98 patients (65.3%) diabetic ulcers healed, 34 patients' ulcers were chronic non-healing, 10 patients underwent disarticulation of single or multiple toes, 6 patients underwent major surgery - below knee amputation and 2 patients needs split skin grafting.

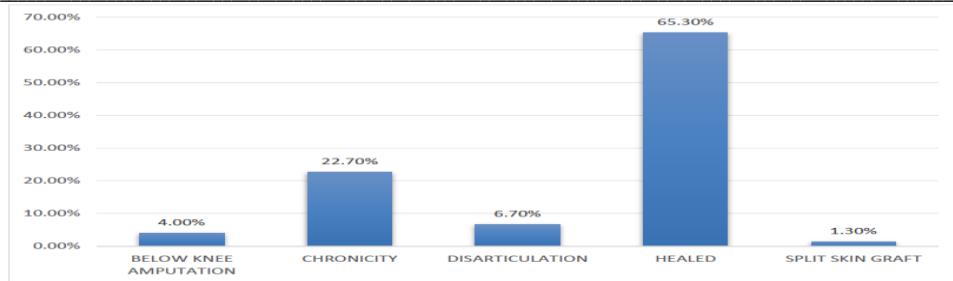


Fig 1: Final outcome in study population

Table 1: Relation between glycemic control in study population and past history of diabetic ulcer or amputation.

Glycemic control	Good	Past history		Total	
		No	Yes		
		Count	%		
Glycemic control	Good	4	0.0%	4	
		3.3%	0.0%	2.7%	
	Average	30	5	35	
		24.4%	18.5%	23.3%	
	Poor	89	22	111	
		72.4%	81.5%	74.0%	
Total		123	27	150	
		100.0%	100.0%	100.0%	

Chi Square = 1.454, P Value = 0.483 (NS)

It is noticed that patients with poor glycaemic control had a significant past history of diabetic ulcer or amputation, and patients who had good control over sugars had no past history of ulcers or infections. In our study p value is not significant but as comparing the results most of the diabetic ulcer patients who had previous ulcer or amputation are in poor glycaemic control group.

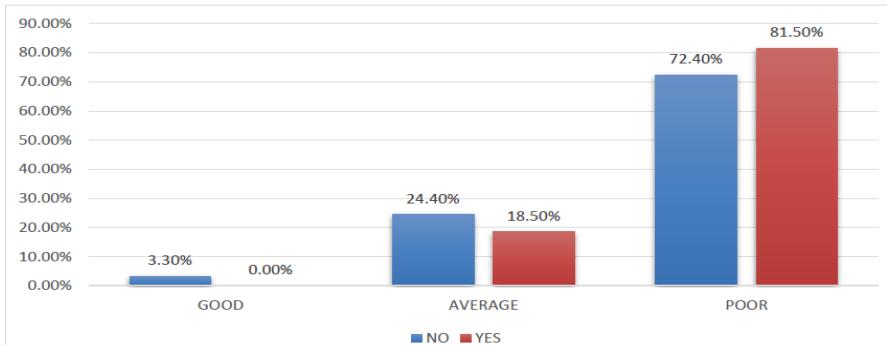


Fig 2: Relation between glycemic control in study population and past history of diabetic ulcer or amputation.

Table 2: Relation of duration of dm with pvd in the study population

Duration of DM	0 - 5 Y	PVD		Total	
		No	Yes		
		Count	%		
Duration of DM	0 - 5 Y	90	18	108	
		82.6%	43.9%	72.0%	
	6 - 10 Y	10	16	26	
		9.2%	39.0%	17.3%	
	11 - 15 Y	9	6	15	
		8.3%	14.6%	10.0%	
	>15 Y	0	1	1	
		0.0%	2.4%	0.7%	
Total		109	41	150	
		100.0%	100.0%	100.0%	

Chi Square = 25.372, P Value = 0.001(S)

It is seen that with the increasing duration of diabetes there is increased incidence of PVD in the study population, as suggested by the p value of 0.001, which is highly significant.

Table 3: Relation of duration of DM with neuropathy in the study population

			Neuropathy		Total	
			No	Yes		
Duration of DM	0 – 5 Y	Count	83	25	108	
		%	86.5%	46.3%	72.0%	
	6 – 10 Y	Count	12	14	26	
		%	12.5%	25.9%	17.3%	
	11 – 15 Y	Count	1	14	15	
		%	1.0%	25.9%	10.0%	
	>15 Y	Count	0	1	1	
		%	0.0%	1.9%	0.7%	
Total		Count	96	54	150	
		%	100.0%	100.0%	100.0%	

Chi Square = 34.515, P Value = 0.001 (S)

In the present study it is evident that there is increased risk for development of neuropathy as the duration of diabetes increases. In the range of more than 10 years of diabetes, there are maximum number of cases who developed neuropathy. The p value is highly statistically significant.

Table 4: Relation of age group with PVD in the study population

			PWD		Total	
			No	Yes		
AGE GROUP	21-40	Count	7	1	8	
		%	6.4%	2.4%	5.3%	
	41-50	Count	21	1	22	
		%	19.3%	2.4%	14.7%	
	51-60	Count	42	9	51	
		%	38.5%	22.0%	34.0%	
	61-70	Count	28	11	39	
		%	25.7%	26.8%	26.0%	
	71-95	Count	11	19	30	
		%	10.1%	46.3%	20.0%	
Total		Count	109	41	150	
		%	100.0%	100.0%	100.0%	

Chi Square = 28.637, P Value = 0.001 (S)

As we see in the above table, with the increasing age, there is significant increased incidence and development of PVD.

In the study population it has been seen that with increasing age in a diabetic patient leads to development of neuropathy, which is a risk factor for development of ulcers evident by the p value which is 0.001 i.e., highly significant.

Table 5: Comparision of outcome with past history in study population

			Neuropathy		Total	
			No	Yes		
Outcome	Below Knee Amputation	Count	3	3	6	
		%	2.4%	11.1%	4.0%	
	Chronicity	Count	26	8	34	
		%	21.1%	29.6%	22.7%	
	Disarticulation	Count	7	3	10	
		%	5.7%	11.1%	6.7%	
	Healed	Count	86	12	98	
		%	69.9%	44.4%	65.3%	
	Split Skin Graft	Count	1	1	2	
		%	0.8%	3.7%	1.3%	
Total		Count	96	54	150	
		%	100.0%	100.0%	100.0%	

Chi Square = 9.429, P Value = 0.045 (S)

As we see in above table, the outcome of the patients with diabetic ulcers is worse, when they have a previous history of amputation or ulcer. They have a significant risk associated with development of ulcers again as suggested by p value in this study.

Table 6: Comparision of PVD with outcome in study population

			PWD		Total	
			No	Yes		
Outcome	Below knee amputation	Count	2	4	6	
		%	1.8%	9.8%	4.0%	
	Chronicity	Count	6	28	34	
		%	5.5%	68.3%	22.7%	
Disarticulation		Count	9	1	10	
		%	8.3%	2.4%	6.7%	

	Healed	Count	91	7	98
	%	83.5%	17.1%	65.3%	
	Split skin graft	Count	1	1	2
	%	0.9%	2.4%	1.3%	
	Total	Count	109	41	150
	%	100.0%	100.0%	100.0%	

Chi Square = 78.636, P Value = 0.001 (S)

In the above comparison the p value is highly significant showing that, patients with peripheral vascular disease have more chronic nature of ulcers and high chances of amputations.

Table 7: Comparison of patients with neuropathy and their outcome

Outcome			Neuropathy		Total
			No	Yes	
			Count	%	
Outcome	Below Knee Amputation	Count	5	1	6
		%	5.2%	1.9%	4.0%
	Chronicity	Count	12	22	34
		%	12.5%	40.7%	22.7%
	Disarticulation	Count	5	5	10
		%	5.2%	9.3%	6.7%
		Count	73	25	98
	Healed	%	76.0%	46.3%	65.3%
		Count	1	1	2
	Split Skin Graft	%	1.0%	1.9%	1.3%
		Count	96	54	150
	Total	%	100.0%	100.0%	100.0%

Chi Square = 18.835, P Value = 0.001 (S)

As we see in above table patients with neuropathy have poor outcome and delayed wound healing. In our study patient with neuropathy had more chronic non healing phase of ulcers and patients with diabetic ulcers with no neuropathy healed well as suggested by the p value 0.001 which is highly significant.

Microbiology: In our study, culture from the wound has shown predominance of gram-negative organism (150 organism), followed by gram positive bacteria. 5 patients showed fungal growth. No growth was seen in 8 patients.

Growth pattern in cultures: Our study showed polymicrobial nature of wound cultures in about 79 patients and mono microbial nature on 71 patients.

Discussion

This observational study included 150 diabetic patients. Most patients were in the age spectrum of 51-60 years (mean age 60.5 years), and lowest cases of diabetic ulcers were seen in 20 to 40 age group. Male: female ratio is 2.5:1 (108 men, 42 women) showing males (72 %) are more affected than females (28%). This study is in comparison with the other studies by Wondwossen Amogne et al, Ethiopia in 2003[29], Abhinav Seth et al ,AIIMS, Delhi 2020[37], Faris g. Bakri et.al,Jordan,2011[26] and Bedilu Deribe1 et.al ,Jimma University,Ethiopia. 2014[32], Fatma Al-Maskari et.al, United Arab Emirates University,Al-Ain, U.A.E 2007[23],Dr. S. R Krishnamurthy, Chennai, 2018[34]In our study most of the patients came from low and medium socio-economic status. Lack of awareness regarding the diabetes and their complications and improper self-care is a contributing factor for development of ulcers. which is comparable with that of Dr. S. R Krishnamurthy, Madha medical college, Chennai, 2018[34] whose study showed that patients coming from a low socioeconomic background had higher incidence of diabetic foot ulcers. The duration of diabetes in the study population ranged from 0 year to more than 15 years. Mean duration is 4.9 years. Most patients were in the duration spectrum of 0-10 years. Most of the previous studies by Fatma Al-Maskari et.al, Al-Ain, U.A.E 2007[23]and Faris G. Bakri,et.al , Jordan 2011 [26] , Nabil Abd El Fatah Al Kafrawy et.al, Menoufia, Egypt 2013[38]and Bedilu Deribe1 et al ,Jimma University, Ethiopia 2014 [32], Abdulhussein Marzoq et al ,Basrah, Iraq 2019[35], Mackson Nongmaithem et al ,

Pimpri 2015[39] and Dr. S. R Krishnamurthy, Chennai 2018[34], most of the studies showed that increased duration of diabetes has a significant risk for diabetic ulcers. but our study has showed that diabetic patients in Indian subcontinent are at high risk of developing diabetic ulcers even at early phases of diabetes. Amongst the study group, smokers are 61 persons (40.7%) and non-smokers are 89 persons (59.3%) and all of them are males. Studies by Mackson Nongmaithem et al, Dr. D.Y. Patil Medical College, Pimpri 2015[39] and Dr. S. R Krishnamurthy, Madha medical college, Chennai 2018 [34], Nabil Abd El Fatah Al Kafrawy et.al, Menoufia, Egypt 2013 [38], Shailesh K. Shahi. Et.al(24) and Misliza A, Mas Ayu Set.al in 2007[25]concluded that smoking is a significant risk factor for development of diabetic foot ulcers. In our study traumatic ulcers are seen in 49 patients (32.7%). Fahrur Nur Rosyid in Indonesia [8] showed that trauma is a predisposing factor for the development of diabetic foot ulcer and Mackson Nongmaithem et al India, 2015 concluded that trauma increases the risk of development of foot ulcers[39].

It has been noted that only 44 patients (29.3%) were obese among the study population. Nabil Abd El Fatah Al Kafrawy et.al, Menoufia, Egypt 2013[38], showed that obesity is not a risk factor for development of diabetic foot ulcers. Whereas in contrast to our study Tesfamichael G. Mariam et al, Ethiopia July 2017[33], Bedilu Deribe1 et.al, Ethiopia 2014[32] and Nagwa Saad et.al, Egypt 2013[28] had concluded that obesity is associated with high risk of development of foot ulcers. In our study population only 27 patients (18%) had a significant past history of diabetic foot infections, ulcers and amputations. Majority of the patients were experiencing the ulcers first time. E. A. Agbor Ndip, et.al 2006[22] showed that 12.3 % of study population had a previous history of ulcers, Nabil Abd El Fatah Al Kafrawy et.al 2013[38] documented that previous ulcer or amputation had a significant risk in developing of new ulcers. The HbA1C values in the study population ranged from 7.3% to 11.1%. The mean HbA1C is 9.08%. Majority of the patients in the study population were having poor glycaemic control as evidenced by HbA1C = 9.08%. Kahsu Gebrekirstos et.al, Mekelle, Ethiopia ,2015 [29], Nabil Abd El Fatah Al Kafrawy et.al, Menoufia, Egypt, 2013[38], Mackson Nongmaithem et al India 2015[39], Dr. S. R

Krishnamurthy, Chennai, 2018[34] and Abdulhussein Marzoq et al, Basrah, Iraq, 2019[35], concluded that poor glycaemic control with elevated levels of HbA1c values was contributing factor for diabetic foot ulcers. The prevalence of peripheral vascular disease (PVD) in this study was 27.3% as evidenced by ABI =0.9. This is comparable with a study by E. A. Agbor Ndip et al 2006[22], which found the prevalence to be 21.3%. Steven P. Marso et al[40] has determined the prevalence of PVD in 29% of patients. Fatma Al-Maskari et.al of UAE 2007[23] shown prevalence of PVD in 12 % of patients. Nabil Abd El Fatah Al Kafrawy et al in Egypt 2013(38), Akaninyene Asuquo Out et al, Nigeria 2013(31), Mackson Nongmaithem et al, India 2015[39] has found that PVD to be a significant risk factor. The prevalence of neuropathy in this study was found to be 36% as evidenced by foot insensitivity to monofilament test at any one of the four tested plantar sites (great toe, base of 1st, 3rd, 5th metatarsal heads). This study correlates with the study done in Dr. D.Y. Patil Medical College, Pune by Mackson Nongmaithem et. al 2015[39], where the prevalence of neuropathy was found to be 47%, E. A. Agbor N dip et.al, in cameroon 2006[22] documented the prevalence of neuropathy in their study population was 27.0%. Another study done by Saba Noor et al, in Aligarh Muslim University [9] has shown the prevalence of neuropathy as 60%. Study by Maren Volmer-Thole and Ralf Lobmann in germany[41] showed about 50% of patients with diabetes mellitus develop symptomatic peripheral neuropathy within 25 years of disease onset and according to epidemiological data, solely neuropathy is accountable for about 50% of the cases of diabetic foot syndrome. Nagwa Saad et.al, Egypt[28], Nabil Abd El Fatah Al Kafrawy et.al Egypt 2013, Akaninyene Asuquo Out et al, Nigeria 2013[31], Faris G. Bakri, MD et.al, Jordan 2011[26], Tesfamichael G. Mariam et al, Ethiopia July 2017 [33] and Dr. S. R Krishnamurthy Chennai, 2018[34], also showed the significant association of neuropathy with development of diabetic foot ulcers. In our study, 4 people (2.7%) had history of bare foot walking, 126 people (84%) used normal footwear and 20 people (13.3 %) used specialized footwear. Wondwossen Amogne et al, Ethiopia 2003(21), showed that lack of patient educated on foot care is a major contributing factor for foot ulcers. E. A. Agbor Ndip, et.al, Yaounde Central Hospital 2006[22], Akaninyene Asuquo Out et al, Nigeria 2013[31], Bedilu Deribe1 et.al, Jimma University, Ethiopia 2014[32], Kahsu Gebrekirstos et.al Ethiopia 2015[29], Tesfamichael G. Mariam et al, Ethiopia 2017[33], Dr. S. R Krishnamurthy, Madha medical college, Chennai 2018[34], concluded that walking bare foot and not using specialized foot wear is significantly associated with development of foot ulcers in diabetics. In our study cultures from the ulcer showed predominance of gram-negative bacteria(150 organism) followed by gram positive(87) and 5 patients showed fungal growth in the ulcer. No growth was seen in 8 patients. In a similar study by Khalifa Al Benwan et.al 2011[29], gram negative isolates were more than the gram-positive isolates are concluded that poly microbial nature is more predominant in diabetic foot ulcers. Abhinav Seth et.al , All India Institute of Medical Sciences, New Delhi, India, 2020[37] showed predominance of gram negative isolates in their study which is similar to our study , but mono microbial growth pattern was seen in about 55 % which is higher compared to our study . In our study, patients were followed for 3 months and found that 98 patients (65.3%) diabetic ulcers healed, 34 patients' ulcers were chronic non healing, 10 patients underwent disarticulation of toes, 6 patients underwent major surgery-below knee amputation and 2 patients had good outcome and split skin grafting was done. Scott D. Ramsey, et al 1998[20], concluded that 15.6% of study population underwent amputations in a large-scale study with 3 years follow up. A cohort study by Abdulhussein Marzoq et.al, at Basrah, Southern Iraq 2019[35], in which outcome of 100 patients with diabetic foot ulcers revealed, ulcers of 60% of the patients healed, whereas 8% persisted unhealed; 25% of the patients had a minor amputation, 5% had a major amputation, 1% had recurrent ulcers, and 1% died. In our study it is seen that with the

increasing duration of diabetes there is an increased incidence of PVD and neuropathy as suggested by p value of 0.001 which is highly significant. Steven P. Marso et al[40] has also shown that duration of diabetes is also significantly associated with PVD. The risk of PAD is associated with advancing age and the presence of peripheral neuropathy as seen in our study is similar to that of by Steven P. Marso et al[40]. Abdulhussein Marzoq et al Iraq 2019[35], showed that patients who had complications of diabetes like peripheral neuropathy had a significant association with outcome. Firomsa Bekele et.al , Ethiopia 2020[36], concluded in their study that , there is a higher incidence of amputation in patients who have neuropathy and had poor outcome. Study by Steven P. Marso et al 2006[40] concluded that patients with diabetes and PAD are at higher risk of lower extremity amputation than those without diabetes. It has also been estimated that up to 80% of all amputations in diabetes are preceded by DFU, a study by Andrew J.M. Boulton 2013[3], therefore any success in reducing the incidence of DFU will also have some impact on amputation rates.

Summary

This observational study was conducted at Kamineni hospital, LB nagar Hyderabad during a period of two years from July 2018 to June 2020. The study population included 150 diabetic patients with a male: female ratio of 2.5:1, with mean age 60.5 years and a mean duration of diabetes is 4.9 years. Risk factors for foot ulcerations were assessed by clinical examination which included 10g/5.07 monofilament test and Ankle Brachial Index (ABI). Glycaemic control was assessed by HbA1 C. The results demonstrated prevalence of neuropathy, PVD, and previous ulcer or amputation as 36%, 27.3%, and 13% respectively. It was found that 13.3 % study population uses specialized footwear, and others are not aware that diabetes can cause foot problems which may subsequently lead to amputations. There is a significant association between increasing duration of diabetes, poor glycaemic control, increasing age and the prevalence of neuropathy, PVD and previous history of ulcer or amputation. As demonstrated in this study, the subjects who are most at risk are elderly patients with a long duration of the disease and poor glycaemic control. It is observed that diabetic patients are at high risk for development of foot ulcers at an early stage of diabetes also, proper knowledge of diabetes related complications and foot care is necessary. However practically any of the study subjects can develop a foot ulcer considering that large percent of them are not using any specialized footwear. Moreover peripheral neuropathy can be largely asymptomatic in many patients and the use of simple screening technique such as a monofilament test can help in early detection of insensitive foot and initiation of preventive measures. Patients should be made aware of foot problems through counselling, visual aids in the form of posters displayed prominently in OPDs, waiting rooms, diabetic clinics, etc., depicting selfcare techniques and the need for regular foot examination every year by a trained professional. It is also necessary to implement screening strategies, especially in the primary care setting and to develop specialized multidisciplinary foot care setting comprising diabetologist, chiropodist, orthotist, vascular surgeon, plastic surgeon for an effective management of the diabetic foot.

Conclusion

In the present study population of 150 diabetic subjects, prevalence of neuropathy in the feet is 36%, prevalence of peripheral vascular disease is 27.3%, prevalence of patients with previous ulcer or amputation is 13 %, Only 13.3 % were practicing specialized foot wear usage, poor glycaemic control is significantly associated with increase in prevalence of neuropathy, PVD which in turn increases the risk of foot ulceration. Mean duration of diabetes was found to be 4.9 years in our study, concluding that diabetic patients are at high risk for development of diabetic ulcers at early stages of diabetes also. Increasing duration of diabetes is also significantly associated with increase in neuropathy, PVD and foot deformities. Age is an independent risk factor. With advancing age, neuropathy, PVD have

significantly increased. Male Gender is significantly associated with diabetic foot ulcers. Polymicrobial nature of culture from ulcer is predominant with gram negative isolates. Diabetic foot ulcer outcomes can be predicted by several factors, some of which are modifiable. Modification for the modifiable factors, such as better glycaemic control, treatment of peripheral neuropathy, and early management of ulcers, may improve the outcome and facilitate healing.

References

- Oberoi S, Kansra P. Economic menace of diabetes in India: a systematic review. *International Journal of Diabetes in Developing Countries*. Springer; 2020.
- Yadav R, Tiwari P, Dhanaraj E. Risk factors and complications of type 2 diabetes in Asians. *Crits [Internet]*. 2008;9(2):8–12. Available from: http://www.niper.gov.in/risk_factor.pdf
- Boulton AJM. The pathway to foot ulceration in diabetes. *Med Clin North Am*. 2013;97(5):775–90.
- Rastogi A, Bhansali A. Diabetic Foot Infection: An Indian Scenario. *J Foot Ankle Surg*. 2016;3(2):71–9.
- Pendsey SP. Understanding diabetic foot. *International Journal of Diabetes in Developing Countries*. 2010;30: 75–9.
- Bañuelos-barrera P, Banuelos-barrera Y. Risk factors of foot ulceration in patients with Diabetes Mellitus type 2. *Investigación en Enfermería*. 2013;31(3):442–9.
- Diabetes DOF. Diagnosis and classification of diabetes mellitus. *Diabetes Care*. 2013;36(SUPPL.1):67–74.
- Rosyid FN. Etiology, pathophysiology, diagnosis and management of diabetics' foot ulcer. *Int J Res Med Sci*. 2017;5(10):4206.
- Noor S, Zubair M, Ahmad J. Diabetic foot ulcer - A review on pathophysiology, classification and microbial etiology. *Diabetes Metab Syndr Clin Res Rev*. 2015;9(3):192–9.
- Aumiller WD, Dollahite HA. Pathogenesis and management of diabetic foot ulcers. *J Am Acad Physician Assist*. 2015;28(5):28–34.
- May K. Preventing foot ulcers. *Aust Prescr*. 2008;31(4):94–6.
- Hoppe H, Kaufman JA. Imaging of the Diabetic Foot. *Levin O'Neal's Diabet Foot*. 2008;(9):227–38.
- Dhanda S, Tian Quek S. Imaging in Diabetic Foot. *J Arthritis*. 2017;6(06):2016–8.
- Jakosz N. Book review – IWGDF Guidelines on the Prevention and Management of Diabetic Foot Disease. *Wound Pract Res*. 2019;27(3):144.
- Naves CCLM. The Diabetic Foot: A Historical Overview and Gaps in Current Treatment. *Adv Wound Care*. 2016;5(5):191–7.
- Amin N, Doupis J. Diabetic foot disease: From the evaluation of the "foot at risk" to the novel diabetic ulcer treatment modalities. *World J Diabetes*. 2016;7(7):153.
- Cavanagh PR, Bus SA. Off-loading the diabetic foot for ulcer prevention and healing. *J Vasc Surg*. 2010;52(3 SUPPL.):37S–43S.
- Premkumar R, Rajan P, Rima J, Richard J. Footwear in the causation and prevention of foot ulcers in diabetes mellitus. *Natl Med J India*. 2017;30(5):255–61.
- Balducci, Stefano, Sacchetti, Massimo, Haxhi, Jonida, Orlando, Giorgio, D'Errico, Valeria, Fallucca, Sara, Menini, Stefano, Pugliese G. Physical Exercise as therapy for type II diabetes. *Diabetes Metab Res Rev*. 2014;32(30):13–23.
- Ramsey SD, Newton K, Blough D, McCulloch DK, Sandhu N, Reiber GE, et al. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. *Diabetes Care*. 1999;22(3):382–7.
- Amogne W, Reja A, Amare A. Diabetic foot disease in Ethiopian patients: A hospital based study. *Ethiop J Heal Dev*. 2011; 25(1):17–21.
- Agbor EA, Tchakonte B, Mbanya JC. A study of the prevalence and risk factors of foot problems in a population of diabetic patients in Cameroon. *Int J Low Extrem Wounds*. 2006; 5(2): 83–8.
- Al-Maskari F, El-Sadig M. Prevalence of risk factors for diabetic foot complications. *BMC Fam Pract*. 2007;8:1–9.
- Shahi SK, Kumar A, Kumar S, Singh MBBS SK, Gupta SK, Singh T. Prevalence of Diabetic Foot Ulcer and Associated Risk Factors in Diabetic Patients from North India. *J Diabet Foot Complicat*. 2012;4(4):83–91.
- Misliza A, Ayu S M. Sociodemographic and lifestyle factors as the risk of diabetic foot ulcer in the university of malaya medical centre. *J Heal Transl Med*. 2009;12(1):15–21.
- Bakri FG, Allan AH, Khader YS, Younes NA, Ajlouni KM. Prevalence of diabetic foot ulcer and its associated risk factors among diabetic patients in Jordan. *Jordan Med J*. 2012; 46(2):118–25.
- Benwan K Al, Mulla A Al, Rotimi VO. A study of the microbiology of diabetic foot infections in a teaching hospital in Kuwait. *J Infect Public Health*. 2012;5(1):1–8.
- Nagwa S, Khaled E, Nagwa R, Osama M and Mahmoud F. The prevalence and risk categorization of diabetic foot complications in cohort group in, Beni Suif, Egypt, 2010–2012, *Life Science Journal* 2013;10(3):1
- Solomon KG. Prevalence and Factors Associated with Diabetic Foot Ulcer among Adult Patients in Ayder Referral Hospital Diabetic Clinic Mekelle. *J Diabetes Metab*. 2015;06(08):12
- Nongmaithem M, Bawa AP, Pithwa A, Bhatia S, Singh G, Gooput S. A study of risk factors and foot care behavior among diabetics. *Journal of Family Medicine and Primary Care*. 2016;5:399.
- Otu AA, Umoh VA, Essien OE, Enang OE, Okpa HO, Mbu PN. Profile, Bacteriology, and Risk Factors for Foot Ulcers among Diabetics in a Tertiary Hospital in Calabar, Nigeria. *Ulcers*. 2013;1–6.
- Deribe B. Prevalence and Factors Influencing Diabetic Foot Ulcer among Diabetic Patients Attending Arbaminch Hospital, South Ethiopia. *J Diabetes Metab*. 2014;05(01):1–6.
- Mariam TG, Alemayehu A, Tesfaye E, Mequannt W, Temesgen K, et al. Prevalence of Diabetic Foot Ulcer and Associated Factors among Adult Diabetic Patients Who Attend the Diabetic Follow-Up Clinic at the University of Gondar Referral Hospital, North West Ethiopia: Institutional-Based Cross-Sectional Study. *J Diabetes Res*. 2017;78.
- Krishnamurthy SR. Risk Factor Analysis in Diabetic Foot Ulcer Patients. 2018;17(4):10–3.
- Marzoq A, Shuaib N, Zaboon R, Baghlyani Q, Alabood M H. Assessment of the Outcome of Diabetic Foot Ulcers in Basrah, Southern Iraq: A Cohort Study. *Int J Diabetes Metab*. 2019; 25(1–2):33–8.
- Bekele F, Chelkeba L, Fekadu G, Bekele K. Risk factors and outcomes of diabetic foot ulcer among diabetes mellitus patients admitted to Nekemte referral hospital, western Ethiopia: Prospective observational study. *Ann Med Surg* 2020; 51:17–23.
- Seth A, Attri AK, Kataria H, Kochhar S, Seth SA, Gautam N. Clinical Profile and Outcome in Patients of Diabetic Foot Infection. *International journal of applied & basic medical research*. 2019;9:14–9.
- Shafi A, Maaz-Ul-Hassan, Tufail S. A study of risk factors of diabetic foot ulcers. *Med Forum Mon*. 2018;29(4):64–6.
- Nongmaithem M, Bawa AP, Pithwa A, Bhatia S, Singh G, Gooput S. A study of risk factors and foot care behavior among diabetics. *J Fam Med Prim Care*. 2016;5(2):399.
- Mars SP, Hiatt WR. Peripheral arterial disease in patients with diabetes. *J Am Coll Cardiol*. 2006;47(5):921–9.
- Volmer-Thole M, Lobmann R. Neuropathy and diabetic foot syndrome. *Int J Mol Sci*. 2016;17(6):917

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