

Detection of diabetic peripheral neuropathy in diabetic patient who are at risk of developing a diabetic foot at earlier stage by simple screening methods and comparison of different screening tests

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Abstract

Diabetes mellitus is a chronic disease which requires continuous long term medical care India is a capital for patients suffering from diabetes mellitus but still there is no better medical management of patients and support to prevent acute complications and reduce risk of long term complications hence there is a need for well-planned diabetes care system.

Diabetes care is complex and requires multifactorial risk reduction strategies beyond glycaemic control a large data exists that support a range of interventions to improve diabetes care and outcomes.

Foot lesion is one of the commonest complications of diabetes DPN is an important complication and contributes to the morbidity of diabetes mellitus. Evidence indicates early detection of DPN results in fewer foot ulcers and amputations.

Keywords: Diabetic Peripheral, diabetic foot, Screening tests

Introduction

Diabetic foot disease is an important contemporary and challenging problem confronting the Diabetologist and surgeons. The advent of insulin overcame the acute problems of diabetes such as diabetic ketoacidosis, acute infections etc. But still could not prevent vascular and neurological problems. (Lavery LA Armstrong DG *et al*).

Foot is the most vulnerable part in diabetic. It is exposed to frequent trauma and at risk of developing an ulcer Foot problems are one of leading causes of morbidity and mortality in diabetic Patients, affecting approximately 15% of diabetes patients (Armstrong DG, Gibbons G *et al*).

The majority of diabetes related inpatient admissions are for problems related to the feet. Foot problems may start off as seemingly trivial cracks and deformities, but can progress to ulceration, infection and gangrene. (Pecoraro RE *et al*).

Diabetes is the major cause of non-traumatic lower extremity amputation. The cost to the individual family and society on account of diabetic foot problems are immense Burden of management of diabetic foot ulcers are due to (Lee JS, Lu M, Lee VS, Russell D *et al*).

Wagner Ulcer Classification System

Grade	Lesion
0	No open lesions; may have deformity or cellulitis
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
4	Gangrene localized to portion of forefoot or heel
5	Extensive gangrenous involvement of the entire foot

The University of Texas Health Science Center San Antonio Diabetic Wound Classification System.

The University of Texas diabetic wound classification system assesses the depth of ulcer penetration, the presence of wound infection, and the presence of clinical signs of lower-extremity ischemia. (Oyibo SO,) This system uses four grades of ulcer

depth (0 to 3) and four stages (A to D), based on ischemia or infection, or both (Lavery LA). The University of Texas system is generally predictive of outcome, because wounds of increasing grade and stage are less likely to heal without revascularization or amputation.

Classification System

a) Stages

- Stage A: No infection or ischemia
- Stage B: Infection present
- Stage C: Ischemia present
- Stage D: Infection and ischemia present

b) Grading

- Grade 0: Epithelialized wound
- Grade 1: Superficial wound
- Grade 2: Wound penetrates to tendon or capsule
- Grade 3: Wound penetrates to bone or joint

Objective

The purpose of this study is to compare different screening tests in the detection of DPN in primary care setting.

Methodology

Study design

It is a cross-sectional study in a random sample (N = 245) of type 2 diabetes mellitus participants at primary care setting. Different screening tests for detecting DPN such as Michigan Neuropathy Screening Instrument (MNSI), Semmes-Weinstein *Monofilament* (SWM), vibration sensation and ankle reflex will be performed for each patient and compare between them.

Randomization method and sample size

The sample size was estimated based on 18-23% proportion of DPN among type 2 diabetics detected by monofilament or validated score using 0.05 precision with 95% C.I and power of 0.80.

$$\text{Sample size} = \frac{(1.96)^2 \times P + (1 - P)}{(0.05)^2} = 245 \text{ samples}$$

Source of data

Department of Medicine, PDVVPF’s Medical College, Ahmednagar Maharashtra India.

Inclusion criteria

Criteria were as follows:

1. Patients aged 35 to 70 years.
2. Male or female.
3. Diagnosed case of Type II DM (Duration of DM upto or more than two years).
4. Willingness to sign informed consent form.

Exclusion criteria

Were;

- 1) Type I diabetes mellitus;
 - 2) History of nerve root compression, cerebral vascular disease, hypothyroidism, pernicious anaemia, alcoholism
- Demographic data such as name, age, sex, occupation, obesity, AND addiction

Procedure

Height measurement by using stadiometer.
 Weight by using weighing machine.
 Blood pressure measurement by using sphygmomanometer.
 Blood glucose measurement by using standard glucometer.
 Proper diabetic history of patient.

Monofilaments for pressure points

Tuning fork 128 mhz detecting neuropathy
 From collective data by using above methods it will be easier to detect the high risk patients who will develop foot ulcer.
 Body mass index (BMI) was calculated from weight in kilogram divided by height in meter square. Categorized as Normal (< 25 kg/m2), overweight (25-30 kg/m2) and obese (>30 kg/m2).

DPN screening

Trained assistants performed the screening for DPN using Michigan Neuropathy Screening Instrument (MNSI) in two-step:

The first part

Assessed a Neuropathic symptom by a history questionnaire consists of 15 "yes or no" questions on foot sensation including pain, numbness and temperature sensitivity

The second part

- 1) It is an important part for brief physical examination involving an detailed inspection of the both feet
- 2) Clinical examination of ankle reflexes, on both limbs
- 3) Vibration sensation using 258htz were used to test vibration sensations on both the limbs
- 4) 10gm monofilament is used to detect the pressure sensations

Neuropathy is defined operationally as seven or more positive responses on the MNSI.

Questionnaire or a score >2.0 on the MNSI examination, thresholds defined by prior validation studies (Feldman EL,) The screening method for fine touch sensation, vibration perception and ankle reflex using 10-g SWM, 128-Hz tuning fork and reflex.

Hummer was followed the practical guideline from Michigan Diabetes Research and Training Centre. (DCCT Research Group) All above-mentioned tests were performed by the same assistant to control for inter-rate reliability.

Results

A total of 240 patients were studied and their characteristics were presented in Table 3. The majority (67.1%) of the patient was male, the median age was 54 years. The mean BMI was 25 Kg/m2. Over 58.4% had normal BMI, while 31.6% were overweight and only 10% were obese. The screening results revealed that overall prevalence of diabetic peripheral neuropathy as assessed by MNSI was 19.3%. 72% of them were symptomatic and 28% were having asymptomatic DPN. Among those with DPN (19.3%), only 3.7% have met the MNSI questionnaire criteria for diagnosed neuropathy (7 or more in MNSI questionnaires part). The detection rate using the 128-Hz tuning fork and 10-g SWM was nearly same (12.9 & 12%) respectively and significantly lower than ankle reflexes (15.4%). Although, the prevalence of DPN determined by the combined two test (128-Hz tuning fork & 10-g SWM) was higher than that through the single test, but lesser than that determined by total MNSI score (15.8 & 19.6%) respectively (Figure 1). Table 2 gives the sensitivity, specificity and predictive value of each diagnostic modality compared with Michigan Neuropathy Screening Instrument (MNSI), which is taken as the gold standard (as 100%). As shown, combined 128-Hz tuning fork and 10-g SWM monofilament was the most sensitive (77.5%) and accurate (95.5%) of all the diagnostic tests. Combined 128-Hz tuning fork and 10-g SWM test was not only most sensitive and accurate but was also specific.

Tables and graphs

Table 1: Characteristics of study population

Demographic	Total N (%)	DPN N (%)	NO DPN N (%)
N (%)	240 (100%)	47(19.6%)	193 (80.4%)
Age	54.6	55	54
Gender	2:1		
Male	161(67.1%)	28(17.4%)	133(82.6%)
Female	79(32.9%)	19(24%)	(76%)
Body mass Index	25.2 ± 14		
Normal	140(58.4%)	27(19.3%)	113(80.7%)
Overweight	76(31.6%)	16(21%)	60(79%)
Obese	24(10%)	4(16.7%)	20(83.3%)
Duration of Diabetes			
<5 year	56(23.4%)	10(17.9%)	46(82.1%)
5-10 year	110(45.8%)	23(20.9%)	87(79.1%)
>10 year	74(30.8%)	14(19%)	60(81%)
Family History of Diabetes			
Yes	178(74.2%)	36(20.2%)	142(79.8%)
NO	62(25.8%)	11(17.7%)	51(82.3%)

Table 2: Diagnostic accuracy of different tests compared to Michigan Neuropathy Screening Instrument (MNSI)

Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Ankle reflexes	76.6	99.4	97.3	94.5	95
10-g SWM	61.7	100	100	91.5	92.5
128-Hz tuning fork	67	100	100	92.3	93.3
Combined tuning fork & SWM	77.5	100	100	94.5	95.5

Conclusion

The present cross-sectional study showed that the prevalence of diabetic peripheral neuropathy among Type II diabetes at PDVVPF's medical college, Ahmednagar is 19.6%, on screening patients with MNSI method. In this study, different screening tests for detecting diabetic neuropathy are used and the results are compared in order to find a simple, reliable and accurate DPN selection method, so that it can be easily implemented in primary care settings. As shown in (Table 4), combined 128-Hz tuning fork and 10-g SWM monofilament was the most sensitive (77.5%) and accurate (95.5%) of all the diagnostic tests which is almost similar to Metab Al-Geffari study. The ankle reflex was more sensitive (76.6%) as compared to 128-Hz tuning fork test (67%) and 10-g SWM monofilament (61.7%) but was less specific which is almost similar to Jayaprakash P. study. The combination of two test (128-Hz tuning fork test and 10-g SWM monofilament), will increase the sensitivity, specificity and accuracy, which is not seen in the previous study.

Each method has a unique way of detecting neuropathy that is why these differences exist. In the symptom score, the result depends on what patients say and in the sign score, the examiner plays the major role. Some methods such as deep tendon reflexes, is operator-dependent and may include personal error. In the present study the prevalence of neuropathy in each method was different from the others.

Our study determined that the combination of two tests (128-Hz tuning fork & 10-g SWM) could increase the detection rate of diabetic peripheral neuropathy relative to 10-g SWM or 128-Hz tuning fork alone in the total population (Figure 1).

The two simple methods require a total of less than two minutes of inspection time per individual which is not time consuming at all. Therefore, the combined 10-g SWM and 128-Hz tuning is a practical, highly efficient method should be used for screening diabetic peripheral neuropathy in T2DM patients.

In our study only 3.7% from those with DPN have met the MNSI questionnaire criteria for diagnosing neuropathy, indicating that questionnaire part of the Michigan Neuropathy screening instrument alone has relatively poor diagnostic accuracy in predicting the presence of diabetic neuropathy in comparison with the part based on clinical examination. And therefore should not be used as a stand-alone test without a neurological examination.

Our study showed that the results of different DPN screening tests, are different even in the same patients. In summary, for the purposes of screening in general practice, 128-Hz tuning fork and 10-g SWM monofilament would appear to be an appropriate, cheap and easy to use tool for identifying patients at risk of having neuropathy and consequently at risk of developing foot ulcers. The combination of both tests will increase the sensitivity and accuracy.

References

- Lavery LA, Ashry HR, Van Houtum W, Pugh JA, Harkless LB, Basu S. Variation in the incidence and proportion of diabetes-related amputations in minorities *Diabetes Care* 1996; 19:48-52.
- Armstrong DG, Lavery LA, Quebedeaux TL, Walker SC. Surgical morbidity and the risk of amputation due to infected puncture wounds in diabetic versus nondiabetic adults *South Med J.* 1997; 90:384-9.
- Gibbons G, Eliopoulos GM. Infection of the diabetic foot. In: Kozak GP *et al.* Management of diabetic foot problems. Philadelphia: Saunders, 1994, 97-102.
- Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation, Basis for prevention *Diabetes Care* 1990; 13:513-21.
- LoGerfo FW, Coffman JD. Vascular and microvascular disease of the foot in diabetes. Implications for foot care *N Engl J Med.* 1994; 311:1615-9.
- Lee JS, Lu M, Lee VS, Russell D, Bahr C, Lee ET. Lower-extremity amputation. Incidence, risk factors, and mortality in the Oklahoma Indian Diabetes Study *Diabetes* 1993; 42:876-82.
- Kannel WB, McGee DL. Update on some epidemiologic features of intermittent claudication: the Framingham study, *J Am Geriatr Soc.* 1985; 33:13-8.
- Brand PW. The insensitive foot (including leprosy). In: Jahss MH. Disorders of the foot & ankle: medical and surgical management, 2d ed Philadelphia: Saunders, 1991, 2173-5.
- Armstrong DG, Todd WF, Lavery LA, Harkless LB, Bushman TR. The natural history of acute Charcot's arthropathy in a diabetic foot specialty clinic *Diabet Med* 1997; 14:357-63.
- Edmonds ME, Clarke MB, Newton S, Barrett J, Watkins PJ. Increased uptake of bone radiopharmaceutical in diabetic neuropathy *Q J Med.* 1985; 57:843-55.
- Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. *Diabetes Care* 1998; 21:2161-2177.
- American Diabetes Association: Preventive foot care in people with diabetes *Diabetes Care.* 2003; 26(Suppl.1):S78-S79.
- Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes *JAMA* 2005; 293:217-228.
- Abbott CA, Carrington AL, Ashe H, Bath S, Every LC, Griffiths J *et al.* The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort *Diabetes Med* 2002; 19:377-384.
- Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA *et al.* Causal pathways for incident lower-

- extremity ulcers in patients with diabetes from two settings *Diabetes Care* 1999; 22:157-162.
16. Boulton AJ, Kirsner RS, Vileikyte L. Clinical practice: neuropathic diabetic foot ulcers, *N Engl J Med.* 2004; 351:48-55.
 17. BoultonAJ, MalikRA, ArezzoJC, Sosenko JM. Diabetic somatic neuropathies *Diabetes Care* 2004; 27:1458-1486.
 18. American Diabetes Association. Peripheral arterial disease in people with diabetes (Consensus Statement). *Diabetes Care* 2003; 26:3333-3341.
 19. Lavery LA, Peters EJ, Williams JR, Murdoch DP, Hudson A, Lavery DC. Reevaluating how we classify the diabetic foot: restructuring the diabetic foot risk classification system of the International Working Group on the Diabetic Foot *Diabetes Care* 2008; 31:154-156.