

DIABETES FOOT CARE AND THE DUROMETER

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ABSTRACT

Annually, one in every six diabetics develops a foot complication in their lifetime. Prevalent in 3.6% of diabetics, they are a rising health problem. With high cost of treatment and patients' ignorance, there is an urgent need for coordinated preventive clinical measures to reduce the impact of diabetic foot. In India, 40,000 legs are annually amputated of which almost 40% - 72% are diabetes related. Reduction of amputation by 49% - 85% through early detection, close monitoring and education is possible; reducing the burden on medical resources. Thus, healthcare providers should educate patients regarding diabetes, its complications and the need for self foot care.

OBJECTIVES

1. Evaluate patients' knowledge of foot problems and care.
2. Systematic foot assessment 'Diabetic Foot Risk Assessment Form'.
3. Footwear evaluation through Durometry.
4. Risk categorization of foot problems and patient education.

METHODS : 300 in-patient diabetics in Department of Medicine, Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh were assessed. Diabetic Foot Risk Assessment Form filled, foot examined & after Durometry, categorised into Low, Moderate or High Risk.

RESULTS : of 300 subjects, 204 (67%) had moderate risk of developing diabetic foot, while 20 (7%) had high risk. Alarmingly, only one subject was adequately aware and practiced an appropriate level of foot care. Socio-economic status, education, duration of disease, co-morbidities, addiction, Body Mass Index (BMI) and complications like neuropathy, significantly increased the risk of diabetic foot. Durometry, Ankle Brachial Index (ABI), Monofilament and Vibration testing of the foot proved simple, cost effective, yet valuable measures for clinical evaluation.

CONCLUSION : Educating a diabetic about foot care should begin early and not when patient becomes symptomatic. Durometer is a novel tool for footwear assessment. This multidisciplinary approach will reduce, if not prevent, the development of diabetic foot.

KEYWORDS : Diabetes Mellitus, Diabetic Foot, Neuropathy, MeSH Heading, Diabetes Mellitus, Diabetic Foot, Diabetic Neuropathies

INTRODUCTION

Foot ulceration, infection, gangrene and amputation are complications often encountered in diabetics. Worldwide up to 70% of leg amputations occur as a result of diabetes or its complications¹. More than one million diabetics

lose a leg every year- meaning that every thirty seconds a lower limb is lost due to diabetes somewhere in the world². The good news, however, is that up to 85% of these amputations are preventable³.

Approximately 3-4 percent of individuals with diabetes

currently have foot ulcers or deep tissue infections. Cost of treating each foot ulcer is about Rs.10, 000 which takes 4-6 weeks to heal⁴. These complications frequently result in extensive morbidity, repeated hospitalizations and mortality.

To develop diabetic foot one or more of the following three components is essential: Neuropathy, vasculopathy or infection. The fourth extremely important risk factor is increased plantar pressure⁵. The feet are the target of peripheral neuropathy leading chiefly to sensory and autonomic dysfunction⁶ and are frequently associated with occlusive disease below the popliteal trifurcation⁷.

Neuropathy results in a warm, numb, dry foot causing neuropathic ulcer and joint. In contrast, the ischemic foot is cold and the pulses are absent. It is complicated by rest pain, ulceration from localized pressure necrosis and gangrene⁸.

Motor neuropathy leads to atrophy and an imbalance between flexors and extensors. High foot pressure and brittle skin leads to callus formation; which acts as a foreign body to cause tissue damage and foot ulceration.

Peripheral sensory neuropathy is the major independent risk factor for diabetic foot ulcerations^{9, 10}. The patient history and physical examination utilizing the Semmes-Weinstein monofilament (10g) is sufficient to identify those individuals at risk for ulceration^{11, 12}.

Peripheral arterial disease (PAD) in diabetes tends to be distal, diffuse and earlier in onset¹³. Prevalence of PAD in India ranges from 4% to 21.3 %¹⁴. Sphygmomanometry method of measuring ABI is a reliable and reproducible method with sensitivity and specificity of 90% for



Figure 1: Durometer

TABLE 1: Personal Characteristics and Diabetic Foot Risk				
CHARACTERISTIC	RISK CATEGORY			
AGE(years)(p= 0.001)	LOW	MOD	HIGH	TOTAL
< 30	5(83.33%)	1(16.67%)	0	6
30-40	9(40.90%)	11(50%)	2(9.1%)	22
40-50	25(35.71%)	44(62.85%)	1(1.44%)	70
50-60	16(19.75%)	58(71.61%)	7(8.64%)	81
>60	21(17.35%)	90(74.39%)	10(8.26%)	121
	76	204	20	300
LIVING(p= 0.0006)	LOW	MOD	HIGH	TOTAL
RURAL	20(15.27%)	98(74.81%)	13(9.92%)	131
URBAN	56(33.13%)	106(62.72%)	7(4.15%)	169
	76	204	20	300
EDUCATION(p= 0.0007)	LOW	MOD	HIGH	TOTAL
ILLITERATE	6(14.28%)	33(79.58%)	3(7.14%)	42
12TH	34(19.54%)	128(73.57%)	12(6.89%)	174
GRADUATE	34(41.46%)	43(52.43%)	5(6.09%)	82
POST GRADUATE	2(100%)	0	0	2
	76	204	20	300
BMI(p=0.015)	LOW	MOD	HIGH	TOTAL
< 18.5	7(53.84%)	6(46.16%)	0	13
18.5 - 25	47(28.83%)	101(61.96%)	15(9.21%)	163
25 - 30	22(18.03%)	95(77.86%)	5(4.09%)	122
> 30	0	2(100%)	0	2
	76	204	20	300

evaluating PAD reliable method of indicator of generalized atherosclerosis¹⁵. Absent posterior tibial, popliteal or femoral pulses with and without bruits indicate significant occlusive PAD especially if associated with symptoms like claudication¹⁶.

Diabetic neuropathy (DN) has been associated with oral dryness and tooth loss. Patients with presence of neuropathic foot ulceration have substantially more Periodontal Disease and edentulism¹⁷.

The Durometer is the international standard for hardness measurement of rubber, plastic, and other non-metallic materials. It evaluates resilience, plasticity, and compression resistance of footwear. The softness of the footwear insole is helpful in the prevention of plantar ulcers¹⁸. The final value of the hardness depends on the depth of the indenter after it has been applied for 15 seconds on the material¹⁹. A value between 8 and 15 Shore Units is desirable for diabetic footwear. Value of less than 8 is too soft and unlikely to give protection, whereas a value above 15 is too hard, leading to callosities due to pressure²⁰. Durometer may be a reliable screening tool to determine the degree of risk²¹ and assist in the institution of timely treatment²².

METHODOLOGY

Subjects include diabetic patients admitted in department of medicine SGMH, Rewa, Madhya Pradesh from

January 2013 to October 2014. A careful history was recorded, general physical examination done and routine blood investigations sent. Diabetic Foot Risk Assessment Form²³ was filled by each patient. Foot Assessment was done based on its structure, joint mobility, skin integrity, vascularity and sensory perception. Footwear was evaluated by durometry. The foot was categorised on its Risk of developing diabetic foot – Low, Moderate or High. Patient was educated based on individual foot care practice. Data analysis was done by calculating the p-value using the Chi Square Test.

Prevalence of ‘high risk’ was highest between 50-60 years (8.66%), also accounting for 35% of the total ‘high risk’ patients. Mayfield²⁴ found most diabetic foot patients in the 56-65 year age group (34%). Thus, the risk of developing diabetic foot begins almost a decade earlier than its actual presentation.

9.92% of the rural population had a ‘high risk’ of developing diabetic foot, contrasted with just 4.15% of the urban group. Diabetics in rural areas are more prone to foot ulcers than those who live in urban areas²⁵. Barefoot habit is more prevalent in the rural society, as is the lack of good footwear.

Although there was an even prevalence of ‘high risk’ feet in the various education standards, the prevalence of ‘moderate risk’ feet dropped from 79.58% among illiterates to 52% among the graduates. Higher prevalence

CO-MORBIDITY	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
DURATION OF DIABETES(p=0.0001)				
NEWLY DETECTED	12(52.17%)	11(47.83%)	0	23
< 10	38(36.53%)	60(57.7%)	6(5.77%)	104
10 – 20	18(14.28%)	99(78.58%)	9(7.14%)	126
> 20	8 (17.02%)	34 (72.34%)	5 (10.64%)	47
	76	204	20	300
NEUROPATHY(p=0.002)				
YES	27(14.51%)	142(76.35%)	17(9.14%)	186
NO	49(41.22%)	62(54.38%)	3(2.6%)	114
	76	204	20	300
HYPERTENSION & CORONARY ARTERY DISEASE(p=0.01)				
YES	7(12.96%)	40(74.08%)	7(12.96%)	54
NO	69(28.05%)	164(66.67%)	13(5.28%)	246
	76	204	20	300

of diabetic foot was seen among the primary schooled (38.4%) compared to tertiary educated (10.4%)²⁶.

Seventy-eight percent of those with high BMI had a moderate risk compared to 60% of normal or sub-normal BMI subjects. A higher incidence of diabetic foot is seen among high BMI individuals²⁶. However, 75% of 'high risk' patients had normal BMI. Although weight control

should be preached by every physician, foot examination must be carried out for normal BMI subjects, not only on the overweight.

Thus, it is pertinent that foot care must be individualised in accordance with age, living, education and BMI of the patient. A patient must be educated regarding foot care at an early age, especially from rural backgrounds

TABLE 3: Addiction and Diabetic Foot Risk

SMOKING(p= 0.042)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
YES	36(25%)	93(64.58%)	15(10.42%)	144
NO	40(25.64%)	111(71.15%)	5(3.21%)	156
	76	204	20	300
ALCOHOL(p = 0.035)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
YES	23(34.33%)	37(55.23%)	7(10.44%)	67
NO	53(22.74%)	167(71.67%)	13(5.59%)	233
	76	204	20	300
TOBACCO(p= 0.039)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
YES	17(21.52%)	52(65.82%)	10(12.66%)	79
NO	59(26.7%)	152(68.78%)	10(4.52%)	221
	76	204	20	300
SMOKING, ALCOHOL & TOBACCO(p = 0.004)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
YES	4(30.76%)	5(38.48%)	4(30.76%)	13
NO	72(25.09%)	199(69.34%)	16(5.57%)	287
	76	204	20	300

having lower literacy levels. This would reduce the risk of diabetic foot among diabetics.

Duration of diabetes is directly proportional to the risk of diabetic foot. More than 10% of those suffering from diabetes for >20 years, had 'high risk' compared to 5.77% among those with diabetes since <10 years. Shahi²⁷ found that patients with diabetic foot had a mean duration of diabetes of 11.5±5.74 years. More importantly, 47.83% of newly detected diabetics presented with 'moderate risk'.

Neuropathy was present in 61% of the patients in this study. Kumar²⁸ found neuropathy in 41.6% of diabetic foot patients. Furthermore, 54.38% without neuropathy had 'moderate risk'.

Among patients with CAD and Hypertension, 12.96% had High Risk compared to only 5.28% among those without both co-morbidities. McNeely²⁹ demonstrated ischemic heart disease in 47.6% of their diabetic foot subjects.

Thus, awareness of foot care must be instituted as early after diagnosis as possible. This would reduce the

progression of diabetic foot in a newly detected diabetic. Meanwhile, lack of neuropathy symptoms must not make doctors procrastinate educating the patient. Stricter control of hypertension and ischemic heart disease must also be undertaken.

Among smokers, 10.42% had a high risk foot compared to 3.21% among non-smokers. While 10.44% of alcohol users had 'high risk', it was prevalent among 5.59% of teetotallers. Our study found this to be a significant association. Similarly, more tobacco users (12.66%) had 'high risk', than their non-tobacco chewing (4.52%) counterparts. This risk was even more significant among users of tobacco, smoking and alcohol (30.76%) than those who did not abuse all three (5.57%).

Shahi²⁷ found 21.64% of diabetic foot patients to be smokers, a lower percentage of alcohol use among patients with diabetic foot (12.37%) and 32.98% of diabetic foot patients to be tobacco chewers while 3.09% of diabetic foot patients were addicted to all 3 compared to 2.06% of patients without diabetic foot.

Hence, any type of addiction increases risk of diabetic

TABLE 4: Clinical Parameters and Diabetic Foot Risk

Blood Glucose(mg/dl)(p=0.032)	DIABETIC FOOT RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
< 100	10(23.25%)	33(76.75%)	0	43
100 – 126	2(7.14%)	24(85.72%)	2(7.14%)	28
126 – 200	14(21.87%)	47(73.44%)	3(4.69%)	64
> 200	50(30.03%)	100(60.06%)	15(9.91%)	165
	76	204	20	300
ABI30(p=0.003)	DIABETIC FOOT RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
> 1.3	2(50%)	0	2(50%)	4
0.91 - 1.3	65(24.9%)	186(71.26%)	10(3.84%)	261
0.5 - 0.9	9(25.71%)	18(51.43%)	8(22.86%)	35
< 0.5	0	0	0	0
	76	204	20	300
PERIODONTAL DISEASE17(p=0.021)	DIABETIC FOOT RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
N/MILD	57(27.8%)	140(68.29%)	8(3.91%)	205
MOD/SEV	19(20.65%)	62(67.29%)	11(11.96%)	92
EDENTULOUS	0	2(66.67%)	1(33.33%)	3
	76	204	20	300
FOOT SENSATION(p=0.010)	DIABETIC FOOT RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
UNILATERAL REDUCED	8(22.22%)	23(63.89%)	5(13.89%)	36
BILATERAL REDUCED	5(20.83%)	14(58.33%)	5(20.84%)	24
NORMAL	63(26.25%)	167(69.58%)	10(4.17%)	240
	76	204	20	300

foot while more than one addiction further increases the risk.

Strict blood glucose control was significantly associated with a lesser risk of diabetic foot. No patient who had

glucose <100 mg/dl had a ‘high risk’, while 75% of the ‘high risk’ patients had blood glucose > 200 mg/dl. It was found that those patients with a history of foot ulcer had higher levels of blood glucose compared to those without

TABLE 5: Durometer Reading and Diabetic Foot Risk

DUROMETER20(p=0.036)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
8 - 15 SHORE UNITS	0	0	0	0
16 - 25	1(33.33%)	2(66.67%)	0	3
26 - 35	26(40.63%)	34(53.13%)	4(6.24%)	64
36 - 50	48(22.43%)	152(71.03%)	14(6.54%)	214
>50	1(5.26%)	16(84.21%)	2(10.53%)	19
	76	204	20	300

ulceration³¹.

Out of the 35 patients who had moderate to severe PAD, 22.86% had a ‘high risk’ of developing diabetic foot. Wang³² also found that an abnormal ABI was more prevalent in patients with non healing ulcers and history of amputation.

This study found Moderate/Severe Periodontal Disease in 30.67% of subjects of which 11.96% had a High Risk of developing Diabetic foot. Although prevalence of PD is

similar to Abrao’s¹⁷ study (32%), they found neuropathic foot ulcer risk in 68.2% of such patients. Thus, the result of this study could be confounded by the fact that tobacco chewing was a common addiction which, in itself causes periodontal disease. Nonetheless, both periodontal disease and diabetic foot being microvascular complications, could be inter related.

Out of the 60 patients with reduced foot sensations, 16.66% had a High Risk of developing diabetic foot. Higher risk was seen in those patients who had bilaterally

TABLE 6: Foot Care Awareness Level and Diabetic Foot Risk

AWARENESS(p=0.227)	RISK CATEGORY			
	LOW	MOD	HIGH	TOTAL
APPROPRIATE	1(100%)	0	0	1
INAPPROPRIATE	75(25.08%)	204(68.23%)	20(6.69%)	299
	76	204	20	300

reduced foot sensations (20.84%). The risk dropped to 13.89% among those with unilateral involvement and only 4.17% of those who had normal sensations. Peters et al³¹ similarly found abnormal Semmes Weinstein monofilament test in 96.9% of patients with a history of foot ulcer.

This study has thus evaluated the clinical methods by which we can predict the progression of diabetic foot. Monitoring blood glucose, Dental hygiene, along with simple clinic based evaluation of ABI and Foot Sensation can go a long way to prevent the onset of diabetic foot.

Alarmingly, not a single patient had an adequate reading for a diabetic; 10.53% of those with a reading >50 had 'high risk' compared to 6.24% with a reading between 26 and 35 and 6.54% with a reading between 36 and 50.

Durometry is of potential value in the assessment and monitoring of preulcerative disease, and could help to identify high-risk patients²². This would assist in the institution of timely and appropriate treatment.

The durometer is a new tool in the world of diabetes. It has the potential not only to predict the risk of progression of diabetic foot, but also to evaluate the wear and tear of footwear. Thus, the patient can also be advised when to discard old footwear or change the insoles.

Among local population, only 1 out of 300 subjects had appropriate awareness level of foot care. This subject was in the medical profession. Yet, his footwear was inappropriate for a diabetic as evaluated by durometer. This highlights the unawareness of the common patient with regards to diabetic foot, and that even medical professionals can overlook the issue of footwear and be at risk of developing a complication that we try hard at preventing in the patient. Another study showed 92% of diabetics never received any form of foot care education³³.

RECOMMENDATIONS

The diabetes pandemic affects everyone from the womb to their tombs. Hence a lack of appropriate foot care awareness is a matter of genuine concern. A bright

aspect, however, is the fact that health-care providers have an ample 'lead time' to prevent the onset of diabetic foot. Education is a highly versatile tool which can be used to prevent, promote and maintain awareness. Moreover, this study has highlighted quick, simple and cost-effective measures to evaluate the risk of progression to diabetic foot. Thus, education should be given to all diabetic patients, not just to the 'high risk' population because in today's era of chronic non-communicable diseases, '*Prevention is the ONLY Cure*'.

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Science may set limits to knowledge, but should not set limits to imagination.
– Bertrand Russell