Classification of functionality of people with diabetic peripheral neuropathy based on international classification of functioning, disability and health Core set (ICF-CS) of diabetes mellitus

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Abstract

Purpose The aim of this study was the application of International Classification of Functioning, Disability and Health Core Set (ICF- CS) of Diabetes Mellitus (DM) to investigate body function impairment (BF) & body structure (BS), activity limitation & participation restriction in people with diabetes mellitus with and without peripheral neuropathy.

Method A total of 120 subjects with diabetes were interviewed using four categories of the ICF-CS of DM through ICF documentation form including body functions, body structures, activities and participation, and environmental factors.

Results Subjects with diabetic peripheral neuropathy (DPN) experienced more physical dysfunctions and impairments when compared with subjects having diabetes without peripheral neuropathy when assessed with ICF-CS of DM. DPN patients experienced significant problem in 19 categories in BF, 3 categories in BS, 10 categories in activity and participation and 4 categories in environmental factors when compared with diabetes patients without peripheral neuropathy on chi square analysis. Findings of regression analysis suggest that people with DPN have more chances of impairments in BF and BS, activities and participation, and environmental factors.

Conclusion The difference observed between subjects having diabetes with and without peripheral neuropathy on the scores of ICF-CS domains suggest that, people with DPN faces more problems in health and function. These people should be targeted with more intensive care for improving the health standards.

Keywords Diabetes mellitus · Function · Health · Diabetes mellitus ICF core-set

Introduction

Diabetic peripheral neuropathy (DPN) is one of the major complications of diabetes mellitus (DM) [1]. DPN affects different parts of the nervous system with varied clinical manifestations. The lifetime prevalence for DPN is roughly around 50% [2]. DPN affects both the peripheral and autonomic nervous system causing a considerable morbidity and mortality in both the Type 1 as well as in Type 2 diabetic patients. Peripheral nerve damage occur insidiously and it can start with sensory deficits followed by motor impairments [3]. People with lower-extremity involvement due to DPN have 3 times more risk of restricted mobility. The most often

reported mobility restrictions are difficulty in walking a quarter of mile (0.4 km) and to climb 10 steps without taking a rest [4].

The International Classification of Functioning, Disability and Health, (ICF) is a classification of health and health-related domains. ICF is the WHO recommended framework for assessing functioning and disability in various health conditions. It measures health and disability at both individual and population levels. The domains of ICF are body function and body structure, activities and participation and environmental factors. It not only relate function and disability to physical and psychological factors, but also to an individual's life situation and social role. WHO developed, ICF-core set (ICF-CS) of DM by tailoring it from 2nd and 3rd level of ICF hierarchy. ICF-CS of DM addresses features within all the categories of body functions, body structure, activity and participation and environmental factors [5]. Management of symptoms depends on assessing the patient's problems, setting of treatment goals, choosing appropriate intervention strategies and evaluation of

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intervention outcomes [6]. ICF-CS of DM can be used as an assessment tool for identifying problems in individuals with DM and the extent of problems in people with DPN.

ICF-CS for DM was developed by Rouf et al. [7]. Tsutsui et al. had reported the use of ICF-CS of DM in identifying the physical and psychological symptoms in people with diabetic nephropathy [8]. Though ICF is recommended frame work for assessing health and disability by WHO, its use in clinical practice is limited. There is lack of information on applicability of ICF on people with DPN. Moreover its not clear how people with DPN differ in terms of health and disability categories. Hence the present study was done to find out whether there is any difference between subjects with and without neuropathy on the scores of ICF-CS domains of DM. The study also explored the association of various categories of ICF-CS domains with DPN and the diagnostic properties of the ICF-CS of DM. The problem identification will help in planning and implementation of appropriate treatment programmes in people with DPN.

Method

Study design and subjects

It was a cross sectional observational study. A convenient sample of 120 subjects were recruited for the study. One hundred forty five subjects with pre-diagnosed DM were screened for inclusion criteria and 25 subjects were excluded. The set inclusion criteria were pre-diagnosed diabetes mellitus, DPN on Michigan neuropathy screening instrument [9]. The exclusion criteria were history or evidence of any other neurological disorder such as hemiparesis, myelopathy, cerebellar ataxia, patient with severe pain on numeric rating pain scale (NPRS, score > 6), cognitive impairment on mini mental status examination (MMSE, score < 26).

Procedure

Subjects were explained about the purpose and methodology of the study. They were given a consent form (English or Hindi version according to participant's preferred language) explaining their rights as research subject along with the details of the study. Medical records of the participants were obtained from the participants. Ethical clearance was obtained from the Institutional Ethical Committee, Jamia Millia Islamia, New Delhi before starting the study. All the information on the consent form and demographic history were kept confidential by assigning a number to each subject.

First evaluation included demographic information such as age, gender, height, weight, body mass index (BMI) and diabetic history (duration of diabetes, medications and blood glucose level), pain using NPRS, cognitive function using

MMSE and comorbid medical conditions. Michigan neuropathy screening instrument score was used for identifying DPN [9]. Then familiarization sessions, were given about the various tests and tools, how they would be administered, how they have to answer and perform during various tests. After familiarization sessions the subjects were interviewed using ICF-CS of DM and was evaluated to find out whether the participants had experienced any problems associated with the 97 categories (12 categories from body structure were excluded) of the ICF-CS of DM through ICF documentation form.

Participants were assessed for body function, body structure, activity and participation and environmental factors based on ICF-CS of DM. 36 categories belong to “body functions (BF)”, 4 categories (12 categories were excluded) since those 12 categories were not possible to be assessed on the interview basis, 18 categories to “activities and participation (AP)”, and 29 categories to “environmental factors (EF)”. It took about 90 min, per subject, in the data collection process which included evaluation, testing and other formalities.

Subjects answered each question with “yes” or “no” followed by detailed explanations. For example, in category “b134Sleep function”, subjects were asked “do you have any difficulty in sleep after you diagnosed with diabetes?” If the subject answered “yes”, we further interviewed solicited details about problems; for example, when it started, how much difficulty you feel falling asleep, how would you rate your sleep quality, how did you overcome the symptoms, etc. Among all categories if on at least one category patient reported a problem, that selected as “problem category”. All the categories were asked in the same manner as above and to evaluate the extent of the patient's problems in each of the ICF categories in the comprehensive ICF- CS of DM. The qualifier scale of the categories of body functions, body structures and activities and participation has 5 response categories, each ranging from 0 to 4: no/mild/moderate/ severe/complete impairment or difficulty. The qualifier scale of the environmental factors has 9 response categories ranging from −4 to +4. A specific environmental factor can be a barrier (−1 to −4), a facilitator (1 to 4), or can have no influence (0) on the patient's life. If the factor has an influence, the extent of the influence (either positive or negative) can be coded with mild/moderate/severe/ complete. In addition, there are the response options “8: not specified” and “9: not applicable” quantified with the WHO Qualifier of ICF-CS of DM [7]. The analysis was done with yes or no response only, as the study was designed to identify the problems in various categories of ICF and its association with neuropathy in DM.

Additionally the area under curve (AUC) ROC, sensitivity, specificity, negative predictive values (NPV), positive predictive value (PPV), negative likelihood ratio (−LR) and positive predictive value(+LR) were also calculated for problem categories, to find out the diagnostic properties. (AUC) ROC is plotted by false positive rate of a test against the true positive

rate. The sensitivity of a clinical test is the ability of the test to identify those patients with disease correctly and specificity is the ability of test to identify those without disease correctly. Positive predictive value is the probability of the subject having the disease when the test is positive and negative predictive value is the probability of the subject not having the disease when the test is negative. Positive likelihood ratio is calculated by sensitivity divided by 1- specificity, whereas negative likelihood ratio is calculated by 1- sensitivity divided by specificity [10].

Data analysis

The descriptive statistics were calculated for age (years), weight (kilogram), height (meter), BMI, duration of diabetes (years), fasting glucose level (FGL) (mg/dl), postprandial glucose (PPG) (mg/dl), HbA1C (%), pain (median and IQR) and MMSE. Then, frequency distribution was calculated for gender, hypertension and dyslipidaemia in both the groups and cross tabulation was done. Mann-Whitney U test was used to analyse difference in NPRS among the groups. Independent t-test was used to compare the continuous variables. Multiple logistic regression model with odds ratio analysis with 95% CI was done to find out associations of problem category in body function, body structure, activity limitation and participation restriction, and environmental factor in people with DPN in reference to subjects without neuropathy by adjusting age, gender, BMI, duration of diabetes, HbA1C, dyslipidaemia and hypertension. Multiple logistic regression allows to adjust the effect of confounding factors on the association between the variables. The odds ratio (OR) quantifies the association between the variable. The disease

condition (DPN and DM without peripheral neuropathy) was used as a predictor variable to predict the body function and body structure, activities and participation and environmental factors.

The area under curve (AUC) ROC, sensitivity, specificity, negative predictive values, positive predictive value, negative likelihood ratio and positive predictive value was also calculated for different categories which had shown significant association with neuropathy. Level of significance was set at $p \leq 0.05$. The statistical analysis was done using SPSS 21 windows version and MedCalc statistical software.

Results

There were 60 subjects each with and without DPN. The sample characteristics are mentioned in Table 1. The values for height, weight, BMI, fasting glucose level (FGL), post prandial glucose level (PPG), HbA1C, duration of diabetes, dyslipidaemia and hypertension did not show any significant difference between both groups except age and MMSE scores. The number of subjects (%) with problem areas in ICF categories and its association with DPN is given in Tables 2, 3, 4, and 5 respectively.

Association of body function, body structure, activity and participation, environmental factors with DPN

Nineteen categories of body function, 3 categories of body structure, 10 categories of activity participation and restriction, and 4 categories of environmental factors showed a significant association (adjusted OR) with DPN. The adjusted OR ranged

Table 1 Characteristics of the study participants

Characteristics	Diabetes mellitus with peripheral neuropathy (n = 60)	Diabetic peripheral neuropathy (n = 60)	t/ χ^2 / U	p
Age (years)	57 ± 9	54 ± 7	2.22	0.02
Gender (men/women)	23/37	31/29	1.46	0.14
Weight (KG)	67.30 ± 9.80	70.30 ± 12.60	-1.4	0.15
Height (m)	1.60 ± 0.09	1.62 ± 0.91	-1.3	0.19
BMI (kg/m ²)	26.20 ± 3.60	26.50 ± 4.50	-0.4	0.62
FGL (mg/dL)	152.70 ± 74.50	132.50 ± 88.30	1.35	0.17
PPG (mg/dL)	225.30 ± 97.20	200.80 ± 113.90	1.26	0.20
HbA1C (%)	7.77 ± 0.91	7.67 ± 1.69	0.4	0.68
Duration of diabetes (years)	6.74 ± 5.06	6.90 ± 5.70	-0.16	0.87
Dyslipidaemia (N)	13	47	1.2	0.21
Hypertension (N)	23	37	0.001	1
NPRS (Pain)	0 [0,3] ⁺	0 [0,3] ⁺	1691	0.52
MMSE	26.80 ± 3.40	28.80 ± 2.50	-3.5	0.01

FGL- Fasting glucose level, PPG-Post prandial glucose level, t-test test value χ^2 - Chi squared test value, U- Mann Whitney U test values, + - median, IQR, NPRS- Numeric pain rating scale, MMSE- Mini mental status examination

Table 2 Association of ICF categories of body function and diabetic peripheral neuropathy

ICF code	ICF category	DM without neuropathy n (%)	Diabetic peripheral neuropathy n (%)	OR Adjusted	95% CI	P
b130	Energy and drive function	20(33)	33 (55)	3.04	1.3–6.9	0.001
b1300	Energy level	18 (30)	27 (45)	2.44	1.0–5.7	0.03
b1302	Appetite	18 (30)	30 (50)	2.40	1.0–5.8	0.04
b 134	Sleep function	21(35)	35(58)	2.71	1.1–6.3	0.01
b140	Attention function	30(50)	42(70)	3.65	1.1–10.09	0.02
b152	Emotional Function	36 (60)	55 (91)	3.67	1.1–10.9	0.02
b260	Proprioceptive Function	46 (76)	57 (93)	6.70	1.6–27.4	0.001
b265	Touch Function	46 (76)	57 (93)	6.70	1.6–27.4	0.001
b270	Sensory Functions related to temperature and other stimuli	50 (83)	58 (96)	7.11	1.2–42.1	0.02
b280	Sensation of Pain	36 (60)	53 (88)	6.50	2.1–19.5	0.001
b415	Blood vessel function	48 (80)	53 (88)	1.01	1.0–1.5	0.01
b420	Blood pressure function	33 (55)	45 (75)	2.61	1.0–6.2	0.03
b515	Digestive Functions	16 (26)	29 (48)	2.40	0.1–5.7	0.03
b545	Water, mineral and electrolyte balance functions	15 (25)	29 (48)	3.21	1.3–7.8	0.001
b610	Urinary excretory functions	18 (30)	30 (50)	2.00	0.9–4.6	0.05
b620	Urination function	8 (13)	19 (31)	2.64	0.9–7.1	0.05
b730	Muscle power functions	16 (26)	30 (50)	2.45	1.0–5.7	0.03
b820	Repair functions of the skin	37 (61)	56 (93)	8.61	2.3–31.4	0.001
b840	Sensation related to skin	51 (95)	59 (98)	11.5	1.1–114.7	0.03

ICF International classification of function, disability and health; DM Diabetes mellitus, OR Odds ratio

from 1.01 (blood vessel function) to 11.5 (sensation related to the skin) for body function and it was 1.71 (structure of ankle and foot) to 8.50 (structure of area of skin) for body structure of the problem categories (Tables 2 and 3). The adjusted OR ranged from 1.6 (looking after one's health) to 8.5 (walking) among the problem categories (Table 4). The adjusted OR ranged from 0.22 (acquaintances, peers, colleagues, neighbours and community members; general social support services, systems and policies; general social support services, systems and policies) to 0.8 (media services, systems and policies; health services, systems and policies) among the problem categories of environmental factors (Table 5).

The diagnostic properties analysis result for the AUC (ROC), sensitivity, specificity, negative predictive values, positive

predictive value, negative likelihood ratio and positive likelihood ratio for the categories significantly associated with neuropathy in each of 4 domains (body function, body structure and activity limitation and participation) is tabulated in Tables 6, 7, 8, and 9.

Area under curve (AUC) ROC

The AUC (ROC) was highest for sensation of pain (0.64) and it was lowest for touch sensation (0.55) in body function, among the body structure highest observed value was for structure of ankle and foot (0.63) with lowest value for structure of nails (0.56). In activity participation and restriction highest value was for handling stress and psychological demands (0.65) and acquisition of goods and services (0.54).

Table 3 Association of ICF categories of body structure and diabetic peripheral neuropathy

ICF code	ICF category	DM without neuropathy n (%)	Diabetic peripheral neuropathy n (%)	OR Adjusted	95% CI	P
s7502	Structure of ankle and foot	42 (70)	58 (96)	1.71	2.3–9.6	0.001
s810	Structure of area of skin	45 (75)	58 (96)	8.50	1.6–14.0	0.01
s830	Structures of nails	50 (83)	58 (96)	7.01	1.0–46.4	0.04

ICF International classification of function, disability and health, DM Diabetes mellitus

Table 4 Association of ICF categories of activity and participation and diabetic peripheral neuropathy

ICF code	ICF category	DM without neuropathy n (%)	Diabetic peripheral neuropathy n (%)	OR adjusted	95% CI	p
d240	Handling stress and psychological demands	8 (13)	29 (48)	5.61	2.0–15.4	0.001
d450	Walking	48 (80)	57 (95)	8.50	1.6–43.7	0.01
d455	Moving around	13 (21)	26 (43)	2.85	1.1–6.6	0.01
d570	Looking after one's health	47 (78)	59 (98)	1.60	2.2–4.2	0.001
d620	Acquisition of goods and services	50 (83)	57 (95)	5.60	1.0–29.8	0.04
d630	Preparing meal	27 (45)	32 (53)	3.90	3.5–4.31	0.001
d750	Informal social relation	45 (75)	55 (91)	3.31	1.0–10.6	0.03
d760	Family relationships	47 (78)	58 (96)	7.11	1.4–35.2	0.01
d920	Recreation and leisure	46 (76)	56 (93)	3.43	0.9–11.9	0.05
d9205	Socializing	18(30)	9(15)	1.80	0.6–4.9	0.02

ICF International classification of function, disability and health, DM Diabetes mellitus

Sensitivity and specificity

Among the body function the sensitivity was found to be highest for sensation related to skin (98.33) and was lowest for muscle power functions and appetite categories (0.50), among the body structure highest value was for structure of ankle and foot along with structure of nails (96.67) with lowest value for structure of area of skin (95). In activity participation and restriction highest value was for looking after one's health, acquisition of goods and services (98.33) and lowest for handling stress and psychological demands (48.33).

The specificity was highest for urination function (86.67) and it was lowest for touch function (13.33) in body function, among the body structure highest observed value was for structure of ankle and foot (30) with lowest value for structure of nails (16.67). In activity participation and restriction highest value was for handling stress and psychological demands (83.33) and lowest for acquisition of goods and services (10).

Negative predictive value and positive predictive value

The negative predictive was highest for sensation related to skin (95.5) and it was lowest for touch function and urinary excretory function (77.2) in body function, among the body structure

highest observed value was for structure of ankle and foot (95.5) with lowest value for structure of nails (92.1). In activity participation and restriction highest value was for looking after one's health (97) and lowest for preparing meal (70).

The positive predictive value was highest for urination function (50.4) and it was lowest for touch function (32.3) in body function, among the body structure highest observed value was for structure of ankle and foot (37.2) with lowest value for structure of nails (33.2). In activity participation and restriction highest value was for handling stress and psychological demands (55.4) and lowest for walking (31).

Negative likelihood ratio and positive likelihood ratio

The negative likelihood ratio was highest for urination function (0.79) and it was lowest for sensation related to skin (0.11) in body function, among the body structure highest observed value was for structure of area of skin (1.27) with lowest value for structure of ankle and foot (0.11). In activity participation and restriction highest value was for preparing meal (1) and lowest for looking after one's health (0.07). The positive likelihood ratio value was highest for urination function (2.38) and it was lowest for touch sensation (0.12) in body function, among the body structure highest observed value was for structure of structure of ankle and foot (1.38) with

Table 5 Association of ICF categories of environmental factors and diabetic peripheral neuropathy

ICF code	ICF category	DM without neuropathy n (%)	Diabetic peripheral neuropathy n (%)	OR adjusted	95% CI	p
e325	Acquaintances, peers, colleagues, neighbours and community members	1(0)	2(3)	0.22	0.07–0.65	0.01
e560	Media services, system and policies	0(00)	1(1)	0.80	0.21–2.8	0.01
e575	General social support services, systems and policies	1(1)	2(3)	0.22	0.07–0.65	0.01
e580	Health services, systems and policies	0(00)	1(1)	0.80	0.21–2.8	0.01

ICF International classification of function, disability and health, DM Diabetes mellitus

Table 6 Area under the ROC curve (AUC), sensitivity, specificity, negative and positive predictive value and negative and positive likelihood ratios of components of body function having significant association with DPN

ICF category	AUC 95% CI (p)	sensitivity 95% CI	specificity 95% CI	NPV 95% CI	PPV 95%CI	-LR	+LR
Energy and drive function	0.60 0.51–0.69 (0.01)	55.5 41.6–67.9	66.67 53.3–78.3	77.6 71.3–82.8	41.4 31.6–52.0	0.68 0.5–0.9	1.65 1.1–2.5
Appetite	0.60 0.50–0.68 (0.02)	50.00 36.8–63.2	70.00 56.8–81.2	76.6 70.7–81.6	41.7 31.0–53.1	0.71 0.5–1.0	1.67 1.1–2.6
Emotional Function	0.60 0.56–0.74 (0.001)	91.67 81.6–97.2	40.00 27.6–53.5	91.8 82.1–96.5	39.6 34.4–44.9	0.21 0.09–0.5	1.53 1.2–1.9
Proprioceptive Function	0.59 0.49 to 0.68 (0.03)	95 86.1–99.0	23.3 13.4–36.0	91.6 76.7–97.3	34.7 31.3–38.2	0.21 0.06–0.7	1.24 1.1–1.4
Touch Function	0.55 0.45–0.64 (0.04)	96.67 88.5–99.6	13.33 5.9–24.6	90.3 67.4–97.7	32.3 30.0–34.8	0.25 0.06–1.1	0.12 1.0–1.2
Sensory Functions related to temperature and other stimuli	0.56 0.47–0.65 (0.01)	96.67 88.5–99.6	16.67 8.3–28.5	92.1 72.7–98.1	33.2 30.5–36.0	0.20 0.05–0.9	1.16 1.0–1.3
Sensation of Pain	0.64 0.54–0.72 (0.002)	88.33 77.4–95.2	40.00 27.6–53.5	88.9 78.9–94.5	38.7 33.5–44.2	0.29 0.1–0.6	1.47 1.2–1.8
Blood pressure function	0.60 0.50–0.68 (0.01)	75.00 62.1–85.3	45.00 32.1–58.4	80.8 71.4–87.6	36.9 30.8–43.4	0.56 0.3–0.9	1.36 1.0–1.8
Digestive Functions	0.61 0.52–0.70 (0.006)	48.33 35.2–61.6	75.00 62.1–85.3	77.2 71.8–81.8	45.3 33.2–58.0	0.69 0.5–0.9	1.93 1.2–3.2
Water, mineral and electrolyte balance functions	0.62 0.53 to 0.71 (0.003)	48.33 35.2–61.6	76.67 64.0–86.6	77.6 72.3–82.1	47.0 34.4–60.1	0.67 0.5–0.9	2.07 1.2–3.5
Urinary excretory functions	0.60 0.51–0.69 (0.01)	51.67 38.4–64.8	70.00 56.8–81.2	77.2 71.3–82.2	42.5 31.8–53.8	0.69 0.5–0.9	1.72 1.1–2.7
Urination function	0.59 0.49–0.68 (0.01)	31.67 20.3–45.0	86.67 75.4–94.1	74.7 70.8–78.3	50.4 32.6–68.2	0.79 0.6–1.0	2.38 1.1–5.0
Muscle power functions	0.61 0.52–0.70 (0.007)	50.00 36.8–63.2	73.33 60.3–83.9	77.4 71.8–82.1	44.6 33.0–56.7	0.68 0.5–0.9	1.87 1.1–3.1
Repair functions of the skin	0.60 0.56–0.74 (0.0001)	93.33 83.8–98.2	38.33 26.1–51.8	93.1 83.2–97.3	39.3 34.4–44.5	0.17 0.06–0.5	1.51 1.2–1.9
Sensation related to skin	0.56 0.47–0.657 (0.006)	98.33 91.1–99.0	15.00 7.1–26.6	95.5 73.3–99.4	33.1 30.7–35.7	0.11 0.01–0.9	1.16 1.0–1.3

AUC Area under curve, NPV Negative Predictive value, PPV Positive predictive Value, -LR Negative Likelihood Ratio, +LR Positive Likelihood Ratio, CI Confidence interval, DPN Diabetic peripheral neuropathy

lowest value for structure of area of skin (0.7). In activity participation and restriction highest value was for handling stress and psychological demands (2.90) and lowest for acquisition of goods and services (1.09).

Table 7 Area under the ROC curve (AUC), sensitivity, specificity, negative and positive predictive value and negative and positive likelihood ratios of components of body structure having significant association with DPN

ICF category	AUC 95% CI (p)	sensitivity 95% CI	specificity 95% CI	NPV 95% CI	PPV 95%CI	-LR	+LR
Structure of ankle and foot	0.63 0.53–0.71 (0.0001)	96.67 88.5–99.6	30.00 18.8–43.2	95.5 83.6–98.9	37.2 33.3–41.3	0.11 0.03–0.5	1.38 1.2–1.6
Structure of area of skin	0.60 0.50–0.68 (0.001)	95.00 86.1–99.0	25.00 14.7–37.9	92.1 78.1–97.5	35.2 31.7–38.8	1.27 0.9–1.30	0.7 1.1–1.5
Structures of nails	0.56 0.473–0.65 (0.01)	96.67 88.5–99.6	16.67 8.3–28.5	92.2 72.7–98.1	33.2 30.5–36.0	0.20 0.05–0.9	1.16 1.0–1.3

AUC Area under curve, NPV Negative Predictive value, PPV Positive predictive Value, -LR Negative Likelihood Ratio, +LR Positive Likelihood Ratio, CI Confidence interval, DPN Diabetic peripheral neuropathy

Table 8 Area under the ROC curve (AUC), sensitivity, specificity, negative and positive predictive value and negative and positive likelihood ratios of components of activity and participation components having significant association with DPN

ICF category	AUC 95% CI (p)	sensitivity 95% CI	specificity 95% CI	NPV 95% CI	PPV 95%CI	-LR	+LR
Handling stress and psychological demands	0.65 0.56–0.74 (0.0001)	48.33 35.2–61.6	83.33 71.5–91.7	79.0 74.2–83.1	55.4 40.0–69.9	0.62 0.5–0.8	2.90 1.6–5.4
Walking	0.58 0.49–0.67 (0.003)	96.67 88.5–99.6	20.00 10.8–32.3	93.3 76.6–98.4	31 31.2–37.2	0.17 0.04–0.7	1.21 1.1–1.4
Moving around	0.61 0.52–0.70 (0.005)	45.00 32.1–58.4	78.33 65.8–87.9	76.9 71.8–81.2	47.1 33.8–60.8	0.70 0.5–0.9	2.08 1.2–3.6
Looking after one's health	0.60 0.515–0.69 (0.0002)	98.33 91.1–99.00	23.33 13.4–36.0	97.0 81.6–99.6	35.5 32.3–38.8	0.07 0.010–0.5	1.28 1.1–1.5
Acquisition of goods and services	0.54 0.44–0.63 (0.04)	98.33 91.2–99.00	10.00 3.8–20.5	93.3 63.5–99.1	31.9 30.0–33.9	0.17 0.02–1.3	1.09 1.0–1.2
Preparing meal	0.61 0.524–0.70 (0.0001)	97 94.0–98.0	23.33 13.4–36.0	70.0 63.5–99.2	30 28.3–38.8	1.00 0.02–1.3	1.30 1.1–1.5
Informal social relation	0.58 0.49–0.67 (0.016)	90.00 79.5–96.2	26.67 16.1–39.7	86.2 72.3–93.7	34.5 30.6–38.5	0.38 0.2–0.9	1.23 1.0–1.5
Family relationships	0.59 0.498–0.68 (0.001)	96.67 88.5–99.6	21.67 12.1–34.2	93.8 78.1–98.5	34.6 31.5–37.9	0.15 0.04–0.7	1.23 1.1–1.4
Recreation and leisure	0.58 0.49–0.67 (0.009)	93.33 83.8–98.2	23.33 13.4–36.0	89.1 74.0–95.9	34.3 30.9–37.9	0.29 0.10–0.8	1.22 1.0–1.4
Socializing	0.57 0.48–0.66 (0.04)	85.00 73.4–92.9	30.00 18.8–43.2	82.4 69.5–90.5	34.2 29.9–38.8	0.50 0.2–1.0	1.20 1.0–1.5

AUC Area under curve, NPV Negative Predictive value, PPV Positive predictive Value, -LR Negative Likelihood Ratio, +LR Positive Likelihood Ratio, CI Confidence interval, DN Diabetic neuropathy

Among the environmental factors, acquaintances, peers, colleagues, neighbours and community members, showed significance in AUC (ROC). The diagnostic property values for the particular category is mentioned in the Table 9.

Discussion

The major finding of study revealed that subjects with DPN experienced more physical dysfunctions and impairments when compared to people having diabetes without

neuropathy. To the best of our knowledge, no study has been conducted using ICF-CS of DM for assessing function, health and disability in patients with DPN.

However, there is study on use of ICF core set of DM to assess physical and psycho-social problems with diabetic nephropathy [8], whose findings were that DM with nephropathy with haemodialysis experienced more problems in 4 categories of ICF followed by the DM nephropathy without haemodialysis. There are other studies which have been conducted using ICF core set of DM but these studies were validation studies [8, 11].

Table 9 Area under the ROC curve (AUC), sensitivity, specificity, negative and positive predictive value and negative and positive likelihood ratios of components of environmental factor components having significant association with DN

ICF category	AUC 95% CI (p)	sensitivity 95% CI	specificity 95% CI	NPV 95% CI	PPV 95%CI	-LR	+LR
Acquaintances, peers, colleagues, neighbours and community members	0.59 0.50–0.68 (0.007)	31.67 20.3–45.0	88.14 77.1–95.1	75.1 71.2–78.5	53.4 34.2–71.6	0.78 0.6–0.9	2.67 1.2–5.9

AUC Area under curve, NPV Negative Predictive value, PPV Positive predictive Value, -LR Negative Likelihood Ratio, +LR Positive Likelihood Ratio, CI Confidence interval, DN Diabetic peripheral neuropathy

The regression coefficient calculated using a logistic regression is the estimated increase in the log odds (odds ratio: OR) of the outcome per unit rise in the value of the exposure. It determine whether a specific exposure is a risk factor for a specific outcome. $OR = 1$, exposure does not affect odds of outcome. $OR > 1$, exposure associated with higher odds of outcome. $OR < 1$, exposure associated with lower odds of outcome [12]. In this study, the number of problem categories was significantly greater in subjects with DPN. The findings of this study using ICF-CS of DM revealed that subjects with DPN were older when compared to the DM without neuropathy group. This suggest that complications increase in DM patients with age. Tsutsui et al. also found the same observations in their study [8]. The subjects with DPN showed more sensory disturbances and urinary dysfunction. In DPN musculoskeletal problems were not much prominent. Only few patients showed muscular weakness with muscle power functions differences in between groups. One of the study on validation of ICF-CS of DM also found the same observations [11].

In body structure, patients with DPN showed problems in 3 categories with issues pronouncing in structure of ankle, structure of nails and foot with skin deterioration. Other studies conducted on ICF-CS of DM also found the similar observations and results [11]. Patients with DPN reported more restriction of activities and limitation in participation than the DM without neuropathy. During this study, it was also found that some patients were unable to perform well at their job and hence they quit their job. DPN patients were significantly more likely to experience problems associated with 10 categories out of 18 categories under activity and participation. Tsutsui et al. observed almost similar results in his study on DM patients with nephropathy [8]. Patients with diabetes mellitus with and without neuropathy reported that they received support from their family and friends while they suffered from DM or DPN and that became their facilitator. Many patients reported products or substances of personal consumption as a barrier because they perceived the side effects of those products. DPN patients were more dependent on family and healthcare professionals for their care. Tsutsui et al. also observed the same problems in environmental factor categories [8]. The changes in the body function and structure might have been one of contributing factors along with others for the activity and participation problem areas. The DM is shown to affect almost all system of human body [13] and affection of nervous system secondary to DM will have additive effect on human body function.

We would like to emphasize the need to increase awareness in media services, systems and policies in people with DPN. It was observed that people with DPN faced barriers in terms of legal services, systems and policies, social security services, general social support services, legal and employment services, systems and policies. These patients should have

support from appropriate legal services, social security services, systems and policies. Keeping in mind the rate of increase of DM patients, proper social support, health services, employment and legal services, systems and policies should be made available for these groups of people.

The diagnostic capabilities of the ICF-CS showed mixed results with AUC (ROC) showing weak values, whereas sensitivity, specificity, negative and positive predictive values, negative and positive likelihood ratios showed weak to strong value in all four domains with categories associated to DPN. ICF is primarily used to rate the function and disability in various disease conditions. This was the first study which tried to investigate the diagnostic properties of ICF- CS of DM. Diagnostic precision evaluation is done to find out how well a test identifies specific condition of interest. Area under the (AUC) ROC curve, sensitivity, specificity, predictive values and likelihood ratios are diverse methods to measure the diagnostic properties of the test [14, 15].

AUC value near to 1 or 1 conveys that a test is effective in separating the conditions. The calculated AUC (ROC) across the different categories of ICF was between 0.64 and 0.54. The values were weak suggesting that the tool may not be good enough in separating the status of the patient among all the four categories of ICF.

High sensitivity matches to high negative predictive value and high specificity corresponds to high positive predictive value. Higher the value for both the positive predictive value and negative predictive value is an indication that test can be used for diagnosis. The sensitivity, specificity, negative and positive predictive values, negative and positive likelihood ratios showed weak to strong value in all four domains with categories associated to DPN. The test was highly sensitive to detect the changes in sensation function related to skin (98.33) and was lowest for the category acquaintances, peers, colleagues, neighbours and community members (31.67). The specificity function was highest for acquaintances, peers, colleagues, neighbours and community members (88.14) and it was lowest for acquisition of goods and services (10). The negative predictive was highest for sensation related to skin and structure of ankle and foot (95.5) and lowest for preparing meal (70). The positive predictive value was highest for handling stress and psychological demands (55.4) with lowest value for walking (31). The results are indicative that test is good enough in sensitive and specificity function in certain categories and it is weak in some other categories. The negative likelihood ratio was highest for structure of area of skin (1.27) and it was lowest for looking after one's health (0.07), whereas the positive likelihood ratio value was highest handling stress and psychological demands (2.90) and it was lowest for touch function (0.12). A likelihood ratio greater than 1 tells that the test result is related with the presence of the condition and a likelihood ratio less than 1 indicates that the test result is related with absence of disease. When tests report,

results as either positive or negative the two likelihood ratios are called the positive likelihood ratio and the negative likelihood ratio. The values observed were weak for likelihood ratios suggesting that the ICF is not good measure in predicting the probability of problem in specific categories of ICF in DPN.

Earlier ICF was typically used for research purposes and educational training but for last few years it has been found that there is much implication of ICF in clinical context. When we access through ICF then it is easier for patients to understand their functioning and health rehabilitation goals and interventional plan based on their language they can understand. The findings of the study indicates that people with DPN should be a special target group within DM. As DPN is a complication, proper medical care, exercise and dietary management should be emphasized from the early stages of diabetes itself. Another important message from the study is that people with DPN are having many dysfunctions related to health and function, so their management and treatment should not only focus on medical care. There should be intervention strategies targeting specific impairment, activity limitation and participation, removing environmental barriers and promoting environmental facilitators.

The limitation of this study includes feasibility of the ICF core set of DM as it contains 99 categories. It may take much more than half an hour to describe and classify a person's functioning and health status. This study is an observational study in which patients were interviewed for the 87 categories. Although this study used comprehensively the ICF core set and observed as much as it could be possible, no other assessment tool was used in assessing the health and function in the current sample. Future studies are recommended for using physical examination and advanced techniques to evaluate ICF-CS of DM.

Conclusion

The difference observed between subjects with and without neuropathy on the scores of ICF-CS of DM domains suggest that, people with DPN faces more problems in health and function. These people should be targeted with more intensive care for improving the health standards.

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Compliance with ethical standards

Conflict of interest There was no conflict of interest involved in this study.

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