Development of ICF based Assessment of Disability in Diabetic Neuropathy (ADDiN)

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Abstract

Background: Diabetes Mellitus (DM) is a clinical syndrome which has an enormous impact on the immediate family, both in developed and developing countries. Assessment of Diabetic Poly Neuropathy (DPN) as a complication of DM becomes even more crucial. There is an urgent need to develop and validate an ICF based assessment on (DPN) relevant to our community life.

Methods: The list of ICF categories that were considered relevant and typical for DPN by experts was formulated, and the formulated assessment was christened as ADDiN (Assessment of Disability in Diabetic Peripheral Neuropathy). Following the ICF Core set for DM, current instrument ADDiN had 130 categories for DPN. The results showed that Cronbach's Alpha Score for all the 5 domains was 0.730 and the 194 individual questions were analyzed and the score was 0.988, showing high reliability and consistency of the ADDiN scale.

Conclusion: The study results showing high sensitivity of ADDiN to DPN and fair specificity in differentiating DM from DPN, and high sensitivity and high specificity in differentiating DPN from control and high sensitivity and high specificity in differentiating DM from control suggests that ADDiN may be employed in future studies.

Key words: *Prevalence of Diabetes, Diabetic Peripheral Neuropathy, ICF for Diabetes.*

Introduction

Diabetes Mellitus (DM) is a clinical syndrome characterized by hyperglycemia due to absolute or relative deficiency of insulin. [1] DM is a chronic disease that is prevalent in many countries. DM can arise in many different ways but is most commonly due to autoimmune type 1 diabetes or to adult-onset type 2 diabetes.

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Worldwide prevalence of type 1 and type 2 DM is 366 million 2011, and by 2030 this would have risen to 552 million. [2] Further, worldwide, 183 million people with DM remain undiagnosed. DM caused 4.6 million deaths and a sum of at least US465$ in health care expenditure in 2011. [3] It is estimated in 2011 that 61.3 million are diabetic in India. People with diabetes are more likely to experience limitations in mobility, social function, and activities of daily living.

According to the recent estimates by the International Diabetes Federation (IDF), South East-Asia (SEA) Region consisting of India, Sri Lanka, Bangladesh, Bhutan, Mauritius and Maldives, is home to more than 72 million adults with diabetes in 2013 and is expected to exceed 123 million in 2035. Nearly 95% of people with diabetes have type II diabetes (T2DM). Although type I

diabetes (T1DM) is relatively rare in these countries, its prevalence is also rising. Elderly population contributed to 7% of the total population of India in 2001 and it will rise to 9% by 2016. In 2010,100 million people were aged above 60 years and by 2020 it will be 177 million.

There are, however, patterns of diabetes incidence that are related to the geographical distribution of diabetes in India. Rough estimates show that the prevalence of diabetes in rural populations is one-quarter that of urban population for India and other Indian sub-continent countries such as Bangladesh, Nepal, Bhutan, and Sri Lanka. [4] Preliminary results from a large community study conducted by the Indian Council of Medical research (ICMR) revealed that a lower proportion of the population is affected in states of Northern India (Chandigarh 0.12 million, Jharkhand 0.96 million) as compared to Maharashtra (9.2 million) and Tamil Nadu (4.8 million). [5] The National Urban Survey conducted across the metropolitan cities of India reported similar trend: 11.7 per cent in Kolkata (Eastern India), 6.1 per cent in Kashmir Valley (Northern India), [6] 11.6 per cent in New Delhi (Northern India), and 9.3 per cent in West India (Mumbai) compared with (13.5 per cent in Chennai (South India), 16.6 per cent in Hyderabad (south India) and 12.4 per cent Bangalore (South India). [7] A suggested explanation for this difference is that the north Indians are migrant Asian populations and south Indians are the host populations. [8]

The associated diabetic complications were neuropathy (60%), Chronic Heart Disease (32.3%) and cataract (20%), retinopathy (15.4%), peripheral vascular disease (11.5%) and cerebrovascular accidents (CVAs) (6.9%). There was rise in the prevalence of all diabetic complications with increase in the duration of diabetes.

Diabetic neuropathy (DN) refers to symptoms and signs of neuropathy in a patient with diabetes in whom other causes of neuropathy have been excluded. Distal symmetrical neuropathy is the commonest; accounting for 75% DN. [9] DPN is often described as a stocking-glove neuropathy, affecting the longest nerves before progressing proximally. [10] It usually presents with sensory symptoms in toes or feet. In some patients neuropathy is mainly loss of feeling, it may present with symptoms in the hand. DPN may or may not be accompanied by autonomic neuropathy. Significant motor symptoms usually occur late.

DPN ultimately results in the loss of both large and small diameter fibers, usually beginning with the small fibers. Vascular changes, such as occluded vessels, shunting and dilated capillaries, accompany progressive loss of nerve fiber. As DPN advances, the axons atrophy and are lost and the nerve is depopulated. This loss of nerve fibers is responsible for the manifestation of DPN, including ataxia, erectile dysfunction, abnormal position sense and abnormal deep tendon reflex, as well as other micro vascular complications. Neuropathy is the most significant step in a series of events that culminates in lower extremity complications of foot ulceration and amputation. Even minor trauma may produce skin ulceration, poor healing, and eventually gangrene. Even in the absence of lower extremity complications, neuropathy can cause significant functional impairment, including painful paresthesia, sensory ataxia and Charcot arthropathy. Of the patients with diabetic neuropathy, 60–70% will develop serious complications that culminate in the amputation of an appendage. [11]

A recent study showed that DPN patients experienced significant problems in 19 Categories in Body Functions, 3 Categories in Body Structures, 10 Categories in Activity and Participation and 4 Categories in Environmental factors when compared with Diabetes patients without Peripheral Neuropathy. [12] However, there are many published neuropathy composites scores available, [13] but there is no systematic framework that covers the spectrum of DPN symptoms and problems in functioning in relevance to our community life have been established thus far. Hence the need to develop and validate an ICF based assessment on (DPN) relevant to our community life. Cultural differences exert a considerable impact on the applicability of individual categories in various countries. It was generalized that DM has an enormous impact on the immediate family, both in developed and developing countries, [14] when DPN as a complication is added to DM, detailed assessment becomes even more crucial. Hence there is an urgent need to develop and validate an ICF based assessment on (DPN) relevant to our community life.

In this complex scenario of peripheral neuropathy of diabetes and serious lower limb complications, there is a felt urgency for a comprehensive assessment scale

for limb problems in diabetes, which would facilitate its early detection and prevent further complications, especially for therapists, who places locomotion as a top priority in human life. So the aim of the study is to create an ICF based Assessment of Disability in Diabetic Neuropathy (ADDiN)

Materials and Methods

International Classification of Functioning, Disability and Health (ICF) is World Health Organization (WHO) frame work for health and disability. [15] The advantage of ICF is the application of it in clinical areas and development of condition specific health status measure. Both the Comprehensive ICF Core set and the Brief Core set were referred, based on which this ICF based scale was developed.

After training in the ICF and based on preliminary studies, relevant ICF categories for DPN were identified by the researcher and placed before the experts from different background for a consensus. The expert team consisted of 10 members out of whom 2 were Physical therapists, 2 Neurologists, 2 Endocrinologists, 2 Epidemiologists and 1 Internal Medicine and 1 Social Workers.

The Questionnaire and Methodology for this study was approved by Institutional Ethical Clearance Certificate, Voluntary Health Services Hospital, Chennai. The expert team met at The Institute of Neurological Sciences, Voluntary Health Services, Multispecialty Hospital, Chennai, and deliberated on their knowledge and expertise on ICF and DPN. The expert team was briefed about ICF and DPN. The consensus was arrived at to use ICF DM as reference and to identify of the most typical and relevant categories of the ICF for patients with DPN. The expert survey using Delphi technique was conducted. The experts were given the autonomy to agree or disagree on a category included in DPN. The experts had to justify their decisions of inclusion or non-inclusion of categories. Data were collected in 3 rounds and answers were linked to the ICF and analyzed for degree of consensus. The list of ICF categories that were considered relevant and typical for DPN by experts was formulated, and the formulated assessment was christened as ADDiN (Assessment of Disability in Diabetic Peripheral Neuropathy).

ICF categories were designated by the letters ‘b’ (Body Functions), ‘s’ (Body Structures), ‘d’ (Activities and Participation), and ‘e’ (Environmental Factors). A comparison of the ICF core set with ADDiN is given below for a broad perspective.

The current version of the Comprehensive ICF Core Set for DM has 99 categories, with 85 categories at the 2nd level of the classification and 14 categories at the 3rd level classification. The 99 categories of the Comprehensive ICF Core Set for DM are made up of 36 categories from Body Functions component, 16 categories from Body Structures component, 18 categories from Activities and Participation component and 29 categories from Environmental Factors component. Following the ICF Core set for DM, the current instrument ADDiN had 130 categories for DPN consisting of 47 categories from the component ‘body functions’, 19 ‘body structures’, 27 ‘activities and participation’, and 37 ‘environmental factors’.

Main components of the ADDIN

Body Function Component

In DM there were 36 categories of the component body functions but were 47 categories of the component body functions were formulated for ADDiN. In DM out of 36 categories 5 categories were at third level and no category in fourth level. But in ADDiN 12 categories were at the third level and 3 are at fourth level of the classification. In second level of body function category b770 (gait pattern function) was included. In the third level of body function category which were included were b1301 (motivation), b1303 (craving), b2700 (sensitivity to temperature), b2701 (sensitivity to vibration), b2703 (sensitivity to noxious stimuli), b7101 (mobility of several joints), b7304 (power of muscles of all limbs). In the fourth level of category b28014 (pain in the upper limb), b28015 (pain in the lower limb) and b28016 (pain in joints) were included.

Body Structure Component

16 from the body structures component of DM were in the comprehensive core set out of 16 categories 6 categories were at third level and no category in fourth level, but 19 from the body structures component of ADDiN were included in which 11in level two, 8 at the

third level and no fourth level of the classification were included. In second level of body structure category s730 (structure of upper extremity) was included. In the third level of body structure category s7502 (structure of ankle and foot), s8102 (skin of upper extremity) and s8104 (skin of lower extremity) were included.

Activities Limitation and Participation Restriction Component

18 from the activities and participation component of DM were in the comprehensive core set out of 15 categories in second level, 3 categories were at third level, but in ADDiN 27 from the activities and participation component were included in which 22 in level two, 5 at the third level classification were included. In second level of activity and participation category d230 (carrying out daily routine), d445 (hand and arm use), d460 (moving around in different locations), d470 (using transportation), d640 (doing house work), d910 (community life) in our diverse community life, d930 (religion and spirituality) felt that it was essential to include this as it was very relevant to our place or country

Environmental Factors Component

29 from the environmental factors component of DM were in the comprehensive core set all 29 were in the second level, but in ADDiN and 37 from the environmental factors component were included in which all 37 were in level two, were included. In second level of environmental category e120 (Product & technology for personal indoor & outdoor mobility & transportation), e145 (Products & technology for the practice of religion & spirituality), e150 (Design, construction & building products & technology of buildings for public use), e 155 (Design, construction & building products & technology of buildings for private use), e460 (Societal attitude), e515 (Architecture & construction services, systems & policies), e525 (Housing systems, services and policies), e540 (Transportation system, services and policies) was found relevant and was included in respect to our country.

Prompts

After the pilot study the researcher and the experts felt that some of the questions were too complex for many of the illiterate subjects. So prompts were developed and used.

For example, b2700 Sensitivity to temperature
Sensory functions of sensing cold and heat
Question: Do you have problem sensing heat or cold?
Prompts: Are you able to tell that the coffee in your tumbler is hot. When you handle the metal tumbler?
Have you walked barefoot on the tar road and not felt the heat and known only after you noticed the blisters on your feet?
d930 Religion and spirituality
Engaging in religious or spiritual activities
Question: Do you have difficulty in engaging in religion and spirituality?
Prompt: Do you have difficulty in attending Church/ temple/mosque/ etc? And also indulging in your practices

Prompts were developed for all the 130 questions and were culture specific questions.

Verbatim

Another inclusion was to use Verbatim for all the questions, in addition to the answers obtained. Verbatim is the exactly using the same words the subjects used in answering the question.

For example

b1303 Craving
Prompt: Do you crave for food, sweet etc?
Verbatim:
Specify:

Additional Information

Another inclusion was to use the specific terms relevant to gather more rich qualitative data of significance from the subjects. The assessments were recorded and anything in excess of the format were included in a separate column created for this purpose 89 only. This we felt would enhance qualitative data with culture or social strata specific indicators from a developing nation

All the team members felt that the inclusions and exclusions (Table 1) were essential and Delphi consensus was once again used and agreed on the revisions to be executed in the main study. It took approximately 45 minutes to 1 hour to administer ADDiN.

TABLE 1: INCLUSIONS AND EXCLUSIONS AFTER DELPHI STUDY

Inclusions	Exclusions
Pain Quality assessment scale	Body structure category structure of nails in hand and feet
Medical Research Council MRC grading of muscle	
Range of motion in individual joints	
Structure of skin in upper extremity and lower extremity	
Activity limitation and participation restriction carrying out daily routines	
Wearing and taking off footwear	
Environmental factors the societal attitude	
Prompts	
Tamil translation	
Verbatim	
Additional information	

Results

Reliability of ADDIN

The reliability of ADDiN was analyzed using Cronbach's Alpha. The body function domain was 0.874. The body structure domain was 0.242 which was low on reliability and consistency. Activity limitation and participation restriction was 0.837 and 0.915 respectively. Environmental Barrier and Facilitator domain was 0.986 and 0.998 respectively. The Reliability and internal consistency of ADDiN analyzed using Cronbach's Alpha and was found to be reliable.

The Cronbach's Alpha Score for all the 5 domains was 0.730 and the 194 individual questions was analyzed and the score was 0.988, showing high reliability and consistency of the ADDiN scale. (Table 2 and 3)

TABLE 2: THE CRONBACH'S ALPHA SCORE FOR THE BODY FUNCTIONS, BODY STRUCTURE, ACTIVITY AND PARTICIPATION AND ENVIRONMENTAL DOMAIN IN ADDiN

Domain	Cronbach's Alpha	N of items
Body Function	0.87	47
Body Structure	0.24	19
Participation Restriction	0.84	27
Activity Limitation	0.91	27
Environmental Barrier	0.97	37
Environmental Facilitator	0.99	37

TABLE 3: THE CRONBACH'S ALPHA SCORE FOR ALL THE INDIVIDUAL QUESTIONS IN ADDiN

Cronbach's Alpha	N of items
0.99	194

Discussion

ADDiN consisting of 47 (36%) categories from the component 'Body Functions', 19 (15%) 'Body Structures', 27 (20%) 'Activities and Participation', and 37 (29%) 'Environmental factors' was used to measure disability in DPN. The Reliability and internal consistency of ADDiN was found to be good except in the body structure domain. The low score perhaps reflects the approach taken to adapt ICF DM as reference and to develop the ICF based scale ADDiN for DPN. The result suggests that the body structure domain which was relevant to DM may not be relevant to DPN and that this section may require further modification prior to its use in wider populations. Nevertheless the overall results suggest that ADDiN is a good scale with reliability and internal consistency indicating it can be used as ICF based assessment for DPN.

The study results showing high sensitivity of ADDiN to DPN and fair specificity in differentiating DM from DPN, and high sensitivity and high specificity in differentiating DPN from control and high sensitivity and high specificity in differentiating DM from control suggests that ADDiN may be employed in future studies. No doubt modification of the body structure component has potential to further increase the specificity of the instrument without a significant drop in sensitivity, given that the overlap between DM and DPN components may have compromised specificity more so than sensitivity.

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