

Original article:

Study of assessment of the sensitivity, specificity and prediction value of Question verbal neuropathy score and Semmes-Weinstein 10 G monofilament wire testing for diabetic neuropathy

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ABSTRACT

Background and objectives: Diabetes mellitus (DM) is one of the public health problems of the whole world. Prevalence of DM is increasing rapidly worldwide and it is reaching the epidemic proportions. Diabetes leads to many macro vascular complications like coronary artery diseases, peripheral vascular disease, stroke etc. And it also causes micro vascular complications leading to end organ damage like cardiomyopathy, nephropathy, retinopathy and neuropathy. This study is about selecting proper tools to identify tests for neuropathy in diabetic patients with “Foot at risk”.

Methodology: Observational analytical study conducted among 40 patients with h/o diabetic foot ulcer (Group A) and 120 patients without h/o diabetic foot ulcer (Group B) with Diabetes Mellitus attending Surgery/Medicine OPD or admitted in Surgery/Medicine wards of BLDE (DU)'s Shri B M Patil Medical College, Hospital and Research Centre, Vijayapur during the study period from October 2017 to May 2019 were considered in the study. Data analyzed using SPSS software version 16. The association between the DM and neuropathy was tested using Chi-square test and Fisher's exact test. p value <0.05 was considered as significant. Sensitivity, specificity, positive predictive value, negative predictive value, % of false positive, % of false negative and accuracy of the screening test were calculated.

Results: The mean age of the study participants in Group A was 59.25 ± 12.22 years and that of Group B was 61.98 ± 10.65 years. Illiteracy, co-morbidities like Hypertension, Dyslipidemia and Heart disease were associated with patients of Group A. As the duration of diabetes (>10 years) increases the probability of foot ulceration was more. Probability of getting foot ulceration was more among patients with uncontrolled diabetes. DPN diagnosis by verbal questionnaire method showed the sensitivity of 87.5% & specificity of 91.67%. By Semmes- Weinstein 10G monofilament wire testing showed the sensitivity of 75% & specificity of 77.5% and by Biothesiometer showed the sensitivity of 72.5% and specificity of 86.67%.

Conclusion: Annual screening of diabetic patients for diabetic neuropathy by verbal questionnaire method had the higher sensitivity and specificity, followed by Semmes- Weinstein 10G monofilament wire testing and Biothesiometer.

Key words: Diabetes mellitus, Screening, Diabetic neuropathy, Micro vascular complications

Introduction:

DFU is a major source of morbidity and leading cause of hospitalisation in patients with diabetes. It is estimated that approximately 20% of hospital admissions are the result of DFU among the diabetic patients.^[1] If untreated, DFU may progress and ultimately may lead to amputation. Also, DFU is associated with substantial emotional and physical distress.^[1]

Peripheral sensory neuropathy is one of the strongest risk factors for foot ulceration and amputation in diabetic patients. Peripheral neuropathy also forms a permissive environment that allows repetitive tissue injury. Peripheral neuropathy includes sensory, motor and autonomic neuropathy. The notion that neuropathy is generally necessary to produce diabetic foot ulcer is well established. However, the methods for testing and identification of loss of protective sensation have been quite variable and ill defined^[2]

This study is about selecting proper tools to identify tests for neuropathy in diabetic patients with “Foot at risk”. Here “Foot at risk” means foot of diabetic patients which are at risk of developing diabetic foot ulcers mainly as a result of diabetic neuropathy, ischemia, immunopathy and high-pressure points.

Hence, with diabetes mellitus being so prevalent in India, it is important to have a clear-cut strategy on assessing neuropathy and determining which group of patients are at risk of developing diabetic foot ulcer so that proper preventive measures can be taken.^[3] Very few studies are conducted to identify proper tools for the screening of neuropathy in diabetic patients. Therefore, the present study has been undertaken.

Methodology:

Observational analytical study conducted among 40 patients with h/o diabetic foot ulcer (Group A) and 120 patients without h/o diabetic foot ulcer (Group B) with Diabetes Mellitus attending Surgery/Medicine OPD or admitted in Surgery/Medicine wards of BLDE (DU)'s Shri B M Patil Medical College, Hospital and Research Centre, Vijayapur during the study period from October 2017 to May 2019 were considered in the study. Data analyzed using SPSS software version 16. The association between the DM and neuropathy was tested using Chi-square test and Fisher's exact test. p value <0.05 was considered as significant. Sensitivity, specificity, positive predictive value, negative predictive value, % of false positive, % of false negative and accuracy of the screening test were calculated.

INCLUSION CRITERIA

- Diabetic patients with risk of developing peripheral neuropathy with or without foot ulcers (up to Wagner grade 3 ulcers).

EXCLUSION CRITERIA

- Patients who had already undergone amputation of toes for diabetic foot.
- Patients with severe co-morbid conditions.
- Patients with ulcers of Wagner grade 4 or more.
- Patients unwilling to participate in the study

Results:

Table 1: Tools of screening tests -1

| Tools of a screening tests | Verbal questionnaire method | Semmes- Weinstein 10G monofilament wire testing | Biothesiometer |
|----------------------------|-----------------------------|---|----------------|
| Sensitivity | 87.5% | 75% | 72.5% |
| Specificity | 91.67% | 77.5% | 86.67% |
| PPV | 77.78% | 52.63% | 64.44% |
| NPV | 95.65% | 90.29% | 90.43% |
| % Of false positive | 8.33% | 22.5% | 13.33% |
| % Of false negative | 12.5% | 25% | 27.5% |
| Accuracy | 90.63% | 76.88% | 83.13% |

Diabetic peripheral neuropathy diagnosis by verbal questionnaire method showed the sensitivity of 87.5%, specificity of 91.67%, positive predictive value of 77.78%, negative predictive value of 95.65%, percentage of false positive were 8.33%, percentage of false negative were 12.5% and accuracy of diagnosis was 90.63%. By Semmes-Weinstein 10G monofilament wire testing showed the sensitivity of 75%, specificity of 77.5%, positive predictive value of 52.63%, negative predictive value of 90.29%, percentage of false positive were 22.5%, percentage of false negative were 25% and accuracy of diagnosis was 76.88%. By Biothesiometer showed the sensitivity of 72.5%, specificity of 86.67%, positive predictive value of 64.44%, negative predictive value of 90.43%, percentage of false positive were 13.33%, percentage of false negative were 27.5% and accuracy of diagnosis was 83.13%.

Table 2 : Combination of Semmes- Weinstein 10G monofilament wire testing and Verbal questionnaire method in the diagnosis of Diabetic Peripheral Neuropathy.

| Semmes- Weinstein 10G monofilament wire testing and Verbal questionnaire method | Group A | | Group B | |
|---|-----------|------------|-----------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| Positive | 35 | 87.5% | 32 | 26.7% |
| Negative | 5 | 12.5% | 88 | 73.3% |
| Total | 40 | 100% | 120 | 100% |

Combination of Semmes- Weinstein 10G monofilament wire testing and Verbal questionnaire method diagnosed diabetic peripheral neuropathy among 35 (87.5%) of the study subjects in Group A and 32 (26.7%) of the study subjects in Group B.

Table 3: Combination of Biothesiometer and Verbal questionnaire method in the diagnosis of Diabetic Peripheral Neuropathy.

| Biothesiometer and Verbal questionnaire method | Group A | | Group B | |
|--|-----------|------------|-----------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| Positive | 35 | 87.5% | 23 | 19.2% |
| Negative | 5 | 12.5% | 97 | 80.8% |
| Total | 40 | 100% | 120 | 100% |

Combination of Biothesiometer and Verbal questionnaire method diagnosed diabetic peripheral neuropathy among 35 (87.5%) of the study subjects in Group A and 23 (19.2%) of the study subjects in Group B.

The mean age of the study participants in Group A was 59.25 ± 12.22 years and that of Group B was 61.98 ± 10.65 years. Illiteracy, co-morbidities like Hypertension, Dyslipidemia and Heart disease were associated with patients of Group A. As the duration of diabetes (>10 years) increases the probability of foot ulceration was more. Probability of getting foot ulceration was more among patients with uncontrolled diabetes. DPN diagnosis by verbal questionnaire method showed the sensitivity of 87.5% & specificity of 91.67%. By Semmes- Weinstein 10G monofilament wire testing showed the sensitivity of 75% & specificity of 77.5% and by Biothesiometer showed the sensitivity of 72.5% and specificity of 86.67%.

Discussion:

Combination of Semmes- Weinstein 10G monofilament wire testing and Verbal questionnaire method diagnosed diabetic peripheral neuropathy among 87.5% of the study subjects in Group A and 26.7% of the study subjects in Group B. Sensitivity and specificity of this combination were 82.5% and 73.33% respectively which are comparable to study conducted by Armstrong DG et al^[38]; in which sensitivity and specificity were 96.7% and 85.9% respectively.

Combination of Biothesiometer and Verbal questionnaire method diagnosed diabetic peripheral neuropathy among 87.5% of the study subjects in Group A and 19.2% of the study subjects in Group B. Combination of Semmes- Weinstein 10G monofilament wire testing and Biothesiometer diagnosed diabetic peripheral neuropathy among 80% of the study subjects in Group A and 28.3% of the study subjects in Group B. Combination of Semmes- Weinstein

10G monofilament wire testing, Biothesiometer and Verbal questionnaire method diagnosed diabetic peripheral neuropathy among 87.5% of the study subjects in Group A and 32.5% of the study subjects in Group B.^[4]

Diabetic peripheral neuropathy diagnosis by combination of Semmes- Weinstein 10G monofilament wire testing and Verbal questionnaire method showed the sensitivity of 82.5%, specificity of 73.33%, positive predictive value of 50.77%, negative predictive value of 92.63%, percentage of false positive were 26.67%, percentage of false negative were 17.5% and accuracy of diagnosis was 75.63%.

By combination of Biothesiometer and Verbal questionnaire method showed the sensitivity of 87.5%, specificity of 80.83%, positive predictive value of 60.34%, negative predictive value of 95.1%, percentage of false positive were 19.17%, percentage of false negative were 12.5% and accuracy of diagnosis was 82.5% which are comparable to study conducted by Armstrong DG et al^[5].

By combination of Semmes- Weinstein 10G monofilament wire testing and Biothesiometer showed the sensitivity of 80%, specificity of 71.67%, positive predictive value of 48.48%, negative predictive value of 91.49%, percentage of false positive were 28.33%, percentage of false negative were 20% and accuracy of diagnosis was 73.75% which are similar to study conducted by Armstrong DG et al^[5]. But in the studies conducted by Perkin's et al^[6] they have not found any significant improvement in diagnostic value when the screening tests are combined.

Diabetic peripheral neuropathy diagnosis by combination of Semmes- Weinstein 10G monofilament wire testing, Biothesiometer and Verbal questionnaire method showed the sensitivity of 87.5%, specificity of 67.5%, positive predictive value of 47.3%, negative predictive value of 94.19%, percentage of false positive were 32.5%, percentage of false negative were 12.5% and accuracy of diagnosis was 72.5% but in study conducted by Armstrong DG et al^[38] sensitivity is similar to our study specificity in their study is increased to 89.4%

According to Harris Mat Foot Imprinting, in Group A and Group B the maximum of the study participants got involvement of the Great toe, 80% and 44.2% and this difference was statistically highly significant. Reason for high pressure points at these sites may be because of motor neuropathy causing muscle weakness leading to imbalance and toe deformities.^[7] and atrophy of muscles leads to loss of cushion over these sites. Patients are likely to develop ulcers over these sites and should be advised to wear footwears with soft soles like microcellular rubber foot wears.

Conclusion:

Annual screening of diabetic patients for diabetic neuropathy by verbal questionnaire method had the higher sensitivity and specificity, followed by Semmes- Weinstein 10G monofilament wire testing and Biothesiometer.

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