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RESEARCH ARTICLE

SCOPE OF SEMMES WEINSTEIN MONOFILAMENT AS A SCREENING TOOL FOR DIABETIC PERIPHERAL NEUROPATHY- A MAJOR ETIOLOGICAL FACTOR FOR DIABETIC FOOT. A CASE CONTROL STUDY

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ABSTRACT

Background and objective: Diabetes is an increasing epidemic in India, and associated diabetic peripheral neuropathy (DPN) is its most common and disabling complication. As DPN has an insidious onset and heterogeneous clinical manifestations it is difficult to detect high-risk patients of DPN. Early diagnosis is recommended and is the key factor for a better prognosis and preventing diabetic foot ulcers, amputation, or disability. We conducted this study to study the scope of Semmes Weinstein Monofilament (SWMF) as a screening tool to identify these patients during the early course of the disease to provide a targeted therapy to modify the course of DPN. **Methods and Materials**: This was a case control study, comprised of 80 subjects.40 type 2 diabetic patients with clinical features of diabetic peripheral neuropathy (DPN) and abnormal nerve conduction studies (NCS) were selected as cases and 40 age, sex and height matched healthy adults were included as controls. All were subjected to NCS and SWMF tests. Diagnostic values were calculated for SWMF test taking NCS as gold standard for diagnosis of DPN. **Results:** The SWMF had sensitivity and specificity of 85% and 75% respectively with a accuracy of 84% for diagnosis of DPN. **Conclusions:** SWMF is a good screening tool for detecting the presence of DPN in diabetes mellitus patients because of its high diagnostic value besides being noninvasive, low cost, rapid and easy to apply test. There is a significant correlation between the NCS and SWMF in the diagnosis of DPN.

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INTRODUCTION

The prevalence of diabetes mellitus is growing rapidly worldwide and is reaching epidemic proportions (King, 1991; Bjork, 2003). It is estimated that currently there are 381 million people with diabetes worldwide and by 2030 this number is projected to double (World Health Organization, 2016; Simple treatment to curb diabetes, 2014). According to the World Diabetes Atlas, India is projected to have around 69 million people with diabetes (Joshi, 2007; Kumar, 2013).

Diabetic peripheral sensory neuropathy (DPN) is a significant independent risk factor for diabetic foot, which is a major cause of foot ulcers and lower extremity amputations in patients with diabetes mellitus (Sumpio, 2000). Diabetic foot ulcers have a lifelong incidence in patients with diabetes mellitusofapproximately15%andareresponsibleformore than 50% of non-traumatic lower limb amputations (Boulton, 2004). Following the diagnosis of diabetes, strict glucose control can be employed to prevent or delay the development of DPN. An effective screening instrument is then required to diagnose DPN early in high risk patients to prevent future ulceration and amputation (Litzelman, 1993; The Diabetes

Control and Complications Trial Research Group, 1995). While physicians may use many quantitative methods to detect peripheral neuropathy, the Semmes Weinstein monofilament (SWMF) examination is a noninvasive, low cost, rapid, and easy-to-apply test often used in clinical testing and rout in eself-assessment. The cost of disposable monofilaments is merely around $0.50 each when purchased from an independent supplier. The SWMF has become closely associated with the detection of DPN in both primary and specialty care over the past five decades since its invention. In 1960, psychologists Florence Semmes and Sidney Weinstein developed a set of nylon monofilaments to measure sensory loss in the hand of patients with brain injury. Currently, the general consensus regarding the definition of loss of protective sensation involves in ability to sense the5.07/10g Semmes Weinstein monofilament. The gauge of this monofilament is 5.07, anumberderived from the logarithm of the applied forceinmilligrams. Thebucklingforceforthe5.07monofilament is 10 grams, which is also the force felt by the patient when the monofilament bends. However, in the literature, the SWMF test sites on the feet vary widely in number and location.

MATERIALS AND METHODS

Study Design

The study was conducted for a period of two years by the departments of Plastic and Reconstructive surgery Sheri-Kashmir Institute of Medical Sciences (SKIMS) Soura Srinagar J &K, India. It was a case control study. The sample size was 80 subjects in the age group of 30- 60 years. Cases were 40 type 2 diabetes mellitus patients with NCS - documented peripheral neuropathy and controls were 40 age, height and sex matched normal subjects, recruited by history, questionnaire and by clinical examination from general population. Informed consent was taken from all subjects.

Inclusion criteria for cases

- Age ≥18 years
- Type 2 Diabetes Mellitus as per WHO criteria (http//www.who.int/diabetes/publications/Definition%20 and%20diagnosis%20 of% 20 diabetes.)
- Good diabetic control.
- Duration of diabetes >8 years.
- Presence of symptomatic neuropathy.
- Nerve conduction studies (NCS)-Positive for neuropathy (Kimura, 1989)

Exclusion Criteria

Age <18 years Those with symptoms related to other neuropathies like chronic renal failure, previous spinal injury, history of cervical or lumbosacral spine disease, history of alcohol abuse, history of vitamin B12 or folate deficiencyetc Refusal to participate in the study.

Inclusion criteria for controls

Healthy subjects with

- Fasting blood sugar < 100mg/dl
- No features of any neuropathy.
- Normal NCS

All the cases and controls were subjected to NCS and Semmes-Weinstein monofilament (SWMF)test.

Nerve conduction studies (ncs): During the test, the nerve was stimulated, usually with a set of surface electrodes attached to the skin. The first set of electrodes was used to send small pulses of electricity to stimulate the nerve. The second set of electrodes transmits the responding electrical signal to a recording machine. This was repeated for each nervebeing tested. The nerve conduction velocity (speed) was then calculated by measuring the distance between electrodes and the time it took for electrical impulses to travel between electrodes.

Nerve Conduction Studies procedure: Subjects were asked to remove any hearing aids, or other metal objects that may interfere with the procedure.

- Subjects were made to lie down for the test.
- Both the feet were cleaned thoroughly with spirit.
- The nerve to be tested was located.
- A recording electrode was attached to the skin over the nerve with a special paste and a stimulating electrode was placed at a known distance away from the recording electrode.
- The nerve was stimulated by a mild and brief electrical shock given through the stimulating electrode.
- Subjects might experience minor discomfort for a few seconds.
- The stimulation of the nerve and the detected response was displayed on a monitor that displays electrical activity in the form of waves.

Posterior tibial nerve conduction: The active surface recording electrodes was placed on abductor hallucis slightly below and anterior to naviculartuberosity. Surface stimulation was given behind and proximal to the medial malleolus and in the popliteal fossa along the flexor crease of the knee slightly lateral to midline in popliteal fossa. The conduction velocity of 48.3±4.5m/s[16]was considered asnormal.

Common peroneal nerve conduction (Misra, 2011**):** Surface recordings were obtained from extensor digitorumbrevis and stimulation was given at ankle, 2 cm distal to fibular neck, at the neck of fibula and 5-8 cm above the fibular neck. Latency and amplitude of compound action potentials were recorded and nerve conduction study velocity calculated. NCV of below knee segment of 48.3±3.9m/s was considered as normal and that of above knee segment of 52±6.2m/s was considered as normal. The latency on ankle stimulation of 3.77±0.86mswas considered as normal. Distal CMAP amplitude of 5.1±2.3 Mv was considered as normal. The Common peroneal conduction of below knee segment of 46.54±4.4m/s was considered as normal and that across fibular neck, 49.67±8.77m/s was considered as normal. The latency on ankle stimulation of 4.55±0.59ms was considered as normal and distal CMAP amplitude of 4.23±1.6mVwas considered as normal.

Sural nerve conduction (Misra, 2011): The surface electrode between lateral malleolus and tendoachilles records nerve conduction of suralnerve. The nerve is stimulated antidromically 10-16 cm proximal to the recording electrode, distal to the lower border of gastronemius at the junction of middle and lower third of leg. Nerve conduction velocity of

50.9±5.4m/swas considered as normal.Amplitude of SNAP 18±10.5 μVwas considered as normal.

Semmes-we instein monofilament examination: Light touch/pressure perception was assessed using a 10 g monofilament designed by Diabetik Foot Care India(Figure 1). The monofilament was held perpendicular to the foot and pressed against the foot, increasing the pressure till the monofilament buckles at seven different sites which are apex of the big toe, and the first, second, third, fourth, and fifth planter metatarso-phalangeal joints and heal(Figure 2).The participant was blinded to the application of the monofilament during testing. A 'yes-no' method was used, meaning that the patient said yes each time he/she sense the application of a monofilament. The ability to correctly sense the monofilament on ≥4 sites were defined as normal, whereas the inability to sense the monofilament correctly on ≤3 was defined as positive for neuropathy (Young, 1998). The procedure was as follows: The patient was made to lie down comfortably in supine position. Should be bare footed. Subject was informed about the procedure properly and explained that it was for testing loss of protective sensation, which increases the risk of foot ulcers and amputation. With 10g monofilament the subject's skin on the arm or hand was touched to demonstrate what the touches feel like. The patient was instructed to respond "YES" each time when he or she felt the pressure of monofilament on the foot during the examination. The subjects were instructed to keep their eyes closed during examination. According to the touch felt, it was recorded as either Response or No Response.

Statistical analysis: The data were analyzed using SPSS statistical package, version 13 (Chicago, IL). Correlations were assessed with Spearman's correlation. BY constructing Receiver operating characteristic curve, sensitivity, specificity, positive and negative predictive values and accuracy were calculated for the various tests using nerve conduction studies (NCS) as the gold standard definition of neuropathy. $P<0.05$ was considered as statistically significant.

RESULTS

The study consisted of 40 cases with DPN and 40 normal healthy controls with age, sex and height matched to the cases .The mean age of the cases was 52.40±5.50 and that for the controls was 54.00±5.40years (Table 1).Samples are age matched with P=0.546. Both groups consist of 22 male and 18 female subjects Table 2). The height of cases and controls was168.60±6.70 cm and 166.70±5.84 cms respectively. Samples were height matched with P= 0.250 (Table 3). The weight of cases in kg was 66.00±7.80 and 68.48±7.64 in controls, with a p value of 0.672 (Table3). The Body Mass Index was 25.70±2.90kg/m2and 24.39±2.70 kg/m2in cases and controls respectively; with p value 0.153. There was no statistically significant difference between cases and controls in the anthropometric parameters. The two groups were comparable. Most of our patients in study group had controlled blood sugar [FPG: 130±20 mg/dl, PPPG: 200±20mg/dl] and had raised HBA1c% (mean 6.5±0.5). Hypertension was the main associated comorbidity with a mean systolic BP of 140±40 & diastolic BP of 84±15 mmHg. Out of the 80 participants who were tested with SWMF, protective sensation (felt filament at ≥4of the seven sites) was present in 36 and absent in 44. Out of the 36 participants in whom protective sensation was present, 30 (True negative) had negative NCS results and 6(False negative) had positive NCS results. Out of 44 participants in whom the protective sensation was absent (felt filament at ≤3 of the seven sites), 34 tested positive(true positive) for neuropathy and 10 tested negative (false positive) on NCV study(Table 4a).The sensitivity and specificity of SWMF was calculated to be 85% and 75% (Table 4b) The positive and negative predictive values were calculated to be 77%and 83% respectively with an accuracy of 80%(Table 4b). The ROC curve of the above data is shown below(Graph 1). When Spearman Correlation test was employed, positive correlation was found between SWMF and NCV results with a significant p valve (Table 4c).

DISCUSSION

Diabetic peripheral neuropathy (DPN) is an important complication and contributes to the morbidity of diabetes mellitus in the form of diabetic foot. In India, upto or more than 37% of patients with diabetes have clinical or subclinical neuropathy and the incidence rises as the duration of diabetes increases (Boulton, 1990). Evidence indicates early detection of DPN results in fewer foot ulcers and amputations (Al-Geffari, 2012). American Diabetes Association and clinical practice guidelines recommend annual screening for neuropathy to identify asymptomatic individuals who are likely to develop complications Initial screening and diagnosis in clinical practice usually depend on assessment of subjective complaints. A need exists for selecting a quick, simple, inexpensive, objective, accurate and reproducible assessment tool that can be readily used in clinical practice. Nerve conduction studies (NCS) are the most sensitive and specific for diagnosis of DPN (Perkins, 2001). There use is recommended for quantitative confirmation of DPN (Boulton, 2005). However there are many limitations with NCV studies as the equipment is not easily available in every hospital, It is expensive, time consuming, and needs trained staff to perform it. So, keeping in view these demerits, the most frequently used bedside modality for detecting neuropathy in clinical practice is the nylon SWMF and Inability to perceive the 10 g of force a 5.07 monofilament applies is associated with clinically significant large-fiber neuropathy.

Various case control studies have reported variable sensitivity and specificity for monofilament sensation up to 95 and 82 per cent respectively (Armstrong., 1998; deSonnaville, 1997). However, another case-control study has shown sensitivity and specificity of 77 and 96 per cent respectively, which was attributed to lack of blinding of examiners for individual screening maneuvers (Perkins, 2001). Our study has shown sensitivity of 85 per cent and specificity of 75 per cent for monofilament sensation for the diagnosis of neuropathy which is lower as compared to the western data possibly because of lack of blinding of examiner for screening maneuver and the subjective variation in this modality. Armstrong DG (Armstrong, 1998) et al, de Sonnaville et al. (1997) in their respective studies reported sensitivity and specificity for monofilament sensation up to 95% and 82%, respectively.In 3 prospective studies conducted by Boyko et al. (1999) Rith-Najarian et al. (1992) and Pham HA et al. (2000) the Semmes Weinstein monofilament identified persons at increased risk of foot ulceration with a sensitivity of 66 to 91 per cent, a specificity of 34 to 86 per cent, a positive predictive value of 18 to 39 per cent, and a negative predictive value of 94 to 95 per cent.

Table 1. Age and Gender distribution of study population

AGE in years	CASES(n=40)		CONTROL(n=40)		P value
	Males (%)	Females (%)	Males (%)	Females (%)	
20-40	6(15%)	6(15%)	7(17.5%)	7(17.5%)	
41-60	16(40%)	12(30%)	15(37.5%)	11(27.5%)	0.546
Total	22(55%)	18(45%)	22(55%)	18(45%)	
Mean Age ±SD	52.40±5.50		54.00±5.40		

Table 2. Characteristics of the study population (n = 80)

Characteristics	CASES(n=40)	CONTROL(n=40)	P value
Height(cm)	168.60±6.70	166.70±5.84	0.250
Weight(Kg)	66.00±7.80	68.48±7.64	0.672
BMI (kg/m2)	25.70±2.90 kg/m^2	24.39±2.70 kg/m^2	0.153

BMI: body mass index

Table 3. Characteristics of the Cases (n=40)

Duration of DM (yr)	15±5 yr
Duration of treatment	15±5yr
Systolic BP (mmHg)	140±40
Diastolic BP (mmHg)	84±15
FPG (mg/dl)	130±20
PPPG (mg/dl)	200±20
HbA1c (%)	6.5±0.5

DM: Diabetes mellitus, BP: Blood pressure, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

Table 4a: Comparison of results of SWMF test with that of NCS

True Positive	False Negative	False Positive	True Negative
34	6	10	30

Table 4b. Diagnostic accuracy of SWMF compared to NCS

Sensitivity	Specificity	PPV	NPV	Accuracy
85%	75%	77%	83%	80%

PPV: Positive Predictive Value, NPV: Negative Predictive Value

Table 4c: Correlation between SWMF and NCS

Correlation coefficient		P value	
SWMF	NCS	SWMF	NCS
0.79		0.04	

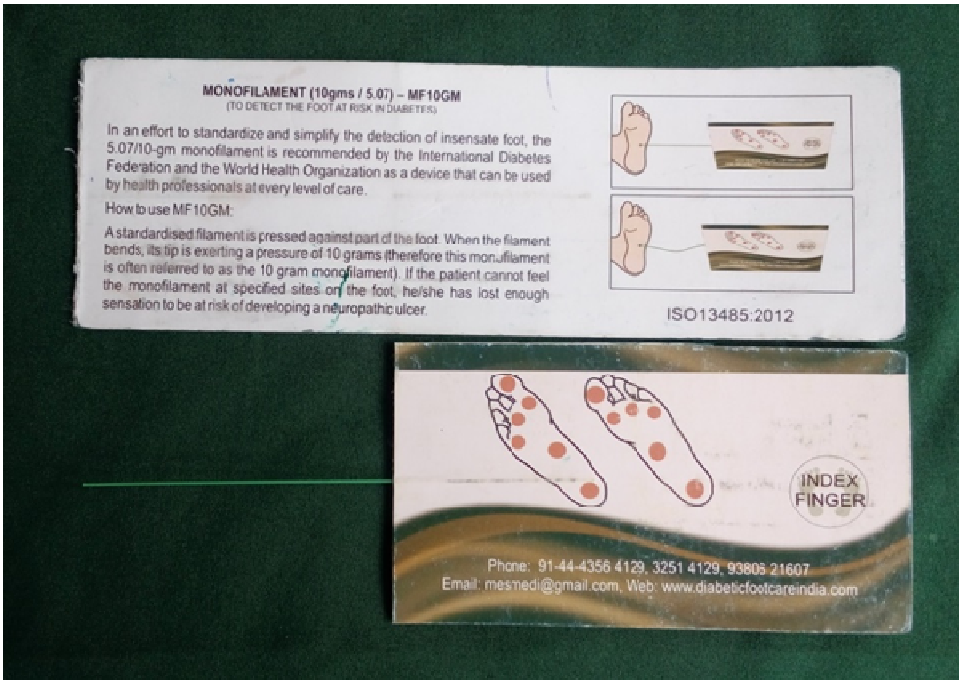

Figure 1. Shows Semmes-Weinstein Monofilament (SWMF) 5.07/10gm used to asses tactile and pressure sensation

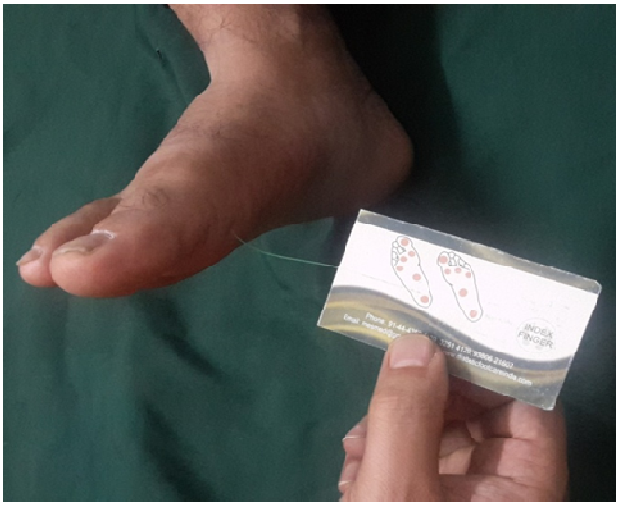

Figure 2. Shows testing for pressure and tactile sensation using Monofilament (SWMF) 5.07/10gm

Conclusion

SWMFcan be used as a screening test for detection of the diabetic peripheral neuropathy (DPN) as it has good diagnostic value besides being simple, easy to do, less time and labourconsuming and cost effective.

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