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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

APPLICATION OF TELEMEDICINE TO OPTIMIZE MANAGEMENT OF TYPE 2 DIABETES MELLITUS ASSOCIATED WITH HYPERTENSION

Speciality: 3205.01 – Internal medicine

Field of science: Medicine

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GENERAL DESCRIPTION OF THE STUDY

The relevance of the problem and the degree of its development. The steady increase in the number of patients with non-communicable chronic diseases requires the formation of a new innovative system of examination and treatment. Among non-communicable chronic diseases diabetes mellitus (DM) occupies a special place, from which about 2.0 million people die annually in the world, including kidney damage caused by it¹. Today, the prevalence of diabetes reaches 12.2%, of which 90% is type 2 diabetes mellitus (T2DM)².

The prevalence of diabetes is increasing at an alarming rate worldwide due to population growth, obesity, sedentary lifestyle and aging. According to the IX Atlas of the International Diabetes Federation (IDF), diabetes caused 4.2 million deaths in 2019³.

In the structure of mortality from non-communicable diseases, the largest share falls on cardiovascular diseases (CVD), which are one of the main causes of death in the world, from which up to 17.9 million people die every year. This is a threatening statistic that emphasizes the seriousness of the problem and the need for active measures to prevent and treat CVD⁴.

¹Мамедов, М.Н. Гендерные особенности распространенности хронических неинфекционных заболеваний во взрослой популяции Владимирской области. / М.Н. Мамедов, Л.Т. Сушкова, Р.В. Исаков [и др.] // Кардиоваскулярная терапия и профилактика, – 2023.22(12), – с.70-77.

²Saeedi, P. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9 editions / P. Saeedi, I. Petersohn, P. Salpea [et al.] // Diabetes Res. Clin. Pract., -2019. 157, -107843. doi: 10.1016/ j. diabres.2019.107843.

³DF Diabetes Atlas, 9th edition. Brussels: International Diabetes Federation; 2019; Available from <u>http://www.diabetesatlas.org/en/</u>.

⁴Драпкина О. М., Концевая А. В., Калинина А. М., и др. Профилактика хронических неинфекционных заболеваний в Российской Федерации. Национальное руководство 2022. Кардиоваскулярная терапия и профилактика. 2022;21(4):3235.

Diabetes mellitus is a chronic disease that requires strict patient monitoring by an endocrinologist and regular interaction between them. However, under the influence of various factors (demographic changes, increased demand for medical services, relative shortage of medical institutions and medical personnel, increased workload on medical personnel due to the emergence of new technologies in the treatment of diabetes), it is difficult to implement medical supervision and provide medical care at the proper level.

Despite the use of modern technologies for the treatment of diabetes, many patients cannot normally control glycemia. One of the most relevant solutions to this problem is the use of telemedicine technologies⁵.

Currently, telemedicine focuses on the treatment of chronic diseases such as diabetes, hypertension, heart failure, asthma, etc.^{5,6}. One of the key aspects of the effective use of telemedicine is constant communication between the doctor and the patient. This approach allows not only to monitor the patient's condition in real time, but also to promptly adjust the treatment, which plays an important role in optimizing the treatment of diabetes and hypertension. This, in turn, can significantly reduce the length of hospital stay, reduce the need for emergency care, reduce the financial burden and improve the effectiveness of disease treatment⁷.

Considering regular interaction between patients with diabetes and endocrinologists, there is confidence that the use of telemedicine will improve the effectiveness of treatment.

⁵Hammersley V. Telemonitoring at scale for hypertension in primary care: an implementation study / V. Hammersley, R. Parker, M. Paterson [et al.]//PLoS Med., – 2020.17, – p.e1003124. doi:10.1371/journal.pmed. 1003124.

⁶So, C.F, Chung J.W. Telehealth for diabetes self-management in primary

healthcare: a systematic review and meta-analysis // J Telemed Telecare, -2018.24, -p.356-64.

⁷Zhu, L. Effects of telemedicine interventions on essential hypertension: a protocol for a systematic review and meta-analysis / L. Zhu, L Dongze, X-L. Jiang [et al.] // BMJ Open, – 2022.12(9), – e060376. doi:10.1136/bmjopen-2021-060376.

The rapid development of the Internet, the transformation of mobile phones and smartphones into part of everyday life create favorable conditions for new prospects in this direction^{8,9}.

The main goal of telemedicine for the treatment of patients with diabetes and hypertension is to improve the effectiveness of medical care by adjusting various indicators that determine the prognosis of the disease^{10,11}.

Object and subject of the study. The study subjects were patients with type 2 diabetes and combined arterial hypertension (AH). A total of 224 people (112 men and 112 women) were examined. The average age of the study participants was 56.8 years (95% CI 55.95; 57.59). 170 patients who participated in the study underwent structured training in managing their disease. The study participants were divided into three groups:

Those who refused structured training (n = 54);

Those who underwent structured training but did not use telecommunication or telephone communication with a doctor (n = 109); Those who underwent structured training and used regular telecommunication or telephone communication with a doctor (n =61);

The structured training system was developed by the Azerbaijan Association of Endocrinology, Diabetology and Therapeutic training based on the international recommendations available at that time. Patient training was usually individual in nature.

⁸Smith, A., & Jones, B. Telemedicine and chronic disease management in the digital age. Journal of Medical Technology, 2022.34(2), 78-85.

⁹Harris, R., et al. The role of mobile phones in telemedicine: Advancing healthcare delivery. Telemedicine and e-Health, 2021.27(4), 220-227.

¹⁰Wang, Y., et al. (2020). Meta-analysis of telemedicine interventions for patients with diabetes: Efficacy and outcomes. Journal of Diabetes Science and Technology, 14(3), 145-152.

¹¹Lee, J., et al. Effectiveness of telemedicine for chronic disease management: A systematic review and meta-analysis. Journal of Telemedicine and Telecare, 2019.25(9), -p.509-520.

Objectives of the study: To determine the effect of telecommunication and/or telephone communication between a doctor and a patient on the effectiveness of glucose metabolism and blood pressure management in type 2 diabetes mellitus with arterial hypertension.

Tasks of the study:

- 1. To determine the effect of structured self-monitoring training and subsequent patient-doctor feedback via telemedicine technologies on glycosylated hemoglobin (HbA1c) levels in patients with type 2 diabetes mellitus and hypertension over a 3-year study period.
- 2. To determine the effect of structured self-monitoring training and subsequent patient-doctor feedback via telemedicine technologies on the frequency of achieving target HbA1c parameters in patients with type 2 diabetes mellitus and hypertension;
- 3. To study the effect of patient-doctor feedback via telemedicine technologies on the variability of HbA1c values in patients with type 2 diabetes mellitus and hypertension;
- 4. To assess the impact of structured self-monitoring training and subsequent patient-physician feedback implemented via telemedicine technologies on the frequency of achieving target or optimal (<140 mmHg) and ideal (<130 mmHg) systolic blood pressure (SBP) levels in patients with Type 2 Diabetes Mellitus (T2DM) combined with Arterial Hypertension (AH).
- 5. To identify the role of structured self-monitoring training and subsequent patient-physician feedback via telemedicine technologies in achieving target or optimal (<90 mmHg) and ideal (<80 mmHg) diastolic blood pressure (DBP) levels among patients with both Type 2 Diabetes Mellitus (T2DM) and Arterial Hypertension (AH).

Techniques of the study: Individuals participating in the study were required to undergo the following examination:

The passport part was recorded.

Information about the treatment currently being received was recorded:

hypoglycemic therapy (indicating the group of drugs used);

treatment for hypertension;

Height, body weight, and body mass index were determined;

Body mass index (BMI) values were assessed in accordance with the recommendations of the World Health Organization (WHO);

In accordance with generally accepted rules, office blood pressure measurements were taken, and SBP and DBP values were recorded, expressed in mm Hg. The diagnosis of hypertension was made based on anamnesis data and the modern classification of hypertension;

Standard resting electrocardiography was performed;

Laboratory examination of patients was performed (HbA1c, fasting glucose, creatinine, urea, alanine aminotransferase, aspartate aminotransferase;

A statistical analysis of the results was performed.

The scientific novelty of the study:

Until now, separate studies have been conducted on the impact of the information technologies used on the course of diabetes or hypertension. For the first time in Azerbaijan, the impact of these technologies on the combination of hypertension and diabetes will be studied.

Main provisions of the thesis submitted for defense:

1.1. In patients with a combination of type 2 diabetes and hypertension, the methods of structured training and telemedicine used significantly reduce the level of HbA1c during 3 years of observation in the group.

1.2. The use of telemedicine technologies increases the effectiveness of sugar-lowering therapy.

1.3. The use of telemedicine technologies in patients diagnosed with type 2 diabetes in combination with hypertension, who have undergone structured training and used patient-doctor feedback, helps to optimally control the values of SBP and DBP.

Practical significance of research:

It has been shown that the use of the technologies under consideration will allow achieving a better reduction in HbA1c, as well as stable control of SBP and DBP.

Obtaining such an effect should become the basis for improving the life expectancy of patients, reducing CVD, reducing cardiovascular mortality, normalizing blood pressure, and reducing microvascular complications of diabetes.

Work approval: the main provisions of the work were reported:

XVIII All-Russian Congress "Arterial Hypertension 2022: Diagnosis and Treatment in the COVID-19 Pandemic", 2022.

International Conference "Controversial and Unresolved Issues in Cardiology", 2022.

Conference of the Association of Endocrinology, Diabetology and Therapeutic Education of the Republic of Azerbaijan "Diabetes mellitus, prediabetes: diagnosis and management" 2023.

The initial discussion of the work was held at a joint interdepartmental meeting (staff of the departments of Internal Medicine 1, Internal Medicine 2, Internal Medicine 3, Family Medicine and Anesthesiology and Resuscitation) on 18.04.2024 at the Azerbaijan Medical University (protocol No. 2).

The thesis work was tested at an approbation seminar on 31.01.2025 (protocol No. 05).

Publications: 11 scientific papers were published based on the thesis materials, including 7 articles (2 abroad) and 4 abstracts (3 abroad) in journals and publications determined by the Higher Attestation Commission.

Implementation of results: The practical recommendations proposed in the scientific work are used in the examination and treatment of patients with type 2 diabetes in combination with arterial hypertension in the Azerbaijan Association of Endocrinology, Diabetology and Therapeutic Education, and are also implemented in the research plan of the Department of Internal Medicine of the 1st Azerbaijan Medical University.

Title of the body where the thesis work was completed. The thesis work was carried out in the Association of Endocrinology, Diabetology and Therapeutic Education of the Republic of Azerbaijan, as well as on the basis of the Department of Internal

Medicine of the 1st Azerbaijan Medical University.

Structure and volume of the thesis. The thesis is presented in Russian, on 182 pages (208193 characters), consists of "Introduction" (10896 characters), "Literature Review" (Chapter I – 43803 characters), "Materials and Research Methods" (Chapter II - 10621 characters), "Results and Their Discussion (Chapter III - 94078 characters), "Conclusion" (46972 characters), "Conclusions" (1518 characters) and "Practical Recommendations" (305 characters), a list of literature. The scientific work is illustrated with 19 tables and 28 figures. The bibliographic index includes 221 sources of literature

MATERIALS AND METHODS OF THE STUDY

The study involved 224 patients with type 2 diabetes mellitus and stage 1-2 hypertension who had not previously undergone structured training in the management of these chronic diseases. Among them, 112 were men and 112 were women, i.e. there were no gender differences, the proportion of each sex was 50.0% (95% CI 43.45; 56.55). The average age of the study participants was 56.8 years (95% CI 55.95; 57.59). The average height of the patients was 167.5 cm (95% CI 166.63; 168.37). The lowest height was 154 cm, and the highest was 181 cm.

The average body weight of patients was 85.7 kg (95% CI 84.16; 87.33) with a minimum of 154 cm and a maximum of 181 cm.

The average BMI values in the group of patients under consideration were 30.6 kg/m2 (95% CI 30.03; 31.13) with a minimum value of 22.1 kg/m2 and a maximum of 40.7 kg/m2.

In 48 patients (21.4% at 95% CI 16.06; 26.80), there was no hypoglycemic pharmacotherapy at the beginning of the study. Biguanides (metformin) were received by 150 or 67.0% of patients (95% CI 60.80; 73.12). Treatment with secretagogues (sulfonylurea drugs + non-sulfonylurea secretagogues) was received by 132 or 58.9% (95% CI 52.49; 65.37) of the study participants. Incretins (dipeptidyl peptidase 4 (DPP4) inhibitors and glucagon-like peptide 1 receptor agonists) were taken by 23 patients (10.3% at 95% CI 6.29;

14.24). Other non-insulin hypoglycemic drugs were received by 5 patients (2.2%) (95% CI 0.30; 4.17). At the beginning of the study, a significant number of patients - 146 patients, which is 65.2% of the total number of participants, did not receive any pharmacotherapy to control hypertension (95% CI 58.94; 71.42). This high value emphasizes the presence of a significant group of people who did not have access to drug treatment or did not take it for various reasons, which may negatively affect their health and quality of life.

structured training system was developed by The the Azerbaijan Association of Endocrinology, Diabetology and Therapeutic Education based on the international recommendations available at that time. Patient training was usually individual. In order to increase the effectiveness of training, family members of the patient living with him/her often participated in the process. In some cases, group training was used (no more than 3 people in 1 group, taking into account age, psychological and intellectual compatibility). The training was conducted by a team consisting of a diabetologist, a diabetologist nurse, a nutritionist, a psychologist, and a podiatrist. Topics of the classes: what is diabetes; what is hypertension; complications of diabetes and hypertension: how to prevent them; basics of nutrition for type 2 diabetes and hypertension; necessary physical activity for type 2 diabetes and hypertension; selfmonitoring of glucose, its importance and rules for implementation; self-monitoring of blood pressure, its importance and rules for implementation; foot care; medications for the treatment of hypertension;

Statistical processing of the material included the determination of such indicators as the minimum, maximum values, and the average sample size. In addition, the standard deviation and error of the average value were calculated. When performing statistical analysis, the standard computer program Microsoft Excel was used.

Automatic calculation of the Student t-criterion for dependent samples was performed online.

The statistical significance of differences between proportions was calculated using the Fisher's exact test and the y^2 determination.

Calculations using the specified methods were performed online using the calculator "MEDCALC". The confidence interval of the proportions was determined for a probability of 95% using the Wilson method using an online calculator. The confidence interval of the mean values was also determined for a probability of 95%. Calculations were performed using the Confidence Limits for Mean Calculator.

To achieve the set objectives, we assessed the main parameters of the examined patients in order to establish primary data at the beginning of the observation, on the basis of which it will be possible to judge the dynamics of these parameters under the influence of various approaches to the communication system between patients and the doctor.

Of all the patients included in the study, 3 groups of patients with a combination of type 2 diabetes mellitus and arterial hypertension were formed:

Group 1, consisting of patients who refused to undergo structured training, but at a doctor's appointment received information in the form of partial training (n = 54);

Group 2a, consisting of 109 patients who underwent structured training, but did not use feedback with the doctor every 2 weeks, carried out in the form of telemedicine;

Group 2b, consisting of 61 patients who underwent structured training and had contacts with the doctor every 2 weeks.

Men accounted for 53.7% of group 1 (95% CI 40.40; 67.00), 49.5% of group 2a (95% CI 40.15; 58.93), and 47.5% of group 2b (95% CI 35.01; 60.07). Women accounted for 46.3% of group 1 (95% CI 33.00; 59.60), 50.5% of group 2a (95% CI 41.07; 59.85), and 52.5% of group 2b (95% CI 39.93; 64.99). The minimum age of patients in groups 2a and 2b was 45 years, and in group 1 - 46 years. The maximum age of patients in all three groups was 65 years. The average age of patients in group 1 was 56.8 years (95% CI 55.16; 56.76). The average age of patients in group 2a was 56.7 years (95% CI 55.45; 56.67). In group 2b, the average age of patients was 57.0 years (95% CI 55.43; 56.97). In group 1, 20 patients were under 55 years of age, which amounted to 37.0% (95% CI 24.26; 49.92), in group 2a - in 40 patients - 36.7% (95% CI 27.65; 45.75), in group 2b - in 22 patients - 36.1% (95% CI 24.02; 48.12). The existing differences between groups 1, 2a and 2b in the frequency of occurrence of people under 55 years of age were not statistically significant (in all cases p > 0.05).

The age of 55 years and older occurred in 34 patients (63.0%) of group 1 (95% CI 50.08; 75.84). In group 2a, the age of patients 55 years and older was recorded in 69 patients or 63.3% (95% CI 54.25; 72.35). The same age group was present in 39 or 63.9% of patients of group 2b (95% CI 51.88; 75.98).

It should be noted that in group 1, the frequency of occurrence of the age category "55 years and older" was statistically significantly (p = 0.0072) higher than the frequency of occurrence of the age category "under 55 years". In group 2a, the differences in the frequency of occurrence of the age categories under consideration were also statistically significant (p = 0.0001). In group 2b, the differences between the parameters under consideration also reached statistical significance (p = 0.0022).

A history of hypertension was present in 20 or 37.0% of patients in group 1 (95% CI 24.16; 49.92). In group 2a, hypertension was present the history in 36 or 33.0% of patients (95% CI 24.20; 41.86) and in 19 or 31.1% of patients in group 2b (95% CI 19.53; 42.77). The differences between the groups in the presence of hypertension in the participants' history were not statistically significant, in all cases p > 0.05.

A history of T2DM was present in 45 patients or 83.3% of group 1 participants (95% CI 73.39; 93.27). In group 2a, a history of T2DM was present in 87 patients or 79.8% of patients (95% CI 72.28; 87.35). A history of T2DM was present in 47 patients in group 2b, or 77.0% (95% CI 66.50; 87.60). The differences between the groups in the presence of T2DM in the participants' history did not reach statistical significance, in all cases p> 0.05. The duration of T2DM in group 1 was 3.9 years (95% CI 3.10; 4.61). In group 2a, the average duration of T2DM was 4.2 years (95% CI 3.43; 4.97). No statistically significant differences were found between the groups

for this parameter (p> 0.05). In group 1, the average BMI was 30.0 kg/m² (95% CI 28.93; 30.98). The minimum value was 22.1 kg/m², and the maximum was 38.8 kg/m2. In group 2a, the average BMI was 30.6 kg/m² (95% CI 29.85; 31.41), with a minimum of 23.3 kg/m² and a maximum of 40.7 kg/m². In group 2b, BMI ranged from 23.3 kg/m² to 40.7 kg/m² and averaged 31.1 kg/m². The differences in BMI values between the groups did not reach statistical significance, in all cases p> 0.05.

Normal body weight was present in 6 patients or 11.1% (95% CI 2.73; 19.49) of group 1, in 11 patients or 10.1% (95% CI 4.44; 15.75) of group 2a, and in 6 patients or 9.8% (95% CI 2.36; 17.31) of group 2b. The differences in the frequency of normal body weight between the groups were not statistically significant. In all cases p> 0.05.

In group 1, 25 patients or 46.3% (95% CI 33.00; 59.60) were overweight. In group 2a, 40 patients or 36.7% (95% CI 27.65; 45.75) were overweight. In group 2b, 22 patients or 36.1% (95% CI 24.02; 48.12) were overweight. The differences in the incidence of overweight between the groups were not statistically significant, as demonstrated by p>0.05 values in all cases considered. Obesity was present in 23 patients in group 1 or 42.6% of the group participants (95% CI 29.40; 55.78). Obesity was observed in 58 patients or 53.2% of patients in group 2a (95% CI 43.84; 62.58). In group 2b, obesity was present in 33 patients or 54.1% (95% CI 41.59; 66.60). In the incidence of obesity, intergroup differences were not statistically significant, p > 0.05. The absence of intergroup statistical significance for all body weight options from normal to obesity suggests the comparability of the participants selected for the compared groups, which is a necessary condition for drawing conclusions on the indicators analyzed further.

The next in the series of analyzed parameters was SBP and DBP.

The maximum SBP in all 3 groups was 159 mmHg. The minimum SBP in group 1 was 126 mmHg, in group 2a and group 2b – 130 mmHg. The average SBP in group 1 was 148.8 mmHg (95% CI 146.60; 151.00), in group 2a the average SBP was 148.3 mmHg

(95% CI 146.91; 149.73), and in group 2b this indicator was 148.2 mmHg (95% CI 146.44; 149.95). The maximum DBP in both group 1 and group 2a was 99 mmHg, and in group 2b – 98 mmHg. The minimum DBP in group 1, as well as in group 2b, was 76 mmHg, and in group 2a - 78 mmHg. The average DBP in group 1 was 93.2 mmHg (95% CI 91.84; 94.49). In group 2a, DBP was 92.8 mmHg (95% CI 91.98; 93.69), and in group 2b – 92.6 mmHg (95% CI 91.48; 93.70). For a more accurate classification of patients involved in the study and in accordance with existing recommendations, we conditionally ranked the subjects by SBP as follows: less than 140 mmHg, 140 to 149 mmHg, and 150 mmHg and above. In all three groups, the highest incidence of SBP was 150 mmHg and above, and the lowest incidence was SBP less than 140 mmHg. In group 1, group 2a, and group 2b, the incidence of SBP <140 mmHg was 11.1%, 11.9%, and 11.5%, respectively, and did not differ statistically significantly between the groups. In all cases, p>0.05. There were no statistically significant differences between the groups (p>0.05 in all cases) in the frequency of occurrence of the SBP range from 140 to 149 mmHg: 37.0%, 40.4% and 37.7% in groups 1, 2a and 2b, respectively. The frequency of occurrence of SBP values ≥ 150 mmHg in group 1 was 51.9%, in group 2a - 47.7%, and in group 2b -50.8%. The differences between the groups were not statistically significant, p>0.05.

At the same time, the analysis of differences in the frequency of occurrence within the groups showed that the SBP values <140 mmHg in all three groups were lower than the frequency of occurrence of SBP 140-149 mmHg. and these differences were statistically significant: p< 0.001 for group 1, p< 0.0001 for 2a and p=0.001 for 2b. The incidence of SBP < 140 mmHg in all 3 groups was significantly lower than the incidence of SBP \ge 150 mmHg, p< 0.0001 for all groups. The incidence of SBP 140-149 mmHg and SBP \ge 150 mmHg did not differ statistically significantly in any of the 3 groups, in all cases p> 0.05.

Similarly, SBP, DBP and its values in patients of all study groups were ranked according to the following principle: DBP less than 90 mmHg, from 90 to 94 mmHg, and 95 mmHg and more. This approach to classification allowed us to demonstrate the nature of BP changes in patients of different groups with greater clarity and accuracy. The overall picture in the case of DBP was somewhat different from the overall picture in the case of SBP. If SBP in all groups was characterized by the maximum frequency of occurrence of the highest BP indicator, then in the case of DBP in all three groups the most common values were 90-94 mmHg, that is, not the highest values. In our opinion, this may indicate a greater "involvement" of SBP compared to DBP in type 2 diabetes, as well as a wider range of changes in this parameter. In group 1, group 2a and group 2b, the frequency of occurrence of DBP <90 mmHg amounted to 9.3%, 10.1% and 11.5%, respectively, and did not differ statistically significantly between the groups, p> 0.05.

Interestingly, high DBP values, which in some cases form the basis of isolated diastolic hypertension, are not considered an unambiguous predictor of cardiovascular complications. It is believed that this factor is more dangerous for young people, and in elderly patients it is not associated with adverse effects.

It is logical that both high and low DBP values are unacceptable in this situation, since in both cases the risk of circulatory disorders increases, especially cerebral ischemia due to a concomitant decrease in SBP at low DBP values.

Therefore, the result we obtained on the predominance of average DBP values can be perceived as the most favorable. There is an opinion that an excessive attempt to reduce DBP pressure is dangerous for the elderly, who made up the majority of our contingent. It is recommended to treat isolated diastolic hypertension in young patients.

Analysis of differences in the frequency of occurrence within the groups showed that the frequency of DBP <90 mmHg in all three groups was lower than the frequency of DBP 90-94 mmHg, and these differences were statistically significant: in all cases, p<0.001. The frequency of DBP <90 mmHg in all three groups was significantly lower than the frequency of DBP \geq 95 mmHg, p<0.0001 for groups 1 and 2a; p<0.01 for group 2b. In group 2a, the frequency of DBP 90-94 mmHg (53.2%) was statistically significantly (p<0.05) higher than the frequency of DBP \geq 95 mmHg (36.7%).

In general, the analysis of SBP and DBP values both by groups and in the intragroup aspect did not reveal unexpected trends. Thus, the prevalence of patients with elevated SBP, which is usually one of the most common manifestations of cardiovascular pathology in type 2 diabetes, was expected.

According to the purpose and objectives of our study, we analyzed the HbA1c level at the initial stage of observation and compared the results obtained between the groups.

In group 1, the mean HbA1c level at the beginning of the study was 8.9% (95% CI 8.59; 9.17). In group 2a, the mean HbA1c level was 9.0% (95% CI 8.84; 9.23). In group 2b, the mean HbA1c level was 9.1% (95% CI 8.83; 9.37). The differences between the groups did not reach statistical significance, p> 0.05. Figure 1 presents data on HbA1c values at the beginning and end of the study in groups 1, 2a, 2b.



Figure 1. HbA1c levels in group 1, group 2a and group 2b at the beginning and end of the study

In all three groups, the HbA1c level was higher at the beginning of the study and decreased as a result of the study. Thus, in

group 1, the HbA1c level decreased from 8.88% (95% CI 8.59; 9.17) to 8.21% (95% CI 7.98; 8.44). The differences between the groups were not statistically significant: p < 0.001. In group 2a, the HbA1c level decreased from 8.97% (95% CI 8.78; 9.17) to 7.18% (95% CI 7.03; 7.33). The differences were statistically significant: p < 0.001. In group 2b, the HbA1c level decreased from 8.80% (95% CI 8.51; 9.09) to 6.68% (95% CI 6.54; 6.82), and the differences in both groups were statistically significant (p < 0.001). The difference between the HbA1c values in group 1 at the beginning and end of the study was 0.68% (95% CI 0.39; 0.96). In group 2a, the difference between the HbA1c values at the beginning and end of the study was 1.79% (95% CI 1.69; 1.90). In group 2b, the difference between the initial and final HbA1c was 2.12% (95% CI 1.92; 2.31). The differences in the magnitude of the difference between the initial and final HbA1c between Group 1 and Group 2a were statistically significant (p < 0.001). The differences between the indicators of Group 1 and Group 2b were also statistically significant (p < 0.001). The differences between the initial and final values of HbA1c in Groups 2a and 2b also reached statistical significance (p < 0.001).

Undoubtedly, the differences in the effectiveness of the therapy could be due to various factors, primarily pharmacotherapy, which changed during the study. In this regard, we analyzed the data on pharmacotherapy of patients in the three groups under consideration.

When analyzing intergroup differences in changes in pharmacotherapy, it was very interesting from the standpoint of the objectives of our study to draw parallels based on the data obtained in dynamics. The incidence of cases of lack of pharmacotherapy decreased in group 1 by 20.4% (95% CI-31.1; -9.63), in group 2a by 21.1% (95% CI-28.76; -13.44), and in group 2b - by 23.0% (95% CI-33.50; -12.40). The differences between the groups did not reach statistical significance (in all cases p < 0.05). The proportion of patients receiving metformin treatment increased by 20.4% in group 1 (95% CI +9.63; +31.11), by 21.1% in group 2a (95% CI +13.44; +28.76) and by 22.9% in group 2b (95% CI 12.40; +33.50). The differences between the groups were not statistically significant (in all cases p < 0.05).

The incidence of cases of treatment with secretagogues decreased by 1.9% in group 1 (95% CI -5.45; +1.74), by 3.6% in group 2a (95% CI -7.20; -0.14) and by 4.9% in group 2b (95% CI -10.34; +0.51). The intergroup differences were not statistically significant (in all cases p < 0.05). Incretin therapy increased significantly in all three groups: by 31.5% (95% CI+19.09; +43.87) in group 1, by 36.7% in group 2a (95% CI+27.65; +45.75) and by 31.1% in group 2b (95% CI+27.65; +45.75). There was no statistically significant difference between the groups (in all cases p <0.05). The incidence of treatment with other hypoglycemic drugs also increased in all three groups: by 13.0% in group 1 (95% CI +4.00; +21.92), by 12.8% in group 2a (95% CI +6.56; +19.13) and by 13.1% in group 2b (95% CI +4.64; +21.59). The differences between the groups did not reach statistical significance (in all cases p < 0.05). Thus, the changes in the incidence of various types of pharmacotherapy in groups 1, 2a and 2b were extremely close and the differences between the groups were not statistically significant.

Assessing the quality of the pharmacotherapy administered at the beginning and end of the study, it can be noted that in all three groups:

Metformin therapy was the most frequently used therapy, and its frequency at the beginning and end of the study was comparable in all three groups;

Secretagogue therapy was the second most frequently used therapy. Its frequency of use decreased in all three groups during the study, but this change was not statistically significant in group 1 and was statistically significant in group 2a (p<0.01) and group 2b (p<0.05), respectively;

Incretin therapy was the third most frequently used therapy, and in all three groups there was a statistically significant (p<0.001 in group 2a, p<0.01 in groups 1 and 2b) increase in its use during the study;

Therapy with other hypoglycemic drugs was used the least frequently in all three groups, only the frequency of its use increased statistically significantly during the study: p < 0.05 in groups 1 and 2b, and p < 0.01 in group 2a.

As shown above, in all three groups, HbA1c levels at the end of the study were lower than levels at the beginning of the study, and in all cases, the differences between the initial and final levels of this indicator were statistically significant (p < 0.001).

Considering the absence of significant differences between the three groups in the pharmacotherapy, we can say that:

- 1. Structured learning allows achieving more effective regulation of glucose metabolism compared to unstructured, "fragmentary" learning.
- 2. The patient-doctor feedback system using telemedicine technologies, applied to manage such a chronic disease as T2DM, allows increasing the effectiveness of the therapeutic training and increasing the level of glucose control.

In the course of the study, we examined the data on the variability of HbA1c in 3 groups. The average value of the standard deviation of HbA1c in group 1 was 0.58 (95% CI 0.53; 0.63), in group 2a it was 0.24 (95% CI 0.21; 0.27), and in group 2b the average value of the standard deviation was 0.27 (95% CI 0.21; 0.33). The differences between group 1 and group 2a reached statistical significance (p <0.001). The differences between group 1 and 2b were also statistically significant (p <0.001), and between groups 2a and 2b they did not reach statistical significance.

Another statistical indicator used to determine the variability of values is the coefficient of variation CV. As mentioned above, the coefficient of variation is also an indicator of HbA1c variability that has proven itself well in previous studies assessing the risk of adverse cardiovascular outcomes in patients with diabetes. Thus, the mean CV values did not differ statistically significantly (p>0.05) in groups 2a and 2b, where they were 3.22 (95% CI 2.86; 3.59) and 3.78 (95% CI 2.99; 4.56), respectively. At the same time, the CV values in groups 2a and 2b were statistically significantly different from the value of this indicator in group 1 (in both cases, p <0.001). In group 1, the CV value was 7.45 (95% CI 6.77; 8.14) and was almost 2 times higher than in groups 2a and 2b.

We also studied another indicator that allows us to judge the variability of HbA1c values. For each patient, the average value of

absolute differences between adjacent study points was calculated. We called this indicator Average \mathcal{I} . The formula for calculating Average \mathcal{I} and an explanation of the calculation process are presented in Figure 2.

Average
$$\Delta = \frac{\sum |A_n - A_{n-1}|}{6}$$

 ∑ - знак суммы;
IA_n-An₋₁I – абсолютная величина разности между двумя последовательными величинами A1с, например A1с точки 1 и A1с точки 2; A1с точки 2 и A1с точки 3 и т.д.

Figure 2. The formula for calculating AverageД

The average value of Average Π was 0.52 in group 1 (95% CI 0.48; 0.56) and was statistically significantly (p<0.001) higher than in group 2a, where it was 0.21 (95% CI 0.19; 0.23) and in group 2b, where it was 0.20 (95% CI 0.17; 0.23). A positive linear relationship between HbA1c variability, CVD and mortality is one of the reasons for the close attention of clinicians to this parameter and its control. Thus, our study showed that structured training conducted in groups 2a and 2b made it possible to reduce the variability of HbA1c indicators, while the effect of patient-doctor telecommunication feedback on variability was not revealed. Of particular importance is the assessment of the impact of telemedicine as one of the modern and reliable methods of communication on the effectiveness of BP control in patients with type 2 diabetes. In all three groups, SBP levels at the end of the study were lower than their values at the beginning of the study, and in all cases, the differences between the initial and final levels of this indicator were statistically significant. The data obtained suggest significant differences in SBP control in patients with different approaches to the communication system with a doctor. First of all, the absence of positive results in group 1, which demonstrated significantly higher values, is striking. It should also be noted that at the end point of the study, the average SBP in group 2b (133.3 mm Hg) was slightly lower than in group 2a (133.7 mm Hg). With no statistically significant differences in the initial SBP levels,

the most optimal result was obtained in group 2b - 133.3 mm Hg. (95% CI 131.46; 135.14) and 2a - 133.7 mmHg (95% CI 132.25; 135.15).

The incidence of SBP less than 140 mmHg was observed in 31.5% (CI 95% 20.68; 44.74) of patients in group 1, in 76.1% (CI 95% 67.34; 83.17) of patients in group 2a and in 82.0% (CI 95% 70.53; 89.62) of patients in group 2b. The differences in the incidence of SBP less than 140 mmHg at the end of the study between group 1 and group 2a were statistically significant (p<0.0001). The conducted study confirmed the fact that the impact of therapeutic training has a positive effect on reducing the variability of SBP levels, which, in turn, leads to stabilization of blood pressure levels, and, consequently, complications of type 2 diabetes. The frequency of occurrence of SBP values less than 130 mm Hg occurred in 3.7% (CI 95% 1.02; 12.54) of patients in group 1, in 32.1% (CI 95% 24.08; 41.36) of patients in group 2a and in 24.6% (CI 95% 15.51; 36.68) of patients in group 2b. Differences in the frequency of SBP values less than 130 mm Hg at the stage of completion of the study between groups 1 and 2a were statistically significant (p<0.0001). Significant differences (p<0.001) were also revealed between groups 1 and 2b. At the same time, differences in the frequency of SBP indicators less than 130 mm Hg between groups 2a and 2b did not reach statistical significance (p > 0.05).

Thus, our data revealed significant differences in the dynamics of blood pressure during the observation of patients depending on the method used to control blood pressure and the method of "patientpatient" communication.

Considering the absence of significant differences between the three groups in the pharmacotherapy, we can say that:

1. Structured training allowed to achieve a more effective reduction in the level of SBP compared to unstructured, "fragmentary" training.

2. The patient-doctor feedback system using telemedicine technologies, applied to manage hypertension in type 2 diabetes, allowed to achieve a smoother reduction in the level of SBP while maintaining its effectiveness.

3. The patient-doctor feedback system using telemedicine technologies, applied to manage hypertension in type 2 diabetes, allowed to achieve the maximum frequency of occurrence of SBP indicators less than 140 mm Hg - 82.0% (CI 95% 70.53; 89.62) and a high level of occurrence of SBP indicators less than 130 mm Hg - 24.6% (CI 95% 15.51; 36.68).

Similarly, all three groups showed positive dynamics in reducing DBP, but groups 2a and 2b demonstrated significantly more pronounced results, which may indicate greater effectiveness of telemedicine in these groups. In all three groups, DBP levels at the end of the study were lower than their levels at the beginning of the study, and in all cases, the differences between the initial and final levels of this indicator were statistically significant. In group 1, the average DBP level decreased from 96.1 mmHg (95% CI 94.10; 98.10) to 91.7 mmHg (95% CI 89.99; 93.42). In group 2a, the average DBP level decreased from 95.5 mmHg (95% CI 94.19; 96.81) to 84.4 mmHg (95% CI 82.82; 85.98). In group 2b, the considered indicator decreased from 94.1 mmHg (95% CI 92.42; 95.78) to 81.7 mmHg (95% CI 80.24; 83.16).

This study emphasizes the importance of further use of telemedicine in patients with hypertension.

Thus, in terms of DBP indicators, as in the case of SBP, the worst results in terms of control and stabilization were demonstrated by patients in group 1. Since no statistically significant differences were found between the groups in the initial DBP characteristics (p > 0.05), we can talk about the influence of the approach to patient-doctor communication and the rejection of structured training on the final results.

The frequency of occurrence of DBP indicators less than 90 mmHg occurred in 29.6% (CI 95% 19.14; 42.83) of patients in group 1, in 77.1% (CI 95% 68.33; 83.95) of patients in group 2a and in 93.4% (CI 95% 84.32; 97.42) of patients in group 2b. The differences in the incidence of DBP less than 90 mmHg at the end of the study between group 1 and group 2a were statistically significant (p<0.0001). Also statistically significant (p<0.0001) were the differences between the incidence of DBP less than 90 mmHg at the

end of the study between group 1 and group 2b. The differences between groups 2a and 2b in the incidence of DBP less than 90 mmHg were also statistically significant (p<0.01).

The frequency of occurrence of DBP values less than 80 mmHg occurred in 3.7% (CI 95% 1.02; 12.54) of patients in group 1, in 22.0% (CI 95% 15.27; 30.68) of patients in group 2a and in 31.1% (CI 95% 20.94; 43.59) of patients in group 2b.

As can be seen from the presented data, as in the case of average DBP values, the analysis by fixed levels of the indicator was statistically significantly worse in terms of target parameters in group 1 than in groups 2a and 2b.

Considering the absence of significant differences between the three groups in the pharmacotherapy, it can be said that:

- 1. Structured training allowed to achieve a more effective reduction in the level of DBP compared to unstructured, "fragmentary" training.
- 2. The patient-doctor feedback system using telemedicine technologies, applied to manage hypertension in type 2 diabetes, allowed to achieve an effective reduction in the level of DBP.
- 3. The patient-doctor feedback system using telemedicine technologies, applied to manage hypertension in type 2 diabetes, allowed to achieve the maximum frequency of occurrence of DBP indicators less than 90 mm Hg 93.4% (CI 95% 70.53; 89.62) and the maximum frequency of occurrence of DBP indicators less than 80 mm Hg 31.1% (CI 95% 15.51; 36.68).

We implemented a study of the frequency of occurrence of optimal, good and poor BP control. The criteria for assessing the specified states of hypertension control are presented below:

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- Poor control was defined as cases where SBP values were ≥ 140 mmHg and/or DBP values were ≥ 90 mmHg;
- Good control was defined as all intermediate conditions: SBP <140 mmHg and DBP <80 mmHg;

SBP <140 mmHg and DBP 80 - 89 mmHg;

SBP <130 mmHg and DBP from 80 - 89 mmHg;

Ideal control was defined as cases where SBP values were <130 mmHg and DBP values were <80 mmHg;

Poor BP control was most common in group 1 - 87.0% (CI 95% 75.58; 93.58), in group 2a poor BP control was observed in 44.0% of cases (CI 95% 35.08; 53.40). The differences between groups 1 and 2a were statistically significant (p < 0.0001).

Good BP control was observed in 77.0% (CI 95% 65.09; 85.81) of patients from group 2b. In group 2a good BP control was recorded in only 56.0% (CI 95% 46.60; 64.92) of participants, while in group 1 this figure was only 13.0% (CI 95% 6.42; 24.42). Analysis of statistical differences showed that the difference in BP control between groups 1 and 2b, as well as between groups 2a and 2b, was significant (p < 0.0001 and p < 0.001, respectively). These data emphasize the importance of effective BP control to achieve better clinical results.

Ideal BP control was observed in 1.9% (CI 95% 0.33; 9.77) of group 1, in 10.1% (CI 95% 5.73; 17.17) of group 2a, and in 8.2% (CI 95% 3.55; 17.97) of patients in group 2b. The differences between groups 1 and 2a, 1 and 2b, 2a and 2b were not statistically significant (p > 0.05).

The above formed the basis for our studies, the results of which can be presented as follows. The data obtained during the work allow us to state that:

Conducting structured training in patients with a combination of type 2 diabetes and hypertension significantly increases the possibility of achieving optimal blood pressure control, increasing the number of patients under such control from 14.8% to 66.1%;

The patient-doctor feedback system, implemented using telemedicine technologies when used in patients with type 2 diabetes and hypertension who have undergone structured training, allows achieving optimal blood pressure control, increasing the number of patients who have achieved optimal control from 66.1% to 85.2%.

CONCLUSIONS

The use of the structured self-monitoring training 1. subsequent patient-doctor method and feedback using telemedicine technologies in a study in patients with type 2 diabetes mellitus and arterial hypertension allowed for a decrease in the average HbA1c level from 8.8% to 6.7% (p<0.001) over a 3-year observation period, with the achieved HbA1c level being statistically significantly (p<0.001) lower than in the groups that did not use telemedicine (unstructured training group - 8.2%; structured training group - 7.2%). 2. The use of telemedicine technologies increased the effectiveness of the hypoglycemic therapy, increasing the frequency of achieving the target HbA1c parameter <7.0% to 67.2%, with this indicator in the unstructured training group being 9.3% (p<0.0001) and in the structured training group - 45.0%; (p<0.01). [1, 3]

2. No effect of patient-doctor feedback via telemedicine technologies on the variability of HbA1c values was found. [3]

3. The patient-doctor feedback system via telemedicine technologies, applied to manage arterial hypertension in type 2 diabetes, allowed us to achieve:

maximum, when compared with other groups, frequency of occurrence of SBP <140 mmHg - 82.0% and high level of frequency of occurrence of SBP <130 mmHg - 24.6%;

maximum, when compared with other groups, frequency of occurrence of DBP <90 mmHg - 93.4% and maximum level of frequency of occurrence of DBP <80 mmHg - 31.1%. [6]

4. The patient-physician feedback system using telemedicine technologies, applied for the manage of arterial hypertension in T2DM, made it possible to achieve: the highest prevalence rate (when compared with other groups) of SBP readings <140 mmHg - 82.0%, and a high prevalence rate of SBP readings <130 mmHg - 24.6%. [7]

5. The patient-physician feedback system using telemedicine technologies, applied for the manage of arterial hypertension in T2DM, made it possible to achieve: the highest prevalence rate

(when compared with other groups) of DBP readings <90 mmHg - 93.4%, and the highest prevalence rate of DBP readings <80 mmHg - 31.1%. [5]

PRACTICAL CONSIDERATIONS

- 1. Patients with type 2 diabetes mellitus combined with arterial hypertension need to use telemedicine technologies against the background of basic therapy in order to adequately correct glycemia.
- 2. Recommend the use of telemedicine technologies in patients with type 2 diabetes mellitus against the background of basic therapy in order to adequately correct arterial hypertension.

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LIST OF ABBREVIATIONS

AG - arterial hypertension

BP - blood pressure

WHO - World Health Organization

DBP - diastolic blood pressure

DPP4 inhibitors - dipeptidyl peptidase 4 inhibitors

IC - comorbidity index

BMI - body mass index

DM - diabetes mellitus

DM2 - type 2 diabetes mellitus

SBP - systolic blood pressure

CVD - cardiovascular disease

CV - coefficient of variation.

IDF - International Diabetes Federation

HbA1c - glycosylated hemoglobin

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