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SCIENTIFIC LETTERS

ViDa1: A new questionnaire for measuring health-related quality of life in patients with type 1 diabetes☆

ViDa1: un nuevo cuestionario para medir calidad de vida relacionada con la salud en la diabetes tipo 1

Type 1 diabetes mellitus (DM1) is characterized by complex therapeutic recommendations that can interfere with and affect patient health-related quality of life (HRQoL). Being aware of the impact of the disease and its treatment is very important in clinical practice, as it allows us to detect needs, establish changes in treatment, identify barriers that complicate self-care, and offer support in decision making.[1,2] In order to evaluate this impact we need specific tools that are more sensitive to the fluctuations of the disease and which afford more detailed information than the generic HRQoL assessment tools.[1]

Until recently there were only two specific questionnaires for measuring HRQoL in diabetes: the Diabetes Quality of Life Measure (DQoL) and the Audit of Diabetes-Dependent Quality of Life (ADDQoL) tool.

The DQoL[3] is the oldest and most widely used in this regard. It was designed for the Diabetes Control and Complications Trial, and there is also a validated and adapted Spanish version (EsDQoL).[4] Although data warranting the validity of its contents and internal consistency have been produced by some studies, a number of limitations have also been found: items with low α coefficients, scant applicability of the social/vocational concern subscale, and items explained in outdated vocabulary.[5] No sensitivity to changes in the intensification of insulin therapy has been demonstrated.[6] Neither has sensitivity been demonstrated among patients subjected to continuous subcutaneous insulin infusion.[7]

A Spanish language version of the ADDQol[8] has been adapted and validated for Argentina, and the data referring to its psychometric properties supports its adequate internal consistency. However, the structure of this questionnaire is complex, since it measures importance and impact separately.[9] Its items are formulated on the basis of a hypothetical situation which the patient may or may not be able to imagine (how life would be without diabetes),[5,9] and which may represent a complex cognitive task. In fact, this type of formulation is advised against by the United States Food and Drug Administration.

We have recently published a validation of a new questionnaire, the Life with Type 1 Diabetes (*Vida con Diabetes tipo 1* [ViDa1]) questionnaire,[10] designed to meet the need for a useful and validated tool capable of measuring HRQoL in individuals with DM1 and which contemplates the most relevant implications of living with DM1 nowadays. We have sought to offer a tool that is easy to administer and useful in both clinical practice and in research.

The DQoL and the ADDQoL are both used in patients with DM1 and DM2, despite the fact that these are two very different diseases. Indeed, DM1 has a greater impact upon the life of the patient from the time of diagnosis. The questionnaires specifically fail to address a series of aspects that are important for the HRQoL of patients with DM1, and which refer to disease care-related activities such as diet carbohydrate count, the self-measurement of blood glucose and concern regarding hypoglycemia. They are also beginning to show their age, while the concerns and needs of people with DM1 have evolved in recent years.

A complex multistep process was involved in the development of the ViDa1: (1) a literature review to gain in-depth knowledge of the existing questionnaires for measuring HRQoL in diabetes, their advantages and limitations; (2) assessment of the opinions of DM1 patients in order for us to become aware of their concerns and needs and of how they view life with diabetes; and (3) evaluation of the opinions of clinical experts such as endocrinologists, diabetes educators and psychologists.

The patient psychometric characteristics were analyzed in a multicenter study involving 578 subjects with DM1 in different hospitals in Spain. The results of the study provided evidence regarding the structure, reliability, convergent and discriminant validity, time stability and sensitivity to change of the tool.[10]

The ViDa1 comprises 34 items grouped into four different dimensions that together shape patient HRQoL: interference with life, self-care, wellbeing and concern about the disease. The questionnaire can be self-administered, with answers based on a Likert-type scale yielding a total score per subscale.

The present letter presents a translation of the original version of the ViDa1 (Table 1) with the purpose of making

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Table 1 The ViDa1 questionnaire.

Please mark with an X your level of agreement with each of the statements below, which refer to your opinion concerning your health-related quality of life. It is very important to answer all the questions and not leave anything in blank. Remember that there are no good or bad answers; what is important is to know your opinion. Thank you.

1 = totally disagree
2 = disagree
3 = neither agree nor disagree
4 = agree
5 = fully agree

1. Having diabetes complicates my social relationships (friends, companions, couple, etc.)	1	2	3	4	5
2. Having diabetes makes me feel different	1	2	3	4	5
3. Having to administer insulin is a daily problem for me	1	2	3	4	5
4. Having diabetes limits my social life and leisure time (eating out, celebrations, travel, etc.)	1	2	3	4	5
5. Having diabetes has changed my life	1	2	3	4	5
6. Having diabetes complicates my family relationships	1	2	3	4	5
7. I feel limited in my professional life because of diabetes	1	2	3	4	5
8. I have some complications/s of diabetes that limit me physically and therefore worsen my quality of life	1	2	3	4	5
9. Daily life with diabetes causes me added stress	1	2	3	4	5
10. I am worried about others knowing that I have diabetes	1	2	3	4	5
11. Having diabetes limits my sex life	1	2	3	4	5
12. I can lead a normal life with diabetes	1	2	3	4	5
13. I feel satisfied with my daily involvement in the self-care of my diabetes	1	2	3	4	5
14. My training/knowledge of diabetes helps me to ensure good control	1	2	3	4	5
15. My training in quantifying carbohydrates allows flexibility in my diet	1	2	3	4	5
16. I feel satisfied with how I deal with my diabetes	1	2	3	4	5
17. I feel motivated with the self-care of my diabetes	1	2	3	4	5
18. I adjust the insulin dose to my diet in order to ensure good control	1	2	3	4	5
19. I feel satisfied with my drug treatment, because it helps control my diabetes	1	2	3	4	5
20. I feel satisfied with my current blood glucose (glycosylated hemoglobin) control	1	2	3	4	5
21. The management of diabetes is normally integrated into my daily life	1	2	3	4	5
22. I consider that I have flexibility and freedom in my diet despite having diabetes	1	2	3	4	5
23. I find it hard to do the daily controls (blood glucose)	1	2	3	4	5
24. I rest well and my sleep at night is good	1	2	3	4	5
25. I feel well physically	1	2	3	4	5
26. I feel well psychologically	1	2	3	4	5
27. I have other illnesses as a consequence of diabetes that worsen my quality of life	1	2	3	4	5
28. I feel satisfied with the time I spend doing physical activity	1	2	3	4	5
29. I consider my quality of life in general to be good	1	2	3	4	5
30. I am afraid of hypoglycemia (drops in sugar level)	1	2	3	4	5
31. I often feel concerned about hypoglycemia	1	2	3	4	5
32. I feel concerned when I have high blood glucose	1	2	3	4	5
33. I often feel concerned about future complications of diabetes	1	2	3	4	5
34. I often feel concerned about having to enter hospital because of poor diabetes control	1	2	3	4	5

Interference with life: (1–12), self-care (13–23), wellbeing (24–29) and concern about the illness (30–34). The scores corresponding to each subscale are added for correction. Items 12, 23 and 27 are inverted for correct interpretation.

it available to those who wish to use it, whether in clinical practice or in research.

This tool is useful for evaluating fluctuations of the disease in the course of the life of the patient, and for assessing the impact of a specific intervention. The ViDa1 is therefore a good alternative for evaluating the HRQoL of DM1 patients within the current context.

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Hypercupremia secondary to oral contraceptives: Report of 2 cases☆

Hipercupremia secundaria a anticonceptivos orales: a propósito de 2 casos

Oral hormonal contraceptives (OHC) are a classical cause of elevated plasma copper (Cu) levels (hypercupremia).[1] We describe two cases of hypercupremia secondary to OHC and discuss the potential implications in relation to its differential diagnosis.

The first case was a 21-year-old woman referred to the Nutrition clinic with denutrition secondary to Crohn's disease (CD), with severe colon involvement and extradigestive symptoms (single-joint osteoarthritis and bilateral anterior uveitis) for the previous two years. At the time of consultation she was enrolled in a clinical trial with Mongersen (antisense oligonucleotide, anti-Smad7) for her CD, and had been receiving OHC (0.03 mg ethinylestradiol/0.15 mg levonorgestrel) for over a year. The patient reported a usual body weight of 64 kg, with a height of 1.8 m, and had lost 6 kg in the previous month as a result of a CD flare-up. Nutritional support was started with oral supplements until resolution of the flare-up and the recovery of body weight. In the absence of data indicative of CD activity, control nutritional tests revealed normal albumin and ferritin levels, with no folic acid, vitamin B12 or liposoluble vitamin (A, E, D) deficiencies. Hypercupremia (plasma Cu 2.68 mg/l [normal range 0.8–1.55 mg/l]) was detected, with normal ceruloplasmin and zinc levels. Since the patient was taking OHC, which could possibly increase Cu levels, oral contraceptive suspension was decided upon, with a re-evaluation three months later, following the normalization of plasma Cu (Table 1).

The second case corresponded to a 19-year-old female with polycystic ovary syndrome receiving treatment with OHC (0.03 mg ethinylestradiol/3 mg drospirenone) for the previous four years. She was referred to the Nutrition clinic due to grade 2 overweight (weight 75 kg, height 1.59 m and a body mass index [BMI] 29.7 kg/m^2), and lifestyle modifications were prescribed (diet and physical exercise). Under asymptomatic conditions, control laboratory testing revealed Cu 2.39 mg/l (range 0.8–1.55 mg/l), with normal ceruloplasmin levels. After the results were confirmed, OHC was suspended, with a re-evaluation three months later, following the normalization of plasma Cu (Table 1).

In both cases the Cu measurements were made by the same laboratory. Cupremia was measured by atomic absorption spectrophotometry. This technique was used for all the Cu measurements (both basal and after the suspension of OHC); the normalization of plasma Cu therefore cannot be attributed to any change in the measurement method.

Copper is the third most abundant oligoelement in the body, after zinc and iron.[2] It is mainly bound to ceruloplasmin, with lesser amounts bound to albumin, or circulating free in plasma.

There is evidence of the influence of estrogens upon copper metabolism.[3] In this regard, there are differences between men and women,[4] with cyclic variations in the course of the menstrual cycle[1,5] or during pregnancy.[1] Although not stated in the Summary of Product Characteristics of most OHC, these drugs have been shown to increase plasma Cu by 0.57 mg/l on average. The mechanism underlying hypercupremia fundamentally comprises an increase in plasma ceruloplasmin as a consequence of estrogen action,[6] in a non-dose dependent manner.[7] The type of progestogen present in the OHC probably modulates the effect upon Cu metabolism, with a greater increase in cupremia among those patients receiving OHC containing progestogens with antiandrogenic actions.[8] The Cu transporters ATP7A and ATP7B are possibly implicated in OHC-mediated hypercupremia.[9] There is, therefore, an individual susceptibility to develop this side effect.

The clinical repercussion of hypercupremia secondary to OHC is not clear. Toxicity symptoms secondary to hypercupremia (usually of a digestive nature) are considered to appear when plasma levels exceed 3 mg/l,[2] with possibly fatal consequences on their exceeding 5 mg/l. According to a meta-analysis published in 2013, hypercupremia due to OHC usually does not exceed 2 mg/l.[6] The question is whether hypercupremia induced by prolonged OHC use can give rise to Cu deposits in the tissues and induce disease over the long term, particularly cardiovascular disorders. Epidemiological studies suggest that there is an association between Cu levels and an increase in mortality due

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