Analysis of the effect of therapeutic adherence on quality of life in patients with type 2 diabetes: A cross-sectional study

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ABSTRACT

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| **Background:** Type 2 diabetes (T2D) is one of the most important chronic non-communicable diseases that seriously threatens well-being, as it has become a significant health burden due to its high incidence, mortality, and secondary disability. Recent studies suggest that adherence to a treatment regimen associated with metabolic control of diabetes can reduce disease-related morbidity and mortality, while also increasing patients' quality of life, which is impaired by the chronic nature of the disease and multi-organ involvement.  **Objective:** To analyze the effect of therapeutic adherence on quality of life in patients with T2D attending the outpatient clinic of the Guanajuato General Hospital, Mexico.  **Study design:** Observational, cross-sectional, quantitative, analytical, and prolific study. Study site and date: The study was conducted in the outpatient clinic of Hospital General Guanajuato, Mexico, in patients with T2D, from January to April 2025. Methodology: Patients attending the outpatient clinic of Guanajuato General Hospital, Mexico, from January to April 2025, were invited to participate. Data such as weight, height, and blood pressure were collected; in addition, two questionnaires were administered: one to measure therapeutic adherence and another to assess health-related quality of life. Medical records were also reviewed to determine glycated hemoglobin levels, and participants who did not have a report within the last 1 month were asked to retest.  **Results:** The sample consisted of 100 patients diagnosed with T2D, of both sexes and aged 30 to 87 years. No statistically significant relationship was found between therapeutic adherence and health-related quality of life (X2 = 0.83; p = 0.36). Furthermore, the data indicated that variables such as age (OR = 1.61; p = 0.03), marital status (OR 1.34; p = 0.06), education (OR = 1.98; p = 0.045), and the presence of microvascular complications (OR 1.24; p = 0.0005) improved the multivariable model and acted as confounders.  **Conclusion:** In accordance with the study's objective, this investigation's findings indicate that there is no statistically significant relationship between therapeutic adherence and quality of life in patients with T2D. Future research should consider confounding variables to improve the association model. |

*Keywords: Type 2 diabetes, therapeutic adherence, metabolic control, quality of life.*

1. INTRODUCTION

Globally, Type 2 Diabetes (T2D) is one of the most important chronic non-communicable diseases that seriously threatens the well-being of the population. It has become a major health burden due to factors such as its high incidence, associated morbidity and mortality, and secondary disability [1]. Furthermore, because it is associated with debilitating and life-threatening diseases, it leads to a greater need for medical care, a decrease in quality of life, and premature death [2,3].

Mexico is among the countries with the highest prevalence of this disease in Latin America and the Caribbean, with a prevalence in adults of 11.0% (9.8% in men and 12.1% in women) according to the 2023 National Continuous Health and Nutrition Survey [3-6]. For the state of Guanajuato, an increase in prevalence is reported. In 2018, 9.9% of the population was reported to suffer from this condition, a figure that contrasts with the 12.5% reported for 2023. Both reports highlight the existence of a directly proportional relationship between prevalence and increasing age [6,7].

Due to its chronic and complex nature, T2D requires ongoing medical care and multifactorial therapeutic strategies focused on risk reduction [8-10], the main objectives of which will be the prevention of complications and optimization of quality of life [9-11].

The design of the therapeutic program should consider aspects such as life expectancy, the existence of complications specific to diabetes, the presence of neuropsychiatric disorders, comorbidities, individual preferences, evaluations, and goals of each patient, as well as the patient's cooperation and ability to understand the therapeutic plan [8-12].

Namely, lack of adherence is postulated as a major barrier to achieving good metabolic control to the detriment of preventing and/or delaying the onset of complications related to the disease [11,12]. Adherence is a multifaceted phenomenon that depends on the interaction of various factors related to the patient, the health care system, the disease, the treatment, and the socioeconomic context [13].

Furthermore, the chronicity, invasive nature of the symptoms, complications, and metabolic deterioration require a significant amount of energy, planning, and daily thought from the patient, resulting in a significant change in their well-being. This has a physical and emotional impact, leading to a reduction in autonomy and confidence. It also alters self-perception as they are unable to meet their goals, ultimately affecting their quality of life [12,13].

A circular relationship has been observed between therapeutic adherence and quality of life, with adherence considered an intermediate variable and quality of life the outcome. An increase in the former will have a positive effect on overall quality of life and diabetes-related quality of life [12, 14,15].

The objective of the study focused on determining the effect of therapeutic adherence on the quality of life of patients with T2D attending the outpatient clinic at the HGG in Mexico.

2. mETHODOLOGY

**2.2 Design and Participants**

The design was quantitative, observational, cross-sectional, analytical, and prolific. The sample consisted of 160 patients with T2D who attend the outpatient clinic monthly at the HGG, Mexico City. The research was conducted from January to April 2025. Simple random sampling was used to select 100 patients from the outpatient clinic.

**2.3 Selection Criteria.**

The inclusion criteria were: patients with T2D attending the HGG outpatient clinic, of both sexes, aged 18 years or older, who agreed to participate by signing an informed consent form.

Exclusion criteria included T2D diagnosed less than 12 months before diagnosis, pregnant women, and hospitalized patients.

Participants who did not attend the laboratory or did not complete the surveys were eliminated from the analysis.

**2.4 Variables.**

Regarding sociodemographic variables, the following were included: sex, age, occupation, marital status, and education. Anthropometric data such as weight, height, body mass index, and systemic blood pressure were also collected.

The following were considered independent variables:

• Therapeutic adherence: This is a dichotomous categorical variable. It corresponds to adherence to the therapeutic regimen. It was assessed using the Type 2 Diabetes Mellitus Treatment Adherence Scale (EATDM-III). It was measured as deficient with a score ranging from 0 to 66 and adequate with a score ranging from 67 to 100; it is presented with frequencies and percentages.

• Time of progression: This is a discrete quantitative variable. It is the time from the diagnosis of T2D to the time of inclusion in the project. It is measured in years. It is presented with mean and standard deviation.

• Complications: This is a nominal categorical variable. It is defined as the presence of macrovascular and microvascular complications. It is measured as the presence or absence of microvascular complications (nephropathy, retinopathy, neuropathy) and macrovascular complications (coronary artery disease, cerebrovascular event, peripheral arterial disease). It is presented with frequencies and percentages.

• Metabolic control: This is a dichotomous categorical variable. It is defined as the patient reaching metabolic balance according to HbA1c; it is measured as adequate <7% and inadequate ≥7%; it is presented with frequencies and percentages.

The dependent variable is:

• Health-related quality of life: This is a dichotomous categorical variable. It is the value assigned to life span, modified by social opportunity, perception, functional status, and impairment caused by illness, accident, treatment, or policy. It is measured using the instrument Diabetes 39. It was measured as unacceptable with ≥ 29 points and acceptable with < 29 points; it is presented as frequencies and percentages.

**2.5 Procedures**

Once approved by the Research Ethics Committee, the HGG outpatient clinic was visited, and patients with T2D were identified. Candidates were invited to participate. The research objectives were explained in detail, the information sheet was provided, and any questions were answered. Informed consent forms were subsequently read and signed by those who agreed to participate.

To collect anthropometric measurements, participants were weighed and measured using a mechanical scale with a Detecto Model 2491 stadiometer, following the manufacturer's specifications. Blood pressure was measured using a Welch Allyn® 767 Tycos® square pedestal android sphygmomanometer with a Velcro cuff for adults, according to the manufacturer's suggestions.

HbA1c levels were collected from the clinical records, and if no results were available within 1 month, a new sample was requested. This sample was processed in the HGG laboratory using the Bio-Rad D-10™ Hemoglobin Testing System and subsequently disposed of according to the provisions of NOM-087-SEMARNAT-SSA1-2002 [16].

Two additional questionnaires were administered. The "Type II Diabetes Mellitus Treatment Adherence Scale, version III (EATDM-III), designed to study treatment adherence in people diagnosed with T2D. The second, called "Diabetes 39," consists of 39 items that assess health-related quality of life.

**2.6 Instruments.**

Adherence will be assessed using the "Type II Diabetes Mellitus Treatment Adherence Scale, version III (EATDM - III)."

This is a 55-item Likert-type scale comprised of 7 behavioral factors: 1) family support; 2) community organization and support; 3) physical exercise; 4) medical monitoring; 5) hygiene and self-care; 6) diet; and 7) assessment of physical fitness.[20] Response options are: 0: "I never do it"; 1: "I rarely do it" (between 1% and 33% of cases); 2: "I do it regularly" (between 34% and 66% of cases); 3: "I almost always do it" (between 67% and 99% of cases); 4: "I always do it" (100% of cases) [17].

The scale is self-administered and may take approximately 20–30 minutes to complete. The items for each factor are indexed, and the total points for each scale are added, divided by the maximum Likert option for the variable, and multiplied by 100. Scores close to 100 indicate self-reported adherence closer to expected adherence guidelines for healthy living in people with T2D [17,18].

The scale has been applied in different contexts in Latin America and Mexico, with a total Cronbach's alpha of 0.88 for the instrument as a whole [17–20].

Villalobos-Pérez et al. report that the scale has adequate internal consistency and factorial structure [17].

Health-related quality of life was assessed using the "Diabetes 39" instrument. The Diabetes 39 questionnaire was designed to measure the quality of life in patients with type 1 diabetes (T1D) and T2D [21]. It is a multidimensional instrument, composed of 39 items that evaluate the Quality of Life Related to Health in relation to five domains: 1) Energy - Mobility (15 items), 2) Diabetes control (12 items), 3) Anxiety - worry (4 items), 4) Social burden (5 items), 5) Sexual functioning (3 items). Patients respond to how much their quality of life is affected during the last month by the action or activity that each item expresses [22].

Response options range from 1 (not at all affected) to 7 (extremely affected). The five domains are then supplemented with two final items that assess the patient's overall perception of their quality of life, with scores ranging from 1 to 7, and T2D severity, ranging from 1 (no severity) to 7 (extremely severe). The sum of the scores obtained in each section, the total score, and the self-perceived quality of life and T2D severity scores were transformed into a 0-to-100 scale using linear transformation formulas (e.g., Energy and Mobility: [(raw score – 15) / (105-15)] x 100]) [21].

It was adapted and validated in the Mexican population by López-Carmona et al. The internal consistency of the Spanish version of Diabetes 39 was high, with Cronbach's alpha values >0.8 for the sections and the total score [22]. It was subsequently culturally adapted by Yam Sosa et al., who reported a total Cronbach's alpha value of 0.94 [21].

**2.7 Sample Size Calculation**

Assuming that 80% of patients with therapeutic adherence will have good quality of life [23] and that 20% without therapeutic adherence will have good quality of life [15], the minimum sample size is 13 with adherence and 13 without adherence, aiming to increase this to 40 in each group, with 95% accuracy and 80% power. (Epi Info 7.2.6.0, 2023, CDC Atlanta, GA, USA).

**2.8 Statistical Analysis**

Descriptive statistics were used for sociodemographic variables. Categorical variables are represented as percentages and frequencies. To assess the association between adherence and quality of life, the chi-square test and *P*-value were calculated.

A multivariate analysis was performed using logistic regression, including sociodemographic variables such as age, gender, marital status, education, occupation, duration of treatment, comorbidities, and microvascular and macrovascular complications to determine whether the association model between adherence group and quality of life improved.

To demonstrate statistical significance of the results, in all cases, the *P*-value was fixed in .05

Statistical analysis was performed using STATA 13.0 software (STATA Corp., College Station, TX, USA).

3. results and discussion

One hundred participants (86.95%) completed the study, of whom 76 (76%) were women. The sample was characterized as follows: of the total interviewees, 53 (53%) were unemployed, up to 53 (53%) were married, and the most frequently reported level of education was primary education (31%). Regarding the therapeutic measures employed, the use of oral hypoglycemic agents was notable in up to 86% of respondents, followed by diet and exercise at 52% and 50%, respectively; and only 45% of respondents used insulin (Table 1).

Regarding complications secondary to T2D, microvascular complications were reported in up to 36 (36%) of the interviewees. Of these, 26 (26%) had retinopathy, 6% had nephropathy, and 14% had peripheral neuropathy. Regarding macrovascular complications, they were found in 9 (9%) participants, of these, 5 (5%) presented coronary artery disease, 0 (0%) cerebrovascular disease, and 4 (4%) peripheral arterial disease. Of the total participants, 4 (4%) manifested diabetic foot and 1 (1%) Charcot foot. Regarding comorbidities, 51% had at least 1 and 28% had none. Arterial hypertension was the most frequently associated comorbidity, being present in up to 67% of participants. Only 39% of participants met acceptable HbA1c levels. (Table 1)

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| **Table 1. Sociodemographic and health characteristics of the participants (n=100)** | | |
| **Sociodemographic variables** | **n %** | |
| **Sex** |  |  |
| Male | 24 | 24 |
| Female | 76 | 76 |
| **Occupation** |  |  |
| Unemployed | 53 | 53 |
| Homemaker | 28 | 28 |
| Employed | 6 | 6 |
| Retired | 5 | 5 |
| Other | 8 | 8 |
| **Marital status** |  |  |
| Single | 18 | 18 |
| Married | 53 | 53 |
| Divorced | 7 | 7 |
| Common-law | 4 | 4 |
| Widowed | 18 | 18 |
| **Education** |  |  |
| None | 24 | 24 |
| Elementary | 31 | 31 |
| Secondary School | 23 | 23 |
| High School | 11 | 11 |
| Technical Degree | 2 | 2 |
| Bachelor´s Degree | 9 | 9 |
| **Therapeutic measures used** | | |
| **Diet** |  |  |
| Takes | 52 | 52 |
| Does not take | 48 | 48 |
| **Exercise** |  |  |
| Takes | 50 | 50 |
| Does not take | 50 | 50 |
| **Oral hypoglycemic agent** | |  |
| Takes | 86 | 86 |
| Does not take | 14 | 14 |
| **Insulin** |  |  |
| Takes | 45 | 45 |
| Does not take | 55 | 55 |
| **Complications related to T2D** | | |
| **Microvascular complications** | | |
| Present | 36 | 36 |
| Absent | 64 | 64 |
| **Nephropathy** |  |  |
| Present | 6 | 6 |
| Absent | 94 | 94 |
| **Retinopathy** |  |  |
| Present | 26 | 26 |
| Absent | 74 | 74 |
| **Neuropathy** |  |  |
| Present | 14 | 14 |
| Absent | 86 | 86 |
| **Macrovascular complications** | | |
| Present | 9 | 9 |
| Absent | 91 | 91 |
| **Coronary artery disease** | |  |
| Present | 5 | 5 |
| Absent | 95 | 95 |
| **Cerebrovascular disease** | | |
| Present | 0 | 0 |
| Absent | 0 | 0 |
| **Peripheral arterial disease** | | |
| Present | 4 | 4 |
| Absent | 96 | 96 |
| **Diabetic foot** | |  |
| Present | 4 | 4 |
| Absent | 96 | 96 |
| **Charcot foot** | |  |
| Present | 1 | 1 |
| Absent | 99 | 99 |
| **Comorbidities** | | |
| **High blood pressure** | |  |
| Present | 67 | 67 |
| Absent | 33 | 33 |
| **Number of comorbidities** | | |
| 3 or more | 6 | 6 |
| 2 comorbidities | 15 | 15 |
| 1 comorbidity | 51 | 51 |
| None | 28 | 28 |
| **Metabolic control (HbA1c)** | | |
| Compliant | 39 | 39 |
| Not compliant | 61 | 61 |
| *T2D Type 2 Diabetes*  *HbA1c: glycated hemoglobin*  *Source: Own design* | | |

The mean age of the sample was 61.31 ± 10.16 years, with a range of 30 to 87 years. The time of evolution of T2D ranged from 1 to 45 years, with a mean and standard deviation of 14.35 ± 10.38 years, respectively. The mean and standard deviation for systolic blood pressure (SBP) were 124.05 ± 15.96, for diastolic blood pressure (DBP) 72.78 ± 9.58, Body Mass Index (BMI) 31.03 ± 5.69 and glycated hemoglobin (HbA1c) was 8.05 ± 2.07 (Table 2).

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| **Table 2. Distribution of quantitative variables (n=100)** | | |
| **Quantitative variable Range Mean ± S** | | |
| Age (years) | 30-87 | 61.31 ± 10.16 |
| Time since onset (years) | 1 a 45 | 14.35 ± 10.38 |
| Weight (Kg) | 48-109.9 | 74.12 ± 14.29 |
| Height (m) | 1.37-1.8 | 1.55 ± 0.09 |
| BMI (kg/m2) | 19.05-48.85 | 31.03 ± 5.69 |
| SBP (mmHg) | 98-190 | 124.05 ± 15.96 |
| DBP (mmHg) | 50-100 | 72.78 ± 9.58 |
| HbA1c (%) | 5-14.5 | 8.05 ± 2.07 |
| *BMI: Body Mass Index, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, HbA1c: Glycated Hemoglobin*  *Source: Own design* | | |
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Table 3 shows the relationship between the therapeutic adherence categories and quality of life, with a σ^20.83, 1 df, and a p-value of 0.36. Regarding therapeutic adherence, 83% (n=83) showed poor therapeutic adherence, while only 17% (n=17) participants reported adequate adherence. Regarding quality of life, 33% (n=33) reported an unacceptable quality of life and 67% (n=67) reported an acceptable quality of life.

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| **Table 3.** Association between therapeutic adherence categories and quality of life | | | | | | | |
|  | **Quality of life** | | | | | | |
|  | Not acceptable | | Acceptable | | **χ2** | **df** | ***P -*value** |
| **Therapeutic adherence** | **n** | **%** | **n** | **%** | 0.83 | 1 | 0.36 |
| Poor | 29 | 87.88 | 54 | 80.6 |  |  |  |
| Adequate | 4 | 12.12 | 13 | 19.4 |  |  |  |
| *df degree of freedom*  *Source: Own elaboration* | | | | | | | |

Table 4 shows the association between the dimensions of therapeutic adherence (family support, community organization and support, physical exercise, medical monitoring, hygiene and self-care, diet, and physical condition assessment) measured with the "Type II Diabetes Mellitus Treatment Adherence Scale version III (EATDM - III)" instrument and the quality of life categories (unacceptable and acceptable) measured with the "Diabetes 39" instrument. The dimensions most affected or with low scores on the scale were found to be: family support 62% (n=62) and medical monitoring 55% (n=55). In contrast, the dimensions with the highest scores were: community organization 59% (n=59) and diet 74% (n=74). However, none of the dimensions showed a statistically significant association. Similarly,

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| **Table 4.** Association between therapeutic adherence dimensions and quality of life categories (n=100) | | | | | | | | | | | |
|  | **Quality of life** | | | | |  | |  | |  | |
| **Therapeutic adherence dimensions** | No acceptable | | Acceptable | | |  | |  | |  | |
|  | **n** | **%** | **n** | | **%** | | **χ2** | | **df** | | ***P*-value** |
| **Family Support** |  |  |  |  | | | 3.02 | | 2 | | 0.22 |
| Low | 20 | 60.61 | 42 | 22.39 | | |  | |  | |  |
| Medium | 9 | 27.27 | 10 | 14.93 | | |  | |  | |  |
| High | 4 | 12.12 | 15 | 62.69 | | |  | |  | |  |
| **Community Organization and Support** |  |  |  |  | | | 0.22 | | 2 | | 0.9 |
| Low | 6 | 18.18 | 11 | 16.42 | | |  | |  | |  |
| Medium | 7 | 21.21 | 17 | 25.37 | | |  | |  | |  |
| High | 20 | 60.61 | 39 | 58.21 | | |  | |  | |  |
| **Physical Exercise** |  |  |  |  | | | 1.17 | | 2 | | 0.6 |
| Low | 3 | 9.09 | 10 | 14.93 | | |  | |  | |  |
| Medium | 15 | 45.45 | 24 | 35.82 | | |  | |  |
| High | 15 | 45.45 | 33 | 49.25 | | |  | |  | |  |
| **Medical Monitoring** |  |  |  |  | | | 2.71 | | 2 | | 0.1 |
| Inadequate | 22 | 66.67 | 33 | 49.25 | | |  | |  | |  |
| Adequate | 11 | 33.33 | 34 | 50.75 | | |  | |  | |  |
| **Hygiene and Self-Care** |  |  |  |  | | | 0.25 | | 1 | | 0.6 |
| Inadequate | 12 | 36.36 | 21 | 31.34 | | |  | |  | |  |
| Adequate | 21 | 63.64 | 46 | 68.66 | | |  | |  | |  |
| **Diet** |  |  |  |  | | | 2.02 | | 2 | | 0.37 |
| Low | 1 | 3.03 | 3 | 4.48 | | |  | |  | |  |
| Medium | 10 | 30.3 | 12 | 17.91 | | |  | |  | |  |
| High | 22 | 66.67 | 52 | 77.61 | | |  | |  | |  |
| **Physical Condition Assessment** |  |  |  |  | | | 1.36 | | 2 | | 0.51 |
| Low | 8 | 24.24 | 24 | 35.82 | | |  | |  | |  |
| Medium | 21 | 63.64 | 36 | 53.73 | | |  | |  | |  |
| High | 4 | 12.12 | 7 | 10.48 | | |  | |  | |  |
| *df degree of freedom*  *Source: Own elaboration* | | | | | | | | | | | |

Table 5 shows the association between quality of life dimensions (Energy and Mobility, Diabetes Control, Anxiety/Worry, Social Burden, and Sexual Functioning) and therapeutic adherence categories. In this regard, most dimensions are classified as acceptable, as more than 50% of participants fall into this category.

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| **Table 5. Association between scores on quality of life dimensions and therapeutic adherence categories (n=100)** | | | | | | | |
| **Quality of life dimensions** | **Therapeutic adherence**  **Poor Adequate** | | | |  |  |  |
|  | **n** | **%** | **n** | **%** | **χ2** | **gl** | ***P* -value** |
| **Energy and mobility** | |  |  |  | 0.12 | 1 | 0.73 |
| Not acceptable | 38 | 84.44 | 7 | 15.56 |  |  |  |
| Acceptable | 45 | 81.22 | 10 | 18.18 |  |  |  |
| **Diabetes control** | |  |  |  | 0.42 | 1 | 0.5 |
| Not acceptable | 32 | 80 | 8 | 20 |  |  |  |
| Acceptable | 51 | 85 | 9 | 25 |  |  |  |
| **Anxiety/Worry** | |  |  |  | 0.18 | 1 | 0.28 |
| Not acceptable | 31 | 88.57 | 4 | 11.43 |  |  |  |
| Acceptable | 52 | 80 | 13 | 20 |  |  |  |
| **Social burden** |  |  |  |  | 0.23 | 1 | 0.63 |
| Not acceptable | 19 | 86.36 | 3 | 13.64 |  |  |  |
| Acceptable | 64 | 82.05 | 14 | 17.95 |  |  |  |
| **Sexual functioning** | |  |  |  | 0.54 | 1 | 0.46 |
| Not acceptable | 22 | 78.57 | 6 | 21.43 |  |  |  |
| Acceptable | 61 | 84.72 | 11 | 15.28 |  |  |  |
| *df degree of freedom*  *Source: Own elaboration* | | | | | | | |

Additionally, the multivariate logistic regression model, using quality of life as the dependent variable and therapeutic adherence as the independent variable for age and education, yielded an OR of 1.75 (95% CI: 0.52 to 5.84), with a p-value of 0.35. These data can be seen in Table 6. Statistical analysis also showed that variables such as age, marital status, and education acted as confounding factors in the relationship between therapeutic adherence and quality of life, changing the OR to 1.61, 1.34, and 1.98, respectively, with p-values of 0.03 for age, 0.06 for marital status, and 0.045 for education.

The remaining sociodemographic variables, such as sex, occupation, and duration of treatment, did not show a statistically significant association (Table 6). Regarding the other variables, only the presence of microvascular comorbidities improved the model, increasing the OR to 1.42 and the p-value to 0.0005. Once all the confounding variables were grouped, the values obtained were an OR of 1.22 and a p-value of 0.0004 (Table 6).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Table 6. Logistic regression multivariable models** | | | | | | | | | | | | |
|  | **QoL / TA** | **QoL/TA/ Sex** | **QoL/AT/Age** | **QoL/AT/ OC** | **QoL/AT/MS** | **QoL/ AT/ ED** | **QoL/ AT/ TO** | **QoL/ AT/ MiC** | **QoL/ AT/ MaC** | **QoL/ AT/ NoCM** | **QoL/ AT/ MC** | **QoL/ AT/ Age/ MS/ ED/MiC** |
| **OR** | 1.75 | 1.6 | 1.61 | 1.79 | 1.34 | 1.98 | 1.75 | 1.42 | 1.75 | 1.78 | 1.56 | 1.22 |
| **CI 95%** | 0.52 -5.84 | 0.47 - 5.45 | 0.47 - 5.55 | 0.52 - 6.18 | 0.38 - 4.71 | 0.58 - 6.85 | 0.52 - 5.85 | 0.39-5.11 | 0.52-5.85 | 0.52-6.07 | 0.43-5.6 | 0.32-4.66 |
| **LR T** | 0.87 | 1.97 | 4.62 | 0.03 | 3.65 | 4.02 | 0.02 | 12.2 | 0 | 2.72 | 0.29 | 20.28 |
| ***P*-value** | 0.35 | 0.16 | 0.03 | 0.87 | 0.06 | 0.045 | 0.9 | 0.0005 | 0.1 | 0.1 | 0.6 | 0.0004 |
| *QoL: Quality of Life, TA: Therapeutic Adherence, OC: Occupation, MS: Marital Status, ED: Education, TO: Time of Onset, MiC: Microvascular Complications, MaC: Macrovascular Complications, NoCM: Number of Comorbidities, MC: Metabolic Control.*  *Source: Own design* | | | | | | | | | | | | |

The main objective of the study was to establish a relationship between therapeutic adherence and health-related quality of life in patients with T2D attending the Guanajuato General Hospital.

The World Health Organization defines therapeutic adherence as the degree to which the patient follows the rules or advice given by healthcare personnel, both regarding non-pharmacological management and pharmacological treatment (medication intake, dietary monitoring, and/or lifestyle changes) [24]. Furthermore, adherence is a phenomenon affected by the interaction of multiple factors surrounding the patient [13].

Lack of treatment adherence has been observed to be a common problem in chronic conditions, present in up to 30–50% of cases in developed countries [13,25]. In the present study, only 17% (n=17) of the population had adequate therapeutic adherence. This figure contrasts with that reported by Vargas et al., who found a high adherence rate in 37.08% of patients with T2D and a moderate adherence rate in 62.92%, with no low adherence in their study [20]. Sánchez W., in turn, reported complete adherence to treatment in 61% and partial adherence in 39% of his population [23]. However, in the study conducted by Custodio et al., they found similar data to ours, reporting poor adherence in 37% of their sample, fair adherence in 47.8%, and optimal adherence in only 15.2% of their population [26].

Our analysis also found that the areas most affected were family support and medical monitoring, while aspects such as community organization and diet showed high adherence. These data differ from those found by Zenteno et al., who reported low adherence in the community organization and support dimension, average adherence in family support and physical exercise, and high adherence in medical monitoring, hygiene, and self-care, diet, and physical fitness assessment [19], even though both studies have similar methodological and population characteristics. For their part, García et al. comments that taking medication has better adherence than following a diet or exercising [27]. For the latter, it is reported that only 25–50% of patients follow the prescribed recommendations [28]. The former is easier since lifestyle changes require a high degree of willpower and perseverance; in addition, they are a slow and continuous process that results from mutual planning between the healthcare provider and the patient [27,28].

Health-related quality of life is defined as the gap between a patient's expectations and experience of health, as expressed by the assessment they place on their physical, emotional, functional, social, and spiritual well-being after diagnosis and treatment [29]. It has become one of the most widely used measures for self-assessing the effect of treatment on chronic diseases, such as T2D, as it represents the final level of interventions [13,15]. It was found that 67% of the study population had an acceptable quality of life (n=67), which differs from the findings of Reyes-Jarquín [11] and Rojas [15]. The former report that 11.5% of patients with T2D have a low quality of life, 46.2% have a moderate quality of life, and 42.3% have a high quality of life [11]. While the latter state that 80% of their population has a good quality of life and 20% a poor quality of life [15].

Regarding the effect between the variable of therapeutic adherence and quality of life, no statistically significant association was found in this study. In this regard, the results of previous research have been contradictory. On the one hand, Sánchez W reports the existence of a direct, moderate, and highly significant relationship (p < 0.001) [23], data similar to those reported by Majeed [12], Custodio [26], and Escandón-Nagel [30], where they express a positive relationship between both variables. In contrast, Martínez et al. [31] found no association between quality of life and treatment adherence. This may be explained by the different study settings and the instruments used. In turn, multivariate analysis showed that factors such as age, marital status, education, and the presence of microvascular complications improved the model, demonstrating that the link between the study variables is complex.

Sánchez et al. [23] found that therapeutic adherence is significantly related to age and family support. Furthermore, it has been shown that older patients are more likely to engage in self-care behaviors and are capable of adopting a healthier lifestyle [32].

On the other hand, the family is postulated as the main motivating agent for patients with T2D to maintain an active, dynamic, and participatory role during their treatment and as a tool for coping with the disease [26]. This has allowed linking adequate family functioning with greater adherence to treatment and better quality of life, as well as with lower glucose levels [19,30].

Likewise, in the study by Bautista et al., it was observed that the quality of life of patients with type 2 DM decreases in those who are single compared to those who are married, which could be explained by the support networks available to these patients [15,33].

Regarding educational level, the results are contradictory. However, it has been postulated that a low level of education prevents patients from understanding basic concepts and treatment instructions [34].

Furthermore, Ramos Rangel et al. found that diabetic patients with a higher level of education may have greater social support, positive self-esteem, and a better understanding of the disease, its treatment, and its complications [32]. These characteristics can promote better knowledge about their disease and a positive attitude toward treatment adherence, reflected in inadequate glycemic control [32,35].

It is also worth noting that disease-related factors such as the presence of comorbidities have been associated with poor treatment adherence [27].

When recalculating the sample size based on the results obtained, with 82.35% acceptable quality of life in the adequate therapeutic adherence group and 65.06% adequate quality of life in the poor therapeutic adherence group, the minimum sample size is 112 participants in each group with 95% accuracy and 80% power. (EpiIfo, 7.2.5.0., 2021, CDC, Atlanta, GA, USA).

Finally, it is necessary to mention the study's limitations. First, the cross-sectional design does not allow for establishing a causal relationship between the variables by simultaneously measuring therapeutic adherence and quality of life. Second, the study population is limited and may not be representative of other populations or regions. Furthermore, the selection of these samples from a single hospital unit and area (outpatient clinic) may lead to selection bias. Additionally, the use of self-administered questionnaires may lead to social desirability bias and recall errors, so the results should be handled with caution.

**5. CONCLUSION**

In the studied sample of participants with T2D, it was observed that the majority of participants had poor treatment adherence and an acceptable quality of life. This, coupled with the fact that only 39% of the sample had metabolic control, highlights a great need to improve the care and follow-up of these patients based on sustainable and individualized goals to avoid catastrophic outcomes and minimize risks.

Although the relationship between adherence and quality of life was not statistically significant, variables such as age, education, marital status, and the presence of microvascular complications were found to improve the association model, leading to alternative hypotheses. Therefore, it is essential to focus on the design and implementation of new studies that consider these variables.

Furthermore, it highlights the need to establish programs that improve modifiable variables to improve the overall health of patients. For example, the establishment of health literacy programs focused on the illiterate stratum of the community.

**DECLARATION (ARTIFICIAL INTELLIGENCE)**

The authors declare that no artificial intelligence technologies, large language models (ChatGPT, COPILOT, etc.), or text generators were used during the writing or editing of the manuscript.

**CONSENT**

All authors declare that written informed consent was obtained and signed by the participating subjects.

**ETHICAL APPROVAL**

The protocol was approved by the Research Ethics Committee of the Hospital General de Salamanca, with registration number CONBIOETICA-11-CEI-002-20210302 and registry number CEI-HGS008-2024. All authors declare that the research was approved by the corresponding committee and, therefore, was conducted by the ethical standards of the Declaration of Helsinki.

**REFERENCES**

1. Lu X, Xie Q, Pan X, Zhang R, Zhang X, Peng G, et al. Type 2 diabetes mellitus in adults: Pathogenesis, prevention, and therapy. Signal Transduct Target Ther. 2024;9:262. DOI: <https://doi.org/10.1038/s41392-024-01951-9>

2. International Diabetes Federation. IDF Atlas, 10th Edition. 2021. Available at: <https://fmdiabetes.org/atlas-idf-10o-edicion-2021/>

3. Basto-Abreu A, López-Olmedo A, Rojas-Martínez R, Ca AS, Gl MB, Ja R, et al. Prevalence of prediabetes and diabetes in Mexico: Ensanut 2022. Salud Publ Mex. 2023;65(Suppl.1):163–168. DOI: <https://doi.org/10.21149/14832>

4. Escamilla-Nuñez MC, Castro-Porras L, Romero-Martinez M, Zárate-Rojas E, Rojas-Martínez R. Screening, prediagnosis, and treatment of chronic noncommunicable diseases in Mexican adults. Ensanut 2022. Salud Publ Mex. 2023; 65 (Suppl. 1):153–162. DOI: <https://doi.org/10.21149/14726>

5. Basto-Abreu AC, López-Olmedo N, Rojas-Martínez R, Aguilar-Salinas CA, De la Cruz-Góngora VV, Rivera-Dommarco J, et al. Prevalence of diabetes and glycemic control in Mexico: national results from 2018 and 2020. Salud Publ Mex. 2021;63 (3): 725–733. DOI: <https://doi.org/10.21149/12842>

6. Shamah-Levy T, Lazcano-Ponce EC, Cuevas-Nasu L, Romero-Martínez M, Gaona-Pineda EB, Gómez-Acosta LM, et al. National Continuous Health and Nutrition Survey 2023. National Results. Cuernavaca, Mexico: National Institute of Public Health, 2024. Available from: <https://ensanut.insp.mx/encuestas/ensanutcontinua2023/doctos/informes/ensanut_23_112024.pdf>

7. Shamah-Levy T, Romero-Martínez M, Barrientos-Gutiérrez T, Cuevas-Nasu L, Navarro-Olivos E, Bautista-Arredondo S, et al. National Continuous Health and Nutrition Survey 2023. Results from Guanajuato. Cuernavaca, Mexico: National Institute of Public Health, 2023. Available at: <https://ensanut.insp.mx/encuestas/ensanutgto2023/informes.php>

8. American Diabetes Association. Standards of Care in Diabetes-2024. Diabetes Care. 2024;47(Suppl.1). Available at: <https://diabetesjournals.org/care/issue/47/Supplement_1>

9. Khdour MR, Awadallah HB, Al-Hamed DH. Treatment Satisfaction and Quality of Life among Type 2 Diabetes Patients: A Cross-Sectional Study in West Bank, Palestine. J Diabetes Res. 2020; 25:1834534. DOI: <https://doi.org/10.1155/2020/1834534>.

10. Secretaria de Gobernación de México. Mexican Official Standard NOM-015-SSA2-2010, For the prevention, treatment, and control of diabetes mellitus. DOF. 2010. Available at: <https://www.hgm.salud.gob.mx/descargas/pdf/dirgral/marco_juridico/normas/nom_14.pdf>

11. Reyes-Jarquín K, Tolentino-Flores F, Guzmán-Saldaña R, Bosques-Brugada LE, Romero-Palencia A, Lerma-Talamantes A, et al. Quality of life in patients with type II diabetes mellitus in Pachuca, Hidalgo. BCEyS. 2019;8(15):1–6. Available at: <https://www.researchgate.net/publication/337806203_Calidad_de_vida_en_pacientes_con_diabetes_mellitus_tipo_II>

12. Majeed A, Rehman M, Hussain I, Imran I, Saleem MU, Saeed H, et al. The Impact of Treatment Adherence on Quality of Life Among Type 2 Diabetes Mellitus Patients - Findings from a Cross-Sectional Study. Patient Prefer Adherence. 2021;15:475-481. DOI: <http://doi.org/10.2147/PPA.S295012>.

13. Chantzaras, A., Yfantopoulos, J. Association between medication adherence and health-related quality of life of patients with diabetes. Hormones. 2022; 21: 691–705. DOI: <https://doi.org/10.1007/s42000-022-00400-y>

14. Jannoo Z, Wah YB, Lazim AM, Hassali MA. Examining diabetes distress, medication adherence, diabetes self-care activities, diabetes-specific quality of life, and health-related quality of life among type 2 diabetes mellitus patients. J Clin Transl Endocrinol. 2017; 9:48–54. DOI: <https://doi.org/10.1016/j.jcte.2017.07.003>

15. Rojas F. Quality of life in patients with type 2 diabetes mellitus at Family Medicine Unit No. 45 of the Mexican Social Security Institute in San Luis Potosí. [Postgraduate thesis] San Luis Potosí: Autonomous University of San Luis Potosí. 2020. Available at: <https://repositorioinstitucional.uaslp.mx/xmlui/bitstream/handle/i/7241/TesisE.FM.2020.Calidad.Rojas.pdf?sequence=8&isAllowed=y>

16. Ministry of the Interior of Mexico. Official Mexican Standard NOM-087-ECOL-SSA1-2002, Environmental Protection - Environmental Health - Biological-Infectious Hazardous Waste - Classification and Management Specifications. DOF. 2003. Available at: <https://www.cndh.org.mx/DocTR/2016/JUR/A70/01/JUR-20170331-NOR14.pdf>

17. Villalobos-Pérez A, Quirós-Morales D, León-Sanabria. Psychometric characteristics of the Treatment Adherence Scale for Type II Diabetes Mellitus – version III (EATDM-III ©) in a sample of diabetic patients from Costa Rica. Act Colom Psicol. 2006 9(2): 31-38. Available at: <http://www.scielo.org.co/scielo.php?script=sci_arttext&pid=S0123-91552006000200004>

18. Urzúa A, Cabrera C, González C, Arenas P, Guzmán M, et al. Preliminary analyses of the adapted version of the therapeutic adherence scale for type 2 diabetes mellitus – EATDM-III. Rev Med Chile; 2015; 143: 733-743. Available at: <https://www.scielo.cl/scielo.php?script=sci_arttext&pid=S0034-98872015000600006>

19. Zenteno M A. Influence of family functioning on treatment adherence and glycemic control in adults and older adults with type 2 diabetes. [Postgraduate thesis] Benemérita Universidad de Puebla. School of Nursing. 2015. Available at: <https://repositorioinstitucional.buap.mx/server/api/core/bitstreams/2e49c35a-5f3e-45fc-86ff-d6f04390ef0e/content>

20. Vargas CG, Toledo A. Treatment adherence and its relationship with metabolic control in patients with type 2 diabetes mellitus, in a family medicine unit in Cuernavaca, Morelos, Mexico. Aten Fam. 2018. 25 (4): 146-150. DOI: <http://dx.doi.org/10.22201/facmed.14058871p.2018.4.67258>

21. Yam A, Candika J, Gómez P. Quality of Life: Adaptation of an instrument for diabetics. Desarrollo Cientif Enferm. 2010; 18(2):75-80. Available at: <https://www.index-f.com/dce/18pdf/18-75.pdf>

22. López-Carmona J M, Rodríguez-Moctezuma R. Adaptation and validation of the Diabetes 39 quality of life instrument in Mexican patients with type 2 diabetes mellitus. Salud Pública Mex. 2006; 48: 200-211. Available at: <https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0036-36342006000300004>

23. Sánchez W. Treatment adherence and quality of life in patients with type 2 diabetes mellitus in a hospital in Ayacucho. Ricardo Palma University. Available at: <https://repositorio.urp.edu.pe/entities/publication/019582f2-6a6a-422c-899f-7d7fff21aecf>

24. World Health Organization. Adherence to long-term therapies: Evidence for action. 2023. Available at: <https://apps.who.int/iris/bitstream/handle/10665/42682/9241545992.pdf>.

25. Pérez MP, Alonso Fernández M, López Simarro F, Soriano Llora T, Peral Martínez I, Mancera Romero J. Adherence to a healthy lifestyle in patients with type 2 diabetes mellitus in Spain. MF-SEMERGEN. 2021;47(3):161–169. DOI: <http://doi.org/10.1016/j.semerg.2020.08.009>

26. Custodio R, Santamaria LR. Quality of life and treatment adherence in patients with type 2 diabetes mellitus in the Non-communicable Diseases (NCD) Program. Belen de Lambayeque Provincial Teaching Hospital. 2016. Available at: <https://repositorio.uss.edu.pe/bitstream/handle/20.500.12802/3395/Custodio%20-%20Santamaria.pdf?sequence=9&isAllowed=y>

27. García Y, Casanova D, Raymond G. Factors associated with therapeutic non-adherence in patients with type 2 diabetes mellitus. Medicentro. 2022; 26(2): 412–435. Available from: <http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S1029-30432022000200412>

28. Padilla G, Aráuz AG, Roselló M. Methodology for assessing dietary adherence in non-insulin-dependent diabetes mellitus. Rev Costarric Cienc Méd. 1997;18(4): 15–28. Available from: <https://www.scielo.sa.cr/scielo.php?script=sci_arttext&pid=S0253-29481997000400002>

29. Miranda G, Villegas- Aguirre EB, Plata-Rendón FI. Quality of life in diabetic patients through the use of the DQOL scale. Regional Military Hospital of Puebla, 2012. An Med (Mex) 2017; 62 (3): 172-179. Available at: <https://www.medigraphic.com/pdfs/abc/bc-2017/bc173c.pdf>

30. Escandón-Nagel N, Azócar Espinoza B, Pérez Villalobos C, Matus Donoso V. Treatment Adherence in Type 2 Diabetes: Its Relationship with Quality of Life and Depression. Rev. Psicoterapia. 2015; 26(101): 125-38. Available at: <https://revistas.uned.es/index.php/rdp/article/view/34804>

31. Martínez YV, Prado-Aguilar CA, Rascón-Pacheco RA, Valdivia-Martínez JJ. Quality of life associated with treatment adherence in patients with type 2 diabetes: a cross-sectional study. BMC Health Serv Res. 2008; 8: 164. DOI: <http://doi.org/10.1186/1472-6963-8-164>.

32. Ramos-Rangel Y, Morejón-Suárez R, Gómez-Valdivia M, Reina-Suárez M, Rangel-Díaz C, Cabrera-Macías Y. Therapeutic adherence in patients with type 2 diabetes mellitus. Finlay Journal. 2017. Available at: <http://revfinlay.sld.cu/index.php/finlay/article/view/474>

33. Bautista LM, Zambrano G. Perceived quality of life in patients with type 2 diabetes. Investg. Enferm. Imagen Desarrollo. 2014; 17(1). Available at: <https://revistas.javeriana.edu.co/index.php/imagenydesarrollo/article/view/9261>

34. Dorado M, Zegbe J, Castañeda J. Psychosocial determinants of therapeutic non-adherence in patients with type 2 diabetes mellitus. Ibnsina. 2017; 7(2): 1-17. DOI: <https://doi.org/10.48777/ibnsina.v7i2.30>

35. Gómez-Encino GC, Cruz-León A, Zapata-Vázquez R, Morales-Ramón F. Level of knowledge of patients with type 2 diabetes mellitus regarding their disease. Salud Tab. 21 (1). Available at: <https://tabasco.gob.mx/sites/default/files/users/ssaludtabasco/17.pdf>