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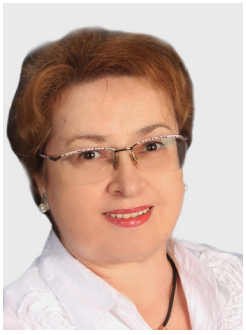

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Role of Adherence to Treatment in the Correction of the Risk of Cardiovascular Complications in Patients with Arterial Hypertension with Accompanying Diabetes Mellitus

Introduction. In modern international classifications of arterial hypertension (AH) it is recommended to take into account not only the stage of AH, the degree of blood pressure (BP) elevation, but also the presence of concomitant pathology, in particular diabetes mellitus, chronic renal failure [9, 14]. In the diagnosis, it is also recommended to indicate the degree of risk of cardiovascular complications (CVC) [2, 9, 14].

The risk assessment for most patients is carried out according to the modified scales of Systemic Coronary Risk Evaluation (SCORE) [4]. In the latest recommendations of the European Society of Hypertension (ESH) of 2023, it is recommended to use the modified SCORE2 and SCORE2 OP for persons of older age (older persons - OP) [9, 15].

The presence of diabetes mellitus (DM), its duration, and the severity of the course significantly affect the degree of damage to target organs and the risk of CVC in patients with hypertension [9, 11]. In a recent publication of 2023 [16], an expert working group of the European Society of Cardiologists (ESC) recommends to use of the SCORE2 diabetes scale for patients with DM and the SCORE2diabetes OP scale for patients older than 70 years. Experts believe that this scale is more accurate for calculating the 10-year risk of CVC in patients with AH with concomitant DM [16].

It is also known that the effectiveness of the correction of the risks of CVC is affected not only by the optimization of therapy but also by the adherence of patients to treatment [7, 12], which determined the relevance of the study of the relationship between the level of adherence to treatment and indicators of the 10-year risk of CVC in patients with AH with accompanying DM.

The aim of the study. To investigate the role of adherence to treatment in the correction of the risk of cardiovascular complications in patients with arterial hypertension with accompanying diabetes mellitus.

Materials and methods. The methodology of conducting the research corresponded to the provisions of the Declaration of Helsinki, which was revised six times: in 1975, 1983, 1989, 1996, 2000 and 2008 [5].

The study, the protocol of which was previously approved by the bioethics commission of Odesa National Medical University (protocol N 2/21 dated 18.10.2021), was carried out under the outpatient conditions of the polyclinic department of the Center for Reconstructive and Restorative Medicine (University Clinic) of Odesa National Medical University. The study included 120 patients with a stable course of stage II AH of 1st-2nd degrees with concomitant type 2 diabetes with the duration of AH and DM for more than 1 year (women, and men aged from 45 to 74). All the patients underwent a comprehensive clinical examination, which took into account complaints; medical history (duration of AH and DM, frequency of exacerbations), life history (family history, information on other concomitant diseases, in particular, Covid-19, was collected etc.).

According to the main indicators of clinical characteristics, age and gender, the patients of both groups were comparable (table 1).

Table 1

Characteristics of patients with arterial hypertension with accompanying diabetes who were included in the study (n; M ± m; %; *p*)

Indicator	Group I (research) (n = 60)	Group II (comparative) (n = 60)	*p*
1	2	3	4
Age, years, M ± m	58.7 ± 0.9	56.8 ± 0.83	>0.5
Men, n, %	31 (51.7 %)	28 (46.7 %)	0.52

Contin of the table 1

1	2	3	4
Women, n, %	29 (48.3 %)	32 (53.3 %)	0.57
SBP, mm Hg	153.8 ± 3.7	159.8 ± 3.2	>0.3
DBP, mm Hg	86.7 ± 4.1	83.3 ± 2.8	>0.5
HbA1c, %, M ± m	8.1 ± 0.9	8.3 ± 1.1	>0.5

Notes: 1 - the quantitative indicators are presented as (M ± m) - mean value ± mathematical error of the mean; 2 - comparison of percentages between groups was carried out according to the $\chi 2$ criterion; 3 - the difference was considered reliable at $p < 0.05$; 4 - BP - blood pressure; 5 - SBP - systolic BP; 6 - DBP - diastolic BP; 7 - HbA1c - glycated hemoglobin.

Table 1 shows that the groups did not differ significantly in terms of SBP, DBP, and glycemia indicators.

Special attention was paid to the evaluation of the effectiveness of drugs used in the basic therapy of AH and DM, the presence of allergies or intolerance to the drugs used by patients, as well as their adherence to treatment in general.

Personal reasons for insufficient adherence to treatment were identified in all patients using Morisky DE, Green LW, and Levine DM questionnaire [10]. Adherence to treatment based on the total number was divided into three levels of adherence: 0 to < 6 (poor); from 6 to < 8 (insufficient); and 8 or more - good.

In all the patients, the risk of the CVC probability over 10 years was calculated according to the SCORE2 diabetes scale, in which the risk calculation takes into account patients with diabetes [16]. In addition to the indicators that are necessary to fill in this calculator (age, gender, systolic blood pressure, smoking, total cholesterol, high-density cholesterol, HbA1c level, glomerular filtration rate, age of the patient who when diabetes was diagnosed), when calculating the riskit was also taken into consideration that, according to the World Health Organization (WHO), Ukraine belongs to countries with a very high risk of CVC [13].

We also calculated the Pearson correlation coefficient [6] between the indicator of adherence to treatment according to D. E. Morisky, L. W. Green, D. M. Levine questionnaire and the indicator of the 10-year risk of CVC according to SCORE2 diabetes.

Antihypertensive and antidiabetic treatment was adjusted in all the patients. All the patients were also recommended measures to reduce the 10-year risk of CVC, which included giving up bad habits, and the need to follow non-drug and drug recommendations of the doctor.

At the first visit, all the patients were explained why it is necessary to maintain a good adherence to treatment. Patients who were included in the study were randomly assigned to the main research group (60 men and women of middle and old age (58.7 (54.1-69.4) years)) and the comparative group (60 men and women aged 56.8 (53.2-70.2) years) Individual methods of correction of insufficient adherence to treatment were applied in the patients of the study group, which took into account gender, age, psychological type of personality [7, 12], and in the patients of the comparative group, generally accepted methods of correction of insufficient adherence to treatment were used. Among the individual, patient-oriented methods of correction of insufficient adherence to treatment, short telephone messages (SMS) or phone calls with a reminder to take medicines, a survey about blood pressure (BP) indicators during the day, individual recommendations for compliance with all the requirements of the standard method of BP measurement, receiving information about blood glucose indicators, reminders about the need to regularly take medicines, etc.

At repeat visits (after 3 weeks and after 3 months), indicators of the course of the disease, treatment adherence, the risk of complications according to SCORE2 diabetes and the need for further correction were assessed.

In addition to the general clinical examination, laboratory indicators were studied, and an electrocardiogram was performed. If necessary, the doctor adjusted the treatment of AH and/or DM. At all visits, recommendations were also provided to improve treatment adherence and reduce the risk of CVC.

During the statistical processing of the data, modern recommendations on the mathematical processing of medical and biological data were taken into account [1, 8]. Statistical processing of the received data was carried out using Microsoft Excel 2013 (Microsoft Corporation, USA, 2013) and Statistica 6.0 (StatSoft, version 13.3.721) computer programs. Indicators with a normal distribution are given as the mean value and the standard error of the mean value (M ± m). The probability of the difference in indicators was calculated using the χ^2 test and Student's t-test in the case of normal distribution of values. The results of comparisons under conditions of $p < 0.05$ were considered reliable. We also calculated the Pearson correlation coefficient [6] between the indicator of adherence to treatment according to D. E. Morisky, L. W. Green, D. M. Levine questionnaire and the indicator of the 10-year risk of CVC according to SCORE2 diabetes.

Results and discussion. The majority of patients in the study group (58 (96.7 %) and 57 (95.5 %) patients in the comparative group had a high or very high risk according to the SCORE2 diabetes scale. The 10-year risk of CVD according to SCORE2 diabetes was also comparable on average at the beginning of the study (in the study group it was on average 38.4 (29.1-46.2) points and in the comparative group - 37.8 (30.0-47.1) points).

The basic therapy of patients with hypertension, according to the current Protocol "Arterial hypertension", which was approved by the Order of the Ministry of Health N 384 of 24.05.2012 [2], and international recomendations [9, 14] included the use of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin reeptor blocker (ARB) in combination with calcium

channel blocker amlodipine or hydrochlorothiazide. A proportion of the patients who received double antihypertensive combinations of ACEI in combination with hydrochlorothiazide or amlodipine in group I was 35.0 %, in group II - 33.3 % ($p > 0.5$), ARB in combination with hydrochlorothiazide or amlodipine in group I was 45.0 %, in II - 41.7 % ($p > 0.5$). The triple antihypertensive combination (ACEI or ARB in combination with hydrochlorothiazide and amlodipine) was 20.0 % in the study group, 25.0 % in the comparative group ($p > 0.5$).

In the treatment of type 2 DM following the current Unified clinical protocol of primary and secondary (specialized) medical care "Type 2 diabetes mellitus", which was approved by Order of the Ministry of Health N 1118 dated 12.21.2012 [3] and Standards of Care in Diabetes - 2023 [11], metformin in combination with glimepiride was included in most patients (83.3 % in group I and 80.0 % in group II ($p > 0.5$)). A triple combination of antidiabetic drugs, which included metformin in combination with glimepiride with the addition of dapagliflozin or empagliflozin, was received by 11.7 % of patients in the study group and 13.3 % in the comparative group ($p > 0.5$)). Only 3 (0.5 %) patients of the study group and 4 (0.7 %) patients of the II group received metformin monotherapy ($p > 0.5$). That is, in the study group and the comparative group, the composition of the basic complex of treatment of patients with AH and DM was almost similar. 14 (23.3 %) patients of the comparative group and 16 (26.7 %) of the study group additionally received sulodexide capsules of 250 lipoprotein lipase units twice a day. All the patients were also prescribed statin therapy with atorvastatin or rosuvastatin in medium therapeutic doses.

At the beginning of the study, at the first visit, poor adherence to treatment according to D. E. Morisky, L. W. Green, D. M. Levine questionnaire in the comparative group was found in 28 (46.7 %) patients, insufficient - in 21 (35.0 %) and good adherence - only in 11 (18.3 %) people, and in the study group - in 29 (48.3 %), 23 (38.3 %) and 8 (13.3 %) patients, respectively, i.e. the initial data on adherence to treatment did not differ significantly in the groups. Analysis of the causes of low adherence to treatment allowed to establishment two study groups of causes: subjective (related to the patient) and objective (caused by the prescribed treatment). Among the reasons for violation of adherence to treatment in patients with hypertension and diabetes, subjective reasons related to the patient prevailed - 80.1 %, the remaining 19.9 % - objective reasons caused by the prescribed treatment.

The analysis showed that the indicators of the 10-year risk of CVC according to SCORE2diabetes were also comparable on average at the beginning of the study (in the study group it was an average of 38.4 (29.1-46.2) points and in the comparative group - 37.8 (30.0-47.1) points).

A detailed analysis revealed a strong inverse relationship between the indicator of risk and A. T. Thus, K. Pearson correlation coefficient between the SCORE2 diabetes risk indicator and the adherence to treatment indicator was: r = -0.916 ($p < 0.05$).

At the 2nd visit, 3 weeks after the correction of treatment, in the group of patients in whom patient-oriented methods were used compared to the generally accepted methods of insufficient adherence to treatment correction in patients with AH with concomitant DM in the comparative group, it was allowed to increase the adherence to treatment in the majority of patients already in the 3rd week and achieve the target level of BP and fasting glucose in a greater percentage of patients (table 2).

Table 2

The frequency of achieving the target indicators of blood pressure and glycemia in patients with various methods of correction of adherence to treatment, patients with arterial hypertension with accompanying diabetes after three weeks of treatment (n; %; *p*)

Indicator	Group I (study) (n = 60)	Group II (comparative) (n = 60)	*p*
Target level of BP, n, %	25 (41.7 %)	11 (18.3 %)	<0.05
Need to correct the AT AH, n, %	16 (26.7 %)	31 (51.7 %)	<0.05
Target level of fasting glucose, n, %	28 (46.7 %)	19 (31.7 %)	>0.05
Need to correct the AT DM, n, %	14 (23.3 %)	24 (40.0 %)	<0.05

Notes: 1 - comparison of percentages between groups was carried out according to the χ^2 criterion, the difference was considered reliable at $p < 0.05$; 2 - AH - arterial hypertension; 3 - BP - blood pressure; 4 - AT - adherence to treatment; 5 - AT AH - adherence to treatment of arterial hypertension; 6 - DM - diabetes mellitus; 7 - AT DM - adherence to the treatment of diabetes.

As evidenced by the information presented in table 2, at the 2nd visit in the study group in which patient-oriented methods of adherence to treatment improvement were implemented, almost half of the patients (41.7 %) achieved the target blood pressure indicator, i.e. less than 130/8 mmHg. In the comparative group, only 18.3 % ($p < 0.05$) of patients achieved the target BP indicator. One-third of patients in both groups needed correction of antihypertensive therapy by a doctor, and almost twice as many patients in the comparison group (51.7 ± 6.5 %) needed correction of BP by the patients themselves as in the study group (26.7 ± 5.7 %), ($p < 0.05$). Analysis of the effectiveness of hypoglycemic therapy showed that at the II visits, the target indicator of fasting glucose content in the blood on an empty stomach (less than 7.0 mmol/l) in the study group was achieved in almost significantly more patients compared to the comparative group (respectively, 46.7 ± 6.4 % vs. 31.7 ± 6.0 %, $p > 0.05$). At the same time, almost twice as many patients in the comparative group than in the study group needed further correction of adherence to diabetes treatment ($p < 0.05$).

After 3 months of treatment, at the third visit, in the main group in which patient-oriented methods of correction of insufficient adherence to treatment were carried out, the percentage of patients with good adherence to treatment, as well as the proportion of patients who reached the target level of BP and glycemia were significantly higher compared to the comparative group (table 3).

Table 3

The frequency of reaching the target indicators of blood pressure and glycemia in patients with arterial hypertension with accompanying diabetes after 3 months of observation (n; %; *p*)

Indicator	Group I (study) (n = 60)	Group II (comparative) (n = 60)	*p*
Target indicator of BP, n, %	47 (78.3 %)	21 (35.0 %)	<0.001
Need to correct the AHT, n, %	9 (15.0 %)	17 (28.3 %)	>0.05
Target indicator of HвA1c, n, %	34 (56.7 %)	19 (31.7 %)	<0.01
Need to correct the HGT, n, %	17 (28.3 %)	12 (20.0 %)	>0.05

Notes: 1 - comparison of percentages between groups was carried out according to the $\chi 2$ criterion, the difference was considered reliable at $p < 0.05$; 2 - AH - arterial hypertension; 3 - BP - blood pressure; 4 - AHT - antihypertensive therapy; 5 - DM - diabetes mellitus; 6 - HGT - hypoglycemic therapy; 7 - HvA1c - glycated hemoglobin.

As evidenced by the information presented in Table 3 after 3 months of treatment, in the study group, in which patient-oriented methods of adherence to treatment improvement were implemented, the target BP indicator was reached in most patients (78.3 ± 5.3 %), and in the comparative group - in half of the percentage (35.0 ± 6.2 %), $p < 0.001$. The dynamics of achieving the target indicator of HvA1c were similar (respectively, in 56.7 ± 6.4 % of patients in the study group versus 31.7 ± 6.0 % in the comparative group, $p < 0.05$). At the same time, AHT correction was needed by almost a third of patients in the comparative group (36.7 ± 6.5 %), and significantly fewer patients in the study group (6.7 ± 3.2 %, $p < 0.001$). Correction of adherence to antidiabetic treatment was also required by significantly more patients in the comparative group than in the study group (respectively, 53.3 ± 6.4 % vs. 15.0 ± 4.6 %, $p < 0.001$).

Analysis of the 10-year risk of CVC according to SCORE2 diabetes showed that in the study group of patients in which individual patient-oriented correction of adherence to treatment was carried out, not only an increase in the proportion of patients with good adherence to treatment occurred, but also a significant decrease in the risk of CVC after 3 months of observation (table 4).

Table 4

Changes in the 10-year risk of cardiovascular complications according to Systemic Coronary Risk Evaluation diabetes in patients with different adherence to treatment (M ± m, points; *p*)

Adherence to treatment	Indicator according to SCORE2 diabetes					
	Group I (study)			Group II (comparative)		
	Visit I	Visit III	*p*	Visit I	Visit III	*p*
Poor	44.6 ± 5.2	37.3 ± 6.7	>0.05	42.4 ± 4.8	38.6 ± 5.1	>0.05
Insufficient	38.3 ± 4.4	33.3 ± 4.1	>0.05	37.3 ± 5.6	36.2 ± 6.3	>0.05
Good	34.1 ± 3.7	25.3 ± 3.8	<0.05	32.3 ± 7.2	31.3 ± 5.4	<0.05

Notes: 1 - quantitative indicators are presented as (M ± m) - mean value ± mathematical error of the mean; 2 - the significance of the difference is represented by the indicator *p.*

Table 4 shows that the best dynamics in the risk of CVC was achieved in patients of the study group with high AT.

The revealed close inverse relationship between the 10-year risk of CVC and adherence to treatment (the correlation coefficient between the SCORE2 diabetes risk indicator and the PL indicator was: r = -0.916, $p < 05$) is another strong argument for both patients and doctors regarding the need to comparative not only the course of the disease, but also to reduce risk factors for CVC and the importance of maintaining good patient adherence to treatment. It was established that good adherence to treatment, compared to patients with insufficient adherence to treatment, contributed to the reduction of AP and HbA1c to target levels in a greater percentage of patients with hypertension with concomitant diabetes, which affected the reduction of the 10-year risk of CVD in this cohort of patients.

Therefore, the results of the study indicate that the goal of the work has been achieved: the influence of adherence to treatment and the effectiveness of patient-oriented methods of correcting insufficient AT on indicators of the 10-year risk of cardiovascular complications in patients with hypertension with accompanying diabetes has been proven.

Studies on determining the influence of other factors on the risk of cardiovascular complications in patients with arterial hypertension and diabetes, in particular, the presence of other concomitant pathology, such as spondyloarthritis, rheumatoid arthritis, venous thrombosis, etc., are considered promising.

Conclusions. Indicators of patient adherence to treatment in patients with arterial hypertension with concomitant diabetes mellitus have a close inverse correlation with indicators of the 10-year risk of cardiovascular complications. Patient-oriented methods of correction of treatment adherence in the majority of patients with hypertension with accompanying diabetes allow to achieve the target levels of arterial pressure and glycemia, significantly reducing the 10-year risk of cardiovascular complications in this comorbid pathology.

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Conflict of interests
The authors declare no conflict of interests.

Role of Adherence to Treatment in the Correction of the Risk of Cardiovascular Complications in Patients with Arterial Hypertension with Accompanying Diabetes Mellitus

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Introduction. The presence of diabetes mellitus (DM), its duration, and the severity of the course significantly affect the degree of damage to target organs and the risk of cardiovascular complications (CVC) in patients with arterial hypertension (AH). It is also known that the effectiveness of the correction of the risks of CVC is influenced

not only by the optimization of disease therapy but also by the adherence of patients to treatment, which created the prerequisites for this study.

The aim of the study. To investigate the role of adherence to treatment in the correction of the risk of cardiovascular complications in patients with arterial hypertension with accompanying diabetes mellitus.

Materials and methods. The study included 120 patients with a stable course of stage II hypertension of 1st-2nd degrees with concomitant type 2 diabetes with the disease duration of more than 1 year.

Results. After 3 months of observation, in most patients with good adherence to treatment the target level of BP (in 78.3 ± 5.3 %) and the target level of HvA1c (in 56.7 ± 6.4 %) and a decrease in the 10-year risk of cardiovascular disease according to the SCORE2 diabetes scale (from 34.1 ± 3.7 points to 27.3 ± 3.8 points, $p < 0.05$) were achieved. The Pearson correlation coefficient between the SCORE2 diabetes risk indicator and the adherence to treatment indicator was: r = -0.916, $p < 0.05$, which indicates a close feedback relationship.

Conclusions. High adherence to treatment in the majority of patients with hypertension with accompanying diabetes allows them to achieve the target levels of blood pressure and glycemia, significantly reduce the risk index of cardiovascular complications, which has a close inverse correlation with the adherence of patients to treatment.

Keywords: risk of cardiovascular complications, arterial hypertension, diabetes, adherence to treatment.

Роль прихильности до лікування у корекції ризику кардіоваскулярних ускладнень у хворих на артеріяльну гіпертензію зі супутнім цукровим діябетом

О. Б. Волошина, Е. А. Зубок

Вступ. Наявність цукрового діябету (ЦД), його тривалість, тяжкість перебігу суттєво впливають на ступінь ураження органів-мішеней і ризик кардіоваскулярних ускладнень (КВУ) у хворих на артеріяльну гіпертензію (АГ). Відомо також, що ефективність корекції ризиків КВУ залежить не лише від оптимізації лікування, а й від прихильности пацієнтів до лікування, що й стало передумовою цього дослідження.

Мета. З'ясувати роль прихильности до лікування у корекції ризику кардіоваскулярних ускладнень у хворих на артеріяльну гіпертензію зі супутнім цукровим діябетом.

Матеріяли й методи. До дослідження залучили 120 пацієнтів зі стабільним перебігом АГ II стадії 1–2 ступенів із супутнім ЦД 2-го типу з тривалістю АГ і ЦД більш як один рік. Проводили комплексне клінічне обстеження, виявляли та коригували особистісні причини поганої прихильности до лікування (ПЛ), визначали ризик вірогідности кардіоваскулярних ускладнень (КВУ) упродовж 10 років за шкалою SCORE2 diabetes. Під час статистичного оброблення інформації враховували рекомендації щодо математичного опрацювання медико-біологічних даних і здійснювали його за допомогою комп'ютерних програм Microsoft Excel 2013 (Microsoft Corporation, США, 2013) і Statistica 6.0 (StatSoft, версія 13.3.721).

Результати. Більшість пацієнтів дослідної групи (58 (96,7 %) і 57 (95,5 %) хворих групи порівняння мали високий або дуже високий ризик за шкалою SCORE2 diabetes. Показники 10-річного ризику КВУ за SCORE2 diabetes також у середньому на початку дослідження були зіставними. У дослідній групі він становив у середньому 38,4 (29,1–46,2) бала, у групі порівняння – 37,8 (30,0–47,1) бала). На початку дослідження, під час першого візиту, низьку ПЛ за опитувальником D. E. Morisky, L. W. Green, D. M. Levine в групі порівняння виявлено у 28 (46,7 %) пацієнтів, середню – у 21 (35,0 %), високу ПЛ – лише в 11 (18,3 %), у дослідній групі – відповідно у 29 (48,3 %), 23 (38,3 %) і 8 (13,3 %) пацієнтів, тобто на початку дослідження ПЛ у групах суттєво не відрізнялась. Через три місяці спостереження у групі, для якої застосовували орієнтовані на пацієнта методи підвищення ПЛ, у більшости пацієнтів (78,3 ± 5,3 %) досягнуто цільового рівня АТ, а в групі порівняння – удвічі меншого відсотка (35,0 ± 6,2 %), $p < 0,001$. Аналогічною була й динаміка досягнення цільового рівня НвА1с (відповідно у 56,7 ± 6,4 % пацієнтів дослідної групи проти 31,7 ± 6,0 % – групи порівняння, $p < 0,05$). Достовірно знизився показник 10-річного ризику КВУ у пацієнтів із високою прихильністю до лікування (із 34,1 ± 3,7 бала до 27,3 ± 3,8 бала, $p < 0,05$).

Констатовано тісний зворотний зв'язок між показником ризику КВУ та прихильністю до лікування. Так, коефіцієнт кореляції за Pearson між показником ризику за SCORE2 diabetes і показником прихильности до лікування (за D. E. Morisky et al., 1986) становив r = -0,916, $p < 0,05$.

Висока прихильність до лікування сприяла зниженню АТ і НвА1с до цільових рівнів, а також зниженню 10-річного ризику КВУ у більшости хворих на АГ зі супутнім ЦД.

Висновки. Показник прихильности до лікування має тісний зворотний кореляційний зв'язок із показником 10-річного ризику кардіоваскулярних ускладнень за SCORE2 diabetes у хворих на артеріяльну гіпертензію із супутнім цукровим діябетом. Орієнтовані на пацієнта методи корекції лікування у більшости хворих на артеріяльну гіпертензію із супутнім цукровим діябетом уможливлюють досягти цільових рівнів артеріяльного тиску та глікемії, суттєвого зниження 10-річного ризику кардіоваскулярних ускладнень.

Ключові слова: ризик кардіоваскулярних ускладнень, артеріяльна гіпертензія, цукровий діябет, прихильність до лікування.

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