The Main Factors Influencing Adherence to drug Therapy in Patients with Diabetes Mellitus

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Authors' contributions

This work was carried out in collaboration between both authors. Author MVV designed the study, performed the statistical analysis and wrote the first draft of the manuscript. Author NVP managed the analyses of the study and also the literature searches. Both authors read and approved the final manuscript.

Original Research Article

ABSTRACT

Introduction: Diabetes mellitus is a disease that requires the patient to strictly adhere to the prescribed treatment throughout his life to prevent the development of various complications of diabetes. The need for repeated daily medication intake, learning knowledge about diabetes, gaining skills of self-monitoring of health indicators (glucose, blood pressure, level of physical activity), visits to healthcare facilities for preventive examinations and treatment is a heavy burden on the patient, reducing the quality of life and motivation to comply with the prescriptions of the attending physician.
Objectives: To analyze the level of adherence to drug therapy and its factors in patients with diabetes mellitus.
Methods: The survey was carried out over the Internet from November 2020 to February 2021. 434 respondents with diabetes mellitus, aged from 18 to 80, were included into study. Among them there were 221 women (50,92%) and 213 men (49,08%). The proportion of respondents with type 1 diabetes mellitus (T1DM) was 23,96% (n = 104, 95% CI 20,17%–28,22%), with type 2 diabetes mellitus (T2DM) – 76,04% (n = 330, 95% CI 71,78%–79,83%). The survey questionnaire consisted of 2 parts. The first part contained 54 questions related to demographic, socioeconomic, and health

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status of participants' along with questions designed to identify respondents' risk factors, diabetes course and complications, information technology usage in treatment and health management process. The second part of the survey contained 25 questions based on the "Russian universal questionnaire for quantifying adherence to treatment" (KOP-25). The Pearson chi-square test and Cramér's V test of the effect size were used to assess the collected nominal data.

Results: A low level of adherence to drug therapy prevailed among all respondents, 38,48% (n = 167). Statistically significant differences in the level of adherence to drug therapy were found among respondents with type 1 diabetes mellitus ($p < 0,0001$), ones visited the schools of diabetes ($p < 0,001$), respondents with a high level of knowledge about diabetes ($p < 0,001$), respondents who adhered to the prescribed medical regimen ($p = 0,001$), respondents who visit a doctor at least 1 time per year ($p = 0,001$), ones who used remote forms of interaction with the attending physician ($p < 0,001$), respondents in younger age groups ($p < 0,001$), respondents with a shorter duration of diabetes mellitus ($p = 0,005$).

Conclusion: The main direction for the quality of life improvement for patients with diabetes mellitus is to increase patients' awareness of possible ways to change their lifestyle while maintaining a high level of adherence to drug therapy using information and communication technologies and telemedicine.

1. INTRODUCTION

The problem of diabetes mellitus (DM) in modern society keeps medical and social relevance because of its high prevalence, high level of disability and mortality. Results of previously conducted researches indicate insufficient primary prevention and early diagnosis of diabetes both at the population level and among people with a high risk of developing this disease. Among the main reasons for this situation, a special place is given to the insufficient adherence of patients to drug and non-drug therapy, as well as to the need to change the lifestyle. Adherence to drug therapy (DT) is the most important component of maintaining life expectancy, preventing the development of complications of diabetes mellitus, and maintaining the required quality of life [1].

Clinical recommendations on the management of patients with diabetes, are considered as the basic direction of treatment for a doctor to improve the patient's health and quality of life, considering the development of complications of diabetes. According to the clinical guidelines in the Russian Federation, diabetes therapy involves long-term administration of medical drugs (MD), compliance with significant restrictions regarding changes in the patient's lifestyle, as well as the necessary skills for self-monitoring of one's health and extensive knowledge about diabetes. At the same time, ensuring the patient's information needs about diabetes mellitus plays an important role [2,3]. One of existing ways to raise the awareness of patients with diabetes in Russian Federation is to send them to specialized schools of diabetes, in which patients are taught about the main causes and possible complications of diabetes, skills of self-health monitoring, and the rules of compliance with the prescribed treatment regimen by health professionals.

According to the definition proposed by the experts of the World Health Organization (WHO), adherence to treatment is the degree of compliance of the patient's behavior with the doctor's recommendations regarding the regularity of drug intake, its dose, and the interval between doses, and an increase in the effectiveness of measures aimed at improving adherence to treatment can have a much greater impact on the health of the population than the improvement of any individual medical procedures [4,5].

Unfortunately, quite often the model of interaction between a patient and a doctor is limited only to drawing up a treatment regimen and an examination plan for the patient, which is a significant disadvantage since, in chronic non-communicable diseases, the patient needs not only medical treatment but also psychological assistance in adapting to the need to develop new habits and rules for monitoring the state of health, information support and consultations of the attending physician, as well as maintaining a high level of motivation to achieve target

indicators reflecting the quality of treatment. Reduced quality of life and the need to adhere to a strict treatment regimen can lead to depression in patients with diabetes mellitus and increase the risk of non-adherence to treatment [6].

Diabetes mellitus, in addition to a direct effect on the body itself, is also a risk factor for the onset or worsening of concomitant diseases. The presence of several diseases in one patient, both related and unrelated pathogenetically or genetically, is typical for patients with long-term diabetes mellitus. The presence of several pathologies often leads to over-treatment, the prescription of a large number of medications and procedures, the need to visit a medical organization more often, which leads to great difficulties and changes in the patient's usual lifestyle, as well as a decrease in adherence to drug therapy [7,8].

A low level of adherence to drug therapy leads not only to a deterioration in the patient's health but also to an increase in the health care system costs for excessive visits to medical institutions, the occurrence of complications requiring expensive treatment, drug provision, a decrease in life expectancy, early disability, and premature mortality. Thus, the formation of a high level of motivation for adherence to DT is a multi-component process associated with social and economic factors, the qualification of the attending physician, the availability and quality of the health care system, the type of disease, and the individual characteristics [6].

The immediate environment, family, friends, work colleagues, housemates, and hospital ward neighbors can have a positive effect on maintaining patient motivation to maintain and increase adherence to DT and adherence to doctor's recommendations. Understanding and support from the family are especially important, since diabetes mellitus requires changes in dietary habits, increased physical activity, quitting bad habits, and maintaining normal body weight, and these changes affect not only the patient himself but also his family [9].

The main goal of the study was to analyze the level of adherence to drug therapy in patients with diabetes mellitus and key factors affecting adherence.

2. MATERIALS AND METHODS

The Google Forms based survey was carried out over the Internet from November 2020 to February 2021. The minimal required number of units of observation (n = 384) was calculated based on the formula provided by C.C. Serdar et al.:

$$N = \frac{Z_{\alpha/2}^2 \times P \times (1-P) \times D}{E^2} \text{ [10]},$$

where N - sample size, P - proportion of event (0,5 was chosen), E – margin of error (0,05 was chosen), D - design effect (1 was chosen), Zα/2 – Z-score (1.96 was chosen for alpha 0.05).

The survey responses were collected until reaching at least minimal required number. The initial sample contained more responses due to open access nature of the survey, providing better power of the research. Eligibility criteria required participants to be 18 years or older and to have confirmed diabetes mellitus diagnosis (ICD-10 codes from E10 to E14). 13 out of 447 received responses were excluded based on participants' age (younger than 18 years old), absence of confirmed diabetes mellitus, multiple form submission (duplicated responses), and missed answers on questions required for further analysis.

434 patients with diabetes mellitus aged from 18 to 80 years were included into the final sample for further analysis. The proportion of respondents with type 1 diabetes mellitus (T1DM) was 23,96% (n = 104), with type 2 diabetes mellitus (T2DM) – 76,04% (n = 330). The largest proportion of respondents was in the 50-59 years old age group (27,65%, n = 120, 95% CI 23,63%–32,07%). One-fourth (25,35%, n= 110) of respondents was in the 30-39 years age group, and 23,96% (n = 104) were in the 40-49 years age group. Other age groups were relatively smaller and included less proportion of survey participants: 60-69 years (14,98%, n = 65), 18-20 years (3,69%, n = 16), 20-29 years (3,46%, n = 15), 80 years or older (0,46%, n = 2) The study sample included 221 women (50,92%) and 213 men (49,08%). For 37,79% of respondents (n = 164) the duration of the DM was from 11 to 15 years, 24,65%of respondents (n=107) had DM from 6 to 10 years, and 24,19% of respondents (n=105) had DM for 16 years or longer.

The survey questionnaire consisted of 2 parts. The first part contained 54 questions related to demographic, socioeconomic, and health status of participant along with questions designed to identify respondents' risk factors, diabetes

course and complications, information technology usage in treatment and health management process. The second part included 25 questions based on the "Russian universal questionnaire for quantifying adherence to treatment" (KOP-25), developed by N.A. Nikolaev and Yu.P. Skirdenko (2008). The confirmed sensitivity of KOP-25 questionnaire is 93%, the specificity is 78%, and the reliability is 94% [11]. Patients' responses to the questions in the second part were assessed according to specially developed criteria for assessing adherence to drug therapy, with the division of respondents into 3 groups: with a high (over 75%), medium (50-75%) and low (less than 50%) adherence to drug therapy.

The study of anthropometric data was carried out in accordance with the classification of the World Health Organization (WHO) by calculating body mass index using the formula: body weight / body length2 (kg/m2).

Statistical processing of the obtained data was carried out using the Stata 14.2 software package. Descriptive statistics results are presented as proportions and 95% confidence intervals. The Pearson chi-square test and Cramér's V test of the effect size were used to assess the nominal data. Yates's continuity correction was used when the number of expected observations in at least one of the cells was less than 10. The null hypothesis of no difference was rejected at $p < 0,05$.

3. RESULTS

The proportion of respondents with type 1 diabetes mellitus (T1DM) was 23,96% (n = 104, 95% CI 20,17%–28,22%), with type 2 diabetes mellitus (T2DM) – 76,04% (n = 330, 95% CI 71,78%–79,83%). A low level of adherence to drug therapy prevailed among all the respondents (38,48%, n = 167, 95% CI 33,99%–43,12%), 30,88% had a high level (n = 134, 95% CI 26,67%–35,34%), the average level was in 30,65% (n = 133, 95% CI 26,45%–35,10%). Only 8,06% (n = 35, 95% CI 5,84%–11,04%) of respondents attended school of diabetes (SD), the remaining 91,94% (n = 399, 95% CI 88,96%–94,16%) did not attend SD. Most of the respondents (52,30%, n = 227, 95% CI 47,60%–56,97%) had an average level of knowledge about diabetes mellitus, its manifestations, methods of treatment and prevention. Nearly half of the respondents (44,70%, n = 194, 95% CI 40,07%–49,40%) answered that they tried to comply with the treatment regimen. About half of

the respondents (47,93%, n = 208, 95% CI 43,25%–52,63%) answered that they visit the attending physician once every 6-12 months. The majority of respondents (90,55%, n = 393, 95% CI 87,53%–93,04%) answered that they did not use remote interactions (via messengers, email, website) with the attending physician. Two-fifth of the respondents (40,55%, n = 176, 95% CI 33,47%–48,24%) answered that they smoked or quitted smoking. More than a half of the respondents (62,21%, n = 270, 95% CI 53,94%–70,99%) had a BMI value of over 24,99. Slightly more than 1⁄3 of the respondents (36,64%, n = 159, 95% CI 32,20%–41,25%) rated their level of physical activity as low. 73,50% (n = 319, 95% CI 69,20%–77,49%) answered that they had concomitant diseases. About half of the respondents (44,47% n = 193, 95% CI 39,84%–49,17%) answered that they had complications resulting from diabetes mellitus

Analysis of the commitment of drug therapy of patients with diabetes mellitus revealed that the commitment to DT was significantly higher in following groups: DM Type 1 vs. DM Type 2 ($chi2_{(2)}$ = 257,639, p <0,0001, V Cramér's = 0,77), those who visited the school of diabetes visit ($chi2_{(2)}$ = 44,575, p <0.001, V Cramér's = 0,32), respondents with a high level of knowledge about diabetes ($chi2_{(4)}$ = 35,359, p <0,001, V Cramér's = 0,32), respondents who followed the prescribed treatment regime ($chi2_{(4)}$ = 19,041, p = 0,001, V Cramér's = 0,14), respondents who visited the doctor 1-2 times in 6-12 months ($chi2_{(8)}$ = 25,142, p = 0,001, V Cramér's = 0,17), respondents who used remote interactions with the attending physician ($chi2_{(4)}$ = 38,920, p <0,001, V Cramér's = 0,21), respondents in younger age groups ($chi2_{(14)}$ = 99,092, p <0,001, V Cramér's = 0,33), respondents with shorter history of diabetes ($chi2_{(8)}$ = 22,17, p = 0,005, V Cramér's = 0,16).

No statistically significant differences in the level of adherence to drug therapy were found in sex groups ($chi2_{(2)}$ = 4,085, p = 0,129, V Cramér's = 0,09), smokers and non-smokers ($chi2_{(4)}$ = 5,421, p = 0,247, V Cramér's = 0,07), respondents with and without concomitant diseases ($chi2_{(4)}$ = 5,007, p = 0,287, V Cramér's = 0,07), those who had and did not have complications of diabetes ($chi2_{(4)}$ = 3,087, p = 0,543, V Cramér's = 0,06), groups with different physical activity levels ($chi2_{(4)}$ = 4,464, p = 0,347, V Cramér's = 0,07), groups with different body mass index ($chi2_{(4)}$ = 5,956, p = 0,202, V Cramér's = 0,08). The analysis result is presented in Table 1.

Table 1. The effect of various factors on the level of adherence to drug therapy, n=434

№	Attribute	level of adherence to drug therapy			Chi2 (df),	V Cramér's
		High	Moderate	Low	p	
1	Type of Diabetes					0,770
	Type 1	98	5	1	257,639 (2)	
	Type 2	36	128	166	p<0,001	
2	Visited the Schools of Diabetes					0,320
	Yes	28	6	1	44,575 (2)	
	No	106	127	166	p<0,001	
3	Level of Knowledge about Diabetes					0,202
	High	41	14	13	35,359 (4)	
	Moderate	41	40	58	p<0,001	
	Low	52	79	96		
4	Adherence to the Treatment Regimen					0,148
	All of the time	78	46	66	19,041 (4)	
	Never	15	18	17	p=0,001	
	Some of the time	41	69	84		
5	Number of Attending Physician Visits					0,170
	1-2 times per month	6	10	3	25,142 (8)	
	1-2 times per 2-5 months	42	54	65	p=0,001	
	1-2 times per 6-12 months	61	57	90		
	Less than 1 time per year	25	11	9		
	Did not visit	0	1	0		
6	Use of Remote Interactions with the Attending Physician					
	Yes	20	2	1	38,920 (4)	0,212
	No	111	122	160	p<0,001	
	Not certain	3	9	6		
7	Age, years					0,338
	Younger than 20	16	0	0	99,092 (14)	
	20 – 29	13	0	2	p<0,001	
	30 – 39	48	23	39		
	40 – 49	26	31	47		
	50 – 59	24	43	53		
	60 – 69	7	33	25		
	70 – 79	0	1	1		
	80 or older	0	2	0		
8	Duration of the Disease, years					
	Less than 1	4	4	14		0,160
	1 – 5	20	8	8	22,17 (8)	
	6 – 10	23	37	47	p=0,005	
	11 – 15	53	48	63		
	16 or longer	34	36	35		
9	Sex					0,097
	Male	60	76	85	4,085 (2)	
	Female	74	57	82	p=0,129	
10	Smoking					
	Yes	39	26	43	5,421 (4)	0,079
	No	80	82	96	p=0,247	
	Quit smoking	15	25	28		
11	Co-morbidities					
	Yes	93	96	130	5,007 (4)	0,076
	No	33	32	34	p=0,287	

№	Attribute	level of adherence to drug therapy			Chi2 (df),	V Cramér's
		High	**Moderate**	**Low**	**p**	
	Not certain	8	5	3		
12	Complications of Diabetes					
	Yes	55	63	75	3,087 (4)	0,060
	No	66	53	77	p=0,543	
	Not certain	13	17	15		
13	Level of Physical Activity					
	High	16	22	18	4,464 (4)	0,072
	Moderate	54	49	56	p=0,347	
	Low	64	62	93		
14	Body Mass Index (BMI)					
	18,5 – 24,99	53	49	62	5,956 (4)	0,083
	25,0 – 29,99	60	50	61	p=0,202	
	30 or more	21	34	44		

4. DISCUSSION

Higher adherence to drug therapy in the group of patients with T1D than in a group of patients with T2D can be due to the fact that the T1D is more often starting in a younger age so patients become accustomed to the need to conduct a strict treatment regimen. Patients with diabetes 1 type also have a higher risk of hypo-or hyperglycemic coma than with T2D. The development of T2D is mainly occurring in patients aged 45 years and older when habits and lifestyle are already formed, so it is harder to adhere to the appointed treatment. These differences are talking about the need to apply different approaches in the formation of sustainable motivation on observance and adherence to DT in patients with different types of diabetes [12].

It was also found that among patients with a smaller duration of diabetes was a high adherence to DT, which may be due to a greater motivation to comply with the treatment regime in the early stages since there is a greater fear of possible complications and consequences, but over time the disease becomes more familiar. And the patient can deliberately make relief in the treatment and compliance of the doctor's prescriptions.

A higher estimated level of knowledge of diabetes and visiting schools of diabetes contributed to an increase in the level of adherence to DT, which is possible due to a higher level of patient awareness of the course of the disease, the possible consequences of non-compliance with the treatment regime, as well as explaining questions of interest about how to change the lifestyle diabetes mellitus [13].

Also, respondents who responded that they comply with the prescribed treatment regime and attend the doctor more often than 1 time per year had a higher level of adherence to DT, which may be due to higher medical activity, the quality of dispensary monitoring of the patient's health and obtaining the necessary information about diabetes mellitus from the attending physician. The use of remote interactions with the attending physician, which allow patients to receive advice on various issues, without the need to visit medical organizations, also raised the level of adherence to DT.

The presence of such risk factors as an excess body or obesity, a low level of physical activity, smoking, related diseases, complications of diabetes mellitus did not increase the level of adherence to treatment, although they are factors for a more responsible approach to their health. This may be due to the fact that a person initially does not form the principles of a healthy lifestyle and the emergence of diabetes did not have a sufficient reason to change the lifestyle [14,15].

Such non-adherence can have various reasons, both unintentional (forgetfulness, mental illness, restrictions associated with living, learning, and working conditions) and intentional (distrust, fear of side effects (real or perceived), cost of drugs, lack of faith in favor of treatment, fear of dependence on drugs, fear of the danger of drugs for the body, unwillingness to be treated and lack of visible results). Therefore, it is very important to observe not only drug support for patients with diabetes but also social and informational support [16].

Also, for the successful treatment of patients, the doctor's adherence to the principles of rational

therapy and recommendations developed by experts for the management of patients with diabetes is required. Unfortunately, a large burden on the doctor, emotional burnout and insufficient level of competence, low level of responsiveness, incorrect behavior become factors that prevent a sufficient level of quality interaction with the patient, which leads to patient dissatisfaction with the information received about the disease itself, about the need for drug therapy and how consequently, low motivation for adherence to treatment. One of the most powerful factors contributing to an increase in motivation for a high level of adherence to DT is precisely the doctor's recommendations and his qualified position in relation to changing the lifestyle of patients with diabetes mellitus [15, 17].

It is important to note that the insufficient work of medical organizations at various levels, starting with the interaction of the patient and the attending physician, the work of schools of diabetes and consultations in narrow specialists of various profiles can lead to a decrease in the motivation of adherence to drug therapy. Specialized schools of diabetes are one of the necessary components of the primary health system, which play an important role in improving the adherence to DT of patients and improving the quality of life, but the low availability of the SD and the insufficient quality and adaptability of training programs are a serious obstacle to maintaining the proper level of motivation to attend SD and save high levels of adherence to treatment. It should be noted that the development of information and communications and telemedicine technologies could increase the availability and quality of the necessary information and medical support for patients with diabetes [18,19].

5. CONCLUSION

A low level of awareness on the importance of adherence to drug therapy, daily self-control of their health, changes in nutritional habits, physical activity as well as literacy in health issues plays a key role in maintaining the compliance with the treatment regimen. Currently, there are enough arguments in favor of the feasibility of learning patients, as this forms the correct idea of the disease, the risk factors of its occurrence, progression, and the development of complications and contributes to the best implementation of medical recommendations. It is also necessary to create

an available system for obtaining high-quality and verified information for patients with diabetes mellitus, which will help them form the necessary self-control skills of their health state.

It is also necessary to begin prevention in groups of patients with a high risk of diabetes or prediabetes. At the same time, an intersectoral integrated approach to the development of preventive measures, taking into account not only the improvement of medical care, but also to increase the availability of medicines and medical devices, specialized foods, the creation of comfortable social conditions for the treatment of diabetes and education of the population about this disease.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. Resolution of the local ethics committee of 11.11.2020 № 31-20.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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