

QUALITY OF LIFE IN PATIENTS WITH TYPE 2 DIABETES AND ESTABLISHED CARDIOVASCULAR DISEASE OF METFORMIN AND SULFONYLUREA TREATMENT

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ABSTRACT

Diabetes has a great effect on the quality of life (QoL) of patients, especially in cases with co-morbidities. In Bulgaria, there is an increase in the prevalence of diabetes by 20.88% and assessment of QoL is of interest for the overall health assessment of the patients. The aim of our study is to investigate satisfaction and health-related QoL in individuals with type 2 diabetes and established cardiovascular complication. Our study includes 40 type 2 patients, 20 men at age of 54.6 ± 9.6 years and 20 women at age of 63.1 ± 10.5 years. All of them with cardiovascular complication diagnosed within 1 month. Diabetes duration in group is 9.0 ± 5.6 years, BMI in group is 33.6 ± 4.95 kg/m², 35% of patients received metformin, 15% were on sulfonylureas 15% and 50% received sulfonylureas plus metformin. HbA1c was 8.5 ± 0.7

and fasting glucose 10.6 ± 3.9 mmol/l. We used an extended version of SF36 questionnaire. The study period is November 2022 – April 2023 30% of men and 20% of women rated general health is very good. 50% of men and 60% of women rated it as good. 20% of men and women rate it as weak. Compared to 1 year ago, 10% of men and none of women rate their health as much better now; 30% of men and 40% of women define it as the same; 50% of men and women think that their health is slightly worse; 10% of both genders believe that their health is much worse now. 10% of men and 20% of women do not experience difficulties as a result of the disease. Patients in both groups are reporting worsening of QoL ($p < 0.05$). 60% of men and 40% of women find it difficult, but manage to cope, and the remaining 30% of men and 40% of women find it difficult and think they are not coping. 10% of both genders reported severely limited physical activity, 50% of men and 30% of

women experienced no limitations. Limited physical activity was reported by 40% of men and 60% of women. Previous cardiovascular incident is decreasing QoL of patients dependent on gender, age and disease duration ($p < 0.05$) Regular assessment of QoL at certain intervals is a necessity in order to improve the management of the disease and for prolonging life and improving QoL. Our group includes only patients on metformin and sulfonylurea and the beneficial effects of initiating GLP1 receptor agonists and SGLT2 inhibitors to further reduce the risk of a future cardiovascular event should also be considered in the choice of therapy.

KEYWORDS: Quality of life, Metformin, sulfonylurea, Diabetes mellitus, Cardiovascular disease.

INTRODUCTION

In Bulgaria, there are about 426,000 people with diagnosed diabetes, which represents 7.9% of the population aged between 20 and 79 (57% men and 43% women). The frequency of diabetes mellitus in Bulgaria (diagnosed and undiagnosed) from 7.9% in 2006 reached 9.55% in 2012, $p = 0.06$. Age is a major risk factor for a significant increase in diabetes, especially in the 50-59 decade. increased from 9.4% in 2006 to 15.7% in 2012, $p < 0.02$.^[1]

Diabetes remains a serious and growing public health challenge and places an enormous burden on affected individuals and their families. People living with diabetes are at risk of developing several debilitating and life-threatening complications, leading to increased need for medical care, reduced quality of life, and premature death. Globally, diabetes ranks among the top 10 causes of death. Diabetes mellitus (DM) is one of the most common chronic diseases in the world and has a great effect on the quality of life of patients, especially when the patient has other co-morbidities.

DM is a significant and growing health care challenge, a leading cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation. DM and its complications have contributed enormously to the burden of mortality and disability worldwide. Patients with chronic diseases are not only physically ill, but also exhibit variable emotional distress and have lower self-reported quality of life compared to the healthy population.^[2]

Progression of diabetes, and particularly poor glycemic control, leads to numerous potentially life-threatening complications. Almost half of adults with chronic kidney disease come from

a diabetic population. Similarly, 9.8% of diabetics had a myocardial infarction, 9.1% suffered from coronary artery disease (CAD), 7.9% had congestive heart failure, 6.6% had a stroke, while more than a quarter of them 27.8% suffer from chronic kidney disease, almost a quarter 22.9% have foot problems and last but not least 18.9% have eye damage.^[3]

Uncontrolled diabetes is associated with the development of complications that can compromise health-related quality of life (HRQoL) and can increase the risk of mortality. These include macrovascular (eg, coronary artery disease, stroke, and peripheral vascular disease) and microvascular (eg, retinopathy, nephropathy, and neuropathy) complications.^[4] Numerous studies have shown that QoL in patients with DM is lower than that of healthy individuals, and the factors involved in this regard are not well defined. It should be noted that some variables such as type of DM, insulin use, age, complications related to DM, social status, psychological factors, ethnicity, level of education, knowledge of the disease, type of help received from others, may affect QoL for these patients.^[5]

In a study (CODE-2) involving 1371 type 2 diabetics in a Dutch population, HRQL was assessed. Lower scores were reported in women with obesity, insulin use and complications. In particular, low scores were observed for the combination of microvascular and macrovascular complications.^[6]

Factors affecting the quality of life can also be side effects of the groups of medications discussed in this article.

Sulfonylureas (SUP) - a group of drugs that stimulate the secretion of insulin by binding to a specific receptor (SUR 1) on the surface of β -cells of the pancreas. In Bulgaria, representatives of the second generation of SUPs are used - Glibenclamide, Glipizide, Gliclazide and Glimepiride. SUPs reduce fasting and postprandial blood sugar. Glimepiride is the only representative of SUP that improves peripheral insulin sensitivity. Hypoglycemia and weight gain are the most common side effects when using this group of medications.

Biguanides - the only representative that is currently used is metformin. Metformin is an insulin sensitizer that acts on the liver, skeletal muscle, and adipose tissue. Activates AMP-dependent protein kinase (AMPK) - a key enzyme in the transmission of the insulin signal in cells and glucose and lipid metabolism. Metformin lowers hyperglycemia but does not affect normal blood sugar levels. It has a beneficial effect on the cardiovascular system and lipid

metabolism, reduces plasma insulin levels, directly affects endothelial dysfunction, fibrinolysis, oxidative stress, atherogenesis processes, microcirculation and non-enzymatic glycation of proteins. It is neutral in terms of body weight. There is evidence of a cancer-protective effect of metformin and of beneficial effects (reduction of liver aminotransferases and liver inflammation) in non-alcoholic steatosis. In recent years, there have also been reports of a neuroprotective effect of metformin. The most common side effects of metformin are gastrointestinal complaints.^[7]

Complications of DM may be responsible for most of the morbidity and mortality associated with the disease. Therefore, regular assessment of patients' QoL at certain intervals is a necessity for DM as a chronic disease. Such assessment, as a powerful tool, is crucial for predicting patients' status for disease management and long-term health care. Regular assessment of QoL as a routine clinical practice can potentially improve the necessary communication between health care providers and their patients, thus identifying complications and assisting them in continuing care leading to improvement in their health status.^[8]

MATERIALS AND METHODS

Our study includes 40 type 2 patients, 20 men at age of 54.6 ± 9.6 years and 20 women at age of 63.1 ± 10.5 years. All of them with cardiovascular complication diagnosed. The patients were surveyed using a questionnaire that is an extended version of the SF36, composed of 69 questions, divided into 3 groups of pre-formulated questions. The SF 36 is a general instrument that measures various health concepts: general health, limitations in physical functioning, physical health problems, bodily pain, vitality, social functioning, emotional changes, and mental health.

Determined total SF 36 score, with higher scores reflecting better QoL. In order to clarify the patient's medical status and history of the disease and accompanying complications and treatment, the patient's medical file was used. The study period is November 2022. – April 2023. Statistical analysis included descriptive statistics, Student's t-test, and Spearman's correlation analysis. A value of $p < 0.05$ is accepted for statistical dependence.

RESULTS AND DISCUSSION

The demographic characteristics of the study group of patients are presented in Table 1.

Sociodemographic characteristics and therapeutic approach in the analysed patients with diabetic polyneuropathy

Table 1

Demographic characteristic (n=20)	Values
Sex (%)	
male	50
female	50
Duration of diabetes (mean years \pm SD)	54,6 \pm 9,57
	63,1 \pm 10,5
	9,0 \pm 5,6
Type of therapy (%)	
metformin	35
sulfonilurea	15
metformin with sulfonilurea	50
HBA1C (%)	8,5 \pm 0.7
Fasting blood sugar (mmol/l)	10.6 \pm 3.9
BMI (kg/m ²)	33,6 \pm 4.95

In the studied group of patients, the duration of diabetes mellitus was 9.0 \pm 5.6 years, BMI was 33.6 \pm 4.95 kg/m². Antidiabetic therapy in the surveyed patients was as follows: - Metformin - 35% (n=14), SUP - 15% (n=6) and SUP + Metformin - 50% (n=20). All respondents had suboptimal glycemic control of diabetes - correspondingly HBA1C-8.5 \pm 0.7% and fasting blood glucose - 10.6 \pm 3.9 mmol/l.

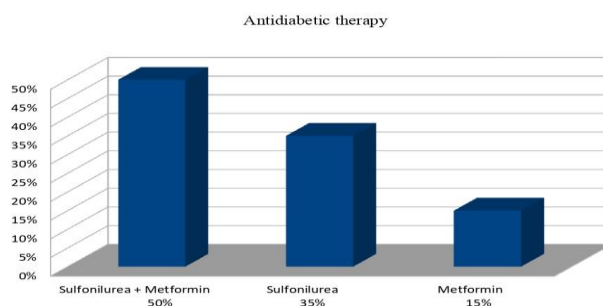


Fig. 1

After processing the data, the results of some of the questions are presented in table 2.

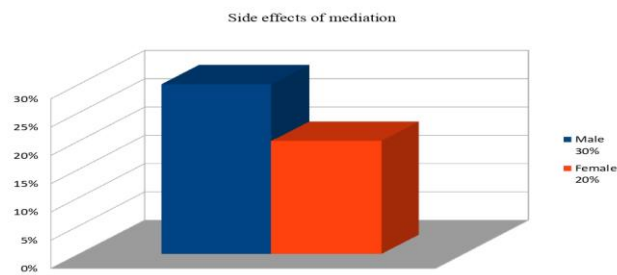
Table 2

How would you rate your health?							
Excellent		Very good		Good		Weakly	
men-0%	women-0%	men-30%	women-20%	men-50%	women-60%	men-20%	women-20%

Compared to 1 year ago, how would you rate it now?							
Much better now		The same		A little worse		Much worse	
men-10%	women-0%	men-30%	women-20%	men-50%	women-50%	men-10%	women-10%
Does the disease make it difficult for you in your daily life?							
No			Yes, it is hard, but i can do it		Yes, it is hard and can not handle it		
men-10%	women-20%		men-60%	women-40%	men-30%	women-40%	
Do you experience limitation of physical activity?							
Yes, very limited			No, it is not limited		Yes, a bit limited		
men-10%	women-10%		men-50%	women-30%	men-40%	women-60%	
Do you find it difficult to take your medication and do you have difficulty taking it?							
No		Yes, there are many		To be accepted precisely		Yes, side effects	
men-60%	women-50%	men-0%	women-0%	men-10%	women-30%	men-30%	women-20%

Regarding general health, 30% (n=6) of men and 20% (n=4) of women rate it as very good. 50% (n=10) of men and 60% (n=12) of women rate it as good. 20% (n=4) of men and 20% (n=4) of women rate it as poor.

Compared to 1 year ago, 10% of men and 0% (n=0) of women rate their health as much better now. 30% (n=6) of men and 40% (n=8) of women define it as the same. 50% (n=10) of men and 50% (n=10) of women consider their health to be low worse compared to 1 year ago. 10% (n=2) of both sexes believe that their health is much worse now compared to the previous year. 10% (n=2) of men and 20% (n=4) of women experience no difficulty in daily life as a result of the disease. 60% (n=12) of men and 40% (n=8) of women find it difficult, but manage to cope, and the remaining 30% (n=6) of men and 40% (n=8) of women find it difficult and think that they are not up to it. 10% (n=2) of both sexes reported severely limited physical activity, and 50% (n=10) of men and 30% (n=6) of women experienced no limitations. Somewhat limited physical activity was reported by 40% (n=8) of men and 60% (n=12) of women. 60% (n=12) of men and 50% (n=10) of women do not experience difficulties and difficulties in taking medication. 10% (n=2) of men and 30% (n=6) of women experience difficulties 30% (n=6) of men and 20% (n=4) of women reported discomfort and difficulties as a result of side effects of the medication.

**Fig. 2**

The aim of the current analysis was to investigate the satisfaction and health-related quality of life in individuals with type 2 diabetes and a diagnosed cardiovascular complication treated with metformin, sulphonylurea and metformin +SUP.

Data from our study confirm the relationship between the quality of life of patients with type 2 diabetes mellitus and a realized cardiovascular complication.

A limitation of our study is the relatively small number of patients followed, as well as the therapy they received. The patients so far have not received treatment to maximize the therapeutic effect (so far they have only been treated with the metformin and SUP groups). Follow-up and evaluation of the quality of life after optimizing glycemic control and adding to the treatment a class of antidiabetic drugs with proven cardioprotective effects. The main drawback of the study is the limited number of patients included and the need for additional and more thorough research.

CONCLUSION

Modern antidiabetic therapy, providing strict glycemic control, is the key to prevention of complications and their negative impact on QoL in patients with type 2 diabetes mellitus. Regular assessment of QoL would give an indication of timely influencing the condition of patients in order to improve their emotional well-being, self-esteem and overall disease control.

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