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## Quality of Life and Metabolic Control in Type 2 Diabetes Mellitus Diagnosed Individuals

(Preprint)

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### Abstract

**Aims:** Determine the correlation of quality of life (QoL) and the impact on the metabolic control of patients with type 2 diabetes mellitus (T2DM). **Methods:** An observational study was conducted at the outpatient consulting service in a specialized hospital in Santo Domingo, DR. We used a non-probabilistic, convenience sampling strategy, and the World Health Organization Quality of Life (WHOQOL-BREF) short form questionnaire was applied. **Results:** The patients presented lower impact in QoL domains was: pain ( $\bar{x} = 29.07$ ,  $SD = 3.04$ ) and negative feelings ( $\bar{x} = 28.70$ ,  $SD = 3.33$ ). We found there is a negative correlation between the psychological domains and the fasting glycemia ( $r_{ho} = -0.192$ ,  $p < 0.05$ ), also between the summary of all domains of QoL and metabolic control, HbA1C ( $r_{ho} = -0.205$ ,  $p < 0.05$ ), and fasting glycaemia ( $r_{ho} = -0.214$ ,  $p < 0.05$ ). There was a significant difference in the physical domains  $F(1, 131) = 9.73$ ,  $p = 0.002$ ,  $\eta^2 = .069$ , indicating that men ( $M = 14.81$ ) have a higher physical QoL than women ( $M = 13.72$ ). **Conclusion:** Given the evidence of the impact of metabolic control and the different domains to QoL, it is necessary to consider these aspects in the treatment plan of patients with diabetes, to ensure adequate management and control of future complications.

**Keywords:** Quality of Life; Metabolic control; Type 2 Diabetes Mellitus.

## Introduction

Since 1948 the World Health Organization defined health from a new perspective, defining health not only by the absence of disease and disability but also by the presence of others components as physical, mental and social well-being<sup>1</sup>. For many years multidisciplinary attention has been focused on the treatment of patients with diabetes in order to improve the aspects that contribute to the quality of life and their interaction with the global health of these patients<sup>2-5</sup>.

Patients with diabetes are facing different challenges related to the disease such as daily intake of multiple medications, the use of the glucometer, injections for insulin administration, multiple complications of this condition such as hypertension, and cognitive disorders<sup>2,3</sup>, symptoms of hyper and hypoglycemia and the challenges of the social environment in which they manage. These challenges impact the quality of life of patients with diabetes and their disposition when making adjustments that improve metabolic control<sup>6,7</sup>, such as creating habits to exercise, eat healthy, take care of their health cardiovascular, among others.

Multiple studies have evaluated the relationship of quality of life (QoL) and its impact on metabolic control in patients with diabetes<sup>8-12</sup>. However, few studies have evaluated the relationship separately from the different domains that contribute to the high quality of life and the impact on the different control measures such as glycosylated hemoglobin (HbA1C) values, fasting glucose (FG) and postprandial glucose (PPG) levels. It is important to evaluate the impact of the different domains of quality of life, such as the physical, psychological, social and environmental aspects, and determine which are the aspects that most affect the quality of life and metabolic control<sup>13</sup>, if there

are any differences in the sex of the patient and if there is a domain that impacts more to the metabolic control according to gender<sup>14</sup>.

It is evident the need to create clinical protocols for comprehensive treatment, including: identification of conditions related to all aspects of quality of life, improvement of metabolic control, and reduction of long-term complications of diabetes. The aim of our study was to determine the correlation of the different components of quality of life, and the impact on metabolic control, and gender in type 2 diabetes mellitus (T2DM) diagnosed individuals.

### **Materials and Methods**

An observational study was conducted with patients diagnosed with diabetes type 2 at the outpatient consulting service at an specialized diabetes hospital. A non-probabilistic, convenience sampling strategy was used. We selected 135 patients receiving regular evaluation from the hospital, Instituto Nacional de Diabetes, Endocrinología y Nutrición (INDEN), this hospital is a major provider for diabetes care in the country with an estimated of 5,000 diabetic patients monthly from across the country. Only those who agreed to participate and met inclusion criteria were given the assessment tools. Inclusion criteria included: patients with the diagnosis of type 2 diabetes mellitus, and older to 18 years of age. All patients not willing to participate and providing informed consent were excluded.

We used factor analysis to calculate QoL global outcome score and univariate analyses of variance (ANOVA) to determinate the differences between the domains o QoL and the differences between levels of glycemic control measures. We used general linear models to evaluate the relationship between changes in glycemic control and changes in QoL scales.

**Instruments.** The Quality of Life (QoL) questionnaire was self-administered before starting the consultation, and guided by a diabetologist.

**Quality of Life Evaluation.** We used the World Health Organization Quality of Life (WHOQOL-BREF)<sup>15</sup> short form questionnaire, which is based on the Spanish version and uses approved by the WHOQOL group, Programme on Mental Health, Switzerland.

The WHOQOL-BREF is based on a four-domain structure in 26 questions: a) Physical health: includes activities of daily living, dependence on medicinal substances and medical aids, energy/fatigue, mobility, pain, and discomfort, sleep and rest and work capacity. b) Psychological: bodily image and appearance, negative feelings, positive feelings, self-esteem, spirituality/religion/personal beliefs, thinking, learning, memory, and concentrations. c) Social relationships: personal relationships, social support, and sexual activity. d) Environment: financial resources, freedom/physical safety and security, health and social care, home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation/leisure activities, physical environment, and transport.

The four domains scores denote an individual perception of the quality of life in each particular domain. Domain score is scaled in a positive direction (i.e., higher scores denote the higher quality of life). The mean score of items within each domain is used to calculate the domain score. The transformation method is converting raw scores to 0-100 scales so that the lowest and highest possible score is set at 0 and 100, respectively. Scores represent the percentage of total possible scores achieved<sup>16</sup>. Some authors usually refer to the QoL items do not reach the metric or values of “50” to notice the reduced values in such domains<sup>17</sup>.

We calculate Cronbach's  $\alpha$  of the WHOQOL-BREF questionnaire resulting in 0.892.

**Metabolic control assessment.** Glycosilated hemoglobin test (HbA1C), fasting glycaemia (FG) and postprandial glycaemia plasmatic levels (PPG) were performed<sup>18</sup>. Prior studies have been demonstrated the correlation between A1C levels and mean glucose levels based. On two studies: the international A1C Derived Average Glucose (ADAG) study, which assessed the correlation between A1C and frequent self-monitoring blood glucose (SMBG) and continuous glucose monitoring (CGM)<sup>19</sup>, and an empirical study of the average blood glucose levels at pre-meal, post-meal, and bedtime associated with specified A1C levels using data from the ADAG trial<sup>20</sup>. The American Diabetes Association (ADA) and the American Association for Clinical Chemistry have determined that the correlation ( $r = 0.92$ ) in the ADAG trial is strong enough to justify reporting both the A1C result and the estimated average glucose (eAG) result when a clinician orders the A1C test<sup>47</sup>.

We consider as patient metabolically controlled levels established by ADA<sup>47</sup>: A1C < 7.0% (53 mmol/mol), preprandial capillary plasma glucose: 80-130 mg/dL (4.4-7.2 mmol/L) and postprandial capillary plasma glucose <180 mg/dL (10.0 mmol/L).

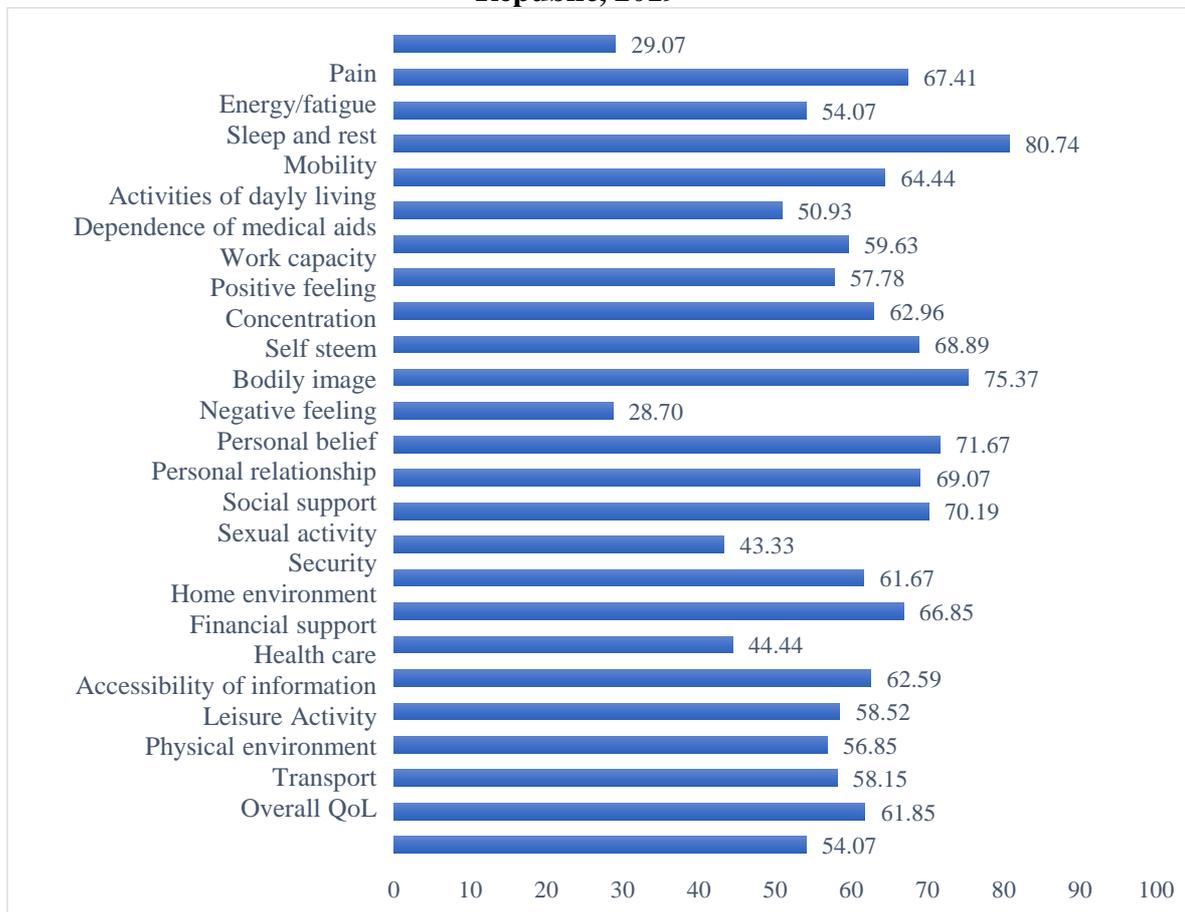
### **Ethics Statement**

The Ethics Committee of Instituto Nacional de Diabetes, Endocrinología y Nutrición (INDEN) approved this study before data collection. The research was conducted with respect for the rights of all participants, and the data were analyzed entirely anonymously. The HbA1c and glycemic tests were taken by clinical records of participants who fully anonymously filled out questionnaires. It was explained to each patient the research aims of the study and signed an informed written consent document. All participants were volunteers, who filled out the questionnaires in a confidential setting.

## RESULTS

Patients with type 2 diabetes presented lower impact in QoL domains were: pain, negative feelings, sexual activities, and financial support, values that did not reach the metric of 50 (see Graphic 1). The domains that present higher impact in QoL were: Mobility, bodily image, personally belief, and social support.

**Figure 1. Quality of Life domains in T2DM diagnosed individuals, Dominican Republic, 2019**



The time of diagnosis of diabetes was less than five years ( $M = 4.19$ ,  $SD = 1.58$ ), most of the patients were decontrolled (HbA1C  $M = 8.14$ ,  $SD = 2.34$ ), with uncontrolled fasting glycaemia ( $M = 144.50$  mg / dL,  $SD = 68.25$ ), and uncontrolled postprandial

glycaemia ( $M = 211.4$  mg/dL,  $SD = 100.8$ ). Considering patients were with no control of diabetes less than 5 years of diagnosis and that 74.8 % were between 40-69 years old at a productive age. Most of the patients (68.1 %) have hypertension add to uncontrolled diabetes, and just 25.2 % of evaluated patients had a combination of insulin and oral antihyperglycemics drugs (see Table 1).

**Table 1. Demographic and Clinical Characteristic of participants, Dominican Republic, 2019.**

| <b>Age</b>               | <b>Frequency</b> | <b>Percent</b> | <b>Valid Percent</b> | <b>Cumulative Percent</b> |
|--------------------------|------------------|----------------|----------------------|---------------------------|
| 30-39                    | 7                | 5.2            | 5.2                  | 5.2                       |
| 40-49                    | 25               | 18.5           | 18.5                 | 23.7                      |
| 50-59                    | 44               | 32.6           | 32.6                 | 56.3                      |
| 60-69                    | 32               | 23.7           | 23.7                 | 80.0                      |
| 70-79                    | 23               | 17.0           | 17.0                 | 97.0                      |
| >80                      | 4                | 3.0            | 3.0                  | 100.0                     |
| <b>Sex</b>               | <b>Frequency</b> | <b>Percent</b> | <b>Valid Percent</b> | <b>Cumulative Percent</b> |
| Men                      | 59               | 43.7           | 43.7                 | 43.7                      |
| Women                    | 76               | 56.3           | 56.3                 | 100.0                     |
| <b>Comorbidities</b>     | <b>Frequency</b> | <b>Percent</b> | <b>Valid percent</b> | <b>Cumulative Percent</b> |
| Hypertension             | 92               | 68.1           | 68.1                 | 68.1                      |
| CKD*                     | 7                | 5.2            | 5.2                  | 73.3                      |
| None                     | 35               | 25.9           | 25.9                 | 99.3                      |
| Hypertension and CKD     | 1                | 0.7            | 0.7                  | 100                       |
| <b>Treatment</b>         | <b>Frequency</b> | <b>Percent</b> | <b>Valid Percent</b> | <b>Cumulative Percent</b> |
| Diet and exercise        | 2                | 1.5            | 1.5                  | 1.5                       |
| Oral Agents (OA)         | 63               | 46.7           | 46.7                 | 48.1                      |
| Human Insulin            | 28               | 20.7           | 20.7                 | 68.9                      |
| Analogs Insulin          | 8                | 5.9            | 5.9                  | 74.8                      |
| OA + Insulin             | 34               | 25.2           | 25.2                 | 100.0                     |
| <b>Time of diagnosis</b> | <b>Frequency</b> | <b>Percent</b> | <b>Valid Percent</b> | <b>Cumulative Percent</b> |
| Debut                    | 5                | 3.7            | 3.7                  | 3.7                       |
| Less than 12 months      | 12               | 8.9            | 8.9                  | 12.6                      |
| 1-5 yrs.                 | 36               | 26.7           | 26.7                 | 39.3                      |
| 6-10 yrs.                | 23               | 17.0           | 17.0                 | 56.3                      |
| 11-15 yrs.               | 28               | 20.7           | 20.7                 | 77.0                      |
| 16-20 yrs.               | 21               | 15.6           | 15.6                 | 92.6                      |
| 21-30 yrs.               | 9                | 6.7            | 6.7                  | 99.3                      |
| >30 yrs.                 | 1                | 0.7            | 0.7                  | 100.0                     |
| Missing                  | 0                | 0.0            |                      |                           |
| <b>Total</b>             | <b>135</b>       | <b>100.0</b>   |                      |                           |

\*Chronic Kidney Disease

We observed a strong correlation among all domains of quality of life (see table 2). In contrast with values of metabolic control, there is a negative correlation between the psychological domains and the fasting glycaemia ( $r_{ho} = -0.192, p < 0.05$ ). There is also a negative correlation between the summary of the whole domains of quality of life and metabolic control, considering HbA1C ( $r_{ho} = -0.205, p < 0.05$ ) and fasting glycemia ( $r_{ho} = -0.214, p < 0.05$ ), with statistical significance. No correlation was found with postprandial glycaemia with the QoL domains.

**Table 2. Summary domains of QoL and metabolic control. Spearman correlation matrix total sample.**

|             | Physi<br>cal | Psychologic<br>al | Social       | Environme<br>nt | Overall<br>QoL | Tota<br>l | HbA1C        | FG        |
|-------------|--------------|-------------------|--------------|-----------------|----------------|-----------|--------------|-----------|
| Psychologic | 0.646<br>*** | —                 |              |                 |                |           |              |           |
| Socials     | 0.389<br>*** | 0.470***          | —            |                 |                |           |              |           |
| Environment | 0.464<br>*** | 0.647***          | 0.566**<br>* | —               |                |           |              |           |
| Overall QoL | 0.432<br>*** | 0.503***          | 0.281**<br>* | 0.354***        | —              |           |              |           |
| Total       | 0.777<br>*** | 0.882***          | 0.660**<br>* | 0.837***        | 0.559**<br>*   | —         |              |           |
| HbA1C       | -<br>0.034   | -0.123            | 0.017        | -0.057          | -0.205*        | -0.060    | —            |           |
| FG          | -<br>0.117   | -0.192*           | -0.103       | -0.041          | -0.214*        | -0.149    | 0.548**<br>* | —         |
| PPG         | -<br>0.023   | -0.217            | 0.040        | -0.074          | -0.258         | -0.116    | 0.412*       | 0.21<br>6 |

\*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ . HbA1C: glycosylated hemoglobin. FG: Fasting glucose. PPG: Postprandial glucose.

The analysis of variance (ANOVA) results show a significant difference between genders in several domains of QoL (see Table 3). There was a significant difference in the physical domains  $F(1, 131) = 9.73, p = 0.002, \eta^2 = .069$ , indicating that men ( $M = 14.81$ ) have a higher physical QoL than women ( $M = 13.72$ ). There was also a significant difference in the psychological domains  $F(1, 131) = 10.66, p = 0.001, \eta^2 = 0.075$  indicating that men ( $M = 15.67$ ) have a higher psychological QoL than women ( $M =$

14.31). The effect of gender in environment domains was significant  $F(1,131) = 3.93$ ,  $p = 0.049$ ,  $\eta^2 = 0.029$  indicating that men ( $M = 13.92$ ) have a higher environmental QoL than women ( $M = 13.06$ ). Finally, when the ANOVA was performed with the overall QoL there was also a significant difference in gender  $F(1,131) = 77.93$ ,  $p = 0.001$ ,  $\eta^2 = 0.087$  indicating that men ( $M = 13.51$ ) have a higher environmental QoL than women ( $M = 12.06$ ).

**Table 3. Analysis of variances (ANOVA) considering psychological, overall QoL domains, metabolic control, and sex.**

| <b>Physical domains and HbA1C</b>      |                       |           |                    |          |          |                            |
|--|-----------------------|-----------|--------------------|----------|----------|----------------------------|
| <b>Cases</b>                           | <b>Sum of Squares</b> | <b>df</b> | <b>Mean Square</b> | <b>F</b> | <b>p</b> | <b><math>\eta^2</math></b> |
| Sex                                    | 38.423                | 1         | 38.423             | 9.726    | 0.002    | 0.069                      |
| HbA1C                                  | 0.022                 | 1         | 0.022              | 0.006    | 0.940    | 0.000                      |
| Sex * HbA1C                            | 0.905                 | 1         | 0.905              | 0.229    | 0.633    | 0.002                      |
| Residual                               | 517.520               | 131       | 3.951              |          |          |                            |
| <b>Psychological domains and HbA1C</b> |                       |           |                    |          |          |                            |
| <b>Cases</b>                           | <b>Sum of Squares</b> | <b>df</b> | <b>Mean Square</b> | <b>F</b> | <b>p</b> | <b><math>\eta^2</math></b> |
| Sex                                    | 59.205                | 1         | 59.205             | 10.657   | 0.001    | 0.075                      |
| HbA1C                                  | 4.113                 | 1         | 4.113              | 0.740    | 0.391    | 0.005                      |
| Sex * HbA1C                            | 0.741                 | 1         | 0.741              | 0.133    | 0.715    | 0.001                      |
| Residual                               | 727.773               | 131       | 5.556              |          |          |                            |
| <b>Social domains and HbA1C</b>        |                       |           |                    |          |          |                            |
| <b>Cases</b>                           | <b>Sum of Squares</b> | <b>df</b> | <b>Mean Square</b> | <b>F</b> | <b>p</b> | <b><math>\eta^2</math></b> |
| Sex                                    | 6.498                 | 1         | 6.498              | 0.971    | 0.326    | 0.007                      |
| HbA1C                                  | 0.194                 | 1         | 0.194              | 0.029    | 0.865    | 0.000                      |
| Sex * HbA1C                            | 1.803                 | 1         | 1.803              | 0.270    | 0.605    | 0.002                      |
| Residual                               | 876.298               | 131       | 6.689              |          |          |                            |
| <b>Environment domains and HbA1C</b>   |                       |           |                    |          |          |                            |
| <b>Cases</b>                           | <b>Sum of Squares</b> | <b>df</b> | <b>Mean Square</b> | <b>F</b> | <b>p</b> | <b><math>\eta^2</math></b> |
| Sex                                    | 23.784                | 1         | 23.784             | 3.931    | 0.049    | 0.029                      |
| HbA1C                                  | 1.864                 | 1         | 1.864              | 0.308    | 0.580    | 0.002                      |
| Sex * HbA1C                            | 0.853                 | 1         | 0.853              | 0.141    | 0.708    | 0.001                      |
| Residual                               | 792.663               | 131       | 6.051              |          |          |                            |

| <b>Overall QoL domains and HbA1C</b> |                       |           |                    |          |          |                            |
|--------------------------------------|-----------------------|-----------|--------------------|----------|----------|----------------------------|
| <b>Cases</b>                         | <b>Sum of Squares</b> | <b>df</b> | <b>Mean Square</b> | <b>F</b> | <b>p</b> | <b><math>\eta^2</math></b> |
| Sex                                  | 77.934                | 1         | 77.934             | 12.714   | 0.001    | 0.087                      |
| HbA1C                                | 6.818                 | 1         | 6.818              | 1.112    | 0.294    | 0.008                      |
| Sex *<br>HbA1C                       | 4.880                 | 1         | 4.880              | 0.796    | 0.374    | 0.005                      |
| Residual                             | 802.982               | 131       | 6.130              |          |          |                            |

HbA1C: glycosylated hemoglobin.

On the other hand, there was not observed differences between men and women on any measures of metabolic control. The mean observed for men on HbA1C,  $M = 7.896$  ( $SD = 2.250$ ), was not statistically different compared to women,  $M = 8.332$  ( $SD = 2.413$ ),  $t(126) = 1.047$ ,  $p = 0.297$ . Related to FG, there was not difference between the mean observed on men  $M = 146.824$  ( $SD = 77.982$ ) compared to women,  $M = 142.833$  ( $SD = 60.947$ ),  $t(121) = 0.318$ ,  $p = 0.751$ . Finally, for PPG there was not differences, being  $M = 216.714$  ( $SD = 94.637$ ) in men, and  $M = 208.045$  ( $SD = 106.566$ ),  $t(34) = 0.248$ ,  $p = 0.805$ .

## Discussion

It is described in multiple studies that QoL is influenced by the diseases suffered by people<sup>21,22</sup>, and the complications of metabolic diseases such as diabetes associated with QoL status have risen with the passage of time<sup>23,24</sup>. Several studies have shown that the affection of the personality, as negative feelings, in patients with diabetes can impact the proper behavior in health<sup>25,26</sup>. Data was consistent that psychological domains were significantly related to fasting glycaemia, which past research<sup>27-29</sup> have linked with behavior choices that do not lead to health improvement. Also, this relationship between psychological domains and fasting glycaemia (in terms of the care and therefore metabolic control) has been found as moderated by the attitude towards the disease<sup>30-33</sup>.

Association of diabetes complications and depressive symptoms have been established in several studies<sup>34-36</sup>, and our results resembled this association, showing a negative relationship between psychological domains and metabolic control. Considering that participants in this study had relatively short diagnostic time for diabetes and hypertension comorbidity, the negative association of the psychological aspect of the quality of life and self-regulation may reflect a flaw in a decision-making process concerning the appropriate habits that might enhance the quality of life. This relationship has been suggested in other works<sup>33,37,38</sup>. That is why, within the protocols of treatment of diabetes, it should be considered the use of recurrent psychological evaluations to provide an improvement of the patients.

As other studies have shown<sup>3,7,39-46</sup>, this study shows that women had a more significant impact on the overall quality of life levels, and specifically on physical, psychological, and environmental domains, always showing lower levels than men<sup>(48-50)</sup>. One aspect that needs to be remarked is the absence of differences in the measures of metabolic control between both sexes. These results indicate the obligation of broadening the representation of women's and men's well-being and mental health, in order to address the overall lower quality of life that women are experiencing. However, we need to consider the possibility of reporting bias; men may be less likely to self-report pain, psychological issues, and social or financial support than women with the same problems. Health professionals require further research to be able to meet the unique needs of each specific diabetic gender group.

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### Supplemental data:

#### Summary of domains of Quality of Life.

