**Editorial** 

# Quality of life and treatment satisfaction are highly relevant patient-reported outcomes in type 2 diabetes mellitus

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What is important for the patient with diabetes? For sure, any person with a given chronic condition, like type 2 diabetes mellitus, is willing that the disease has a minimal impact of his/her life expectancy (years of life), and also that the condition does not impose a relevant burden on his/her daily life and well-being [quality of life (QoL)]. Clearly, the patient's desire is that the management of the disease keeps his/her life expectancy with the minimal burden on the QoL and optimal satisfaction with the therapeutic measures.

Type 2 diabetes has been shown to have a negative impact on the QoL of persons carrying this chronic condition (1). This impact involves the physical and emotional overload of diabetes, a disease that requires lifelong treatment, including lifestyle and pharmacological measures, often with multiple drugs. QoL is regarded as a subjective measure of health and well-being related to a disease. Although satisfaction with treatment has often been placed under the umbrella of QoL, this patientreported outcome stands on its own as a separate patientreported outcome that should be assessed with specific tools. Treatment satisfaction is a subjective measure that evaluates the patient's experience of the processes and results of treatment. Further, it is known that poor satisfaction with treatment compromises treatment adherence (2), which may have adverse consequences on the metabolic control of the disease and the risk of late complications and mortality (3,4).

There is a need to assess the impact of type 2 diabetes and its complications and of its overall clinical management on these patient-reported outcomes (3). Interestingly, an original article published recently by Bradley et al. reports on the different predictors of patient-reported outcomes in type 2 diabetes in the PANORAMA study (5). This was a large observational, multinational, multicenter crosssectional study in Europe, designed with the primary objective of assessing QoL and treatment satisfaction in a total of 5,813 subjects from nine countries (6). The researchers performed a thorough evaluation of demographic and clinical characteristics of the included subjects. QoL was measured by means of a specific tool, the Audit of Diabetes-Dependent Quality of Life (ADDQoL) (7), and the satisfaction with diabetes treatment was assessed through the Diabetes Treatment Satisfaction Questionnaire (DTSQ) (8). Both tools have been validated in different languages and settings, and they have been extensively used for research on these patient-reported outcomes in subjects with diabetes. Additionally, the PANORAMA researchers measured other PROs: the fear of hypoglycemia and the patient-reported health status.

Regarding QoL, the results of the PANORAMA study revealed that, despite the mean generic QoL score approached "good", the diabetes-related QoL was negative. The latter finding is in line with previous evidence coming from other studies (3,9,10). All the items in the QoL

questionnaire had a substantial negative average weighted impact, with all items having a negative score. Interestingly, the patient-reported health status in the PANORAMA study, as measured by a well-known generic tool (EQ-5D), had a quite positive score of 70.55 (maximum 100). These findings point to the importance of using disease-specific tools designed to assess QoL when studying a given chronic condition such as diabetes mellitus. It should be highlighted that many other studies on QoL in diabetes did not use questionnaires that are specifically designed for patients with the disease, like in a landmark trial of type 2 diabetes treatment (the United Kingdom Prospective Diabetes Study) (11). Additionally, as pointed out by the authors of the PANORAMA study, it is important to distinguish between health status and QoL; the measures of health status are often inadequately interpreted as and referred to as health related QoL. Thus, the ADDQoL, but not the EQ-5D scale, measures QoL. This may, at least in part, explain the discordance between the results of these two measures in many studies.

It should be pointed out that from all the items of the ADDQoL questionnaire the one that most negatively impacted was the "freedom to eat as I wish". This result confirms the findings of several other studies (3,9,10). Actually, using the ADDQoL and the DTSQ, our group has recently shown that the adherence to a healthy dietary pattern is positively associated to treatment satisfaction and some of QoL dimensions in type 2 diabetic patients (12).

The main interest of the PANORAMA study was that several potential predictors of the patient-reported outcomes could be assessed through multivariable analyses; this strategy allowed the study of the different contributors to QoL and treatment satisfaction. The assessment of the diabetes-related QoL (average impact score) showed a less negative impact of diabetes with increasing age. Additionally, insulin alone or in combination with other agents exerted an important negative impact on QoL. Other variables with a negative effect on QoL were poor glycemic control, microvascular complications and a diagnosis of depression. Concerning the ADDQoL generic QoL score, male sex, physician-reported good adherence and self-monitoring were associated with a better QoL, while depression, sleep disorders and insulin had strong negative impact.

Further, the results of the specific treatment satisfaction questionnaire showed that the DTSQ score was generally high, as perceived by the patients. Additionally, the authors also assessed the perception of the treating physicians who rated this lower than the patients. Thus, physicians perceived less satisfaction than the one rated by the own patient. This misperception of the treating physician was also confirmed for the specific items of hyper and hypoglycemia, i.e., physicians underestimated the impact of hypo and hyperglycemias as perceived by the patient. This misperception of the health-care professionals should be underlined as these findings emphasize the importance of the assessment of patient-reported outcomes in diabetes.

In the analysis of predictors of treatment satisfaction, while no patient characteristics were associated with this patient-reported outcome, good glycemic control and physician-reported good medication adherence were positively associated with satisfaction. Meanwhile, several other variables were associated with poorer treatment satisfaction: depression, weight gain and complexity of hypoglycemic treatment, among others. Importantly, treatment was not associated with the health status (EQ-5D scale), indicating that this is not a good measure to be used in clinical trials of diabetes treatment.

The PANORAMA study confirmed that the predictors of patient-reported outcomes varied widely. To reach valid conclusions on QoL in any study, we should measure QoL with a specific tool, and health-status is not a substitute of this outcome. Apart from the freedom to eat, there are two other predictors, insulin treatment and poor glycemic control, that were associated with worse QoL and treatment satisfaction. These findings are also in line with several other studies (3,7,9,13-16).

Unfortunately, in the PANORAMA study symptoms of depression were not assessed; however, a diagnosis of depression was associated with poorer QoL and treatment satisfaction. Future research in this field should focus on the study of the factors associated to any given therapeutic measures in type 2 diabetes to these patient-reported outcomes.

Healthcare professionals should bear in mind which are the primary goals of treatment in patients with diabetes, i.e., to prevent or delay the appearance of diabetes complications and increase the QoL (well-being) of the person with the disease. Of course, we clinicians use surrogate targets to take therapeutic decisions, i.e., glycated hemoglobin to assess glycemic control, and low-density lipoprotein concentrations or blood pressure for lipid-lowering and antihypertensive therapies, respectively, etc. However, the above-mentioned primary objectives are those that are actually relevant for the patient, and this includes relevant patient-reported outcomes, like the self-perceived QoL

and satisfaction with treatment among others. Additionally, we should consider the impact of any decision on the choice of any therapeutic measure, as this has an impact on the satisfaction perceived by the person with diabetes. Therefore, these patient-reported outcomes have to be taken into consideration in the clinical setting and in future research in the management of type 2 diabetes mellitus as these are important indicators of the quality of healthcare.

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#### **Footnote**

*Conflicts of Interest:* The author has no conflicts of interest to declare.

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