

## Patient-reported outcome measures in type 1 diabetes outpatient care

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### Abstract

**Background:** Patient-reported outcome measures (PROMs) assess how individuals perceive the disease and its impact on quality of life, representing an important complement to the metabolic evaluation in type 1 diabetes mellitus (T1DM). This study aimed to assess the PROMs and their association with metabolic control.

**Methods:** A cross-sectional study of adults with T1DM was conducted in the outpatient Endocrinology department between October 2022 and May 2023. Clinical, demographic, and continuous glucose monitoring (CGM) data were collected. Three PROMs were applied: the diabetes psychological adjustment scale (ATT18), the World Health Organization well-being index (WHO-5), and the patient health questionnaire (PHQ-9). Descriptive and bivariate statistical analyses were performed.

**Results:** We included 56 participants, aged  $41.2 \pm 14.6$  years, 58 % female, and 64 % of medium-high socioeconomic class. The disease duration of the cohort was  $21 \pm 14.6$  years, with 44.6 % on continuous subcutaneous insulin infusion (CSII) and 39.3 % presenting microvascular complications. Glycated hemoglobin of the cohort was  $8.0 \pm 1.4$  %, time in range (TIR)  $52 \pm 22$  %, coefficient of variation (CV)  $37 \pm 8$  %, and median time below range (TBR) 2 %. Individuals on CSII had higher TIR ( $p=0.03$ ). CV was related to TBR ( $p=0.643$ ,  $p<0.001$ ). The majority had satisfactory psychological adjustment to diabetes (ATT18  $\geq 60$ ), which correlated directly with WHO-5 ( $r=0.511$ ,  $p<0.001$ ) and inversely with depression symptoms ( $r=-0.676$ ,  $p<0.001$ ). No relationships were identified between metabolic control and PROMs ( $p=0.63$ ).

**Conclusions:** Including PROMs alongside detailed metabolic evaluation allows for individualized decision-making and active patient participation in diabetes management. These results underscore the importance of preventing depression, promoting well-being, and enhancing diabetes psychological adjustment in these patients, aiming to improve their quality of life. HIPPOKRATIA 2024, 28 (1):17-21.

**Keywords:** Type 1 diabetes, quality of life, metabolic control, patient reported outcome measures, psychological adjustment to diabetes

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### Introduction

Type 1 Diabetes Mellitus (T1DM) is a chronic, autoimmune disease often diagnosed at young ages with necessary lifelong insulin therapy and additional care regarding diet and lifestyle, resulting in a significant impact on daily life<sup>1,2</sup>. The patient's elevated responsibility for self-management and the requirement for continuous and daily treatment can lead to psychological distress and reduced quality of life<sup>3,4</sup>. Therefore, T1DM control and treatment should extend beyond assessing and optimizing glycemic control and complications. It should also encompass evaluating the psychological dimension by analyzing satisfaction with healthcare, well-being, and quality of life through assessing patient-reported outcome measures (PROMs)<sup>5</sup>.

PROMs are direct reports that extract health outcomes from the patient. Unlike clinical efficacy measures, evaluate how the patient feels about their health condition and/or treatment, their expectations, and the impact on quality

of life allowing a patient-centered approach by promoting communication and self-efficacy and involving the patient in setting goals for disease control<sup>6,7</sup>. Furthermore, PROMs can be quality indicators of the health system, enabling active patient participation to improve health care quality and guiding professionals to tailor their approach based on patient preferences, resulting in health gains<sup>7,8</sup>. Several studies have demonstrated that quality of life and psychological well-being determine the capacity and effectiveness of diabetes control as evidenced by the association between PROMs and glycemic control indicators, such as glycated hemoglobin (HbA1c)<sup>1,5,9,10</sup>. In the Portuguese context, Góis et al<sup>3</sup> with the diabetes psychological adjustment scale (ATT18) adapted and validated for the Portuguese population, revealed a positive association between psychological adjustment to diabetes and HbA1c in both type of patients with T1DM and T2DM<sup>3,4</sup> and suggested that lower distress and less depressive

symptoms are associated with better psychological adjustment<sup>4</sup>. In young adults with T1DM, a positive association between psychological adjustment to diabetes and treatment adherence was suggested<sup>11</sup>. The objective of this study is to assess the PROMs and how well-being and depressive symptoms relate to psychological adjustment to diabetes, and evaluate the relationship between PROMs and metabolic control.

## Materials and Methods

### Study Population

This study used a convenience sample of adults with T1DM seen in the Diabetes outpatient department of Endocrinology, Diabetes, and Metabolism of Santa Maria Hospital, Lisbon, between October 2022 and May 2023. Written consent was obtained from all patients, and the study was conducted following approval from the Ethics Committee of the Academic Medical Center of Lisbon-CAML (decision No 187/22, date: 15/07/2022). We obtained demographic and clinical information for enrolled patients. Glycemic control indicators were recorded, including: i) HbA1c from the latest analyses, ii) data from the ambulatory glucose profile generated by the FreeStyle Libre® software, obtained through the continuous glucose monitoring (CGM) system over the 14 days preceding the consultation day, and iii) presence of chronic complications. HbA1c was determined by high-pressure liquid chromatography, with a normal range of 4.0-6.0 % and a target <7.0 %, which is recommended for most adults diagnosed with T1DM<sup>12</sup>. Data obtained through CGM included: a) time in range (TIR): percentage of time in recommended glycemic range for individuals with T1DM (70-180 mg/dl), with a target value of  $\geq 70$  %; b) total time below range (TBR): percentage of time in hypoglycemia (<70 mg/dl), with the target value <4 % of the time; c) coefficient of variation (CV): glucose variability, with target values <36 % indicating greater glycemic stability<sup>12,13</sup>.

### PROMs

Well-being was assessed using the World Health Organization well-being index (WHO-5), with a score ranging from 0 (absence of well-being) to 100 (maximum well-being), and suboptimal well-being was considered to score <50<sup>9,14</sup>. The patient health questionnaire (PHQ-9) was used to evaluate the frequency of depression symptoms, with a score range of 0 to 25, and depression screening was conducted with scores  $\geq 10$  points<sup>15,16</sup>. We used the WHO-5 and PHQ-9 following the recommendations of the International Consortium for Health Outcomes<sup>7</sup>. To evaluate subjective adaptation to diabetes, the ATT18 was employed, comprising 18 questions related to stress and feelings of disintegration, guilt, embarrassment, and self-perceived ability to manage diabetes, including satisfaction with healthcare professionals<sup>3</sup>. Better psychological adjustment was considered to scores >60<sup>17</sup>. The content of this measure pertains to the previous two weeks. The questionnaires are self-fulfillment, with a Likert scale, and validated for the Portuguese population.

### Statistical Analysis

Data was analyzed using the IBM SPSS Statistics for Macintosh, Version 28.0 for Mac OS (IBM Corp., Armonk, NY, USA). We present parametric quantitative variables as mean  $\pm$  standard deviation, non-parametric data as median (minimum-maximum), and categorical variables as percentages. We verified the data's normal distribution of continuous variables with the Kolmogorov-Smirnov test and performed group comparisons using the t-student or chi-square tests. Metabolic control variables were dichotomized based on target values established for adults with T1DM<sup>12,13</sup>. We conducted bivariate correlations using Pearson correlation and Spearman correlation tests. Internal consistency analysis was performed for the applied questionnaires using the Cronbach's Alpha test to assess reliability. We considered p-values <0.05 (two-tailed) statistically significant.

## Results

A sample of 56 participants was obtained. The mean age was  $41.2 \pm 14.6$ . The majority were female (58.9 %) and of medium-high socioeconomic class (64.3 %) with a long duration of T1DM diagnosis ( $21.0 \pm 14.6$  years), mostly exceeding 10 years (71.4 %). Regarding the type of insulin treatment, 55.4% patients were on multiple daily insulin injections (MDII), while 44.6 % were under continuous subcutaneous insulin infusion (CSII), without integrated CGM. Thirty-nine percent of patients had at least one microvascular complication, 33.9 % retinopathy, 14.3 % nephropathy, 7.1 % neuropathy, and 7.1 % had at least one macrovascular complication.

### Metabolic control

The mean HbA1c was  $8.0 \pm 1.4$  %, with 67.9 % of individuals with HbA1c  $\geq 7.0$  %. The average percentage of TIR was  $52 \pm 22$  %, with 26.8 % of patients with TIR  $\geq 70$  % and 71.4 % below the recommended threshold. TIR correlated negatively with HbA1c ( $r = -0.631$ ,  $p < 0.001$ ). The mean CV was  $37 \pm 8$  %, above the recommended maximum of 36 %. In individuals with HbA1c <7.0 %, the mean CV was within the recommended range ( $33.5 \pm 8.5$  % vs.  $39.8 \pm 7.3$  %,  $p = 0.01$ ). Also, there was a trend for a lower CV in individuals with TIR  $\geq 70$  % ( $34.4 \pm 8.1$  % vs.  $38.9 \pm 8$  %,  $p = 0.082$ ). About TBR, median was 2 % and 64.7 % had recommended TBR of <4 %. A positive correlation was found between CV and TBR ( $\rho = 0.643$ ,  $p < 0.001$ ). Individuals on CSII spent an average of 13.03 % more TIR than those using MDII, and the difference is significant ( $59.2 \pm 17.9$  % vs.  $46.1 \pm 24.1$  %,  $p = 0.03$ ). However, no differences were observed in HbA1c between treatment groups ( $p = 0.86$ ).

### Psychological adjustment to diabetes

The Cronbach's Alpha test value obtained was 0.823, indicating good internal consistency for the scale. The percentages of responses for each question based on factors related to psychological adjustment to diabetes<sup>18</sup> are presented in Table 1. The mean value obtained for psychological adjustment to diabetes ATT18 was  $62.9 \pm 11.6$ , slightly

above the median for better adjustment, 60. About 63 % of individuals had an ATT18 score  $\geq 60$ , revealing good psychological adjustment to diabetes, contrasting with 37.5 % below the cut-point. No significant association was found between psychological adjustment to diabetes (ATT18) and the type of treatment, as well as metabolic control ( $p=0.63$ ).

#### WHO-5 and PHQ-9

The Cronbach's Alpha test values obtained for PHQ-9 and WHO-5 questionnaires were 0.857 and 0.939, indicating good and very good internal consistency. The mean score obtained in the PHQ-9 questionnaire was  $6.6 \pm 5.9$ , below the cutoff of 10, indicating the absence of depression, and a PHQ-9  $\geq 10$  was observed in 17.9 %. The mean score for the WHO-5 index was  $58.5 \pm 26.4$ , and a score  $< 50$  was identified in 33.9 %.

PHQ-9 correlated inversely with WHO-5 index scores ( $r = -0.694$ ,  $p < 0.001$ ). A PHQ-9 score  $\geq 10$  points (depression) was observed in 17.9 % of participants.

A negative correlation between psychological adjustment to diabetes (ATT18) and PHQ-9 ( $r = -0.676$ ,  $p < 0.001$ ) was identified. Psychological adjustment to diabetes was better in participants with no suggested depression (PHQ-9  $< 10$ ) ( $65.3 \pm 9.9$  vs.  $51.8 \pm 12.8$ ,  $p < 0.001$ ). The psychological adjustment to diabetes also positively correlated with the WHO-5 well-being index ( $r = 0.511$ ,  $p < 0.001$ ). No significant relation was observed between the WHO-5 and PHQ-9 and metabolic control.

#### Discussion

In this study, the majority of patients had HbA1c  $\geq 7.0$  % and TIR  $< 70$  %, falling outside the recommended target values<sup>12,13</sup>. This may be justifiable given the complexity of disease management and the significant level of responsibility for glycemic control placed on the patient themselves<sup>3,5</sup>. Besides that, despite many individuals being on CSII, these devices do not have integrated CGM ("hybrid insulin devices"), which continues to make self-management of glycemic control complex. This aspect reinforces the importance of personalized healthcare and a patient-centered approach to optimize metabolic control and prevent diabetes complications<sup>19</sup>. To achieve this, it is crucial to incorporate into the clinical assessment not only the monitoring of HbA1c but also the Ambulatory Glucose Profile, including CGM indicators such as TIR, TBR and CV<sup>12,13</sup>. Additionally, monitoring psychological well-being, quality of life, and attitude toward diabetes should be included, as their association with metabolic control has been demonstrated<sup>1,3,5,9</sup>.

HbA1c is unquestionably a key marker in clinical practice for assessing metabolic control. However, it only reflects the average glycemia over the past 2-3 months, presenting some limitations in the individualized management of the patient due to the lack of information on glycemic dynamics<sup>13</sup>. Therefore, including parameters related to glycemic variation obtained through CGM systems is an excellent complement to improving the qual-

**Table 1:** Psychological adjustment to diabetes (ATT18): Results were obtained for each question in order of concordance, according to the different factors related to psychological adjustment to diabetes ( $n=56$ ).

Question	Agree (%)	I don't know (%)	Disagree (%)
<b>Stress and feeling of disintegration</b>			
2. Diabetes has not changed my life at all.	89.3	1.8	9
7. The proper control of diabetes involves a lot of sacrifice and inconvenience.	66	1.8	32.1
1. If I did not have diabetes. I think I would be quite a different person.	60.7	7.1	32.2
11. Having diabetes for a long period changes the personality.	53.6	3.6	42.9
9. Being told you have diabetes is like being sentenced to a lifetime of illness.	37.5	8.9	53.6
18. I often think it is unfair that I should have diabetes when other people are so healthy.	26.8	12.5	60.7
3. Diabetes is the worst thing that has ever happened to me.	25	14.3	60.7
6. There is almost no hope of leading a normal life with diabetes.	10.8	1.8	87.5
<b>Guilt and embarrassment</b>			
10. In general, doctors need to be a lot more sympathetic in their treatment of people with diabetes.	28.5	14.3	57.1
5. There is not much I seem to be able to do to control my diabetes.	19.7	5.4	75
16. There is really no-one I feel I can talk openly about my diabetes.	17.8	5.4	76.7
8. I try not to let people know about my diabetes.	14.2	1.8	84
4. I often feel embarrassed about having diabetes.	10.7	0	89.3
<b>Self-perceived ability to manage stress and competence</b>			
12. Many times I even forget that I have diabetes.	44.6	1.8	53.5
13. Diabetes is not really a problem because it can be controlled.	35.7	5.4	58.9
17. I believe I have adjusted well to having diabetes.	26.8	7.1	66.1
15. I would like to know if my diabetes control has been poor.	17.9	17.9	64.3
<b>Tolerance for ambiguity</b>			
14. There is really nothing you can do if you have diabetes.	7.2	3.6	89.3

ity of metabolic assessment. These parameters provide a direct measure of glycemic variability that is easily interpretable by both patients and healthcare professionals and can facilitate individualized therapeutic decision-making, adjustments to insulin dosage, lifestyle changes, and the prevention of complications<sup>12,13</sup>. This study reinforces this idea, as significant associations were observed between CGM parameters such as TIR, TBR, and CV, as well as the important association between TIR and HbA1c and type of treatment. The relationship between TIR and HbA1c has been widely demonstrated, indicating that time spent within the recommended glycemic range significantly reduces HbA1c<sup>20-22</sup>. A similar association is observed in the present study, given the significant negative correlation found between TIR and HbA1c. Also, a significant association between CV and TBR was identified, indicating that lower glycemic variability is associated with a lower TBR. This finding is consistent with previous studies that suggested a positive association between the frequency of hypoglycemia and glycemic instability, as higher CV increases the risk of hypoglycemia<sup>23,24</sup>. Nevertheless, it was observed that patients with HbA1c <7.0 % had lower CV, suggesting that glycemic stability is also related to lower HbA1c<sup>24</sup>. Regarding the type of treatment, it was observed that patients on CSII spent more TIR than those with MDII. It can be explained by the greater glycemic stability provided by this type of treatment, which closely mimics physiological pancreatic function, is associated with a lower risk of hypoglycemia, and allows for more precise therapeutic adjustments based on the patient's needs<sup>25</sup>. In addition to a lower risk of hypoglycemia and no need for daily injections, CSII allows greater flexibility in lifestyle without compromising the quality of life for these individuals<sup>26</sup>. However, no significant differences were found in the HbA1c values between treatment groups ( $p = 0.86$ ).

Regarding the PROMs, most participants demonstrated good psychological adjustment to diabetes (ATT18 mean score >60) since the majority agreed that diabetes had not changed their life, had hope in leading an everyday life, and believed they could control diabetes, revealing a proactive approach to disease management (Table 1). These findings indicate increased flexibility and tolerance toward ambiguity and anxiety associated with the challenges in diabetes management<sup>18</sup>. Additionally, the limited perception of change in their lives due to diabetes can be explained by the prolonged time since diagnosis and the fact that their life choices have not been altered due to having diabetes<sup>4</sup>. However, many respondents consider that diabetes control entails significant sacrifice and inconvenience, which can be justified given the substantial responsibility of daily self-management of therapy, additional care regarding diet and lifestyle, and the resultant impact on daily life<sup>1,3,4</sup>. Negative feelings towards diabetes, such as guilt and embarrassment, were reported by only a small number of participants (Table 1). The majority also expressed satisfaction with medical care and considered that there exists understanding from

healthcare professionals in diabetes treatment. However, nearly 30 % believed that doctors should be more understanding in treating people with diabetes, revealing there is an opportunity for improvement in this regard. The satisfaction with healthcare professionals also reflects a more independent attitude in diabetes management<sup>18</sup>. Nevertheless, it is important to note that more than half considered that, in general, they have not adapted well to diabetes and yet still appreciate receiving feedback about poor control. This underscores the need to focus our efforts on understanding a patient's life experience in the context of their pathology, determining the psychological adjustment, well-being, and depression<sup>3,8,17</sup>.

Most participants demonstrate a favorable emotional state characterized by a predominantly positive attitude. Despite the low incidence of depressive symptoms, as indicated by PHQ-9, and predominantly favorable indicators of well-being given by WHO-5 results, the presence of depression was identified in 17.9 %, as well as suboptimal well-being in 33.9 %. According to previous studies, it is recommended to conduct further testing for depression in these patients, and these issues must be taken into account in patient management<sup>9</sup>. The applicability of both questionnaires has been demonstrated in the assessment of patients with diabetes, showing good sensitivity and specificity in identifying depressive symptoms in this group of patients<sup>9,14,15</sup>. The negative correlation between the WHO-5 well-being index and depression scores (PHQ-9) confirms concurrent validity between both tests in this study, similar to the findings of Hajos et al<sup>9</sup>. Additionally, ATT18 correlated inversely with PHQ-9 and directly with the WHO-5 index, suggesting that patients with better psychological adjustment to diabetes experience fewer symptoms of depression and enhanced well-being, indicating that lower distress aligns with better psychological adjustment. This highlights the importance of promoting behaviors in patients with T1DM that help overcome depression, enhance well-being, and facilitate adaptation to diabetes<sup>17</sup>.

It is considered that the present study contributes to the existing knowledge regarding patients with T1DM concerning their psychological adjustment to diabetes, quality of life, and metabolic control. However, such studies remain scarce, highlighting the need to further understand this group of patients according to their concerns to provide better healthcare. Therefore, this study emphasizes the importance of investigating CGM metrics and their utilization in clinical assessment, facilitating the necessary adjustments in a personalized way and making it more comfortable and intuitive to interpret for patients with diabetes. The fragilities of this study include the small sample size and the use of a convenience sample, which may compromise the statistical significance of the data and lead to limitations in the generalization of some obtained results. Therefore, the need for future research persists, particularly prospective studies that can better ascertain whether psychological adjustment, well-being, and quality of life indeed influence the ability to control diabetes, since the

present study did not allow for the demonstration of a significant relationship between these factors.

### Conclusion

In addition to the significant association between CGM metrics, HbA1c, and type of treatment, we identified that patients with positive adaptation to diabetes tend to experience fewer symptoms of depression and enjoy improved well-being. This suggests that reduced distress corresponds to better psychological adjustment. These results underscore the importance of preventing depression, promoting well-being, and enhancing psychological adjustment in this group, aiming to improve the quality of life. According to the results, to provide quality healthcare and a patient-centered approach, it is important to include PROMs as indicators of the well-being and quality of life, as well as psychological adjustment to diabetes, in assessing patients with diabetes alongside the detailed metabolic evaluation.

### Conflict of interest

The authors declare no conflict of interest.

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