# **ORIGINAL ARTICLE**

Quality of life in diabetes mellitus and the International Classification of Functioning Disability and Health – a study of some aspects

Qualidade de vida em diabetes mellitus e Classificação Internacional de Funcionalidade, Incapacidade e Saúde - estudo de alguns aspectos

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### ABSTRACT

Introduction: Diabetes mellitus (DM) can have a profound impact on the patients' quality of life and the International Classification on Functioning, Disability and Health (ICF) is a valid tool to verify the influence of the health components on quality of life. Objective: The aim of this study is to present the frequency distribution of the ICF categories of the summarized Core Set for DM with severe involvement in a group of patients whose quality of life was deeply affected by DM. Methods: A total of 38 patients with DM were studied, of whom 76.3 % had DM2 and 23.7% had DM1, using the clinical data, information on the quality of life associated to DM from the AddQoL questionnaire and the disability associated to diabetes: categories of the summarized Core Set of the ICF with severe and complete involvement and categories of which information was insufficient to specify the severity of the involvement. Statistical analysis: The descriptive analysis of the data was performed. Results: The bodily function categories that were more severely affected were b130, b210, b530, b540; categories of body structures were s220, s410, s740; of activities/participation were d240, d570 and of environmental factors were e110, e115. The least classified structures were the pancreas (s550), ocular globe (s220) and parasympathetic nervous system (s150). Conclusion: In the studied group of patients with DM that presented chronic complications, inadequate metabolic control and quality of life that was deeply affected by the disease, the presence of disability in self-care and environmental barriers suggests that these factors can contribute to a worsening in the quality of life, although bodily function and structure involvements were the most prevalent ones.

#### **KEYWORDS**

International Classification of Functioning, Disability and Health, diabetes mellitus, quality of life

### RESUMO

Introdução: O diabetes mellitus (DM) pode ter um efeito profundo na qualidade de vida dos pacientes e a Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF) é um instrumento válido para verificar a influência dos componentes de saúde na qualidade de vida. O objetivo deste estudo, é apresentar a distribuição de freqüência das categorias das CIF do Core Set resumido para DM, com comprometimento grave em um grupo de pacientes com a qualidade de vida muito afetada pelo diabetes. Métodos: Foram estudados 38 pacientes diabéticos, 76,3 % com DM2 e 23,7 % com DM1, utilizando-se dados clínicos, informação de qualidade de vida associada ao diabetes do questionário AddQoL e incapacidade associada ao diabetes: categorias do Core Set resumido da CIF com comprometimento grave e completo, e categorias cuja informação era insuficiente para especificar a gravidade do comprometimento. Análise estatística: análise descritiva dos dados. Resultados: Categorias de funções corporais mais gravemente afetadas foram b130, b210, b530, b540, de estruturas corporais foram s220, s410, s740, de atividades/participação foram d240, d570 e de fatores ambientais foram e110, e115. As estruturas menos classificadas foram pâncreas (s550), globo ocular (s220) e sistema nervoso parassimpático (s150). Conclusão: No grupo estudado de diabéticos com complicações crônicas, controle metabólico inadequado e qualidade de vida muito afetada pela doença, a presença de incapacidade no cuidado pessoal e de barreiras ambientais, é sugestivo de que estes fatores possam contribuir para uma pior qualidade de vida, embora comprometimentos nas funções e estruturas corporais tenham sido os mais prevalentes.

#### PALAVRAS-CHAVE

Classificação Internacional de Funcionalidades, Incapacidades e Saúde, diabetes mellitus, qualidade de vida

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## INTRODUCTION

Diabetes mellitus (DM) can have a profound impact on the quality of life of the patients, not only due to the direct effects of the disease and its complications in the individual's health, but also due to the disease control measures, such as dieting and automonitoring.<sup>1,2,3</sup>

In a previous study by this group,\* the use of a specific questionnaire for diabetes, the Audit of diabetes dependent Quality of life (AddQol),<sup>4</sup> in 50 patients showed that 76% of them considered their quality of life much affected by the diabetes. This specific subgroup was then chosen as the target-population, to identify the disability associated to a worse quality of life according to the International Classification of Functioning Disability and Health (ICF)<sup>5</sup>. The tool used was the summarized ICF core set for DM<sup>6</sup> that evaluates 12 body functions, 6 body structures, 5 items of activities/participation and 10 types of environmental factors.

Therefore, the objective of the present study was to present the distribution of the frequency of the categories of the summarized ICF core set for DM in a group of patients whose quality of life was profoundly affected by the DM.

Data were extracted from the ICF Core Sets – Multicenter International Validation Study- Munich University-WHO Collaboration Project, of which the HUCFF-UFRJ is a collaborator center.

### **METHODS**

A sample of 50 patients with diabetes mellitus was introduced to question II from the quality of life questionnaire associated to diabetes (AddQol) (Table 1). Those who chose the responses Very much better and Much better were identified as individuals whose quality of life was profoundly affected by the DM, which resulted in a final sample of 38 patients – 9 men and 29 women – of whom 76.3% had DM2 and 23.7% had DM1, being followed at the Outpatient Clinic of the Service of Nutrology and Physical Medicine and Rehabilitation of the HUCFF-UFRJ. All of them were part of the group interviewed for the "Multicentric International ICF Core Set Validation Study for Diabetes Mellitus". The study was approved by the Ethics Committee in Research of HUCFF-UFRJ (protocol CONEP # 461/2007) and all the participants signed the free and informed consent form. The following data were obtained systematically:

• *Clinical data:* demographic data, BMI (Kg/m2), glycemia control adequacy (glycated hemoglobin  $\leq 7\%$ ), lipid control adequacy (total cholesterol <200 mg/mL), according to the ADA criteria.<sup>7</sup>

• *Question II of the AddQoL questionnaire:*<sup>4</sup> "In the following sentence, please, consider the effects of diabetes and its control (including medication, medical visits, changes in your diet) and any complications you might have."

Chart 1 Summarized ICF Core Set for diabetes mellitus.<sup>6</sup>

Body functions	
b540	general metabolic functions
b210	sight functions
b530	weight maintenance functions
b130	energy and impulse functions
b270	sensory functions related to temperature and other stimuli
b420	blood pressure functions
b415	blood vessel functions
b455	exercise tolerance function
b410	heart functions
b545	hydric, mineral and electrolytic balance functions
b610	urinary excretion functions
b730	muscular strength functions
Body structure	S:
s550	pancreas structure
s410	cardiovascular system structure
s220	ocular globe structure
s610	urinary system structure
s750	lower extremity structure
s150	parasympathetic nervous system structure
Activities and F	Participation:
d570	care after one's health
d520	care after body parts
d240	deal with stress and other psychological burdens
d630	preparation of meals
Environmental	factors:
e310	close family members
e355	healthcare professionals
e580	health services, systems and policies
e110	products or substances for personal consumption
ell5	products and technology for personal use in daily life
e570	social security services, systems and policies
e465	social norms, practices and ideologies
e585	work and employment services, systems and policies
e320	friends
e555	association and organization services, systems and policies

If I didn't have diabetes, my quality of life would be: () Very much better () A little better () The same () A little worse () Much worse () Very much worse.

• *Diabetes-associated disability:* Summarized ICF<sup>6</sup> Core Set categories (Chart 1) with severe and full impairment.<sup>5</sup> The decision to record only the categories with severe and full impairment was based on the supposition that these would be the ones with the highest negative impact on quality of life. Only the categories that affected 10% or more of the patients were listed.

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Table 1
Percentage distribution of the perception of quality of life without diabetes, among 50
diabetic patients, according to the answers to Question II of the AddQoL questionnaire.

		The same -	Very much better	Much better	Alittle better	A little worse	Muito pior	Very much worse	
Men	DM2	33%	53.3%	46.6%	-	-	-	-	
	DM1	6.25%	33%	33%	-	-	-	-	
Women	DM2	31.2%	44%	44%	6.25%	-	-	-	
	DM1		19%	25%	25%	-	-	-	
Table 2 General characteristics of the studied population (n=38).									
Characteristic				DM1			DM2		
Man/Woman				02/07			15/14		
Age (yrs)				34 ± 10.3		60	.9 ± 9.6		
Insulin use (%)			I	100			48.3		
Time of diagnosis (yrs)			(yrs)	7 ± 4.8		14	.6 ± 8.6		
BMI (Kg/m2)				24 ± 2.4		28	.8 ± 6.5		
Adequate glycemia control (%)			ntrol (%)	30			20.7		
Adequate lipid control (%)			ol (%)	90			55.2		
Years of formal education			cation	11 ± 5.5		7.	7 ± 3.5		
Retired individuals (man/woman)			ı/woman)	0	/1		11/4		

• *Non-specified ICF categories:* categories of which information was insufficient to specify the severity of the impairment<sup>5</sup> (Table 4).

The data were submitted to the statistical analysis through the descriptive analysis of the data.

# RESULTS

Table 1 shows the percentage distribution of 50 patients regarding the perception of their quality of life, without diabetes. Those that answered Very much better and Much better were the ones selected for this study (n=38).

Table 2 presents the demographic characteristics of the patients with DM according to the clinical presentation of the disease. The clinical differences observed between the groups are within the expected, that is, the patients with DM1 were younger and the diagnosis was more recent, there was better clinical control and the use of insulin was frequent. On the other hand, in the group with DM2, the BMI was, on average, more elevated and the number of retired individuals was more significant.

Table 3 presents the percentage participation of the diabetic patients with severe impairment of the categories of summarized ICF core set. It can be observed that in the DM1 as well as in the DM2 group, the Body Functions were the categories in which there was the highest number of patients with severe impairment.

Table 4
Percentage distribution of the categories of the summarized ICF core set for diabetes
mellitus, without information for the classification of the degree of impairment.

Body functions	%	
b410- heart	31	
b270- feelings of temperature, pressure	20.7	
Body structures		
s550- pancreas	93	
s610- urinary system	82.8	
s150- parasympathetic nervous system	48.3	

Table 3

Percentage distribution of the categories of summarized ICF core set for diabetes mellitus with severe impairment in diabetic patients whose quality of life is very much affected by the disease (n=38).

		· · ·		
DM2		DM1		
(29 patients)		(9 patients)		
Body functions		Body functions		
b540- general metabolic functions	76.1	b540- general metabolic functions	50	
b530- weight maintenance functions	38.1	b130- energy and impulse functions	50	
b130- energy and impulse functions	28.6	b530- weight maintenance functions	33.3	
Body structures		Body structures		
s750 - lower extremity structure	28.3	s750- lower extremity structure	10	
s410 - cardiovascular system structure	14.3			
s210 - ocular globe structure	14.3			
Activities /Participation		Atividade /Participação		
d240- deal with stress and other psychological burdens	14.3	d570- care after one's health	20	
d570- care after one's health	10			
Environmental factors		Environmental factors		
e115- products and technology for personal use in daily life	14.3	e110- products or substances for personal use	20	
e110- products or substances for personal use	19	e465- social norms, practices and ideologies	20	

# DISCUSSION

The ICF is a recent and complex classification, which presents a certain degree of difficulty to be applied,<sup>8</sup> but that has an acknowledged potential to measure the quality of life through functionality and the sociocultural condition in which the individual is included.<sup>9</sup>

At the current phase of its development,<sup>10</sup> in order to be incorporated as a valid tool of health outcome assessment, it is necessary to institute the communication among professionals from several disciplines and health divisions to establish the diffusion and discussion of results obtained with the ICF.

The present study is, therefore, carried out under this perspective, as it is an exercise of exploratory analysis of data that can be used as the basis for the discussion of other groups of professionals interested in the ICF. The Core Set represents the set of the main ICF categories for the classification of a certain disease. When the international validation process is concluded, the list of ICF categories will be recommended by the WHO to appear in epidemiological and clinical studies that involve patients with these diagnoses.<sup>11</sup>

Considering the entire group, the body function component concentrated the highest number of more severely affected categories (4), followed by the body structure component (3). The activities/ participation component and the environmental factors presented 2 categories each with more severe problems. These categories are related to symptoms (b130), disease control (b540), complications (b210, s220, s410, s740) and associated comorbidities (b530). In men, a higher impairment of metabolic control (b540) and of sight (b210) predominated, whereas in women, the weight control (b530) and metabolic control (b540) functions were the most affected ones (data not presented). There were five prosthetized leg amputees in the group of diabetes type 2, which can explain the higher degree of impairment of the lower limb structure (s740) observed. Still in the same group, the presence of categories related to chronic macrovascular (s410) and microvascular (s220) complications was observed. In the activities/participation items, care after one's health (d570) is the category with the highest degree of problems, reported both in the DM1 and the DM2 groups. In second place is the item deal with stress and other psychological burdens.

It is interesting to mention that both categories are usually not evaluated in the studies on disability in general, focused mainly on the impairment of mobility and the basic and instrumental activities of daily living. This finding might indicate that these patients need treatment in the areas of Nutrition, Psychology and Social Work and/or groups of patients to receive instructions and exchange experiences in order to overcome problems in these areas (awareness and positive attitudes to follow medical recommendations, diet, practice physical activities, etc). In the summarized Core Set for diabetes, there are no ICF categories of activities and participation related to work and employment. Thus, it was not possible to acquire the characteristic of incapacity to work due to disease, presented by around 40% of the patients.

Among the environmental factors, difficulties with medications

(category e110) and with material used for the monitoring of the glycemia control and/or technical help (category e115), were considered the most important barriers and had prevalence similar to the limitations in activities/participation. For these types of impairment, possible economic causes and/or difficulties to access healthcare services might be implicated. The fact that having diabetes (category e465) was indicated by women with DM1 as a significant social barrier was unexpected and must be verified in further studies. The group of environmental factor categories related to health, social security, work and employment services, systems and policies were undoubtedly the ones that were the most difficult to answer by the participants. Few of them knew how to position themselves regarding actions in this area. Also, probably due to the difficulties faced by the population in general, regarding access to healthcare services, the fact that they were being treated at a public hospital led most of the participants to answer that there were no barriers in the item health services, systems and policies. Wolff et al,<sup>12</sup> in their study on the outcomes used in randomized clinical studies in four chronic conditions and the ICF components, refers that less than 10% among 257 studies on diabetes focused on environmental factors. This finding shows that this aspect has been of the least relevant ones when interpreting clinical outcomes in diabetes.

The least evaluated body structure in the entire group was the pancreas, which can be explained by the absence of patients with diabetes associated to exocrine pancreatic failure. The second least evaluated structure was the urinary system, which can be justified by the fact that the diabetic nephropathy is a clinical syndrome, with a laboratory diagnosis.<sup>13</sup> Although a comparison between the phases of nephropathy progression in DM1 and the corresponding renal histological alteration can be made,<sup>1</sup> this description is not usually found in the medical files. The most relevant absence from a clinical point of view, however, was the description of the eye globe structure. Retinopathy, one of most feared chronic complications of DM, can remain asymptomatic until a severe retinal involvement is attained.15 It is recommended, thus, to undergo fundus examination of the eye.<sup>13</sup> In the studied cases, the cause of the absence of this information in 30% of the men with DM2 deserves investigation, so that the adequate measures can be taken in order to revert such condition.

The structure of the parasympathetic nervous system is the third least evaluated structure. Although manifestations of autonomic dysfunction have been reported in medical files, mainly neurogenic bladder and lack of perception of hyperglycemia, it was difficult to convey these signs/symptoms to the corresponding degree of impairment of the parasympathetic nerves. In this study, it was the most difficult ICF category to be classified. On the other hand, the trunk structure category (s760), which is not part of the summarized Core Set for DM, was very affected (18% of the cases) in patients with increased waist circumference due to centripetal obesity.

It is clear that this profile of categories reflects the studied population, selected from Outpatient Clinics of Nutrology and Physical Medicine and Rehabilitation of university hospitals, and therefore, with a high prevalence of overweight/obesity and amputation of toes and/or leg, with well-adapted prostheses. Patients with severe nephropathy or cardiopathy, vascular encephalic accident, severe symptomatic neuropathy, amaurosis, decompensated ischemic syndrome or those amputated above the knee as well as cases that did not have prosthesis indication were not part of the evaluated group.

In general, the results obtained have confirmed previous studies on type 2 diabetes, which demonstrated that the quality of life is worse for patients with chronic complications.<sup>16,17</sup> The contribution of the glycemia control is still a debatable issue. Some studies indicate its negative influence on quality of life,<sup>18,19</sup> whereas an important epidemiology research in the United Kingdom,<sup>18</sup> consisting of 2 transversal studies and a longitudinal one, did not verify any detectable difference regarding quality of life when comparing different therapeutic programs for the stringent control of glycemia. The influence of environmental factors has also been neglected in studies assessing quality of life in general and also in diabetic patients. The WHOQOL,<sup>20</sup> however, contemplates both the Environment domain and the dependence on medication or treatments in the Level of Independence domain. In the Mexican study<sup>21</sup> with patients who have type 2 diabetes, to whom the summarized version of the WHOQOL-BREF, was applied, the percentage of patients dependent on medication or treatment was 27.8% in those with very bad or bad quality of life and 31% in those with quite good or very good quality of life. These results do not allow further conclusions and were not discussed by the author.

The study is ongoing and must be complemented with data on the AddQol domains, comorbidities, types of medication and the analysis of the association between demographic variables, clinical variables, disability and quality of life. The categories that are not part of the summarized Core Set, but that are relevant for the definition of the functionality profile and patients' disability are also going to be included.

### CONCLUSION

In a group of diabetic patients with chronic complications, inadequate metabolic control and quality of life that is very affected by the disease, the presence of disability regarding self-care and the environmental barriers suggests that these factors can contribute to a worse quality of life, although the impairments of body functions and structures were the most prevalent ones.

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