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# Patient Reported Outcome Measures in Type 1 Diabetes Outpatient Care

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RESUMO

**Introdução |** As medidas de Resultados Reportados pelos Doentes (PROMs), avaliam como os próprios percecionam a doença e o impacto na qualidade de vida, representando um importante complemento à avaliação metabólica da pessoa com diabetes *mellitus* tipo 1 (DM1).

**Objetivo |** Avaliação dos PROMs e sua relação com controlo metabólico.

**Metodologia |** Estudo transversal de adultos com DM1 seguidos em consulta externa do serviço de Endocrinologia do Hospital de Santa Maria. Recolheram-se dados demográficos, clínicos, hemoglobina glicada (HbA1c) e perfil de ambulatório da glicose. Aplicaram-se 3 PROMs: Escala de Ajustamento Psicológico à Diabetes (ATT18), Índice de Bem Estar da OMS (WHO-5) e Questionário Sobre a Saúde do Paciente (PHQ-9). Realizou-se análise descritiva e bivariada dos dados.

**Resultados |** Incluídas 56 pessoas com DM1, com 41,2±14,6 anos, 58,9% do sexo feminino, 64,3% da classe socioeconómica média-alta e duração da doença 21,0±14,6 anos. 44,6% com perfusão subcutânea contínua de insulina (PSCI); 39,3% apresentam complicações microvasculares. HbA1c 8.0 ± 1.4%, Tempo no alvo (TIR) 52±22%, Coeficiente-de-Variação (CV) 37±8% e mediana de Tempo abaixo do alvo (TBR) 2%. As pessoas sob PSCI apresentaram maior TIR (59,2±17,9% vs. 46,1±24,1%, $p$=0.03), apesar de HbA1c idêntica. O CV relacionou-se diretamente com TBR ($\rho$ =0,643, $p$<0.001). A pontuação nos questionários foi: ATT18 62.89 ± 11.586, WHO-5 58.50 ± 26.429 e PHQ-9 6.61 ± 5.963. O ATT18 correlacionou-se diretamente com WHO-5 (r=0.511, $p$<0.001) e inversamente com PHQ-9 (r=-0.676, $p$ <0.001). Não foram identificadas relações entre o controlo metabólico e PROMs ($p$>0.05).

**Conclusões |** A monitorização contínua da glicose permite uma avaliação detalhada e ajustes terapêuticos mais precisos. A maioria revelou bom ajustamento psicológico à diabetes e este relaciona-se com o bem-estar e menor frequência de sintomas depressivos. Não se encontrou uma relação significativa entre PROMs e controlo metabólico, contudo, cerca de 1/3 dos indivíduos apresentou índice de bem-estar subótimo e 1/5 sintomas de depressão, revelando a importância de abordar a saúde mental a par do controlo metabólico. Incluir estas medidas possibilita uma abordagem individualizada, promovendo a adequação dos cuidados e a qualidade de vida desta população.

**Palavras-chave:** Diabetes tipo 1, PROMs, Ajustamento psicológico à diabetes, Qualidade de vida, Controlo metabólico.

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ABSTRACT

**Background |** The 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 of individuals with type 1 diabetes mellitus (T1DM).

**Purpose |** Assess the PROMs and their association with metabolic control.

**Materials and methods |** Cross-sectional study of adults with T1DM from the outpatient Endocrinology Department of Hospital de Santa Maria. Demographic and clinical data were obtained, as glycated hemoglobin (HbA1c) and ambulatory glucose profile. Three PROMs were applied: Diabetes Adjustment Scale (ATT18), WHO-5 Well-Being Index, and Patient Health Questionnaire (PHQ-9). Descriptive and bivariate analysis of the data was conducted.

**Results |** Included 56 individuals with T1DM, aged 41.2 ± 14.6 years, 58.9% female, 64.3% from the medium-high socioeconomic class, with a disease duration of 21.0 ± 14.6 years. 44.6% with continuous subcutaneous insulin infusion (CSII), 39.3% presented microvascular complications. HbA1c 8.0 ± 1.4%, Time in Range (TIR) 52 ± 22%, Coefficient of Variation (CV) 37 ± 8%, and median Time Below Range (TBR) 2%. Individuals on CSII had higher TIR (59.2 ± 17.9% vs. 46.1 ± 24.1%, $p$=0.03), despite similar HbA1c. CV was directly related to TBR (ρ =0.643, $p$ <0.001). The questionnaires scores were: ATT18 62.89 ± 11.586, WHO-5 58.50 ± 26.429, and PHQ-9 6.61 ± 5.963. ATT18 correlated directly with WHO-5 (r=0.511, $p$<0.001) and inversely with PHQ-9 (r=-0.676, $p$<0.001). No relationships were identified between metabolic control and PROMs ($p$>0.05).

**Conclusions |** Continuous glucose monitoring (CGM) allows for detailed assessment and precise therapeutic adjustments. Most individuals had good psychological adjustment to diabetes, which correlates with well-being and a low frequency of depressive symptoms. No significant relationship was found between PROMs and metabolic control, however, about 1/3 of individuals had suboptimal well-being scores, and 1/5 reported depressive symptoms, highlighting the importance of addressing mental health alongside metabolic control. Including these measures enables a personalized approach, promoting the adequacy of care and the quality of life of this population.

**Key words:** Type 1 Diabetes, PROMs, Psychological Adjustment to Diabetes, Quality of Life, Metabolic Control.

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# ABBREVIATIONS

ATT18 - Diabetes Psychological Adjustment Scale ATT18

CGM – Continuous Glucose Monitoring

CSII – Continuous Subcutaneous Insulin Infusion

CV – Coefficient of Variation

HbA1c – Glycated Hemoglobin

MDII – Multiple Daily Insulin Injections

PHQ-9 – Patient Health Questionnaire

PROMs – Patient Reported Outcome Measures

T1DM – Type 1 Diabetes *mellitus*

T2DM – Type 2 Diabetes *mellitus*

TBR - Time Below Range

TIR – Time In Range

WHO-5 – World Health Organization Well Being Index

# INTRODUCTION

Type 1 Diabetes Mellitus (T1DM) is a chronic, autoimmune disease often diagnosed at younger ages with necessary lifelong insulin therapy and additional care regarding diet and lifestyle, resulting in a significant impact on daily life (Alvarado-Martel et al., 2015; DiMeglio et al., 2018). The patients have substantial responsibility for disease control and complication prevention. T1DM demands a high level of daily self-management, involving frequent blood glucose level monitoring, insulin self-injection or handling continuous subcutaneous insulin infusion devices ("insulin pump"), regular insulin dose adjustments, carbohydrate counting, planning therapeutic adjustments based on daily changes, physical activity levels, regular attendance at periodic appointments and managing the chronic complications (Alvarado-Martel et al., 2015; Renard et al., 2021).

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 (Góis et al., 2006; C. J. Gois et al., 2012; Van Duinkerken et al., 2020).

The goal of treatment for T1DM patients is to maintain metabolic control and prevent the onset of chronic complications. Additionally, it is equally important for T1DM patients to achieve and maintain a good quality of life (Ehrmann et al., 2021; Saisho, 2018). Therefore, success in 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 the assessment of Patient-Reported Outcome Measures (PROMs) (Agarwal et al., 2022; Borg et al., 2019; Ehrmann et al., 2021; Wilmot et al., 2021).

PROMs are direct reports that extract health outcomes from the patient. Unlike clinical efficacy measures, PROMs evaluate how the patient feels about their health condition and/or treatment, their expectations, and the impact on quality of life (Churruca et al., 2021; Weldring & Smith, 2013). PROMs play a crucial role in healthcare, allowing a patient-centered approach by promoting communication and self-efficacy and involving the patient in setting goals for disease control (Nano et al., 2020; Van Der Wees et al., 2019). Furthermore, PROMs can be essential as quality indicators of the health system, enabling active patient participation to improve quality of health care, guiding professionals to tailor their approach based on patient preferences, resulting in health gains (Martin-Delgado et al., 2021; Nano et al., 2020).

Given that diabetes, particularly T1DM, is a chronic condition without a cure and associated with a significant impact on quality of life, the analysis of PROMs has the potential to develop stress management strategies related to the diabetes and achieve patient-centered care, going beyond decisions focused solely on optimizing glycemic control (C. J. Gois et al., 2012; Martin-Delgado et al., 2021).

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 HbA1c (Alvarado-Martel et al., 2015; Ehrmann et al., 2021; Hajos et al., 2013; Kuniss et al., 2016; Renard et al., 2021; Wilmot et al., 2021). Quality of life and the incidence of depressive symptoms in T1DM and Type 2 Diabetes *mellitus* (T2DM) patients have also been studied using the World Health Organization's Well-Being Index (WHO-5) and the Patient Health Questionnaire (PHQ-9) (Costantini et al., 2021; Hajos et al., 2013; Topp et al., 2015). The WHO-5 instrument can be used to track changes in well-being over time, and is recommended as a screening tool for emotional well-being by the International Diabetes Federation (Hajos et al., 2013).

In the Portuguese context, the WHO-5 questionnaire, alongside other measures, was also used to investigate the psychosocial factors in adults with T1DM and T2DM, their families and healthcare professionals and it was demonstrated that diabetes is associated with a significant impact on physical health and emotional well-being for patients as well psychosocial burden for their families (Nascimento Do Ó et al., 2022).

Furthermore, in Portugal studies focusing on T1DM and T2DM used the Diabetes Adjustment Scale (ATT18) adapted and validated for the Portuguese population by Góis *et al.* (2006). These studies revealed a positive association between psychological adjustment to diabetes and metabolic control, indicated by HbA1c values (C. Gois et al., 2011; Góis et al., 2006). Additionally, Góis *et al.* (2012) correlated diabetes psychological adjustment and self-regulation factors in patients with T1DM and T2DM, suggesting that lower distress and less depressive symptoms are associated with better psychological adjustment. In young adults with T1DM, the Diabetes Adjustment Scale (ATT18) was employed, revealing a positive association between psychological adjustment to diabetes and treatment adherence as well as a negative correlation between treatment adherence and life satisfaction and HbA1c (Serrabulho et al., 2014).

The objective of this study is to assess psychological adjustment to diabetes, well-being, and depressive symptoms, as well as to characterize the metabolic control of the sample. Additionally, it aims to evaluate relationships between metabolic control, psychological adjustment, and well-being. In addition to enhancing existing knowledge in the field, this work will provide a more detailed characterization of glycemic control in this group of patients since it includes data from continuous glucose monitoring (CGM) system, beyond HbA1c, type of insulin treatment and the presence of complications.

## MATERIALS AND METHODS

Study Population | This study was conducted using a convenience sample composed by adult patients, aged >18 years, diagnosed with T1DM seen in the Type 1 Diabetes and Continuous Subcutaneous Insulin Infusion (CSII) outpatient department of Endocrinology, Diabetes and Metabolism of Santa Maria Hospital, Lisbon. Each patient provided informed consent to participate in the study after receiving an invitation and explanation of the objectives. PROMs were collected by patient self-fulfill questionnaires while awaiting the consultation. The data from questionnaires and clinical information collection took place between October 2022 and May 2023. The entire study was conducted following approval from the Ethics Committee of the Academic Medical Center of Lisbon – CAML.

Demographic and clinical information | The demographic and clinical information was obtained through the clinical records prepared on the same day as the questionnaire completion. Socioeconomic class was obtained by applying the Graffar socioeconomic index, in which, class I represents the highest socioeconomic class, and Class V represents the lowest.

For the assessment of metabolic control, glycemic control indicators were recorded, including: 1) HbA1c value from the latest analyses, determined by high-pressure liquid chromatography (HPLC), with a normal range of 4.0% to 6.0%. Target HbA1c values < 7.0% are recommended for most adults diagnosed with T1DM (ElSayed et al., 2023a); 2) Data from the Ambulatory Glucose Profile generated by the *FreeStyle Libre*® software, obtained through the CGM system over the 14 days preceding the consultation day, including: a) Time in range (TIR), representing the percentage of time in the

recommended glycemic range for individuals with T1DM (70-180 mg/dl), with a target value of ≥70%; b) Time below range (TBR), representing the percentage of time spent in hypoglycemia, level 1 (54-69 mg/dl) and level 2 (<54 mg/dl). Total time below range (<70 mg/dl) was considered for present data analysis, with the target being <4% of the time; c) Glucose variability assessed by the coefficient of variation (CV), with target values <36% indicating greater glycemic stability (Battelino et al., 2019; Cardoso et al., 2018; ElSayed et al., 2023a); 3) presence of microvascular complications, including retinopathy, nephropathy and neuropathy; 4) presence of macrovascular complications, including cerebrovascular disease, peripheral vascular disease and ischemic heart disease. Additional recorded data also included: 1) presence of associated autoimmune diseases; 2) presence of Hashimoto's thyroiditis with or without hypothyroidism; 3) health services utilization like hospitalization or emergency episodes due to acute diabetes complications, hypoglycemia or ketoacidosis, in the 12 months preceding the consultation day; 4) attendance in psychiatry/psychology consultations; 5) presence of prescription of any drug treatment such as antidepressants, anxiolytics or antipsychotics.

### Patient Reported Outcome Measures

A combination of disease-specific and a generic PROMs was used. The World Health Organization Well-Being Index with 5 items (WHO-5) and the Patient Health Questionnaire (PHQ-9) were used as generic PROMs to evaluate the well-being and quality of life of patients, following the recommendations of the International Consortium for Health Outcomes (Nano et al., 2020). The Psychological Adjustment to Diabetes Scale (ATT18) was employed as a disease-specific PROM (Góis et al., 2006). The mentioned questionnaires are self-fulfillment, translated and validated for the Portuguese population.

Psychological Adjustment to Diabetes | To assess how the patient feels about diabetes, Psychological Adjustment to Diabetes questionnaire (ATT18), validated for the Portuguese population, was used (Góis et al., 2006). This instrument consists of 18 questions related to the patient individual perception of their own abilities to manage diabetes, integration, adaptation, and acceptance of diabetes, as well as the degree of satisfaction with healthcare professionals. Responses are scored on a Likert scale from 1

to 5: 1 = "strongly agree," 2 = "agree," 3 = "I don't know," 4 = "disagree," and 5 = "strongly disagree." To streamline data analysis, responses of "strongly agree" and "agree" as well as "strongly disagree" and "disagree" were combined into "agree" and "disagree" categories, as performed by Serrabulho *et al.* (2014).

Psychological adjustment and a positive attitude towards diabetes are greater as higher the total score obtained from the sum of the items and the total score varies from 18 to 90. A low score suggests that the patient perceives diabetes as inconvenient and intrusive (Góis et al., 2006). A median cut-off value of 60 was assumed for better psychological adjustment, according to Góis *et al.* (2011) meaning that scores higher than 60 indicate a positive attitude toward diabetes. Individual instructions for completing the scale were explained, as well as the interest in evaluating the patient's attitude towards diabetes.

Well-being | The patient well-being was assessed by the WHO-5 index that consists of 5 simple statements exploring the respondent subjective well-being during the 14 days preceding the assessment: "I felt cheerful and in good spirits," "I felt calm and relaxed," "I felt active and energetic," "I woke up feeling fresh and rested," and "My day has been filled with things that interest me." The degree to which these feelings are present is categorized on a Likert scale from 0 (never) to 5 (all the time). The score ranges from 0 to 25, multiplied by 4 to provide a final score as a percentage between 0 (absence of well-being) and 100 (maximum well-being). According to previous studies, a WHO-5 index cut-off < 50 indicates likely depression and further testing for depression is recommended in these patients (Hajos et al., 2013; Topp et al., 2015).

Depression Symptoms | The presence of depression symptoms was assessed by the PHQ-9 questionnaire, consisting of 9 questions related to diagnostic criteria for major depression, categorized on a Likert scale from 0 (never) to 3 (nearly every day). Total score range between 0 and 27. Participants indicate the frequency with which depression symptoms were experienced in the 14 days preceding the questionnaire completion, including the presence of depressed mood, diminished interest, changes in sleep and appetite, fatigue, feelings of worthlessness or excessive guilt, decreased ability to concentrate, psychomotor agitation or retardation and thoughts of self-harm or death. The total score corresponds to severity intervals of depression: 0-4, none-mild depression; 5-9, mild depression; 10-14, moderate depression; 15-19, moderately severe depression; and 20-27, severe depression (Kroenke et al., 2001). In this study, screening

of depression was conducted with scores ≥ 10 points (Costantini et al., 2021; He et al., 2020).

### Statistical Analysis

Data analysis was conducted using the "Statistical Package for Social Science" (SPSS) version 28.0 for Mac OS (SPSS Inc., IBM, New York, USA). Parametric quantitative variables are presented as mean ± standard deviation, non-parametric data as median (minimum-maximum) and categorical variables as percentages. The normal distribution of continuous variables was verified with Kolmogorov-Smirnov test. Group comparisons were performed using the t-Student test or Chi-square test, as appropriate. Metabolic control variables were dichotomized based on target values established for adults diagnosed with T1DM (Battelino et al., 2019; ElSayed et al., 2023a) to enable comparison between groups with better and worse glycemic control. Bivariate correlations were conducted using Pearson correlation and Spearman correlation tests, as appropriate. To assess the reliability of the scale results, internal consistency analysis was performed for the applied questionnaires using the Cronbach's Alpha test. *P* values < 0.05 (two-tailed) were considered statistically significant.

## RESULTS

The patient characteristics (56 patients) are presented in Table 1. The mean age was 41.2 ± 14.6 ranging from 20 to 73 years. The majority were female (58.9%, n=33) and medium-high socioeconomic class (64.3%). Patients have a long duration of T1DM diagnosis (21.0 ± 14.6 yeas), mostly exceeding 10 years (71.4%).

Regarding the type of insulin treatment, 31 participants (55.4%) on multiple daily insulin injections (MDII), while 25 (44.6%) are under continuous subcutaneous insulin infusion (CSII) Thirty-nine percent of patients (n=31) have at least one microvascular complication (33.9% with retinopathy, 14.3% with nephropathy, and 7.1% with neuropathy), and 7.1% (n=6) have at least one macrovascular complication. An association with other autoimmune disease is present in 30.4% (n=16), specifically Hashimoto's thyroiditis (18.8%, n=16) [with hypothyroidism (10.7%, n=6) and Hashimoto's thyroiditis without hypothyroidism (17.9%, n=10)] (Table1).

Hospital emergency care due to acute diabetes complications (ketoacidosis or hypoglycemia) in the 12 months preceding the consultation were need for 12.5% (n=7) of the individuals. Regarding the mental health, 19.6% (n=11) receive psychological/psychiatric counseling, and a quarter of the individuals (n=14) regularly receive psychoactive medications.

Metabolic Control | The results regarding HbA1c and CGM data are presented in Table 2. The HbA1c (%) values were available for the entire sample (n=56). TIR, CV and TBR were available for 55, 46, and 51 patients, respectively. A comparison was made between individuals with HbA1c ≥ 7.0% (worse metabolic control) and those with HbA1c <7.0% (better metabolic control) as shown in Table 3. The mean HbA1c value is 8.0 ± 1.4%, with 67.9% (n=38) of individuals having HbA1c values ≥ 7.0% (Table 2). The mean age of individuals with HbA1c <7.0% is not statistically different from the mean age of the group with HbA1c ≥ 7.0% (42.2 ± 16 vs. 40.8 ± 14.1; t=0.346; df= 54; $p$ =0.731).

Individuals with TIR ≥70% (better metabolic control) were compared to those with TIR<70% (worse metabolic control) (Table 4). The average percentage of TIR is 52 ± 22% (n=55), with 26.8% (n=15) of patients with TIR ≥ 70% and the majority (71.4%, n=40) below the recommended threshold.

A higher percentage of TIR correlates negatively with HbA1c values, indicating better metabolic control (r=-0.631, $p$ <0.01) (Figure 1). The majority of individuals with TIR ≥70%

(23.6%, n=13) have HbA1c values < 7.0%, while most individuals with HbA1c ≥7.0% (63.6%, n=35) spend less than 70% of time in range ($\chi^2$=27.256, df=1, *p* <0.001) (Table 3). The negative correlation and group comparison provided by the Chi-square test reveal that the association between HbA1c and TIR is statistically significant (*p* <0.05).

The CV mean value was 37 ± 8% (n=46), above the recommended maximum of 36%. In individuals with HbA1c < 7.0% (better metabolic control), the mean CV is within the recommended range (33.5 ± 8.5% vs. 39.8 ± 7.3%, t=2.663, df=44, *p*=0.01) (Table 3). Also, CV is lower in individuals with TIR ≥ 70% (34.4 ± 8.1% vs. 38.9 ± 8%, t=1.780, df=44, *p*=0.082) however this difference is not significant (Table 4).

In that concern about TBR, the median was 2% (n=51) and the majority of individuals 64.7% (n=33) had recommended TBR of <4% (better metabolic control), as shown in Table 2. A significant association between CV and TBR was found since it was observed that patients with TBR <4% (better metabolic control) have lower CV than patients with TBR ≥ 4% (worse metabolic control) (33.0 ± 6.6% vs. 44.2 ± 5.7%, t= -5.842, df = 43, *p* <0,001). Additionally positive correlation was found between CV and TBR ($\rho$ = 0,643, *p* <0.001) indicating that the lower glucose variability, the lower the TBR (Figure 2).

Individuals on CSII spend an average of 13.03% more TIR than those using MDII, and the difference is statistically significant (59.2 ± 17.9% vs. 46.1 ± 24.1%, t= -2.235, df=53, *p*=0.03). However, no differences were observed in HbA1c between treatment groups (8.0 ± 1.4% vs. 8.0 ± 1.5%; t= 0.112; df= 54; *p*= 0.911) and no differences were observed in CV (37.7 ± 9.3% vs. 37.2 ± 7.3%; t=0.213; df=44; *p*=0.833).

Mean age in TIR ≥ 70% group is similar to the mean age in the group with TIR <70% (45.8 ± 16.5 vs. 39.8 ± 13.8; t= -1.359; df=53; *p* =0.217). Similar observations are made with HbA1c <7.0% group (42.2 ± 16 vs. 40.7 ± 14.1, t=0.346, df=54, *p* =0.731).

Between individuals with and without microvascular complications, no significant differences were observed in HbA1c values (8.2 ± 1.7% vs. 7.8 ± 1.2%, t= -1,185, df= 54, *p*= 0.24) and CV (39.2 ± 8.9% vs. 36.3 ± 7.8%, t= -1.185, df= 44, *p*= 0.24).

Psychological Adjustment to Diabetes (ATT18) | The psychological adjustment to diabetes was analyzed using the ATT18 questionnaire. The internal consistency of the questionnaire was assessed through the Cronbach's Alpha test, yielding a value of 0.823, indicating good internal consistency for the scale.

In Table 6 and Figure 4, the percentages of responses for each content are presented in descending order of concordance. The analysis of questions was conducted based on different factors related to psychological adjustment to diabetes (Welch et al., 1994).

Regarding stress and feelings of disintegration (items 1, 2, 3, 4, 6, 7, 9, 11, and 18), it was observed that 89.3% (n=50) of individuals believe that their life is not altered by diabetes. However, two-thirds (66%, n=37) reported sacrifice and inconvenience in disease management. Approximately 60% (n=34) agreed that they would be different person if do not have diabetes, and 53.6% (n=30) considered that a prolonged diabetes diagnosis changes personality. More than a third (37.5%, n=21) felt condemned to be sentenced to a lifetime of illness. About a quarter (n=15) expressed a feeling of injustice compared to people without diabetes, stating that diabetes was the worst event in their life. Nevertheless, the majority (87.5%, n=49) expressed hope in leading a normal life.

Concerning feelings of guilt and embarrassment (items 4, 5, 8, 10, 16), the majority (89.3%, n=50) did not feel ashamed of having diabetes, did not try to hide their diabetes (84%, n=47), and 76.7% (n=43) had someone to talk to openly about their diabetes. Three-quarters of individuals (n=42) agreed that they can do something to control diabetes and 57.1% (n=32) believed that doctors are generally understanding in treating people with diabetes.

Regarding questions related to self-perceived ability to manage stress and competence to deal with diabetes (items 13, 15, 17), over half (66.1%, n=37) considered that they did not adjust well to having diabetes and 64.3% (n=36) and want to receiving feedback about poor diabetes control. However, only 35.7% (n=20) agreed that diabetes is not a problem because it is controllable. Concerning item 12, 53.5% (n=30) did not forgetting about having diabetes. Regarding aspects related to tolerance for ambiguity (item 14), 89.3% (n=50) of individuals did not feel incapable of controlling diabetes.

The mean value obtained for psychological adjustment to diabetes ATT18 was 62.89 ± 11.586 (Table 5), slightly above the median cut-point value for better adjustment, 60. About 63% of individuals had ATT18 score ≥ 60, revealing good psychological adjustment to diabetes, contrasting with 37,5% below de cut-point. In group comparisons (Table 7), similar psychological adjustment was found in both genders (64 ± 9.384 vs. 61± 12.940, t= 0.805, df=54, *p*=0.424), individuals aged ≥ 40 years or below 40 years (64.72 ± 12.404 vs. 60.93 ± 10.513, t= -1.232, df=54, *p* = 0.223), and those with a diagnosis duration ≥ 10

years or below 10 years (63.68 ± 10.990 vs. 60.94 ± 13.132, t=-0.796, df=54, *p*=0.429). Psychological adjustment in individuals using CSII is not significantly different from that of individuals performing MDII (65.28 ± 10.861 vs. 60.97 ± 11.965, t=-1.396, df=54, *p*=0.168).

Regarding the correlation with metabolic control (Table 8), no significant relation between psychological adjustment to diabetes and HbA1c was observed (r= - 0.065, *p*= 0.634), TBR (ρ=-0.014, *p*=0.92), TIR (r=-0.087, *p* = 0.58) and CV (r= 0.026, *p* = 0.863).

Well-being and Quality of Life (PHQ-9 and WHO-5) | The internal consistency of the PHQ-9 and the WHO-5 questionnaires was analyzed using the Cronbach's Alpha test, with values of 0.857 and 0.939, respectively. This classification indicates good and very good internal consistency for both scales. The mean score obtained in the PHQ-9 questionnaire was 6.61 ± 5.963, below the cutoff of 10, indicating the absence of depression. The mean score for the WHO-5 well-being index was 58.50 ± 26.429, above the cut-off <50 for likely depression (Table 5).

The PHQ-9 questionnaire is negatively correlated with the WHO-5 well-being index, revealing that higher scores on the PHQ-9, indicative of depressive symptoms, are associated with lower well-being (WHO-5). This association is statistically significant (r= -0.694, *p*<0.001), confirming the coherence between both tests results.

The frequency of each depression symptom experienced by participants in this study can be found in Table 9 and Figure 6 as well as the WHO-5 well-being indicators in Table 11 and Figure 5. A PHQ-9 score of ≥10 points (depression) was observed in 17.9% (n=10) of participants (Figure 7).

There is a strong negative correlation between psychological adjustment to diabetes (ATT18) and PHQ-9 (r=-0.676, *p* <0.001), as shown in Figure 3. Participants with no suggested depression (PHQ-9 < 10), psychological adjustment to diabetes is better than in participants with depression (65.30 ± 9.890 vs. 51.80 ± 12.839, t= 3.707, df= 54; *p*<0.001). The psychological adjustment to diabetes also showed a positive correlation with the WHO-5 well-being index (r=0.511, *p*<0.001), indicating that higher psychological adjustment to diabetes is associated with greater well-being (Figure 3).

No relation was observed between the WHO-5 index and HbA1c (r= -0.012, *p*= 0.932) or PHQ-9 and HbA1c (r= 0.032, *p*=0.813). Well-being indices in individuals with TIR ≥ 70%

were not different from those individuals with TIR <70% (worse metabolic control) (63.73 ± 20.334 vs. 57.50 ± 25.032, t=-0.785, df= 53, *p*=0.436).

No relation was found between age and the WHO-5 well-being index (r= 0.087, *p*= 0.523), or the PHQ-9 score (r= -0.056, *p*=0.684). No significant differences were observed in WHO-5 scores between male and female gender (63.9 ± 18 vs. 54.8± 30.6; t= 1.266, df= 54, *p* = 0.211) and between CSII treatment and MDII (64.3 ± 23.4 vs. 53.8 ± 28.1; t= -1.496, df= 54, *p* = 0.140).

## DISCUSSION

In this study, the majority of patients had HbA1c levels ≥ 7.0% and TIR <70%, falling outside the recommended target values (Battelino et al., 2019; ElSayed et al., 2023a). This may be justifiable given the complexity in disease management and the significant level of responsibility for glycemic control placed on the patient themselves (Góis et al., 2006; Shaban, 2015; Wilmot et al., 2021). This aspect reinforces the importance of personalized healthcare and a patient-centered approach to optimize metabolic control and prevent diabetes complications (Agarwal et al., 2022; Saisho, 2018). To achieve this, it is crucial to incorporate to the clinical assessment, not only the monitoring of HbA1c but also CGM indicators such as TIR, TBR and CV (Battelino et al., 2019; Cardoso et al., 2018; ElSayed et al., 2023a). Additionally, monitoring psychological well-being, quality of life and attitude toward diabetes should be included, as their association with metabolic control has been demonstrated (Alvarado-Martel et al., 2015; Borg et al., 2019; Góis et al., 2006; Hajos et al., 2013; Nardi et al., 2008; Wilmot et al., 2021).

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 (Battelino et al., 2019; Cardoso et al., 2018). Therefore, the inclusion of parameters related to glycemic variation obtained through CGM systems, such as TIR, TBR and CV, serves as an excellent complement to improve the quality of metabolic assessment. These parameters provide a more direct measure of glycemic variability that is easily interpretable by both patients and healthcare professionals (Battelino et al., 2019; Bellido et al., 2021; Cardoso et al., 2018). This inclusion is an important aid in individualized therapeutic decision-making, encompassing adjustments

to insulin dosage, lifestyle changes and the prevention of complications (Battelino et al., 2019; ElSayed et al., 2023a). So, 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 has a significant impact on reducing HbA1c values (Beck et al., 2019; Bellido et al., 2021; El Malahi et al., 2022; Vigersky & McMahon, 2019). A similar association is observed in the present study, given the significant negative correlation founded between TIR and HbA1c, with individuals with TIR ≥ 70% tending to have HbA1c <7.0%.

Additionally, a significant association between CV and TBR was identified. The results indicate that lower glycemic variability is associated with a lower TBR. This finding is in accordance with previous studies that suggested a positive association between the frequency of hypoglycemia and glycemic instability, as it is suggested that higher CV increases the risk of hypoglycemia (Bellido et al., 2021; Rodbard, 2020; Škrha et al., 2016). Nevertheless, it was observed that patients with better metabolic control given by HbA1c <7.0% have lower CV, suggesting that glycemic stability is related to lower HbA1c values (Škrha et al., 2016).

Regarding the type of treatment, it was observed that patients on CSII spend more TIR than those with MDII. However, no differences were found in the HbA1c values between treatment groups. Despite the clear differences between both study samples, this association between higher TIR and CSII treatment complements the results obtained by Figueiredo *et al.* (2023) where it was observed that individuals in CSII have lower HbA1c levels. This association between CSII and better glycemic control 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 needs (Abraham et al., 2021; Karges et al., 2017). 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 (Figueiredo et al., 2023). Furthermore, it might be possible that this group, due to increased training opportunities in diabetes management provided by healthcare system, is more motivated and capable of metabolic control.

The unequivocal advantages of using CGM and their metrics in metabolic assessment, alongside the benefits of CSII systems, reinforce the potential benefit that accessibility to *Hybrid Closed-Loop Insulin Delivery Devices* may have in the future for patients with T1DM (Phillip et al., 2023; Seget et al., 2023). Thus, this integration of insulin delivery systems with real-time continuous interstitial glucose monitoring has the potential to allow automatic adjustments in insulin administration, offering a significant improvement in glycemic control outcomes and quality of life (Phillip et al., 2023). Recently, in Portugal, strategies have been developed to make *Hybrid Closed-Loop Insulin Delivery Devices* available, aiming to ensure universal access for patients with T1DM in accordance with international recommendations (Direção Geral da Saúde, 2023).

Concerning chronic complications, no significant differences were observed in HbA1c and CV between patients with and without microvascular complications ($p$>0,05). This can be explained by the small sample size, as well as the cross-sectional type of this study, which does not allow us to know the type of metabolic control over time for individuals in this sample. However, this association between the risk for the development of complications and glycemic control has been strongly demonstrated (El Malahi et al., 2022; Kilpatrick et al., 2008; Škrha et al., 2016; Virk et al., 2016). This reinforces the clinical relevance of metabolic assessment in order to prevent the onset of complications. (Battelino et al., 2019; Bellido et al., 2021)

Regarding the PROMs, most participants demonstrated good psychological adjustment to diabetes (ATT18 mean score ≥60), since the majority has hope in leading a normal life and believe to have the capability to control diabetes, revealing a proactive approach to disease management (Figure 4 and 8). These findings indicate increased flexibility and tolerance toward ambiguity and anxiety associated with the challenges in diabetes management (Welch et al., 1994). The majority also expressed satisfaction with medical care and consider that exists understanding from healthcare professionals in diabetes treatment, however nearly 30% believe that doctors should be more understanding in the treatment of people with diabetes, revealing there is an opportunity for improvement in this regard. The satisfaction with healthcare professionals reflects a more independent attitude in diabetes management, in contrast to a small minority displaying a more dependent attitude on healthcare professionals (Welch et al., 1994). Negative feelings

towards diabetes, such as guilt, shame, and embarrassment, were reported by only a small number of participants, however, many respondents consider that diabetes control entails significant sacrifice and inconvenience. Nevertheless, it is important to note that more than half consider that, in general, they have not adapted well to diabetes and yet still appreciate receiving feedback about poor control. This underscores the need of focusing our efforts on understanding a patient's life experience in the context of their pathology, determining the psychological adjustment, well-being and depression (C. Gois et al., 2011; Góis et al., 2006; Martin-Delgado et al., 2021).

No significant differences were found in psychological adjustment to diabetes based on gender, age, duration of diagnosis, or type of treatment. Group comparisons generally revealed good psychological adjustment to diabetes, with an average score > 60 in all compared groups (Table 7).

No significant relationship was found between psychological adjustment (ATT18) and metabolic control given by HbA1c (%), contrasting with the results obtained in previous studies conducted in patients with T1DM and T2DM in Portugal (C. Gois et al., 2011; Góis et al., 2006). Also, no significant relationship between psychological adjustment was observed regarding de CGM parameters, TIR, TBR and CV.

Assuming the presence of depressive symptoms and well-being as indicators of quality of life (Nano et al., 2020), according to the results from the WHO-5 index and the PHQ-9, it is considered that the majority of individuals in this study exhibit a favorable emotional state characterized by a predominantly positive attitude. Despite the low incidence of depressive symptoms, as indicated by the responses obtained in PHQ-9 (Figure 6), and predominantly favorable indicators of well-being given by WHO-5 results (Figure 5), it was identified presence of depression (PHQ-9 ≥10) in 17.9%, as well as a suboptimal well-being (WHO-5<50) in 33.9% (Figure 7 and 8). 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 (Hajos et al., 2013). 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 (Costantini et al., 2021; Hajos et al., 2013; Topp et al., 2015). The strong 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 (2012).

Additionally, a negative correlation was observed between ATT18 scores (psychological adjustment to diabetes) and PHQ-9 scores, while a positive correlation was found between ATT18 scores, and the WHO-5 index. These results suggest that patients exhibiting better psychological adjustment to diabetes experience less 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 (C. Gois et al., 2011). Specifically in this context, according to Góis *et al.* (2011), it is suggested that the best way to address depressive symptoms simultaneously with diabetes management is through an integrated approach involving optimism, self-efficacy, and social functioning, alongside the promotion of behavioral strategies that facilitate adaptation to diabetes. Besides that, given that one-fourth regularly take psychoactive drugs and one-fifth of patients receive psychological support through regular consultations (Table 1), it is suggested that there is a potential benefit by reinforcing the network of psychological support for these patients alongside a careful assessment of the patient's social context.

The use of disease-specific PROMs in combination with generic PROMs has been recommended in the evaluation of individuals living with diabetes, aiming to engage these patients in the management of their treatment and the disease itself, providing better healthcare (Terwee et al., 2023). However, further studies are still needed, particularly regarding diabetes-specific PROMs. In this regard, it is considered that the present study provides a significant contribution to the existing knowledge regarding patients with T1DM concerning psychological adjustment to diabetes, well-being, quality of life and metabolic control.

Strengths in this research include the variability of clinical data, including chronic complications and type of insulin treatment alongside the diversity of parameters for evaluating glycemic control beyond HbA1c, including measures of glycemic dynamics provided by CGM systems such as TIR, TBR and glucose variability. This has permitted the identification of important relationships between these parameters and other indicators

of diabetes control. Therefore, this study emphasizes the importance of investigating these metrics of CGM systems and their utilization in clinical assessment, facilitating the necessary adjustments in a personalized way, more comfortable and more intuitive in interpretation for patients with diabetes.

The fragilities of this study include the small sample size, compromising the statistical significance of the data and leading to limitations in the generalization of the 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. A prospective assessment of PROMs will also enable a better evaluation of the effectiveness of treatments and patient satisfaction about healthcare provided, offering crucial insights as its primary purpose. In addition, it is important to provide prospective studies to better investigate the long-term benefits of CSII systems on metabolic control (ElSayed et al., 2023b). Considering the evident benefits of using CGM parameters in assessing glycemic control, as well as the benefits of CSII devices in improving metabolic control, it is also suggested to evaluate in the future, the benefits of introducing *Hybrid Closed Loop/Automatic Insulin Delivery Systems* in what concern the metabolic outcomes and patient reported outcomes.

## CONCLUSIONS

A T1DM is a condition with high complexity in its management, requiring significant responsibility on the part of the patient in disease management and control. In this study, the average TIR, CV and HbA1c are slightly outside the recommended values, confirming the complexity of achieving good metabolic control in these patients. A higher percentage of TIR is strongly associated with a lower HbA1c and with a reduction in glycemic variability. Nonetheless, a significant positive association between CV and TBR was identified, confirming that increased glycemic instability promotes hypoglycemia. The effect of CV in HbA1c was also noted, suggesting that less glycemic variability is related to better HbA1c control. Patients on CSII showed a 13% higher TIR compared to those undergoing MDII, revealing the benefit of this treatment in continuous glycemic control. Regarding de PROMs, it is generally considered that there is good psychological adjustment to diabetes. Most individuals had good psychological adjustment to diabetes, which correlates with well-being and a low frequency of depressive symptoms, and no relationship was found between PROMs and metabolic control. However, about 1/3 of individuals had suboptimal well-being scores, and 1/5 reported depressive symptoms, highlighting the importance of addressing mental health alongside metabolic control. Including these measures promotes a more personalized approach and quality of life of this population.

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## APPENDIX

| **Table 1** Demographic and clinical characteristics | |
|---|---|
| Male gender (*n, %*) | 23 (41.1%) |
| Female gender (*n, %*) | 33 (58. 9%) |
| Age (years)* | 41.2 ± 14.6 |
| ≥40 years (*n, %*) | 29 (51.8%) |
| <40 years (*n, %*) | 27 (48.2%) |
| Graffar socioeconomic index (*n, %*) | |
| Class I: high | 10 (17.9%) |
| Class II: medium-high | 36 (64.3%) |
| Class III: medium | 10 (17.9%) |
| Duration of T1DM* | 21.0 ± 14.6 |
| ≥10 years of T1DM (*n, %*) | 40 (71.4%) |
| <10 years of T1DM (*n, %*) | 16 (28.6%) |
| Treatment | |
| Multiple Daily Insulin Injection (*n, %*) | 31 (55.4%) |
| Continuous Subcutaneous Insulin Infusion (*n, %*) | 25 (44.6%) |
| Microvascular complications (*n, %*) | 31 (39.3%) |
| Retinopathy (*n, %*) | 19 (33.9%) |
| Neuropathy (*n, %*) | 4 (7.1%) |
| Nephropathy (*n, %*) | 8 (14.3%) |
| Macrovascular complications (*n, %*) | 6 (7.1%) |
| Ischemic heart disease (*n, %*) | 1 (1.8%) |
| Peripheral vascular disease (*n, %*) | 2 (3.6%) |
| Cerebrovascular disease (*n, %*) | 3 (5.4%) |
| Autoimmune disease (*n, %*) | 16 (30.4%) |
| Hashimoto Thyroiditis with hypothyroidism (*n, %*) | 6 (10.7%) |
| Hashimoto Thyroiditis without hypothyroidism (*n, %*) | 10 (17.9%) |
| Health service utilization due acute complications (*n, %*) | 7 (12.5%) |
| Psychiatric/Psychological consultations (*n, %*) | 11 (19.6%) |
| Drug treatment – antidepressants, antypsychotics, anxiolytics (*n, %*) | 14 (25%) |

*Data are presented as mean ± SD;

T1DM: Type 1 Diabetes mellitus.

| Table 2 HbA1c and Continuous Glucose Monitoring Data | |
|---|---|
| HbA1c (%)* | 8.0 ± 1.4 % |
| HbA1c ≥7,0 (*n, %*) | 38 (67.9%) |
| HbA1c < 7,0 (*n, %*) | 18 (32.1%) |
| TIR (%)* | 52 ± 22% |
| TIR ≥ 70% (*n, %*) | 15 (26.8%) |
| TIR <70% (*n, %*) | 40 (71.4%) |
| TBR (%)* | 2,0 % (0 – 38) |
| TBR < 4% (*n, %*) | 33 (64.7%) |
| TBR ≥ 4% (*n, %*) | 18 (35,3 %) |
| CV (%)* | 37 ± 8% |
| CV ≥ 36% (*n, %*) | 16 (28,6%) |
| CV < 36 % (*n, %*) | 30 (53,6%) |

HbA1c: glycated hemoglobin; TIR: time in range TBR: time below range; CV: coefficient of variation.

*Data shown are represented as means ± SD or median (minimum-maximum)

| Table 3 Comparison between patients with HbA1c ≥7.0% and HbA1c <7.0% | | | |
|---|---|---|---|
| | HbA1c ≥7.0% (n=38) | HbA1c < 7.0% (n=18) | *p*-value |
| Male gender (*n, %*) | 17 (30.4) | 6 (10.7) | 0.418 |
| Female gender (*n, %*) | 21 (37.5) | 12 (21.4) | 0.418 |
| Age* | 40.7 ± 14.1 | 42.2 ± 16 | 0.731 |
| Duration of T1DM* | 21.1 ± 14.1 | 20.8 ± 15.9 | 0.948 |
| TIR (%) * | 41.2 ± 16.3 | 74.4 ± 15.2 | <0.001 |
| TIR ≥ 70% (*n, %*) | 2 (3.6) | 13 (23.6) | <0.001 |
| TIR < 70% (*n, %*) | 35 (63.6) | 5 (9.1) | <0.001 |
| CV* | 39.8 ± 7.3 | 33.5 ± 8.5 | 0.011 |
| Microvascular complications (*n, %*) | 17 (30.4) | 5 (8.9) | 0.225 |

*P*-values were determined by student t-test and qui-square test.

T1DM: type 1 diabetes mellitus; HbA1c: glycated hemoglobin; TIR: time in range; CV: coefficient of variation.

*Data shown are represented as means ± SD

**Table 4**. Metabolic Control | Comparison between patients with TIR ≥70% and TIR <70%

| | TIR ≥70%<br>n=40 | TIR <70%<br>n=15 | *p*-value |
|---|---|---|---|
| Male gender (*n, %*) | 6 (10.9) | 16 (29.1) | 1.000 |
| Female gender (*n, %*) | 9 (16.4) | 24 (43.6) | |
| Age* | 45.8 ± 16.5 | 39.8 ± 13.8 | 0.180 |
| Duration of T1DM* | 25.7 ± 16.9 | 19.6 ± 13.3 | 0.165 |
| HbA1c (%)* | 6.7 ± 0.4 | 8.4 ± 1.4 | <0.001 |
| Glycemic variability (CV) * | 34.4 ± 8.1 | 38.9 ± 8 | 0.082 |
| Microvascular complications (*n, %*) | 6 (10.9) | 16 (29.1%) | 1.000 |

*P*-values were determined by student t-test and qui-square test.
T1DM: type 1 diabetes mellitus; HbA1c: glycated hemoglobin; TIR: time in range; CV: coefficient of variation.
*Data shown are represented as means ± SD

**Table 5.** PROMs | questionnaire scores

| | ATT18<br>n=56 | PHQ-9<br>n=56 | WHO-5<br>n=56 |
|---|---|---|---|
| Mean score* | 62.89 ± 11.586 | 6.61 ± 5.963 | 58.50 ± 26.429 |

*Data are presented as mean ± SD;
ATT18: Psychological adjustment to diabetes; PHQ-9: Patient Health Questionnaire; WHO-5: World Health Organization Well-being index

**Table 6.** PROMs | Psychological Adjustment to Diabetes (ATT18) – results obtained for each question in descending order of concordance (n=56).

| Question | Agree (%) | I don't know (%) | Disagree (%) |
|---|---|---|---|
| 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 |
| 12. Many times I even forget that I have diabetes. | 44.6 | 1.8 | 53.5 |
| 9. Being told you have diabetes is like being sentenced to a lifetime of illness. | 37.5 | 8.9 | 53.6 |
| 13. Diabetes is not really a problem because it can be controlled. | 35.7 | 5.4 | 58.9 |
| 10. In general. doctors need to be a lot more sympathetic in their treatment of people with diabetes. | 28.5 | 14.3 | 57.1 |
| 17. I believe I have adjusted well to having diabetes. | 26.8 | 7.1 | 66.1 |
| 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 |
| 5. There is not much I seem to be able to do to control my diabetes. | 19.7 | 5.4 | 75 |
| 15. I would like to know if my diabetes control has been poor. | 17.9 | 17.9 | 64.3 |
| 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 |
| 6. There is almost no hope of leading a normal life with diabetes. | 10.8 | 1.8 | 87.5 |
| 4. I often feel embarrassed about having diabetes. | 10.7 | 0 | 89.3 |
| 14. There is really nothing you can do if you have diabetes. | 7.2 | 3.6 | 89.3 |

**Table 7.** Psychological Adjustment to Diabetes (ATT18) - Comparison between groups

| | ATT18 | *p*-value |
|---|---|---|
| Male gender* | 64 ± 9.384 | 0.424 |
| Female gender* | 61 ± 12.940 | |
| Age ≥ 40 years* | 64.72 ± 12.404 | 0.223 |
| Age < 40 years* | 60.93 ± 10.513 | |
| Duration of T1DM ≥ 10 years* | 63.68 ± 10.990 | 0.429 |
| Duration of T1DM <10 years* | 60.94 ± 13.132 | |
| CSII* | 65.28 ± 10.861 | 0.168 |
| MDII* | 60.97 ± 11.965 | |

*P*-values were determined by student t-test.
T1DM: type 1 diabetes mellitus; CSII: continuous subcutaneous insulin infusion; MDII: multiple insulin injections
*Data shown are represented as means ± SD

**Table 8.** Psychological Adjustment to Diabetes (ATT18) - correlations with metabolic control

| | Test | *p*- value |
|---|---|---|
| HbA1c (%) | r = -0.065 | 0.634 |
| TIR (%) | r = - 0.087 | 0.58 |
| TBR (%) | $\rho$ = -0.014 | 0.92 |
| CV | r = 0.026 | 0.863 |

HbA1c: Glycated Hemoglobin; TIR: Time in Range TBR: Time Below Range; CV: coefficient of variation

**Table 9**. PROMs | PHQ-9 - results obtained for each question (n=56)

| Over the last two weeks. how often have you been bothered by any of the following problems? | Not al all (%) | Several days (%) | More than half the days (%) | Nearly every day (%) |
|---|---|---|---|---|
| Q1: Little interest or pleasure in doing things? | 37.5 | 44.6 | 8.9 | 8.9 |
| Q2. Feeling down, depressed, or hopeless? | 50 | 37.5 | 3.6 | 8.9 |
| Q3. Trouble falling or staying asleep. or sleeping too much? | 39.3 | 30.4 | 14.3 | 16.1 |
| Q4. Feeling tired or having little energy? | 14.3 | 51.8 | 21.4 | 12.5 |
| Q5. Poor appetite or overeating? | 53.6 | 28.6 | 7.1 | 10.7 |
| Q6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down? | 71.4 | 17.9 | 3.6 | 7.1 |
| Q7. Trouble concentrating on things. such as reading the newspaper or watching television? | 62.5 | 19.6 | 10.7 | 7.1 |
| Q8. Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual? | 64.3 | 30.4 | 3.6 | 1.8 |
| Q9. Thoughts that you would be better off dead or hurting yourself in some way? | 89.3 | 3.6 | 1.8 | 3.6 |

**Table 10**. PHQ-9: Major depression screening (n=56)

| PHQ-9 score | Total (n, %) |
|---|---|
| PHQ-9 ≥10 (depression) | 10 (17.9) |
| PHQ-9 < 10 (no depression) | 46 (82.1) |

Table 11. Well-being index WHO-5 | results obtained for each question (n=56)

| How did you feel in the last two weeks? | At no time (%) | Some of the time (%) | Less than half of the time (%) | More than half of the time (%) | Most of the time (%) | All of the time (%) |
|---|---|---|---|---|---|---|
| Q1: I have felt cheerful in good spirits. | 3.6 | 16.1 | 3.6 | 23.2 | 44.6 | 8.9 |
| Q2: I have felt calm and relaxed | 5.4 | 12.5 | 8.9 | 25 | 39.3 | 8.9 |
| Q3: I have felt active and vigorous | 8.9 | 12.5 | 12.5 | 26.8 | 28.6 | 10.7 |
| Q4: I woke up feeling fresh and rested | 12.5 | 16.1 | 8.9 | 26.8 | 28.6 | 7.1 |
| Q5: My daily life has been filled with things that interest me | 7.1 | 17.9 | 5.4 | 17.9 | 41.1 | 10.7 |

**Figure 1.** Correlation between Time in Range (TIR) and Glycated Hemoglobin (HbA1c)

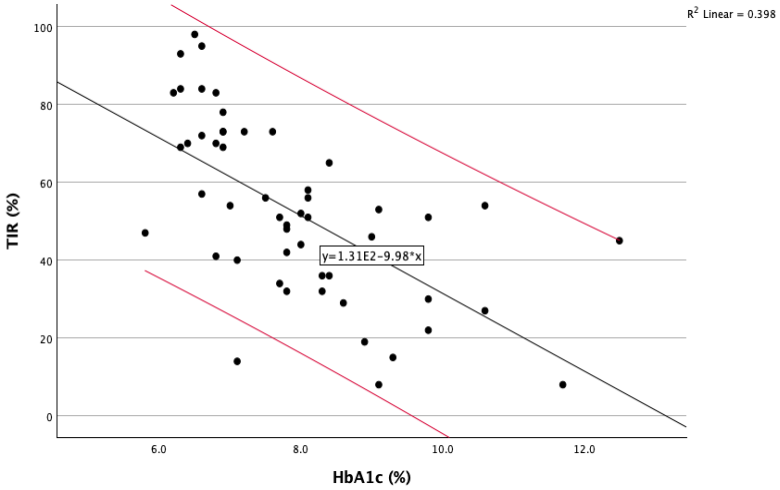


**Figure 2**. Correlation between glycemic variability (CV) and Time Below Range (TBR)

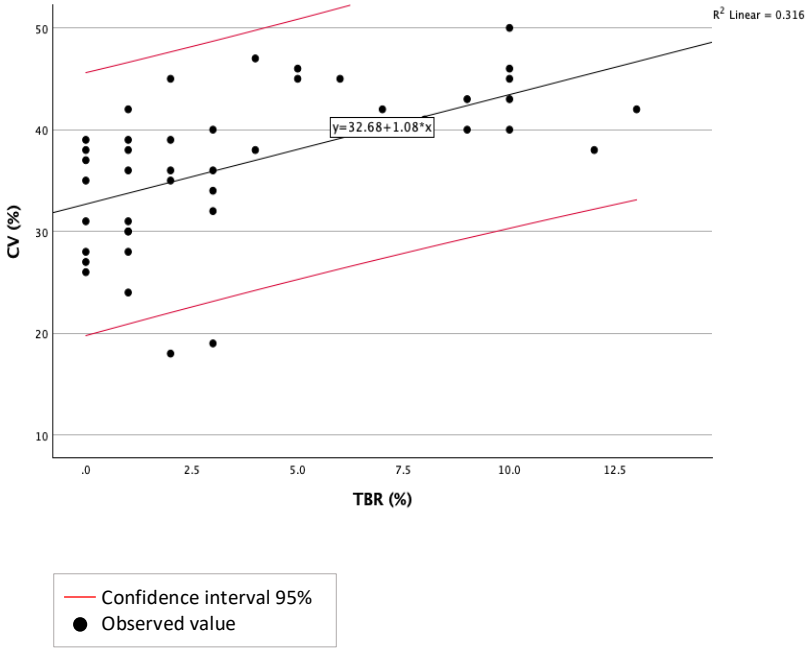

**Figure 3.** PROMs | Correlation between Psychological Adjustment (ATT18) and Well-being (WHO5) and Depression symptoms (PHQ-9)

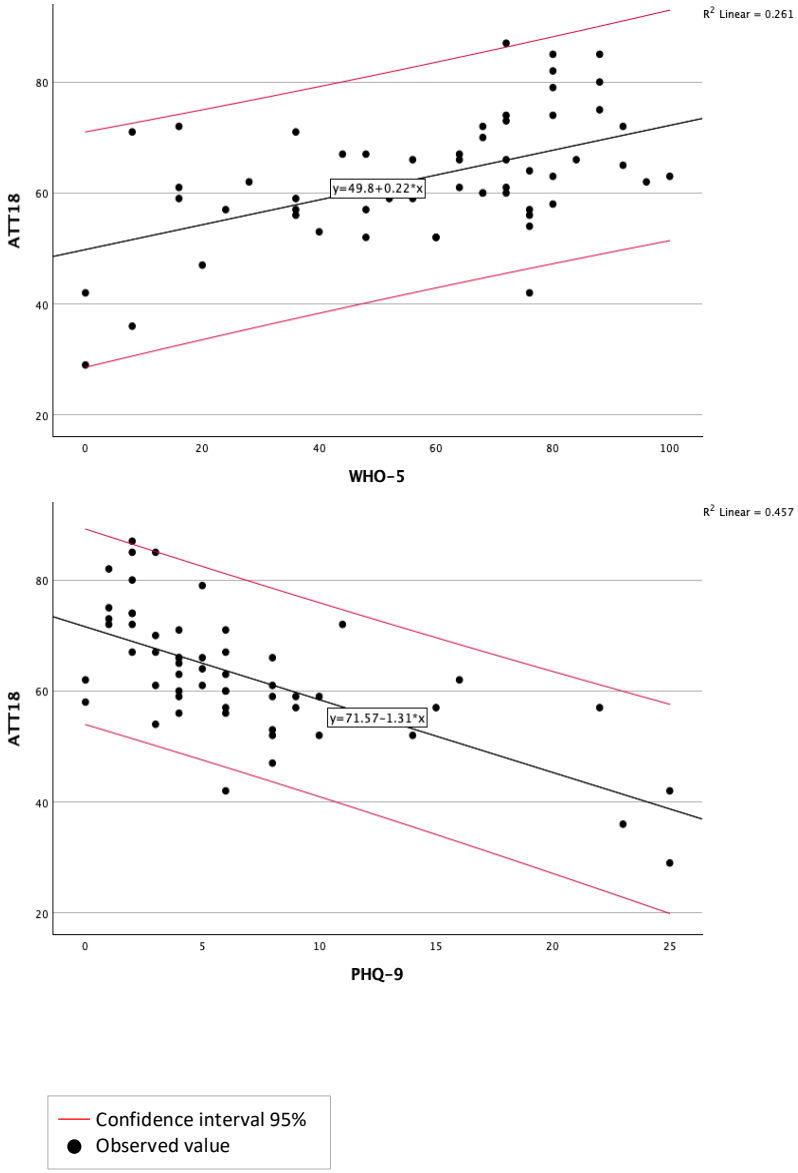

**Figure 4.** PROMs| Psychological Adjustment to Diabetes (ATT18) – results obtained for each question (n=56).

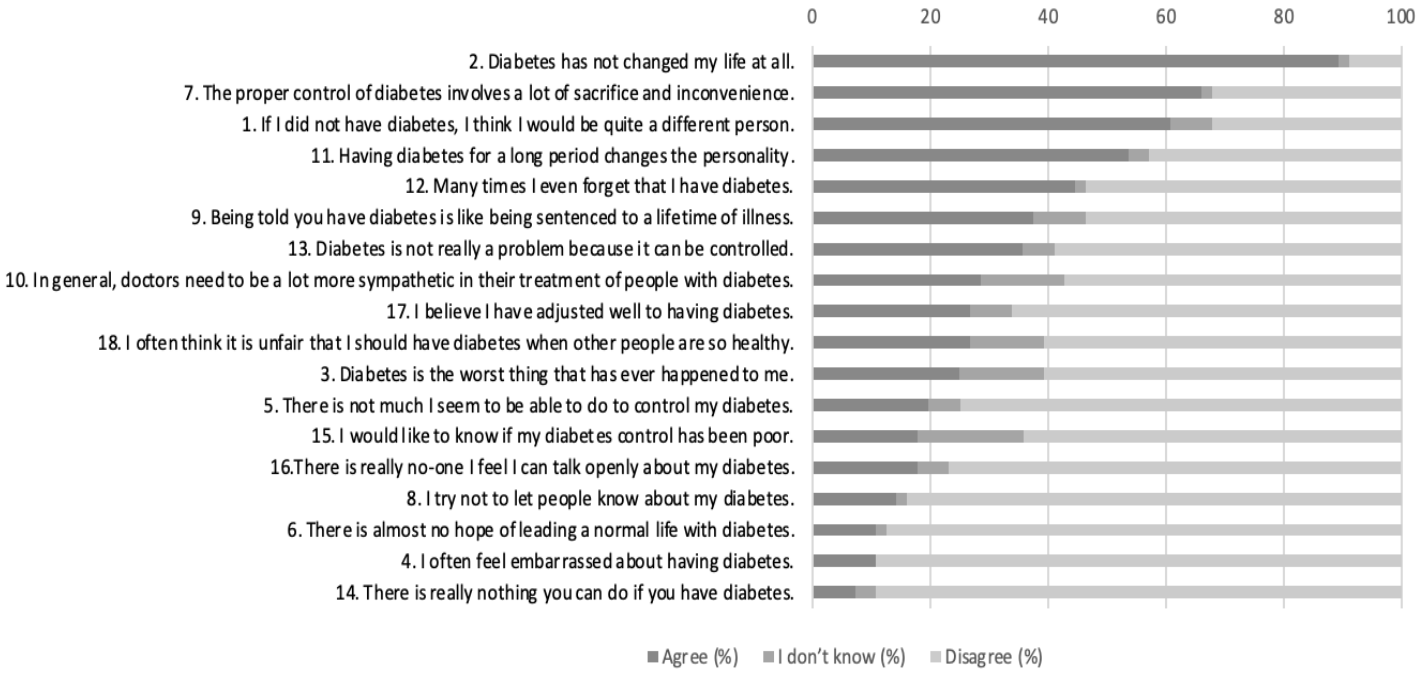


**Figure 5.** Well-being index WHO-5 | results obtained for each question (n=56).

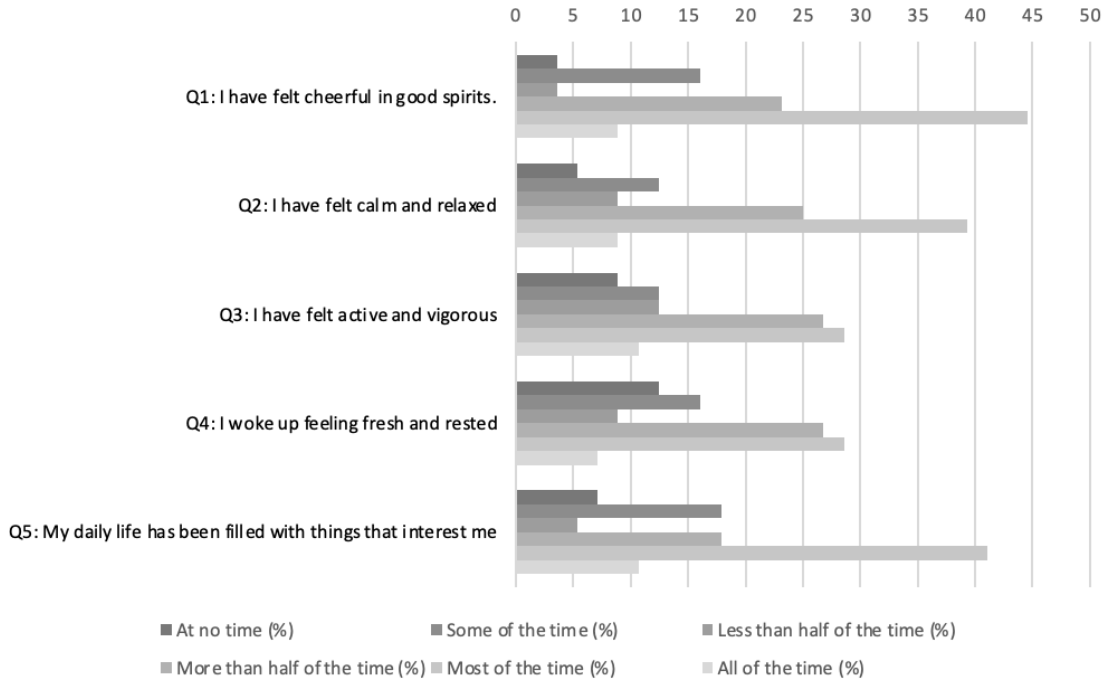

**Figure 6.** PROMs | PHQ-9 (Depression symptoms): results obtained for each question (n=56).

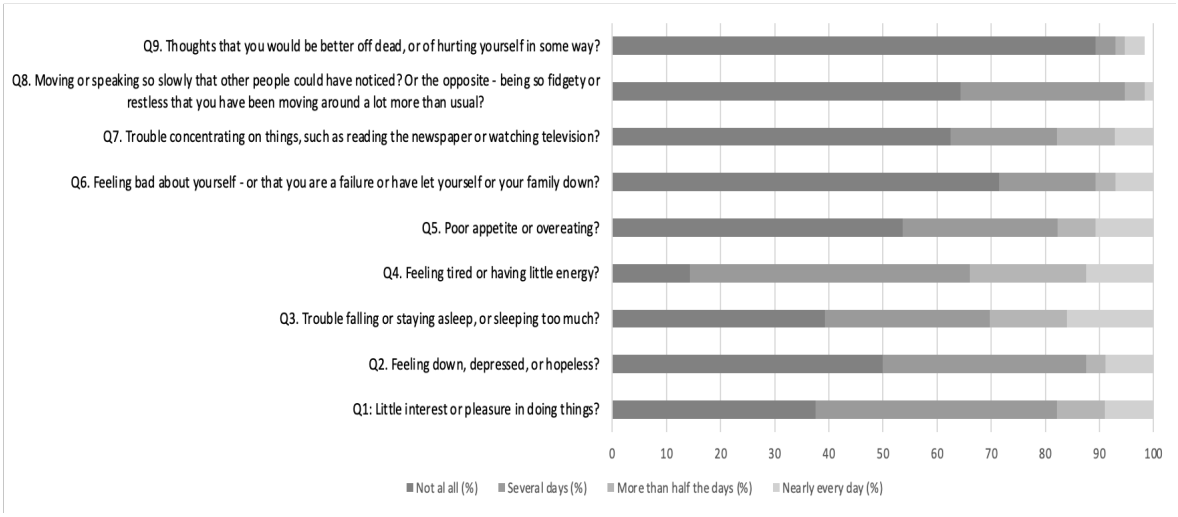


**Figure 6.** PROMs | PHQ-9: Major depression screening PHQ-9 ≥10

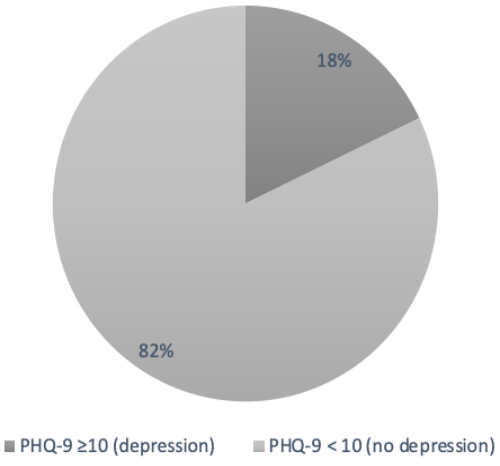


**Figure 7.** PROMs | WHO-5: Well-being index – recommended further testing for depression WHO <50.

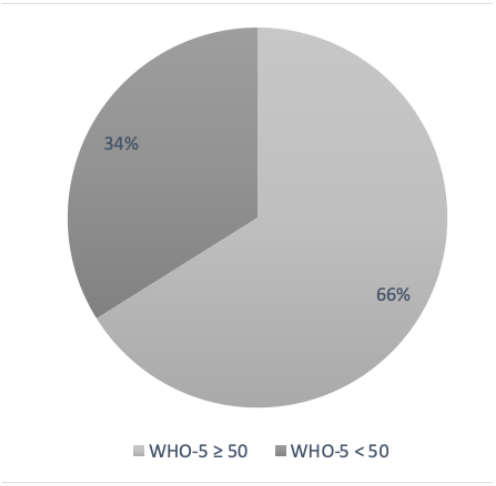


**Figure 8.** PROMs | ATT18 score ≥60: better psychological adjustment to diabetes