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Application of neuropathy disability score for lower limb amputation: risk in patients with DM-II at National Diabetes Hospital

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Abstract: Diabetes mellitus (DM) is considered the major cause of non-traumatic limb amputation, the impact on patient, family and community psychologically and physically is overwhelming. The aim of this study was to determine the lower limb amputation risk by application of Neuropathy Disability Score. This is a case series study involving 712 patients with DM type II admitted at National Diabetic Hospital (Tripoli) from June 2015 until Jan 2016. One hundred patients who were diagnosed with diabetic peripheral neuropathy (DPN) were selected. Verbal consent was taken for each patient. A special Performa was completed for each patient that included details about patient's demographics, some important points in clinical history, relevant investigations and clinical examination (application of NDS) were recorded. The study reported 100 patients diagnosed with DPN out of 712 admitted patients with DM type II within a study period (the prevalence was 14%). 76% of them was female and their age range was between 40 - 87 years with a mean age of 62.45 ± 11.34 years. The duration of diabetes was ranged from newly diagnosed to 40 years with a mean 12.7 ± 9.5 years. 17% of them have morbid obesity (BMI > 40), 76% have neuropathy symptoms, 84% were non-smoker, 40% hypertensive and 34% on treatment of lipid lowering drugs. Calculation of Neuropathy Disability Score (NDS) to each patients has shown that 67 out 100 patients had NDS ≥ 6 which was 52 of them were female. Their mean age was 64.4 years, mean duration of DM was 15 years and mean HBA1c was 9.7 g% with all were symptomatic. In conclusion, the usefulness of commonly used bed side tests to screen for DPN with a predominant focus on application of NDS, that patient had increased risk of lower limb amputation within one year when NDS more than six.

***Keywords**:* NDS; neuropathy disability score, diabetic peripheral neuropathy, BMI, Libya.

Introduction

The International Neuropathy Guidelines define diabetic peripheral neuropathy (DPN) as the presence of symptoms and/or signs of peripheral nerve dysfunction in patients with diabetes after exclusion of other causes (1). DPN affects 30%-50% of the patient population with diabetes and this prevalence tends to increase proportionally with the duration of diabetes (2). Neuropathy often

presents with a loss of protective sensation, defined as a level of sensory deficit, where a patient can sustain an injury without recognizing any inciting trauma (1). The progression from minor injury into ulceration and, ultimately, evolution into a non-healing wound with underlying infection has been documented as the most common series of events preceding lower extremity amputation (3). A panel of clinicians under the direction of the American Diabetes Association Interest Group on Foot Care has recommended that neurologic assessment in patients with diabetes should include routine screening with SWM in addition to one other clinical test (e.g., 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold testing) (4).

Early detection of DPN is important because preventive interventions can be applied to decrease morbidity (5). Unfortunately, no "gold standard" exists for diagnosing DPN, but frequently used and accepted examination scores for diabetic neuropathy are the Neuropathy Disability Score (NDS), the Neuropathy Impairment Score in the Lower Limbs (NIS-LL), various modified NDS Scores, the Neuropathy Deficit Score, the Michigan Neuropathy Screening Instrument (MNSI) and the Clinical Examination score of Valk (CE-V) (6). The NDS was designed for neuropathy in general is a widely accepted and validated physical examination scoring system. Its predictive value and reproducibility are high. People with an NDS of six points or more are considered to show abnormal finding (6). Thus, our aim to give an overview of the usefulness of commonly used bed side tests and clinical techniques to screen for DPN with a predominant focus on application of NDS to determine the risk of lower limb amputation in patients with DM type II.

Materials and methods

This is a case series study involving 712 patients with DM type II admitted to National Diabetic hospital (Tripoli) from June 2015 until Jan 2016. One hundred patients who were diagnosed with DPN were selected. Verbal consent was taken for each patient. A special Performa was completed for every patient which included details on gender, BMI, age, duration of diabetes, history of hypertension, smoker, mode of diabetic treatment, history of dyslipidemia. Presence of symptoms of peripheral neuropathy, examination of foot ulcer, pulses of feet (Dorsalispedis artery) and investigation results of HB_{A1C}, LDL, HDL, TGA, serum creatinine level and spot urine sample for proteinuria

The Neuropathy Disability Score (NDS) consists of four clinical tests on both feet. The procedure was explained and the tests were done on the patient's hand prior to the test on feet. The patient was asked to close the eyes during the test. Every test was evaluated with points to estimate the total disability score. The total maximum abnormal disability score is ten points. The four clinical tests are ankle reflex, vibration perception, thermal sensation and tactile sensation. The ankle reflex was done by using Babinski reflex hammer. If there is no jerk, it considered (two points) for each side, jerk with reinforcement considered (one point) for each side. Normal ankle reflex considered (zero points).

The vibration perception was tested by using a 128-Hz vibrating fork. The fork was put on the first toe three times with at least one false application (not vibrating fork). The patient was asked to recognize which application that was vibrating or not. Two of three right responds set to be a correct answer (zero points); two of three wrong responds was an incorrect answer (one point) for each side.

The thermal sensation was done by using one cold and one room temperature sponge. The sponge was applied on the dorsum of the foot. The patients required to tell which application was cold or normal, a correct answer (zero points), an incorrect answer (one point) for each side. Tactile sensation (pin-prick): The pin-prick was done at the first toe by using the reverse ends of the turning fork and tendon hammer. The patients asked to recognize which application was sharp or dull, a correct answer (zero points), an incorrect answer (one point) for each side. A total disability score 3-5 points considered mild disability, 6-8 points as moderate disability and 9-10 points as severe disability" (7). According to Young et al. (7). The minimum acceptable criteria for diagnosis of diabetic peripheral neuropathy were moderate disability, with or without symptoms, or mild disability with moderate symptoms.

Table 1: Revised Neuropathy Disability Score

1- Vibration perception	128-Hz tuning fork applied at apex of big toes Normal = (0) feel vibration, Abnormal = (1) not feel Right/Left
2- Temperature perception	Cold/worm water in tube applied on dorsum of feet Normal = 0, abnormal = (1)
3- Pin prick /pain perception	Apply pin proximal to big toes just enough to deform the skin trial pair = sharp, blunt Normal = can distinguish sharp /not sharp, abnormal cannot distinguish
4- Ankle reflex	Present = 0 Present with reinforcement = 1 Absent = 2
Total NDS score	Max Right and Left = 10

Statistical analysis: Descriptive statistic was used and all the data were presented as frequencies, means ± standard deviation and percentages. Statistics was performed using statistical software (SPSS). A p-value was calculated by independent sample t-test for age, weight, height, duration of DM, and HBA1c, LDL-C, HDL-C, TGA, values and also blood urea, serum creatinine. A Pearson, Chi-square test for gender, history of hypertension, smoking as well as mode of treatment taken for DM, dyslipidemia. Presence of symptoms, protein in urine, foot ulcer and also feet pulses. A p-value is considered significant if < 0.05.

Results

The study reported 100 patients diagnosed with DPN out of 712 admitted patients with DM type II within a study period (the prevalence was 14%), DPN diagnosis based on presence of positive test with SWM in addition to one other clinical test (thermal perception, pinprick sensation, ankle reflexes, or vibration perception threshold testing) (8). This study included 100 patients, 76% of them was female their age range was between 40 – 87 years with mean age 62.45 ± 11.34 years, the duration of diabetes ranged from newly diagnosed to 40 years with mean 12.7 ± 9.5 years, 17% of them have morbid obesity (BMI > 40), 76% have neuropathy symptoms, 84% were non-smoker, 40% hypertensive and 34% on treatment of lipid lowering drugs.

Table 2: Distribution of the patients characters (clinical presentation: history examination) at National Diabetes Hospital

Parameters	Frequency (%)
Sex	76 **(76%)**
Female	24 **(24%)**
Male	
Age in years	
40 - 50	18 **(18%)**
51 - 61	32 **(32%)**
62 - 72	28 **(28%)**
> 73	03 **(03%)**
Mean age	62 ± 11.34
Height in m	
1.5 - 1.3	49 **(49%)**
> 1.5	51 **(51%)**
Mean height	1.56 ± 0.1
Body Mass Index	
(normal 18.5 - 24.5%	13 **(13%)**
(Over wt 29.5 -25 %)	24 **(24%)**
(Obese 30 -39.5 %)	44 **(44%)**
(Morbid obesity > 40%)	17 **(17%)**
Mean BMI 32.29 ± 7.5	
Duration of DM	
Newly - 10	36 **(36%)**
20 - 11	38 **(38%)**
30 - 21	20 **(20%)**
40 - 31	6 **(6%)**
Mean Duration 12.7 ± 9.5	
Hypertension	
present	40 **(40%)**
Absent	60 **(60%)**
Symptom f neuropathy	76 **(76%)**
Smoker	16 **(16%)**
Treatment for DM	
Oral hypoglycemic agent	19 **(19%)**
Insulin	59 **(59%)**
Combined	22 **(22%)**
Treatment for Dyslipidemia	66 **(66%)**

Table 3: Distribution of the patient's character (investigations) at National Diabetes Hospital Tripoli

Investigations	Frequency (%)
$_{c1A}$HB **6.5 - 7%** **> 7 - 9%** **> 9%** **Mean HB_{A1C} 2.79 ± 9.79 gm%**	 11 **(11%)** 35 **(35%)** 54 **(54%)**
LDL cholesterol **mg/dl ≥ 100 mg/dl** **Mean 42.63 ± 114 mg/dl**	70 **(70%)**
TGA Triglycaeridemia **≥ 150 mg/dl** **Mean 145.2 ± 156.6 mg/dl**	42 **(42%)**
proteinurea **Present**	 16 **(16%)**

Calculation of total Neuropathy Disability Score for each patients ; to identify those with high risk for lower limb amputation within one year (who have NDS ≥ 6) ; shown 67 out 100 patients had NDS ≥ 6 which was 52 of them were female, there mean age 64.4 years ,mean duration of DM was 15years,mean HBA1c was 9.7 g%, all were symptomatic. We exclude possible other causes of peripheral neuropathy like vitamin B_{12}all patient are with normal range for vitamin B12.

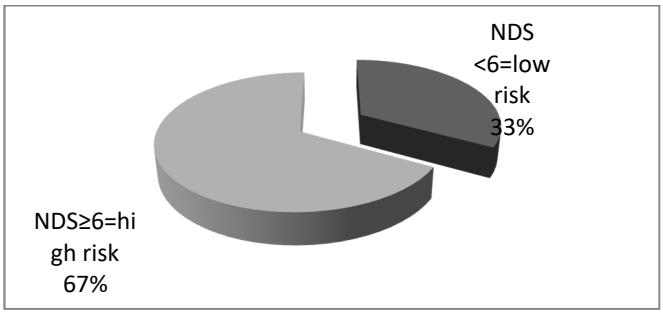

Figure 1: Neuropathy Disability Score distribution of the studied sample (National Diabetes Hospital, Libya 2016).

Factor	NDS < 6	NDS ≥ 6	P-value
Age	58.28 ± 11.06	64.44 ± 11	0.011
Weight	81.26 ± 25.8	76.94 ± 14.3	0.288
Height	1.56 ± 0.103	1.55 ± 0.098	0.751
BMI:	33.27 ± 10.07	31.81 ± 6.009	0.372
Duration of DM	7.95 ± 7.74	15.04 ± 9.58	< 0.01
HBA1c	9.88 ± 2.73	9.75 ± 2.83	0.843
LDL-C level	1.22 ± 33.48	1.09 ± 46.49	0.174
HDL-C level	43.6 ± 19.08	36.4 ± 13.02	0.042
TGA level	1.41 ± 173.53	1.65 ± 173.3	0.451
B. Urea	35.81 ± 20.99	41.82 ± 18.83	0.152
S. Creatinin	1.03 ± 0.74	1.00 ± 0.37	0.839

Table 4A: Distribution of the patient's character according to NDS and p value.

Factor	NDS < 6	NDS ≥ 6	asymp. sig (2-sided)
Sex:			
Male	9	15	0.591
Female	24	52	
Hypertension:			
Yes	14	26	0.728
Not	19	41	
Smoker:			
Yes	6	10	0.676
No	27	57	
Dyslipidemia:			0.921
Yes	11	23	
No	22	44	
Treatment: OHD	11	8	0.033
Insulin	17	42	
Combination	5	17	
Proteinuria:			
no	24	48	0.081
With pus cells	2	1	
Microalbuminuria	3	2	
Frank proteinuria	2	15	
Missed	2	1	
Symptomatic:			
yes	17	59	< 0.01
No	16	8	0.00
Foot ulcer:			
No	33	56	
Rt	0	5	0.107
Lt	0	4	
Both	0	2	
Foot pulse:			
normal	33	59	
Absent Rt	0	4	0.232
Absent Lt	0	3	
Absent both	0	1	

Table 4B: Distribution of the patient's character according to NDS and p value.

Discussion

The current study shown the usefulness of simple bedside tests for screening of neuropathic feet in patients with DMII and identification of high risk group for lower limb amputation within one year. The prevalence of DPN in current study was 14%, DPN diagnosis based on presence of positive test with SWM in addition to 1 other clinical test (thermal perception, pinprick sensation, ankle reflexes, or vibration perception threshold testing) (9), and calculation of total Neuropathy Disability Score (NDS) for each patients, to identify those with high risk of lower limb amputation with one year who have NDS ≥ 6.

Lisiane et al. recommended not to use only questionnaires to define the presence of neuropathy in diabetic patients-in daily practice, physical examination (MNSI or NDS) must be used (10). A Chawla et al study revealed neurological examination like NSS and NDS can be an important bed side tool in the clinics for early diagnosis of DPN with a sensitivity of 71.1% and specificity of 90%. It is a simple, acceptable, reproducible and validated (11). The most recent data are derived from the Gulf Diab Care survey of 1290 diabetic patients from specialist clinics and general hospitals in KSA, Kuwait, and the UAE (12). DPN was reported to be the most common long-term complication, with a prevalence of 34.9%. However, a major limitation of this survey was the lack of a clear definition to identify DPN; the inclusion criteria for neuropathy were, in fact, a simple dichotomous input of yes versus no for amputation, absent foot pulses, active or healed ulcers and previous bypass or angioplasty, all of which are end stage manifestation of DPN, reflecting the derivation of these data from specialist clinics. Al-Mahroos et al. undertook a much more rigorous approach and enrolled 1477 patients from primary care diabetes clinics in Bahrain, with predominantly DMII (93%), and diagnosed DPN based on the presence of 2 out of 3 abnormal assessments in the Neuropathy Disability Score (NDS), Neuropathy Symptom Score (NSS) or VPT (13). The study shown that 36.6% of the patients had DPN, 11.8% had peripheral vascular disease and 5.9% had foot ulcers.

In a study of a random sample of 2455 adult Emirati citizens living in Al-Ain, the prevalence of peripheral neuropathy diagnosed using the Diabetic Neuropathy Examination Score was 34.7% in patients with known diabetes, 16.2% in those with undiagnosed diabetes and 11.5% in those with pre-diabetes (14). In a recent study from Abu-Dhabi, of 422 adults with T2DM, DPN was detected in 26% of patients, and those who were illiterate were more likely to have neuropathy, reduced monofilaments and vibration sensations (15). In a study of 1000 systematically selected patients with diabetes from the National Centre for Diabetes in Jordan, 5.3% had foot ulcers, 1.7% had undergone amputation and 17.2% had an at-risk foot. Loss of protective sensation was detected in 17.4% of patients, and loss of vibratory sensation was found in 16.2% (16).

In a cross-sectional study of 351 diabetic patients in a specialist diabetic center in Riyadh, DPN, as defined by NDS ≥ 3, was present in 22.8% of the patients. Additionally, 16.2% had an increased risk of foot ulcer as defined by NDS ≥ 6, whereas 4.3% had a prior history of foot ulceration (17). Recently, an observational cohort study of primary and secondary care in Qatar, the prevalence of neuropathy was 9.5%; but the assessment was based on a simple yes/no answer on a questionnaire administered to patients (18).

In a large survey of 4926 diabetic patients attending a specialist diabetes clinic in Basrah, Iraq between 2003 and 2009, the prevalence of advanced DPN was 13.8% based on the presence of numbness, paranesthesia, an absent sense of vibrations and loss of knee and ankle jerks in a population with sub-optimal diabetes control (HbA1c 9.3 ± 2.0%) (19). The only available data from Syria (20) is from a study of 237 adult patients with T2DM and latent autoimmune diabetes,

among which DPN was detected in 39.7% and 44.4% of the groups, respectively, although the diagnosis of DPN was based on clinical records.

In a study of 320 diabetic patients referred to a secondary care clinic in Oran, Algeria, with poor glycaemia control (HbA1c 10.0 ± 2.6%), the prevalence of DPN was 33.2% based on abnormal pinprick sensation, loss of big toe proprioception and loss of ankle jerks (21). A cross-sectional study of 2320 diabetic patients in Monastir, Tunisia, the reported prevalence of DPN was 18.7%; however, no definition of DPN was provided (22). The EpiDiaM cohort study established a DPN prevalence of 45.6% in 1196 patients in a basic health care network in Fez, Morocco, but no definition of DPN was provided (23). The only study from Yemen, 1095 diabetic patients attending a specialist diabetes clinic over a 5-year period were reported to have a DPN prevalence of 40.7%, but again the definition of DPN not indicated (24).

In a study of 986, Omani patients with T2DM, the prevalence of DPN was 9% based on a clinical history of symptoms of peripheral neuropathy or abnormal nerve conduction studies (25). In a study of 413 Sudanese patients, the prevalence of neuropathy, defined as an obvious deficit (loss of pinprick, touch, vibration and ankle jerk), was 31.5%. Other studies conducted in the area have reported a similar prevalence of 37% (26). A recent meta-analysis of the prevalence of DPN in Iran amongst patients with T1 and T2DM showed an estimated overall prevalence at 53% (27). A cross-sectional study of 866 patients with T2DM from a major diabetes care center in Turkey assessed the prevalence of DPN using NSS, NDS and VPT (28). DPN was present in 60% of patients and age, duration of diabetes and HbA1c were significant risk factors. In India ,the study with a total of 1044 patients with DM attending the Diabetes clinic from January 2007 to May 2008, were included, all subjects had a detailed clinical assessment including Diabetic Neuropathy Symptom (DNS) score, Diabetic Neuropathy Examination (DNE) score, the prevalence of peripheral neuropathy was 34.9 % (29). In large, community-based survey of 9,710 predominantly type 2 diabetic patients derived from general practice in northwest England, the prevalence was 22% as defined by a neuropathy disability score (NDS $\geq$ 6) and at least moderate neuropathy symptoms as defined by the neuropathy symptom score (NSS $\geq$ 5) was 34% (30). Unfortunately, we have no data about prognosis of our high risk group patients because of loss of follow up. In conclusion, the usefulness of commonly used bed side tests and clinical techniques to screen for DPN with a predominant focus on application of NDS, that patient had increased risk of lower limb amputation within one year when NDS more than six. Thus, educate all people with diabetes about foot care. Identify those with high risk and interfere as early as possible. It important to pay attention to preventative measures.

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