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# TREATMENT WITH GLP-1 RECEPTOR AGONISTS AND IMPACT ON QUALITY OF LIFE

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## ABSTRACT

Diabetes mellitus is among the four most common chronic diseases in Bulgaria. Its impact on affected individuals seriously reduces the quality of life in physical, psychological and social aspects. Patients often have to adhere to strict diets and take regular medications. This can lead to feelings of limitation and stress that affect an individual's quality of life. The concept of quality of life makes it possible to address and satisfy all the individual physical and mental health needs of patients. Quality of life is generally defined as a subjective sense of well-being that is influenced by various factors. The object of the present study is the quality of life of patients with type 2 diabetes mellitus treated with GLP-1 receptor agonists and how these medications affect various aspects of quality of life. The aim of the present analysis is to investigate the quality of life of patients with type 2 diabetes mellitus treated with GLP-1 receptor agonists and how the latter affects different aspects of quality of life. A total of 66 patients treated with a GLP-1 receptor agonist were studied, whose quality of life was assessed using the SF-36 and ADDQoL questionnaires. Quality-of-life factors were identified, including characteristics related to the type of treatment given and the group of GLP-1 receptor agonists used.

**KEYWORDS:** type-2 diabetes mellitus, GLP-1 receptor agonists, quality of life.

## INTRODUCTION

Globally, more than one in 10 adults are now living with diabetes. In 2000 the estimated prevalence of the disease in people aged 20-79 years was 4.6% (151 million) of the world's population, today it is 10.5% (537 million). Without sufficient action to address the situation,

predictions are that 643 million people will have diabetes by 2030. (11.3% of the population). If trends continue, the number will increase to a significant 783 million. (12.2%) by 2045.[1]

Diabetes remains a serious and growing public health challenge and places a huge burden on affected individuals and their families. Type 2 diabetes is the most common type of diabetes, accounting for over 90% of all diabetics worldwide.

Major goals in the care of patients with type 2 diabetes mellitus are early diagnosis and treatment, which are directly related to quality of life (QoL).

The term quality of life consists of five components: physical, mental, cognitive, psychological and social components (Fig.1)[2]

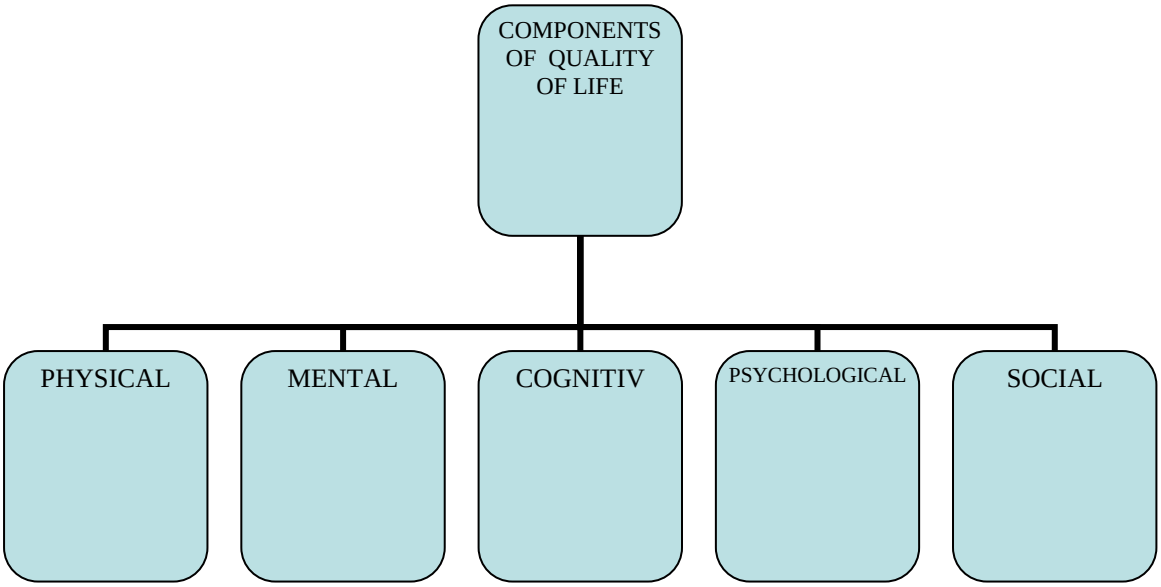


**Fig. 1: Components of quality of life.**

The quality of life is impaired especially in patients with type 2 diabetes mellitus with poor glycemic control, and the initiation of treatment with various antidiabetic drugs has a positive effect on it.[3] Furthermore, blood glucose regulation alone improves QoL in patients with type 2 diabetes.[4]

In recent decades, researcher interest has turned to the concept of disease-specific QoL/ HRQoL/ with treatment as an important component. The entire philosophy of diabetes care has changed from physician-centered to patient-centered. The ADA-EASD guidelines focus on patient participation in treatment options with the physician. Simultaneously, HRQoL questionnaires have become an important component of public health and are considered

valid indicators of intervention outcomes and a powerful predictor of mortality and morbidity[5]

The concept of health-related quality of life (Health Related Quality of Life, HRQoL) began its development in the 1980s. From a health (or disease) perspective, quality of life is translated into patients' social, emotional, and physical well-being after treatment[6]

Patients' perceptions of health and the impact of treatment on their daily physical and psychosocial functioning and well-being can provide important information to clinicians.[7]

There are many factors determining the quality of life in patients with DM / table 1/

**Table 1. Factors determining the quality of life.**

| Factors related to the disease | Factors related to the social environment |
|---|---|
| Duration of diabetes | Education |
| Dietary control | Social relations and employment |
| Physical exercise/restrictions | Income |
| Glucose variability/glycemic control | Infrastructure and housing conditions |
| Complications- Diabetic neuropathy, diabetic retinopathy and nephropathy, diabetic macroangiopathy | Environment |
| Type of treatment provided | Family relationships |
| Emotional status, anxiety and depression | Access to the health system |

Quality of life indicators help answer the question of whether treatment leads to better lives for chronically ill individuals. QoL is best assessed by patients themselves, usually using standardized questionnaires: disease-specific and/or general (generic). Assessment of QoL in patients with T2DM is considered an important part of diabetes management.[8]

The ultimate goal of diabetes treatment is to improve people's quality of life.
GLP-1 receptor agonists include 2 subgroups - GLP-1 mimetics and GLP-1 analogs.
GLP-1 receptor agonists stimulate insulin secretion from pancreatic β-cells, suppress glucagon secretion, delay gastric emptying, and reduce appetite. They lower fasting and postprandial blood sugar. The most common side effects are from the side of the gastro-intestinal tract.[9]

GLP-1 receptor agonists provide effective glycemic control and have shown beneficial effects on HRQoL and treatment satisfaction. Available once-weekly GLP-1 receptor agonists may offer greater convenience than daily GLP-1 receptor agonists.

This class of drugs is also associated with weight reduction, which, along with other mechanisms, may contribute to improved psychological and emotional well-being, social, daily functioning, and health perceptions.[10] Weight loss has a positive effect on QoL.[11]

GLP-1 receptor agonists effectively reduce hyperglycemia and have shown beneficial effects on HRQoL and treatment satisfaction.[12]

Compared with oral antihyperglycemic drugs, insulin, and daily GLP-1 receptor agonists, once-weekly regimens offer advantages in terms of HRQoL and treatment satisfaction.

These benefits appear to be largely mediated by the relative effects of the drug on glycemic control, weight, and hypoglycemia. Once-weekly GLP-1 receptor agonists represent an effective and convenient treatment option that can potentially increase treatment satisfaction and improve adherence, contributing to improved health outcomes.

Once-weekly GLP-1 receptor agonists may potentially maintain greater adherence than daily GLP-1 receptor agonists due to the convenience of less frequent dosing.[13]

Compared with oral antidiabetic medications, once-weekly GLP-1 receptor agonists demonstrated some advantages in terms of glycemic control, weight, and risk of hypoglycemia, which in some, but not all cases, were associated with significantly greater improvement in relevant aspects of HRQoL and treatment satisfaction.For example, in DURATION-2, exenatide ER significantly reduced weight compared to both sitagliptin and pioglitazone and also significantly improved weight-related HRQoL compared to pioglitazone (but not sitagliptin).[14]

In this study, there was a significant correlation between changes in weight and changes in weight-related HRQoL. AWARD-3 found that dulaglutide improved glycated hemoglobin compared to metformin and the 1.5 mg dose of dulaglutide was associated with a greater improvement in perceived hyperglycemia than metformin.[15]

In AWARD-2, dulaglutide was associated with significantly greater improvement compared to insulin glargine in HRQoL, ability to perform physical activities of daily living, and hypoglycemia-related PROs. Similarly, in SUSTAIN-4, semaglutide was associated with greater treatment satisfaction than insulin glargine, and the higher dose of semaglutide (1.0

mg) also demonstrated significant improvement compared with insulin glargine in the role, emotional, and general health domains of the SF-36.[16]

These findings suggest that once-weekly GLP-1 receptor agonists may have some advantages over insulin in terms of HRQoL and treatment satisfaction.

In studies, patients with T2DM reported a preference for once-weekly over daily dosing.[17]

When choosing a treatment regimen for patients with type 2 diabetes mellitus, it is important to consider the impact of treatment on HRQoL. Once-weekly GLP-1 RAs appear to offer advantages in terms of HRQoL and treatment satisfaction compared with oral antidiabetic medications, insulin, and daily GLP-1 receptor agonists. The observed benefits are often related to the relative effects of the drug on glycemic control, weight, and hypoglycemia, and their detection depends on the use of appropriate assessment tools.

Generic quality of life assessment tools are questionnaires that measure several aspects of quality of life in healthy individuals and in individuals with disease.These tools typically provide a scoring system that allows results to be summarized as a number of points or a single score (often as an index). The most widely used in endocrinology studies are: Medical Outcome Study Health Survey 36-Item Short Form (SF-36). The SF-36 is one of the most widely used generic instruments to measure health status and health-related quality of life. This questionnaire has been shown to capture differences in health status between individuals with different chronic diseases and between individuals with different degrees of severity of the same disease. There are also short alternative forms of the questionnaire. The SF-36 has also demonstrated sensitivity to significant treatment effects in different patient populations. The questionnaire consists of thirty-six questions that are divided into eight areas of measurement. Physical function, pain, general and mental health, emotional and social function are assessed.[18]

Of the large number of diabetes-specific questionnaires, the most promising approach to assessing HRQoL is the Audit of Diabetes-Dependent Quality of Life (ADDQoL).[19] The Audit of Diabetes-Devendent Quality of Life (ADDQoL) questionnaire is a third-generation individualized QoL instrument. It is a disease-specific measure that is increasingly being used to explore patients' perspectives on the impact of diabetes on their quality of life in a number of domains. The ADDQoL is a valid and reliable questionnaire originally developed in the

United Kingdom.[20] What makes this questionnaire unique compared to others is that patients are able to indicate whether potentially affected areas of life apply to them and rate their impact along with the perceived importance of each area to their QoL.[21]

The Diabetes-Dependent Quality of Life (ADDQoL) audit has 19 questions measuring life domains: career, social life, family, friendships, sex life, free time, time options, travel, worries about the future, worries about the future of family and friends, and motivation to achieve things.[22] The ADDQoL attempts to comprehensively assess diabetes-specific QoL by assessing how people perceive diabetes, how the disease interferes with their well-being, or conversely, how diabetes can have a positive effect on some aspects of life. There is still no single instrument that can be used as a "gold standard".[23]

The aim of the present analysis is to investigate the quality of life of patients with type 2 diabetes mellitus treated with GLP-1 receptor agonists and how the latter affects different aspects of quality of life.

## MATERIAL AND METHODS

The survey was conducted in the period of November 2022. – July 2023 in Burgas region. The study group included 66 patients with type 2 diabetes mellitus on initial treatment with metformin and/or SUP. Participants are randomly selected.

The medical information and the survey was carried out in medical facilities for outpatient medical care.

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Monitoring indicators are social health status and quality of life in patients with type 2 DM on different therapy.

The methods for collecting scientific information are

- Documentary method - analysis of documents and collection of primary medical information - outpatient lists, epicrisis, laboratory tests, consultations
- Survey method - direct individual survey of patients in outpatient care. The patients were asked to fill in two types of questionnaires assessing the physical and mental health of the

patients at the beginning and 6 months later (after included treatment with SGLT-2 inhibitors).

1. SF36 including 36 questions
2. Validated Bulgarian version of ADDQoL including 19 questions.

- Applied statistical methods - Chi-Square Test was applied to establish dependencies between categorical values. Applying this test, it is determined whether there are statistically significant differences in quality of life indicators at the beginning of follow-up and after 6 months.

The obtained data were processed with the statistical package SPSS 22.

All patients included in the study were thoroughly informed about its purpose and tasks and gave their written informed consent.

## RESULTS AND DISCUSSION

From a total of 66 patients treated with a GLP-1 receptor agonist, 26 were men (39.4%) and 40 were women (60.6%) (Fig. 2).

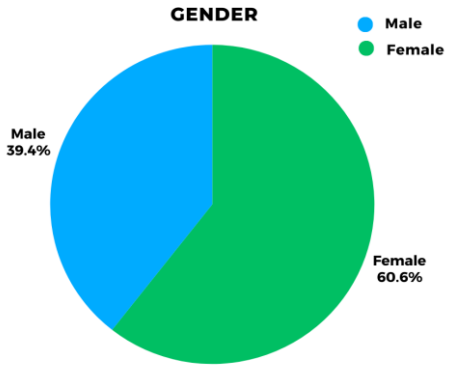


**Fig. 2 Distribution of patients treated with GLP-1 receptor agonists.**

The mean age of patients treated with GLP-1 receptor agonist was 54.74±10.22 years. The minimum age in this group is 33 years and the maximum age is 75 years.

ANALYSIS AND ASSESSMENT OF PATIENTS' QUALITY OF LIFE THROUGH THE ADDQoL SURVEY

Regarding the assessment of how important certain activities are for the patient, the latter give the following answers (table 2).

**Table 2 : Responses regarding the importance of certain activities of daily living in patients taking a GLP-1 receptor agonist.**

| | beginning | after 6 months | p |
|---|---|---|---|
| **Leisure activities** | 3.33±1.12 | 3.79±1.00 | *p<0.05 0.015<0.05 |
| **Working life** | 2.79±1.33 | 3.20±1.36 | 0.077>0.05 |
| **Local or long distance journeys** | 2.41±1.34 | 2.47±1.43 | 0.794>0.05 |
| **holidays** | 3.32±1.48 | 3.44±1.58 | 0.637>0.05 |
| **Physical can do** | 4.74±0.53 | 4.83±0.41 | 0.295>0.05 |
| **Family life** | 4.67±0.81 | 4.69±0.86 | 0.895>0.05 |
| **Friendship and social life** | 4.08±0.88 | 4.19±0.90 | 0.475>0.05 |
| **Close personal relationship** | 4.68±0.72 | 4.74±0.58 | 0.589>0.05 |
| **Sex life** | 3.26±1.5 | 3.37±1.58 | 0.668>0.05 |
| **Physical appearance** | 3.85±1.28 | 3.94±1.2 | 0.658>0.05 |
| **Self-confidence** | 3.97±1.06 | 3.16±1.07 | 0.309>0.05 |
| **motivation** | 2.67±1.38 | 3.84±1.31 | *p<0.05 0.000<α=0.05 |
| **People~s reaction** | 2.7±1.31 | 3.11±1.29 | 0.064>0.05 |
| **Feeling about the future** | 3.45±1.11 | 3.77±1.14 | 0.104>0.05 |
| **Financial situation** | 4.67±0.66 | 4.76±0.52 | 0.378>0.05 |
| **Living conditions** | 4.03±1.1 | 4.11±1.07 | 0.654>0.05 |
| **Depend on other** | 1.86±1.05 | 1.63±0.83 | 0.150>0.05 |
| **Freedom of eat** | 3.24±1.34 | 3.04±1.29 | 0.379>0.05 |
| **Freedom of drink** | 2.33±1.5 | 1.8±1.34 | *p<0.05 0.031<0.05 |

*significance at p<0.05

From the table of comparative analysis of the quality of life of patients who took GLP-1 receptor agonist medication during the first and second stages of follow-up, we can derive the following observations: there are statistically significant differences in aspects such as "Leisure activities" and "Motivation" between the beginning of the follow-up and after 6 months. Improvements in aspects such as "Motivation" and "Freedom to drink" were statistically significant, indicating a greater impact of taking a GLP-1 receptor agonist medication in these aspects. Aspects such as "Work life", "Tourism near or long distance" and "Sex life" did not show significant changes between the beginning and the end of the follow-up.

These results highlight the impact of the GLP-1 receptor agonist medication on various aspects of patients' lives and emphasize the importance of continued monitoring and evaluation of treatment impact.

In the second part of the study, the patients assessed the extent to which they were able to carry out the listed daily activities (Table 3)

**Table 3 : Answers regarding the question of how well GLP-1 receptor agonist patients manage to accomplish these aspects of life.**

| | beginning | after 6 months | p |
|---|---|---|---|
| **Leisure activities** | 2.98±1.06 | 3.79±1.00 | *p<0.05 0.000≤0.05 |
| **Working life** | 3.83±1.31 | 3.93±1.25 | 0.667<α=0.05 |
| **Local or long distance journeys** | 2.53±1.32 | 2.74±1.35 | 0.358>0.05 |
| **holidays** | 2.58±1.35 | 2.71±1.53 | 0.579>0.05 |
| **Physical can do** | 3.47±1.15 | 4.07±1.01 | *p<0.05 0.002<0.05 |
| **Family life** | 3.85±1.55 | 4.16±1.56 | 0.251>0.05 |
| **Friendship and social life** | 3.79±1.04 | 4.16±1.56 | *p<0.05 0.012<0.05 |
| **Close personal relationship** | 3.94±1.35 | 4.33±1.16 | 0.074>0.05 |
| **Sex life** | 2.76±1.39 | 3.01±1.51 | 0.307<α=0.05 |
| **Physical appearance** | 2.71±0.92 | 3.69±0.94 | *p<0.05 0.000<α=0.05 |
| **Self-confidence** | 2.03±0.84 | 3.79±1.08 | *p<0.05 0.000≤0.05 |
| **motivation** | 2.11±1.04 | 3.77±1.35 | *p<0.05 0.000≤0.05 |
| **Peoples reaction** | 2.76±1.16 | 3.04±1.29 | 0.179>0.05 |
| **Feeling about the future** | 3.00±1.19 | 3.57±1.22 | *p<0.05 0.007≤0.05 |
| **Financial situation** | 3.55±1.21 | 4.14±1.05 | *p<0.05 0.003≤0.05 |
| **Living conditions** | 4.2±1.01 | 4.39±0.92 | 0.257≥0.05 |
| **Depend on other** | 2.08±0.99 | 1.87±0.93 | 0.219≥0.05 |
| **Freedom of eat** | 3.58±1.06 | 3.13±0.97 | *p<0.05 0.012≤0.05 |
| **Freedom of drink** | 2.55±1.5 | 1.69±1.14 | *p<0.05 0.000≤0.05 |

*significance at p<0.05

There were statistically significant improvements in aspects such as leisure activities, physical strength, friendships and social life, appearance, self-esteem, motivation, sense of the future, financial status, freedom to eat and freedom to drink. Some aspects such as work life, short or long distance travel, vacation, family life, close personal relationship, sex life,

the way people relate, living conditions and dependence on others did not show statistically significant differences.

These observations reflect the important impact of GLP-1 receptor agonist medication on the lives of T2DM patients and support the need for continued follow-up and evaluation of therapy.

ANALYSIS AND ASSESSMENT OF PATIENTS' QUALITY OF LIFE THROUGH THE SF 36 QUESTIONNAIRE

Most patients reported that they were not very nervous (47.0% at baseline and 50.0% at 6 months). The majority of patients declared that they did not feel so down that nothing could cheer them up (65.2% at the beginning of the follow-up and 72.9% after 6 months). There was a significant improvement in the percentage of patients feeling calm and peaceful (42.4% at baseline and 45.7% at 6 months). The number of those who felt very energetic increased from 9.1% at the beginning of the follow-up to 32.9% after 6 months. On the issue of discouragement, there was a reduction in the percentage of patients feeling discouraged (27.3% at baseline and 2.9% at 6 months).

Overall, these observations contribute to the understanding of the influence of GLP-1 receptor agonist drugs on the energy and emotions of T2DM patients. Improvements in various aspects of emotional well-being may be a key element in evaluating treatment effectiveness.

A Chi-Square Test showed that there was a statistically significant difference in the responses of patients taking a GLP-1 receptor agonist regarding whether they felt full of energy at baseline and after 6 months. The basis for this conclusion is given by the characteristic Pearson Chi-Square = 15.811, which has a level of significance Asymp. Sig. (2-sided)= 0.007 $< \alpha = 0.05$. The coefficient Cramer's V = 0.341 indicates that there is a moderate dependence. There was a statistically significant difference in the responses of patients taking a GLP-1 receptor agonist regarding whether they had a lot of energy at baseline and after 6 months. The basis for this conclusion is given by the characteristic Pearson Chi-Square = 23.265, which has a level of significance Asymp. Sig. (2-sided)= 0.000 $< \alpha = 0.05$. The coefficient Cramer's V = 0.414 indicates that there is a moderate dependence. A statistically significant difference was found in the responses of patients taking a GLP-1 receptor agonist regarding

whether they felt tired at baseline and after 6 months. The basis for this conclusion is given by the characteristic Pearson Chi-Square = 18.313, which has a level of significance Asymp. Sig. (2-sided)= 0.003 < α =0.05. The coefficient Cramer's V = 0.3367 indicates that there is a moderate dependence.

## CONCLUSION

The emergence of new medicinal products for the treatment of type 2 DM in recent years is increasingly displacing the traditional conventional treatment with metformin and SUP. This necessitates the preparation of an analysis and evaluation of the quality of life during treatment with these groups of medications.

A particularly important element appears to be an understanding of the impact of treatment of diabetes mellitus on quality of life, given the goal of treatment to reduce disease-related QoL impairment.

Treatment-related improvements in HRQoL may allow patients to better manage their self-care and engage in health-promoting activities.

Improvements in treatment satisfaction can improve HRQoL and can also potentially lead to better treatment adherence, which in turn can improve disease control and lead to better health outcomes.

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