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A Study on Prevalence of Peripheral Vascular Disease in Patients with Diabetic Foot in A Tertiary Care Hospital

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Abstract
Diabetes mellitus is a major risk factor for atherosclerosis. The most common macrovascular complications associated with diabetes mellitus are coronary artery disease, cerebrovascular disease, renal disease, and peripheral vascular disease. The aim of the study is to detect prevalence of peripheral vascular disease in patients with diabetic foot. Single institution based observational study done at Department of General Surgery, GMC Ongole during the period from January, 2021 to December, 2021 on 95 cases. The mean average age was 52.0+7.2 years and male to female ratio was 3.75:1. The commonest clinical presentation was ulcers followed by gangrene and Cellulitis. Prevalence of PVD in patients with diabetic foot was 47.3%. Advanced age and poorly controlled diabetes increase the risk of PVD. Significant association of Major amputation with Severity of PVD and Wagner's grading was observed, indicating a positive association between amputation and severity of PVD. Lower Wagner's Grading was associated with lower chances of major amputation.

INTRODUCTION

Diabetes mellitus and its complications have become a main global health problem, accounting for highest morbidity and mortality all around the world[1]. The global burden of the disease in the year 2021 is about 537 million and by the year 2045 it is estimated to increase by 46% and reach 784 million[1].

Diabetes mellitus is a major risk factor for atherosclerosis. The most common macrovascular complications associated with diabetes mellitus are coronary artery disease, cerebrovascular disease, renal disease, and peripheral vascular disease. There are many guidelines and screening procedures available for atherosclerosis affecting coronary and cerebrovascular disease[2,3]. Whereas there are no such protocols available for screening of peripheral vascular disease and the available literature on the co-existing ischemia in diabetic foot is sparse[4].

Diabetic Foot is a commonly known and one of the dreaded complications of diabetes mellitus which is multi-factorial in nature. There are several known pathologies for developing diabetic foot disease and among them, diabetes associated peripheral neuropathy and peripheral vascular disease play an important role in resulting formation of foot ulceration[5]. The three associated components of the diabetic foot are: ischemia, infection and neuropathy. 6 In diabetic patients, peripheral neuropathy a known complication of the disease masks the intermittent claudication pain, a major symptom which helps us in diagnosing peripheral vascular disease at an earlier stage[7].

The presence of ischemia delays the healing of the diabetic foot ulcers and may lead to amputation. More than 50% of lower extremity amputations occur in diabetics, in addition to neuropathy and trophic ulcers., peripheral vascular disease plays a major role in the evolution and outcome of diabetic foot infection.

Aims and Objectives: The aim of the study is to detect prevalence of peripheral vascular disease in patients with diabetic foot.

To detect the prevalence of peripheral vascular disease by measuring ankle-brachial index in patients presenting with diabetic foot and to compare the outcome of treatment in these patients with severity of peripheral vascular disease.

MATERIALS AND METHODS

Single institution based observational study done at Department of General Surgery, GMC Ongole during the period from January, 2021 to December, 2021 on 95 cases.

Inclusion Criteria: Patients with diabetic foot, who have given consent. Patients who had arterial doppler study of the lower limb arterial system.

Exclusion Criteria: Patients with type 1 diabetes mellitus, diabetes associated with pregnancy and lactation. Patients didn't undergo arterial doppler study of the lower limb arterial system.

After taking informed consent from patients with diabetic foot, detailed history and clinical examination were done by both investigator and guide followed by various investigations like HbA1C and Arterial doppler of the lower limb. The following data was be collected from all the study population.

Demographic Data: Name, age, sex, I.P number, duration of diabetes mellites and type of diabetes.

Data Related to the Study Criteria: Location of the ulcer, size of the ulcer, duration and the description of the various parts of the ulcer and categorization the ulcer as per the Wagner's diabetic wound classification system. Data regarding the grading of ulcer as per Wagner's classification and details of treatment were recorded in all the patients. All patients were subjected to imaging (x-ray) where indicated and the estimation of ankle brachial index by arterial doppler was done and all patients were categorized as suffering from no ischemia, mild ischemia, moderate ischemia and severe ischemia based on ABI. All the patients were subjected to the standard treatment with dressing, antibiotics, diabetic control and other treatments as per the individual needs of the patient.

RESULTS AND DISCUSSIONS

The mean age of the study population is 52.0+7.2 years.

The most common complication in diabetic patients is developing diabetic foot and it is the important cause for the morbidity in those patients and it also affects the quality of life and accounts for a significant part of financial burden in terms of better health care.

Diabetic foot complications are severe and chronic. They consist of lesions in the deep tissues associated with neurological disorders and peripheral vascular disease (PVD) in the lower limbs. To decrease the morbidity caused by the foot ulceration, diagnosing the peripheral vascular disease i.e., one of the macro-vascular complications of the diabetes, at an early stage plays an important role. Peripheral vascular disease plays an important role in the pathogenesis of foot ulcer and good circulation is required for early healing. Hence there is a need for early diagnosis of peripheral vascular disease in diabetics with foot infections. This study tends to detect peripheral

Table 1: Distribution of Patients - According to their Age

Age Group	Total No. of Patients			Percentage
	Males	Females	Total	
41-45 years	14	5	19	20%
46-50 years	20	6	26	27.3%
51-55 years	18	3	21	22.1%
56- 60 years	14	5	19	20%
61-65 years	4	0	04	4.3%
More than 65years	5	01	06	6.3%
Total No. of Cases	75	20	95	100%

The mean age of the study population is 52.0 + 7.2 years.

Table 2: Distribution of Patients - According to Gender

Gender	No. of Cases	Percentage
Males	75	78.9%
Females	20	21.1%
Total	95	100%

Male: Female ratio was 3.75:1.

Table 3: Distribution of patients according to the duration of diabetes

Duration of Diabetes(In Years)	No. of Cases	Percentage
Newly Diagnosed	05	5.3%
<5 Years	17	17.8%
5-10 Years	33	34.8%
1-15 Years	15	15.8%
16-20 Years	11	11.5%
>20 Years	14	14.8%
Total No of cases	95	100%

Table 4: Distribution of Patients: HbA1C and PVD

Glycemic Control	No. of Patients	Percentage
Good (< 6.5%)	15	33.3%
Fairly Good (6.5-7.9%)	17	37.8%
Poor (>8%)	13	28.9%
Total No. of Cases	45	100%

Table 5: Distribution of Patients - Clinical Presentation

Clinical Presentation	No. of Cases	Percentage
Cellulitis	30	31.5%
Ulcer	32	33.7%
Abscess	02	2.1%
Gangrene	31	32.7%
Total No. of Cases	95	100%

Table 6: Distribution of patients – According to Wagner's Grading of ulcer

Wagner's Grading	No. of Patients
Grade-1	17.9% (n=17)
Grade-2	15.7% (n=15)
Grade-3	11.5% (n=11)
Grade-4	18.9% (n=18)
Grade-5	4.3% (n=04)

Table 7: Distribution according to Grading of ABI in the Study Population

ABI Grading	No. of Cases	Percentage
Mild	20	44.5%
Moderate	17	37.8%
Severe	8	17.7%
Total No. of Cases	45	100%

Table 8: Distribution of Patients - Mode of Management

Mode of Management	No. of Cases	Percentage
Conservative Management	30	31.5%
Debridement, Regular Dressings and SSG	32	33.7%
Incision and Drainage	02	2.1%
Minor Amputation / Disarticulation	25	26.3%
Below Knee Amputation	06	6.4%
Total No. of Cases	95	100%

Table 9: Comparison of Various Studies- Mean Age of the Study Population

Various Studies	Mean Age
Present Study	52.0 + 7.2 years.
Praveena DL *et al*[8]	55.8 + 10.45 years
Jawed Akther *et al*[9]	55.6 + 12 years.
Muduli *et al*[10]	54.57+ 13 years.
Kummankandath SA *et al*[11]	54.6 + 12.4 years.
Byung-Joon Joen *et al*[12]	61.1 years

Table No 10: Various Studies – Male: Female Ratio of the Study Population

Various Studies	Male: Female Ratio
Present Study	3.75:1
Praveena DL *et al*[8]	3.76:1
Muduli *et al*[10]	2.33:1
Stefan Beckert *et al*[13]	2.07:1
Jawed Akther *et al*[9]	5.8:1
Anil Gupta *et al*[14]	1.94:1
Byung- Joon Joen *et al*[13]	1.32:1

Table 11: Prevalence of PVD according to Duration of Diabetes Mellitus

Duration of DM	Newly Diagnosed	1-10 Years	11-20 Years	More than 20 Years
Present Study	8.9% (04)	22.2% (10)	37.8% (17)	31.1% (14)
Muthaiah *et al*[15]	01	16% (24)	14% (21)	11
Immanuel Amissah *et al*[16]	9.8%	30.9%	59.1	
Kristianstad 11		16.4%	38.4%	

Table 12 - Comparison of different studies on Wagner's grading with the present study

Wagner's Grading	Grade-1	Grade 2	Grade 3	Grade 4	Grade 5
Present Study	17	15	11	18	4
Anil Gupta *et al*[14]	18 (18%)	22 (22%)	16 (16%)	34 (34%)	10 (10%)
Ravidas VS *et al*[22]	51 (48.6%)	12 (11.4%)	22 (21%)	11 (10.5%)	9 (8.6%)
Jawed akther *et al*[9]	9 (16.4%)	19 (34.5%)	13 (23.6%)	11 (20%)	3 (5.4%)
Muduli *et al*[10]	06 (10%)	10 (17%)	18 (30%)	15 (25%)	8 (13%)

Table No 13: Comparison of different studies: Clinical Presentation

	Cellulitis	Ulcer	Abscess	Gangrene
Present Study	30 (31.5%)	32(33.7%)	2(2.1%)	31 (32.7%)
Dhanraj M *et al*[23]	20 (20%)	48 (48%)	8 (8%)	24 (24%)

Table No 14: Comparison of different studies: Clinical Presentation

	Cellulitis	Ulcer	Abscess	Gangrene
Present Study	30 (31.5%)	32(33.7%)	2(2.1%)	31 (32.7%)
Dhanraj M *et al*[23]	20 (20%)	48 (48%)	8 (8%)	24 (24%)

Table No 15: Comparison of different studies: Management

Management Various Studies	Debridement f/b Regular dressings	Minor amputations	Major amputations
Present study	32 (33.6%)	25(26.3%)	06(6.31%)
Beckert's *et al*[13]		99 (9.9%)	26 (2.6%)
Ravidas VS *et al*[22]	56 (53.3%)	34 (32.4%)	13 (12.4%)
Anil gupta *et al*[14]	36	39	12
Muduli *et al*[10]	25 (46%)	12 (23%)	5 (10%)

Table No 16: Prevalence of PVD in various studies

Study	Prevalence
Present Study	47.3%
Janbakhsh *et al*[24]	61.2%
Ravidas VS *et al*[22]	66.7%
Muthaiah *et al*[15]	38%
Muduli *et al*[10]	35%
Marinelli *et al*[25]	33%
Migdalis *et al*[15]	44%

Table 17: Association of Age group and Prevalence of PVD

Age Group	Normal	PVD
41- 45	15	04
46- 50	19	07
51-55	12	09
56-60	04	15
61-65	00	04
More than 65 Years	00	06
	Chi – 28.520 P – 0.000029 Statistically Significant	

Table 18: Association of Age Group and Severity of PVD

	Severity of PVD		
	Mild	Moderate	Severe
41-45	4	0	0
46-50	4	3	0
51-55	5	4	0
56-60	6	5	4
61-65	0	2	2
More than 65 Years	1	3	2

Chi- 15.68151 P- 0.109105 Statistically Not Significant

Table 19: Association of Duration of Diabetes and Prevalence of PVD

	Normal	PVD
Newly Diagnosed	**01**	**04**
< 5 Years	**15**	**02**
5-10 Years	**25**	**08**
11-15 Years	**05**	**10**
16-20 Years	**04**	**07**
>20 Years	**00**	**14**
Chi-36.822	**P < 0.00001**	**Statistically Significant**

Table 20: Association of Duration of Diabetes and Severity of PVD

	Severity of PVD		
	Mild	Moderate	Severe
Newly Diagnosed	3	1	0
< 5 Years	2	0	0
5-10 Years	7	0	1
11-15 Years	1	8	1
16-20 Years	5	1	1
>20 Years	2	7	5
Chi- 26.60696	P-0.003004	Statistically Significant	

Table 21: Association of Wagner's Grading & Management

	Debridement	Incision and Drainage	Minor Amputation	Major Amputation
Wagner 1	17	0	0	0
Wagner 2	15	0	0	0
Wagner 3	0	2	09	0
Wagner 4	0	0	16	02
Wagner 5	0	0	0	04
Chi-113.68	P <0.00001	Statistically Significant		

Table 22: Association between Wagner's Grading and Prevalence of PVD

	Normal	PVD
Wagner 1	14	02
Wagner 2	4	11
Wagner 3	5	06
Wagner 4	0	18

vascular disease in patients with diabetic foot by non-invasive methods such as measurement of ankle-brachial index with doppler and there by proving it as a better screening modality for the detection of PVD.

Glycemic Control: In the present study, out of 45 patients who are diagnosed with PVD, 37.8% of the cases had fairly good glycemic control i.e., 17 patients with HbA1C within the range of 6.5%-7.9%, followed by 33.3% of the cases had good glycemic control and 28.9% of the cases i.e., 13 patients had poor glycemic control i.e., HbA1C levels > 8%.

Although the actual prevalence of PVD in diabetics is unknown, the United Kingdom Prospective Diabetes Study (UKPDS) reported that 1.2 percent of type 2 diabetes patients had PVD at the time of diagnosis. With each 1% increase in HbA1C, there was a 28% higher risk of PVD at 6-year follow-up in those who did not have PVD at diagnosis[17]. Arya *et al.* found that each 1% rise in A1C above 6.0% was associated with a 25% higher risk of amputation and a 105% increased risk of a major adverse limb event[17,18]. There is a paucity of evidence to support intensive glycemic management can lower the risk associated with PVD. Current guidelines from the ADA recommend a target glycosylated hemoglobin level of <7.0% in diabetic individuals in order to prevent microvascular complications[19]. It should be highlighted that the ADA consensus statement's current guidelines for glucose management are not based on clinical trial data in people with diabetes and PVD. In this population, further research is needed, particularly with medicines that enhance insulin sensitivity[20]. But poor glycemic control has been associated with a higher prevalence of PVD and risk of adverse outcomes, including need for lower extremity bypass surgery, amputation and poor glycemic control is also associated with worse outcomes following vascular surgery or endovascular intervention[21].

Mode of Management: In the present study, out of 95 patients, 32 patients required debridement followed by regular dressings., 26.3% of the cases (25 patients) underwent minor amputations (ray amputations) and 6.3% of the cases underwent major amputations (only below knee amputations). Debridement is foremost and important mode of management, which helps in faster healing of the diabetic foot ulcer.e-1 and Grade -5. In study of Muduli[10], majority of the patients presented with Grade-3, followed by Grade-4, Grade-2, Grade-5 and Grade-1.

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