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ORIGINAL ARTICLE

RISK OF DIABETIC FOOT IN DIABETICS WITH MICRO AND MACROVASCULAR COMPLICATIONS

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ABSTRACT: CONTEXT: Foot complications are one of the most serious and costly complications of diabetes, but are usually neglected. Since most Indians still walk barefoot and are ignorant of foot care, there is an urgent need for preventive clinical measures to reduce the impact of diabetic foot. **AIMS:** To evaluate micro and macro vascular complications in diabetics as predictors of diabetic foot risk. **SETTINGS & DESIGN:** The study was conducted in Shyam Shah Medical College and associated Sanjay Gandhi Memorial Hospital, Rewa (MP), in 2013 on 200 diabetics. **METHODS & MATERIAL:** A complete general and systemic examination to be carried out on diabetic subjects, analysing their micro and macrovascular complications and evaluating their risk of developing diabetic foot. Data analysis was done by calculating the p-value using the Chi Square Test. **RESULTS:** Out of 200 patients, 12 were at a high risk of developing diabetic foot, while 57 and 131 were at low and moderate risk respectively. Demographic profile revealed a higher risk among the older population (p=0.0003), low Socioeconomic strata (p=0.007), rural population (p=0.006) and a lower risk among the literate (p=0.01) and with a shorter history of duration of diabetes (p=0.02). The presence of retinopathy (p=0.01), nephropathy (p=0.02), neuropathy (p=0.0006), and periodontal disease (p=0.006) was significant in those with high risk as was the presence of coronary artery disease (p=0.04), hypertension (p=0.02) and peripheral arterial disease (p=0.0005). Other factors, such as blood glucose control (p=0.0002), waist circumference (p=0.04) and various addictions, were also contributory factors to the risk of diabetic foot. **CONCLUSION:** Diabetic foot is an advanced complication of diabetes from where there is no turning back. The evaluation of risk factors that contribute to it, also serve as intervention points - their control can retard the development of diabetic foot. Thus, this study reveals such factors, detectable through clinical measures and may be the potential solution of impeding the progress of diabetic foot.

KEYWORDS: Diabetes Mellitus, Diabetic Foot.
MESH HEADING: Diabetes Mellitus, Diabetes Complications, Diabetic Foot, Diabetic Neuropathies.

INTRODUCTION: Diabetic foot ulcer is a health problem rising with the increasing prevalence of diabetes. Worldwide, up to 70% of all leg amputations are carried out in diabetics.[1] A multidisciplinary approach including preventive strategy, patient and staff education, and multifactorial treatment of foot ulcers has been reported to reduce the amputation rate by more than 50%.[2]

In Indians, the prevalence of microvascular complications like retinopathy and microalbuminuria among Type II diabetic subjects has been reported to be 17.6% and 26.9%, respectively.[3] The prevalence of macrovascular complications like Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD) was 21.4%[4] and 6.3%[5] respectively.

The feet are the target of peripheral neuropathy leading chiefly to sensory deficit and autonomic dysfunction. Diabetic patients are at high risk for PAD.[6] It leads to the decreased flow of

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blood to the foot, resulting in decreased delivery of oxygen, nutrients and antibodies to the foot further hampering the chances of healing. The risk for neuropathic ulcer increases with age, duration of diabetes, presence of nephropathy and retinopathy.[7] Diabetic neuropathy affects sensory, motor, and autonomic nervous function, but sensation is often affected first.[8] It is complicated by peripheral neuropathy and susceptibility to infection which leads to foot ulceration, gangrene, and amputation of affect limb.

Diagnostic procedures are indicated in the assessment and care of the diabetic foot. Clinical laboratory tests that are needed in appropriate clinical situations include Fasting or Random Blood Sugar, Complete Blood Count and Serum Chemistries.

Peripheral sensory neuropathy is the major independent risk factor for diabetic foot ulcerations.[9] The patient history and physical examination utilizing the 5.07 Semmes-Weinstein monofilament (10g) is sufficient to identify those individuals at risk for ulceration.[10] Absence of peripheral pulses in posterior tibial, popliteal or femoral arteries, indicate significant occlusive PAD especially if associated with symptoms like claudication.[11]

Most epidemiological studies have used Ankle Brachial Index (ABI) to diagnose PAD[12]. ABI between 0.51-0.9 indicates moderate-severe PAD. The patients are at high risk of developing micro and macrovascular complications.[13]

MATERIALS & METHODS: AIMS & OBJECTIVES: To evaluate micro and macro vascular complications in diabetics as predictors of diabetic foot risk.

SETTINGS & DESIGN: The study was conducted in Shyam Shah Medical College and associated Sanjay Gandhi Memorial Hospital, Rewa (MP), in 2013 on 200 admitted diabetics.

MATERIALS & METHODS: Routine investigations were carried out; specific and special investigations were done as and when indicated. Diabetic Foot Risk Assessment Form was filled up by each patient. It comprises the assessment of the foots skin, structure, vascularity, sensation and mobility as well as the level of care the patient practices with regards to hygiene and footwear.[14]

On visual inspection of the top and bottom of both feet, general shape and deformities, if present, were duly noted. Signs of dry or sweaty feet were looked for, as well as for any corns, calluses, fissures, cracks, maceration and other skin abnormalities. Signs of skin breakdown, infection, inflammation, discharge, and pain were also examined.

To screen for the presence or absence of neuropathy in the diabetic foot, the ten-site test using 10g Semmes-Weinstein 5.07 monofilament was carried out. Range of motion of toes and ankles was checked by passive motion. Presence of PAD was investigated through ABI determination and peripheral pulse evaluation.

Based on this survey & foot characteristics, each patients foot is categorized into Low, Moderate or High Risk Categories. A Low risk foot was normal in all these aspects; Moderate Risk foot had abnormalities like calluses, fissures, cracks, healed ulcer but intact skin integrity. A High risk foot showed loss of skin integrity with or without associated abnormalities as found in the moderate risk foot.[14]

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OBSERVATIONS:

DIABETIC FOOT RISK	NUMBER OF PATIENTS
LOW RISK	57
MODERATE RISK	131
HIGH RISK	12

TABLE 1: Risk Stratification

Out of the total 200 diabetics evaluated, 12 had a High Risk Foot, 57 had Low Risk while the maximum number (131) had a Moderate Risk.

VARIABLE	DIABETIC FOOT RISK			
AGE (years) p=0.0003	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
<40	14(60.87%)	9(39.13%)	0(0%)	23
40-60	31(31%)	65(65%)	4(4%)	100
>60	12(15.59%)	57(74.02%)	8(10.39%)	77
SEX p=0.305				
MALE	37	74	9	120
FEMALE	29	57	3	80
OCCUPATION p=0.055				
LABOURER	6(18.18%)	26(78.79%)	1(3.03%)	33
HOUSEWIFE	19(24.05%)	57(72.15%)	3(3.8%)	79
OFFICE-GOING	32(36.36%)	48(54.54%)	8(9.1%)	88
SOCIOECONOMIC STATUS p=0.007				
UPPER CLASS	35(42.68%)	43(52.44%)	4(4.88%)	82
MIDDLE CLASS	12(21.05%)	41(71.93%)	4(7.02%)	57
LOW CLASS	10(16.39%)	47(77.05%)	4(6.56%)	61
EDUCATION p=0.010				
ILLITERATE	4(14.28%)	22(78.57%)	2(7.15%)	28
UPTO SENIOR SECONDARY	25(22.52%)	79(71.18%)	7(6.3%)	111
GRADUATE	26(44.07%)	30(50.85%)	3(5.08%)	59
POST GRADUATE	2(100%)	0	0	2

TABLE 2: Demographic Profile

There was a significantly sharp rise in the percentage of High Risk cases with age. In the ages <40 years, none had a High Risk while in the >60 year group, it was seen among 10.39%. Although more number of males had a high risk, it was statistically insignificant.

Among occupational groups, office goers had the highest propensity to develop diabetic foot (9.1%), while subjects from higher socioeconomic strata had a lower risk (4.88%). High risk patients were more common among those with lower level of formal education (7.15%).

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VARIABLE	DIABETIC FOOT RISK			
FAMILY HISTORY p=0.0009	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
FATHER	14(50%)	13(46.43%)	1(3.57%)	28
MOTHER	9(42.86%)	11(52.38%)	1(4.76%)	21
BOTH	10(55.56%)	8(44.44%)	0	18
NONE	24(18.05%)	99(74.43%)	10(7.52%)	133
DURATION p=0.020				
NEWLY DETECTED	9(47.37%)	10(52.63%)	0	19
< 10 years	27(36.99%)	43(58.9%)	3(4.11%)	73
>10	21(19.45%)	78(72.22%)	9(8.33%)	108
TYPE p=0.010				
TYPE I	5(83.33%)	1(16.67%)	0	6
TYPE II	52(26.8%)	130(67.01%)	12(6.19%)	194
TREATMENT p=0.817				
INSULIN	2(28.57%)	5(71.43%)	0	7
ORAL HYPOGLYCEMIC AGENTS (OHA)	55(28.8%)	124(64.92%)	12(6.28%)	191
INSULIN + OHA	0	2(100%)	0	2
BLOOD GLUCOSE CONTROL p=0.002				
>200mg/dl	21(18.75%)	84(75%)	7(6.25%)	112
<200mg/dl	36(40.9%)	47(53.41%)	5(5.69%)	88

TABLE 3: HISTORY OF DIABETES

Most of the patients with high risk had no family history of diabetes. Only 3 patients had a high risk with disease duration <10 years compared to 9 patients whose disease duration was >10 years. In our study, all the high risk patients were type II diabetics.

All the patients with a high risk were on oral hypoglycaemic agents; which was statistically insignificant. Meanwhile, better blood glucose control (40.9%) was significantly associated with lower risk of diabetic foot.

VARIABLE	DIABETIC FOOT RISK			
LIVING p=0.006	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
RURAL	16(17.98%)	65(73.03%)	8(8.99%)	89
URBAN	41(36.94%)	66(59.46%)	4(3.6%)	111
BODY MASS INDEX p=0.188				
<18.5	5(50%)	5(50%)	0	10
18.5-25	35(30.7%)	69(60.52%)	10(8.78%)	114
25.1-30	17(22.98%)	55(74.32%)	2(2.7%)	74
>30	0	2(100%)	0	2
WAIST CIRCUMFERENCE (cm) p=0.046				
F <80, M<90	40(37.38%)	60(56.07%)	7(6.55%)	107
F 81-90, M 91-100	9(18%)	38(36%)	3(6%)	50
F >90, M >100	8(18.61%)	33(76.74%)	2(4.65%)	43

TABLE 4: PERSONAL HISTORY

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Patients hailing from rural areas (8.99%) had a higher risk of diabetic foot compared to their urban cohort (3.6%). Most of the patients of high risk had a normal Body Mass Index. However this association was statistically insignificant. On the other hand, a higher waist circumference (4.65%) significantly correlated with a higher risk of diabetic foot.

VARIABLE	DIABETIC FOOT RISK			
ANKLE BRACHIAL INDEX p=0.0005	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
>1.3	0	0	0	0
0.91-1.3	49(28.33%)	118(68.2%)	6(3.47%)	173
0.5-0.9	8(29.63%)	13(48.15%)	6(22.22%)	27
<0.5	0	0	0	0
PERIPHERAL PULSES p=0.010				
REDUCED	15(26.31%)	34(59.65%)	8(14.04%)	57
PALPABLE	42(29.37%)	97(67.83%)	4(2.8%)	143
FOOT SENSATION p=0.0004				
NORMAL	50(32.05%)	103(66.02%)	3(1.93%)	156
LEFT FOOT REDUCED	3(27.27%)	6(54.55%)	2(18.18%)	11
RIGHT FOOT REDUCED	2(18.18%)	7(63.64%)	2(18.18%)	11
BILATERAL REDUCED	2(9.1%)	15(68.18%)	5(22.72%)	22
FOOT VIBRATION p=0.014				
NORMAL	52(30.59%)	111(65.3%)	7(4.11%)	170
IMPAIRED	5(16.67%)	20(66.66%)	5(16.67%)	30

TABLE 5: FOOT EVALUATION

The ankle brachial index significantly identified those with a high risk (22.22%) of developing diabetic foot. The reduced palpability of peripheral pulses (p=0.010), foot sensation (p=0.0004) and vibration (p=0.014) also significantly marked those with a higher risk of diabetic foot.

VARIABLE	DIABETIC FOOT RISK			
SMOKING p=0.009	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
YES	21(21.43%)	67(68.37%)	10(10.2%)	98
NO	36(35.29%)	64(62.75%)	2(1.96%)	102
ALCOHOL p=0.017				
YES	15(30%)	28(56%)	7(14%)	50
NO	42(28%)	103(68.67%)	5(3.33%)	150
ALCOHOL + SMOKING p=0.010				
YES	13(28.26%)	26(56.52%)	7(15.22%)	46
NO	44(28.57%)	105(68.18%)	5(3.25%)	154

TABLE 6: ADDICTIONS

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Addictions to smoking (p=0.009) and alcohol (p=0.017) contributed significantly to the risk of diabetic foot. This risk was also significant among alcohol users who smoked (p=0.010).

VARIABLE	DIABETIC FOOT RISK			
RETINOPATHY p=0.01	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
YES	8(36.37%)	10(45.45%)	4(18.18%)	22
NO	49(27.52%)	121(67.98%)	8(4.5%)	178
NEPHROPATHY p=0.02				
YES	9(15%)	47(78.33%)	4(6.67%)	60
NO	48(34.28%)	84(60%)	8(5.72%)	140
NEUROPATHY p=0.0006				
YES	22(18.8%)	85(72.65%)	10(8.55%)	117
NO	35(42.16%)	46(55.43%)	2(2.41%)	83
NEPHROPATHY + NEUROPATHY p=0.03				
YES	7(14%)	39(78%)	4(8%)	50
NO	50(33.33%)	92(61.34%)	8(5.33%)	150
RETINOPATHY + NEUROPATHY p=0.009				
YES	5(27.78%)	9(50%)	4(22.22%)	18
NO	52(28.57%)	122(68.54%)	8(4.39%)	182
NEPHROPATHY + RETINOPATHY + NEUROPATHY p=0.004				
YES	2(20%)	5(50%)	3(30%)	10
NO	55(28.95%)	126(66.31%)	9(4.74%)	190
PERIODONTAL DISEASE p=0.006				
NONE/MILD	43(34.13%)	79(62.7%)	4(3.17%)	126
MODERATE/SEVERE	14(19.44%)	51(70.83%)	7(9.73%)	72
EDENTULOUS	0	1(50%)	1(50%)	2

TABLE 7: MICROVASCULAR COMPLICATIONS

The presence of retinopathy (p=0.01), nephropathy (p=0.02) and neuropathy (p=0.0006) significantly increased the risk of diabetic foot. The superimposition of neuropathy on retinopathy (p=0.009) and nephropathy (p=0.03) further increased the risk. The most significant risk was seen among those who had all three of these microvascular complications (p=0.004). Periodontal disease (PD) was also more frequent among those with a higher risk of diabetic foot (p=0.006).

VARIABLE	DIABETIC FOOT RISK			
HYPERTENSION (HTN) p=0.021	**LOW**	**MODERATE**	**HIGH**	**TOTAL**
YES	20(26.67%)	46(61.33%)	9(12%)	75
NO	37(29.6%)	85(68%)	3(2.4%)	125
CORONARY ARTERY DISEASE (CAD) p=0.041				
YES	17(20.99%)	56(69.13%)	8(9.88%)	81
NO	40(33.61%)	75(63.03%)	4(3.36%)	119

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CAD + HTN p=0.024				
YES	9(22.5%)	25(62.5%)	6(15%)	40
NO	48(30%)	106(66.25%)	6(3.75%)	160
CAD + PAD p=0.002				
YES	3(20%)	8(53.33%)	4(26.67%)	15
NO	54(29.19%)	123(66.49%)	8(4.32%)	185

TABLE 8: MACROVASCULAR CO-MORBIDITIES

Among macrovascular complications, hypertension (12%) was more often seen in the patients with a high risk of diabetic foot. The presence of Coronary Artery Disease (CAD) also increased this risk (9.88%). The combined effect of CAD and hypertension (15%) was also significant in the risk of developing diabetic foot. Patients who had PAD as well CAD (26.67%) suffered the most significant risk among the macrovascular complications.

DISCUSSION: In our study, the maximum 'high risk' patients were in the >60 year age group (10.39%) while no patient <40 years had high risk. Similarly, Margolis[15] found an increasing incidence of diabetic foot ulcer with age (6.5% <45 years to 11.3% >95 years). As the risk of diabetic foot increases with age, knowing its risk factors will help us modify them to prevent the onset of diabetic foot.

A high risk of diabetic foot was seen in 9.1% of office-goers and only among 3.03% of labourers. Misliza[16] found that 22.4% of diabetic foot patients were manual workers while the remaining 77.6% were unemployed or working as professionals (non-manual workers).

This study also revealed that the least number of high risk subjects were in the upper socioeconomic group (4.88%). Misliza[16] similarly found that only 24% of diabetic foot patients had income >3000 while 35.2% had an income of 1000-1999. These differences may be associated with the higher level of education and self-care in the higher income group.

In our study, no postgraduate patient had a high risk, while 7.15% of the illiterates had a high risk. Misliza also[16] found higher prevalence of diabetic foot among the primary schooled (38.4%) compared to those who had tertiary level education (10.4%).

All the 'high risk' patients in our study were type II diabetics. In similar comparison between type I and type II diabetes mellitus by Muquim[17] on diabetic foot, only 2% of their cases were type I diabetes, while the remainder 98% were type II. This is also influenced by the fact that all of our type I patients were young with just 4-5 year disease duration.

A high risk was found among 8.33% of the patients who had been diseased since >10 years. Shahi[18] also found that patients with diabetic foot had a mean duration of diabetes of 11.5±5.74 years compared to 7.59±4.86 years in those without diabetic foot. A new finding that our study depicts is 52.63% of the newly detected had a moderate risk. This underlines that the impairment of blood sugar itself may predispose to diabetic foot, even before the full blown diabetic state is reached.

Peters found that those patients with a history of foot ulcer had higher levels of blood glucose compared to those without ulceration.[19] We came to a similar conclusion as a greater number of high risk patients had a blood glucose of >200mg/dl (6.25%) compared to the group whose blood glucose was <200mg/dl (5.69%). In Shahis' study,[18] 86.59% of patients with diabetic foot were on insulin therapy compared to just 13.4% on oral hypoglycaemic agents. On the contrary, we found a high risk to be more common in those who were on oral therapy (6.28%). The reluctance to insulin therapy-

which would allow stricter control thus reducing risk is a major obstacle we must overcome to reduce the incidence of diabetic foot.

In this study 8.99% of rural dwellers had a high risk compared to only 3.6% of urban dwellers. Vishwanathan[20] also concluded that diabetics who live in rural areas are more prone to foot ulcers than those who live in urban areas. The habit of walking barefoot, as well as the impoverishment to afford good footwear is more prevalent among rural habitat and could be a contributory factor that can be easily overcome through social upliftment.

A higher risk of diabetic foot was found in those who had normal BMI in this study; which was statistically insignificant. However, we found a significant association between waist circumference and the risk of developing diabetic foot (p=0.046). Misliza, however, found a higher incidence of diabetic foot in patients with high BMI.[16] As Indians are prone to abdominal obesity, as reflected by waist circumference, it could be a better marker than BMI to reflect diabetic foot risk. Further comparative evaluation should be done.

High Risk was seen among 22.2% of diabetics with abnormal Ankle Brachial Index (ABI) and among 3.47% of diabetics with normal ABI. Wang[21] also found that an abnormal ABI was more prevalent in patients with non-healing ulcers. High risk was also more prevalent among diabetics with reduced palpability of lower limb pulses (14.04%); correlating with Margolis, in whose study of diabetic foot patients, 20% had distal vasculopathy.[22] Thus, PAD evaluation through ABI and peripheral pulses can help predict the risk for diabetic foot.

Among our high risk subjects, abnormal Semmes Weinstein monofilament test was seen in 75% while Peters[19] similarly found abnormal test in 96.9% of patients with a history of foot ulcer. Vibration perception by 128 Hz Tuning fork showed high risk among 16.67% with abnormal perception. Piagessi[23] found that patients with neuropathy showed higher values of Vibration Perception Threshold.

This study revealed high risk to be more common among smokers (10.2%) vs. non-smokers (1.96%); among alcohol users (14%) vs. non-users (3.33%); and significant among addicts of both smoking and alcohol (15.22%). Similarly, Shahi[18] found 21.64% of diabetic foot patients to be smokers compared to only 14.8% among those without diabetic foot. But, Shahi[18] found a lower percentage of alcohol use among patients with diabetic foot (12.37%) than among those without diabetic foot (15.66%); as well as 7.21% of diabetic foot patients who had both addictions while 11.87% of those without diabetic foot had both addictions. On the whole, it can be said that as smoking is contributory to development of PAD, it also increases the risk of diabetic foot. Association of alcohol would need further evaluation.

A significantly high risk was seen among those diabetics who had developed microvascular complications like retinopathy (18.18%), nephropathy (6.67%), neuropathy (8.55%) and periodontal disease (9.73%). Kamran[24] determined the association between the high risk foot and progressive retinopathy to be highly significant at a p-value of <0.001. Neders[25] studied diabetics with end-stage renal disease and found a much higher incidence of foot complications and risk for amputation among them. In Kumars' study,[26] 41.6% of patients with diabetic foot had neuropathy. Abrao[27] found neuropathic foot ulcer risk in 68.2% of patients with Periodontal Disease. In this study, only 19.44% of patients with moderate-severe PD had a low risk of developing diabetic foot. We also evaluated the effect of the presence of more than one such complication, on the risk of diabetic foot. Such associations significantly increased the high risk patients from 18.18% in pure retinopathy to 22.22% in those with neuropathy and retinopathy; from 6.67% in pure nephropathy to 8% in those with

neuropathy and nephropathy; and in 30% of patients with all three complications. It is hence conclusive that microvascular complications are significant contributors in the development of diabetic foot.

Among macrovascular co-morbidities, high risk was seen among 12% hypertensives, 9.88% of CAD patients which significantly increased to 15% among patients with both co-morbidities. Apelqvist[28] found patients whose foot ulcer healed had a lower blood pressure than those who required amputation. McNeely[29] demonstrated ischemic heart disease in 47.6% of diabetic foot subjects. We also found that the presence of CAD and PAD in a diabetic synergistically increased the risk (26.67%) of diabetic foot. Thus, macrovascular co-morbidities are a potential risk towards the development of diabetic foot.

RECOMMENDATIONS: This study has comprehensively shown the effect micro and macrovascular complications have on the risk of developing diabetic foot. Thus, the screening for such complications should be done from the newly detected diabetic stage after which its progression can be evaluated. The non-modifiable risk factors such as Age, Sex and Family history can be subdued through appropriate monitoring of blood glucose, and keeping micro and macrovascular complications in check.

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