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ABSTRACT

of the dissertation submitted for the degree of Doctor of Philosophy

PREVALENCE OF ARTERIAL HYPERTENSION AND ASSESSMENT OF CARDIOVASCULAR RISK ACCORDING TO DIFFERENT CLASSIFICATIONS IN PREDIABETES AND TYPE 2 DIABETES

Speciality: 3205.01 – Internal diseases

Field of science: Medicine

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GENERAL CHARACTERISTICS OF THE SCIENTIFIC WORK

Relevance of the research. According to global statistical data, arterial hypertension is considered one of the leading causes of mortality worldwide, accounting for 10.4 million deaths annually[1]. The coexistence of arterial hypertension and diabetes increases the risk of cardiovascular events and mortality by 41% and 44%, respectively, whereas these risks are 9% and 7% respectively in individuals suffering from diabetes alone[2].

The coexistence of prediabetes with arterial hypertension can increase the risk of cardiovascular diseases.[3]

Currently, there are two documents that determine the diagnosis of arterial hypertension. The 2017 guidelines were prepared[4] by the American College of Cardiology / American Heart Association (ACC/AHA), and the 2018 guidelines were prepared[5] by the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH). In our country, European guidelines are traditionally preferred. However, the importance of this approach has not been definitively supported by scientific evidence.

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[1] Global Burden of Disease Risk Factor Collaborators. Global, regional, and national comparative risk assessment of 84 behavioral, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990–2017: a systematic analysis for the

[2] Diabetes and Hypertension: A Position Statement by the American Diabetes Association // Diabetes Care–2017.-v.40,-p.1273–1284. https://doi.org/10.2337/ dci 17-0026.

[3] Liu H.-H. Impacts of Prediabetes Mellitus Alone or Plus Hypertension on the Coronary Severity and Cardiovascular Outcomes / H.-H. Liu, Y.-X.Cao , S. Liu H.-H. [et al.] // Hypertension : - 2018. – v. 71(6), - p. 1039-1046.

[4] Whelton P.K. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/ NMA/ PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. / P.K. Whelton, R.M. Carey, W.S. Aronow [et al.] // Hypertension: - 2018. v. 71, e13-e115.

[5] Williams B. 2018 ESC/ESH Guidelines for the management of arterial hypertension. The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH) / B. Williams, G.Mancia, W.Spiering, [et al.] 2018 //European Heart Journal: - 2018. v. 39, - p. 3021–3104.

It should be noted that the issue of when to start pharmacological treatment for arterial hypertension in prediabetes has not been investigated comprehensively before.

There are the following risk scales that can be used to assess cardiovascular risk in both normal carbohydrate metabolism, prediabetes, and diabetes:

- PROCAM risk scale[6]
- Framigham risk scale based on lipid profile[7]
- Framigham risk scale on body mass index[7]
- QRESEARCH Cardiovascular risk (QRISK 2) scale[8]
- Atherosclerotic Cardiovascular Diseases (ASCVD) risk scale[9]
- Pooled Cohort Equations risk scale[10]

In summary, the following questions should be investigated:

– What is the difference in diagnostic criteria for detection arterial hypertension in normal carbohydrate metabolism, prediabetes, and type 2 diabetes?

– What is the contribution of the blood pressure range of 130-139/80-89 mmHg and the status of carbohydrate metabolism to the level of cardiovascular risk?

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[6] MDApp. Cardiovascular Risk PROCAM Score [Electronic resource] June 12, 2017. 11:59 AM. https://www.mdapp.co/cardiovascular-risk-procam-score-calcula-tor-255

[7] MDCALC. Framingham Risk Score for Cardiovascular disease (10 year risk) MDCalc 2018. [Electronic resource] https://www.framinghamheartstudy.org/fhs-risk-functions/cardiovascular-disease-10-year-risk/

[8] Predicting cardiovascular risk in England and Wales: prospective derivation and validation of QRISK2 // BMJ: - 2008. v.336, - p.1475-1482.

[9] Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report From the American Heart Association and American College of Cardiology. // [Electronic resource] / J Am Coll Cardi-ol: Nov 4, 2016. https://www.acc.org/latest-in-cardiology/ten-points-to-remember /2016/11/02/09/33/estimating-longitudinal-risks-and-benefits-million-hearts

[10] MSD Manual Professional version. Cardiovascular Risk Assesment (10-year, Revised Pooled Cohort Equations, 2018). [Electronic resource]https://www. msdmanuals.com/professional/multimedia/clinical-calculator/cardiovascular-risk-assessment-10-year-revised-pooled-cohort-equations-2018

– What is the effect of the blood pressure range of 130-139/80-89 mmHg after excluding the influence of other numerous associated clinical-metabolic factors?

– What levels of systolic and diastolic blood pressure are associated with "absolutely high" cardiovascular risk (≥10%) in normal carbohydrate metabolism, prediabetes, and type 2 diabetes?

Object and subject of the study:

The object of the study consists of outpatient data of indivi-duals with normal carbohydrate metabolism, prediabetes, and type 2 diabetes from the database of the Azerbaijan Association of Endocrinology, Diabetology, and Therapeutic Instructions. The subject of the study is the frequency of occurrence of arterial hypertension and the evaluation of cardiovascular risk.

Purpose of the study:

The purpose of the study was evaluation of diagnostic criteria for arterial hypertension on the frequency of occurrence of arterial hypertension and cardiovascular risk in individuals with type 2 diabetes, prediabetes and normal carbohydrate metabolism.

Tasks of the study:

To achieve the stated purpose, it is necessary to accomplish the following tasks:

1. To determine the effect of diagnostic criteria for arterial hypertension on the prevalence of arterial hypertension in individuals with type 2 diabetes, prediabetes, and normal carbohydrate metabolism;
2. To determine the effect of systolic blood pressure range of 130-139 mmHg and diastolic blood pressure 80-89 mmHg on the risk of cardiovascular disease development using six international accepted risk scales (PROCAM risk scale, Framingham risk scale based on lipid profile, Framingham risk scale based on body mass index, QRISK 2 scale, ASCVD risk scale, Pooled Cohort Equations risk scale) in individuals with type 2 diabetes, prediabetes, and normal carbohydrate metabolism;
3. To determine the effect of systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg on the risk of cardiovascular disease development using six international accepted risk scales in individuals with type 2 diabetes, prediabetes, and normal carbohydrate metabolism;

4. To develop a virtual risk model that neutralizes other factors affecting cardiovascular risk, aside from blood pressure and carbohydrate metabolism status;

5. In the developed virtual risk model using six cardiovascular risk scales, determine the effect of systolic blood pressure range of 130-139 mmHg and diastolic blood pressure range of 80-89 mmHg on the risk of cardiovascular disease development in type 2 diabetes, prediabetes, and normal carbohydrate metabolism.

Methods of the study:

Among the methods used, clinical examination occupied a special place. In addition, laboratory and instrumental diagnostic methods were used to obtain accurate results. The methods applied include assessment of arterial hypertension according to international recommendations and cardiovascular risk according to cardiovascular scales, as well as statistical methods.

The main provisions of the defense are:

1. The diagnostic criteria for arterial hypertension [ACC/AHA (2018), ESC/ESH (2017)] have a statistically significant impact on its prevalence.

2. Based on the results of six international recognized cardiovascular risk scales, an increase in systolic blood pressure to 130-139 mmHg and/or diastolic blood pressure to 80-89 mmHg raises the average cardiovascular risk indicators in the object of the study.

3. According to the results of six international recognized cardiovascular risk scales, systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg leads to a more significant rise in average cardiovascular risk indicators. The minimal increase is observed in individuals with normal carbohydrate metabolism, while the maximal increase is seen in individuals with type 2 diabetes.

4. A virtual risk model has been developed that neutralizes other factors affecting cardiovascular risk aside from blood pressure and carbohydrate metabolism status.

5. According to the virtual risk model, in type 2 diabetes a systolic blood pressure range of 130-139 mmHg and/or a diastolic blood pressure range of 80-89 mmHg significantly increases the incidence of high cardiovascular risk (≥10%).

The scientific novelty of the study:

– The impact of diagnostic criteria has been investigated for arterial hypertension on its prevalence in individuals with type 2 diabetes, prediabetes, and normal carbohydrate metabolism.

– Using various cardiovascular risk scales, the effect of systolic blood pressure range of 130-139 mmHg and diastolic blood pressure range of 80-89 mmHg on the development of cardiovascular diseases in individuals with type 2 diabetes, prediabetes, and normal carbohydrate metabolism has been demonstrated.

– A virtual risk model has been developed to assess the impact of systolic blood pressure range of 130-139 mmHg and diastolic blood pressure range of 80-89 mmHg on cardiovascular disease risk while neutralizing other risk factors.

– Based on the developed virtual risk model, the impact of systolic blood pressure range of 130-139 mmHg and diastolic blood pressure range of 80-89 mmHg on cardiovascular disease risk in type 2 diabetes has been determined, and recommendations regarding the initiation of pharmacological treatment for arterial hypertension have been proposed.

Theoretical and practical significance of the research:

– The necessity of controlling the risk of development of cardiovascular diseases in prediabetes and type 2 diabetes has been demonstrated.

– It has been shown that the risk of development of cardiovascular diseases is significantly higher in prediabetes and especially in type 2 diabetes.

– A recommendation has been proposed to initiate early pharmacological treatment for arterial hypertension when systolic blood pressure is ≥130 mmHg and diastolic blood pressure is ≥80 mmHg in individuals with type 2 diabetes.

Approval of the research work:

The research findings were presented at the International Diabetes Federation Congress ("The incidence of Arterial Hypertension in Patients with Type 2 Diabetes in Azerbaijan", XXI International Scientific-Practical Online Congress, 2021) and at the Azerbaijan Diabetes Congress ("Comparative evaluation of the prevalence of arterial hypertension based on ACC/AHA and ESC/ESH guidelines in prediabetes and type 2 diabetes", "The prevalence of arterial hypertension in patients with prediabetes in Azerbaijan", Scientific-Practical Congress, Baku, 2020 and 2021).

The results of the dissertation were discussed in an inter-departmental meeting at Azerbaijan Medical University on December 18, 2024 (Protocol № 2) and at the Scientific Seminar of the ED 2.27 Dissertation Council on April 22, 2025 (Protocol № 6).

Publications. A total of 12 scientific publications (9 articles, 3 theses) related to the dissertation have been published, including one in an internationally indexed journal. The articles were published in journals recommended by the Supreme Attestation Commission under the President of the Republic of Azerbaijan.

Practical application of the results. The results of the dissertation have been applied in the educational process of the Department of Family Medicine at Azerbaijan Medical University, in the practical activities of the Teaching Therapeutic Clinic of Azerbaijan Medical University, and the Azerbaijan Association of Endocrinology, Diabetology, and Therapeutic Instructions.

The organization where the dissertation work was performed. The dissertation was carried out at the Teaching Therapeutic Clinic and the Department of Family Medicine of Azerbaijan Medical University.

The scope and structure of the dissertation work. The dissertation consists of 177 pages (excluding figures, tables, notes related to them, bibliography) is 216 100 characters. There were introduced 44 tables and 26 figures in dissertasion. Its structure includes an introduction (13 000 characters), a literature review (Chapter I – 60 200 characters), a description of materials and methods (Chapter II – 16 500 characters), analysis of personal results (Chapter III – 103 000 characters, Chapter IV – 20 000 characters), results (2 000 characters), practical recommendations (1 400 charac-ters), and the list of used literature. The bibliography includes 238 references.

RESEARCH MATERIALS AND METHODS

Study Design

Retrospective multicenter cross-sectional case-control study.

Study Location: Teaching Therapeutic Clinic of Azerbaijan Medical University (using the database of the Azerbaijan Association of Endocrinology, Diabetology, and Therapeutic Instructions).

Inclusion Criteria: The outpatient records of 596 patients from the database of the Azerbaijan Association of Endocrinology, Diabetology, and Therapeutic Instructions were analyzed. Based on the data available in the outpatient records, the patients were included to the study according to the following criteria:

- Treatment doctor's surname and name;
- Date of initial examination;
- Patient's gender;
- Patient's age;
- Height;
- Body weight;
- Blood pressure measurements;
- Medical history;
- History of diabetes mellitus and/or use of antidiabetic medications;
- Glycated hemoglobin levels;
- Fasting glucose results;

Lipid profile measurements:

- Total cholesterol;
- High-density lipoprotein cholesterol;
- Low-density lipoprotein cholesterol;
- Triglycerides.

Exclusion Criteria:

- Type 1 diabetes or other (specific) types of diabetes mellitus;
- Pregnancy;
- Acute, free, or concurrent endocrine pathology that may affect Glycated hemoglobin levels, blood pressure, and other metabolic parameters;
- Concurrent acute pathologies of internal organs that may affect carbohydrate metabolism and blood pressure.

The main inclusion criterion for patients in the type 2 diabetes group was the presence of type 2 diabetes mellitus in the medical history or the use of antidiabetic medications. In the absence of the main inclusion criterion, the patient was required to meet at least two of the following minimum criteria:

– Glycated hemoglobin level of ≥6.5% (48 mmol/mol);

– Fasting venous plasma glucose level of ≥126 mg/dL (7.0 mmol/L);

– Venous plasma glucose level of ≥200 mg/dL (11.1 mmol/L) 2 hours after a 75 g glucose load.

Individuals with normal carbohydrate metabolism were included in the following three criteria:

1. Glycated hemoglobin of level ≤5.6% (38 mmol/mol);
2. Fasting venous plasma glucose level of ≤110 mg/dL (6.1 mmol/L);
3. Venous plasma glucose level of <140 mg/dL (7.8 mmol/L) 2 hours after a 75 g glucose load.

The group with normal carbohydrate metabolism will be presented as the control group (CG). Individuals who did not meet the appropriate criteria for normal carbohydrate metabolism and diabetes mellitus were classified into the prediabetes group:

1.Glycated hemoglobin level of 5.7-6.4% (39-47 mmol/mol);
2. Fasting venous plasma glucose level of 110-124 mg/dl (6.1-6.8 mmol/l);
3. Venous plasma glucose level of 140-199 mg/dl, (7.8-11 mmol/l) 2 hours after a 75 g glucose load.

The cardiovascular risk was determined using the following risk scales:

- PROCAM risk scale
- Framingham risk scale based on lipid profile
- Framingham risk scale based on body mass index
- QRISK 2 risk scale
- ASCVD risk scale
- PCE risk scale

Considering the variability of age-specific indicators in these risk scales, study participants were evaluated within the 40-65 age category. Participants younger than 40 were assigned an age of 40, those older than 65 were assigned an age of 65, while individuals within the 40-65 age range were assessed according to their real age.

Statistical analysis of materials: Statistical analysis was performed using the standard computer program Microsoft Excel. During the statistical evaluation, minimum, maximum, and mean values, standard deviation, and standard error of the mean were determined. Student's t-test was applied and differences between mean values were considered statistically significant when $p<0.05$.

The confidence interval (CI) for proportions was calculated using the Wilson method with an online calculator at a 95% confidence level. The CI for mean values was also determined at a 95% confidence level using the Confidence Limits for Mean Calculator. The significance of differences between proportions was assessed using the χ^2 method and Fisher's exact test. These calculations were performed using the «MEDCALC» online calculator.

RESULTS OF THE STUDY AND DISCUSSION

Evaluation of the Prevalence of Arterial Hypertension in Normal Carbohydrate Metabolism, Prediabetes, and Type 2 Diabetes According to Different Classifications

In the study, the prevalence of arterial hypertension was evaluated based on the diagnostic criteria of ESC/ESH (2018) and ACC/AHA (2017) guidelines.

The mean systolic blood pressure in the "CG normotensive ESC/ESH (2018)" subgroup was 114.8 mmHg (95% CI 112.20; 117.35), while the mean systolic blood pressure in the "CG hypertensive ESC/ESH (2018)" subgroup was 143.0 mmHg (95% CI 138.38; 147.56). Thus, the difference between the two subgroups was statistically significant: $p<0.001$.

The mean systolic blood pressure in the "CG normotensive ACC/AHA (2017)" subgroup was 110.0 mmHg (95% CI 107.04; 112.96), while the mean systolic blood pressure in the "CG hypertension ACC/AHA (2017)" subgroup was 133.3 mmHg (95% CI 129.37; 137.24). Thus, the difference between the two subgroups was statistically significant: $p<0.001$.

The mean diastolic blood pressure in the "CG normotensive ESC/ESH (2018)" subgroup was 74.3 mmHg (95% CI 72.74; 75.91), while the mean diastolic blood pressure in the "CG hypertensive ESC/ESH (2018)" subgroup was 89.5 mmHg (95% CI 86.81; 92.26).

Thus, the difference between the two subgroups was statistically significant: p <0.001.

The mean diastolic blood pressure in the "CG normotensive ACC/AHA (2017)" subgroup was 70.9 mmHg (95% CI 69.62; 72.13), while the mean diastolic blood pressure in the "CG hypertension ACC/AHA (2017)" subgroup was 84.9 mmHg (95% CI 82.67; 87.16). Thus, the difference between the two subgroups was statistically significant: p <0.001.

In the group with normal carbohydrate metabolism or the CG, according to the diagnostic criteria of ESC/ESH (2018) normotension was observed in 67.7% (95% CI 58.42; 76.94), while arterial hypertension was observed in 32.3% (95% CI 23.06; 41.58) of the individuals.

According to the diagnostic criteria of ACC/AHA (2017) normotension was found in 40.4% (95% CI 30.69; 50.12), and arterial hypertension was found in 59.6% (95% CI 49.88; 69.31) of individuals in the control group. When comparing the diagnostic criteria of ESC/ESH (2018) with ACC/AHA (2017), the prevalence of arterial hypertension was significantly higher according to ACC/AHA (2017) classification.

The mean systolic blood pressure in the "Prediabetes Normotensive ESC/ESH (2018)" subgroup was 119.1 mmHg (95% CI 113.25; 124.88), while the mean systolic blood pressure in the "Prediabetes Hypertensive ESC/ESH (2018)" subgroup was 146.5 mmHg (95% CI 141.43; 151.48). Thus, the difference between the two subgroups was statistically significant: p <0.001.

The mean systolic blood pressure in the "Prediabetes normotensive ACC/AHA (2017)" subgroup was 112.1 mmHg (95% CI 106.15; 118.14), while the mean systolic blood pressure in the "Prediabetes hypertension ACC/AHA (2017)" subgroup was 141.5 mmHg (95% CI 136.39; 146.61). Thus, the difference between the two subgroups was statistically significant: p <0.001.

The mean diastolic blood pressure in the "Prediabetes Normotensive ESC/ESH (2018)" subgroup was 76.6 mmHg (95% CI 73.13; 79.99), while the mean systolic blood pressure in the "Prediabetes Hypertension ESC/ESH (2018)" subgroup was 91.6 mmHg (95% CI

88.65; 94.57). Thus, the difference between the two subgroups was statistically significant: $p<0.001$.

The mean diastolic blood pressure in the "Prediabetes normotensive ACC/AHA (2017)" subgroup was 70.0 mmHg (95% CI 66.30; 73.70), while the mean diastolic blood pressure in the "Prediabetes hypertension ACC/AHA (2017)" subgroup was 89.4 mmHg (95% CI 86.72; 92.03). Thus, the difference between the two subgroups was statistically significant: $p < 0.001$.

In the prediabetes group, based on the diagnostic criteria of ESC/ESH (2018), normotension was observed in 34.0% (95% CI 20.35; 47.74), while arterial hypertension was found in the majority of the group, 66.0% (95% CI 52.26; 79.65).

According to the diagnostic criteria of ACC/AHA (2017), normotension was found in 14.9% (95% CI 4.60; 25.18) of the prediabetes group, and arterial hypertension was observed in 85.1% (95% CI 74.82; 95.40). The prevalence of arterial hypertension in prediabetic patients according to ACC/AHA (2017) was significantly higher compared to the diagnostic criteria of ESC/ESH (2018) ($p<0.05$).

The mean systolic blood pressure in the subgroup "Diabetes mellitus type 2 normotensive ESC/ESH (2018)" was 119.3 mmHg (95% CI 118.07; 120.62), while the mean systolic blood pressure in the subgroup "Diabetes mellitus type 2 hypertension ESC/ESH (2018)" was 146.3 mmHg (95% CI 144.52; 148.16). Thus, the difference between the two subgroups was statistically significant: $p<0.001$.

The mean systolic arterial pressure in the subgroup "Diabetes mellitus type 2 normotensive ACC/AHA (2017)" was 110 mmHg (95% CI 109.27; 112.79), while the mean systolic arterial pressure in the subgroup "Diabetes mellitus type 2 hypertension ACC/AHA (2017)" was 139 mmHg (95% CI 137.33; 140.63). Thus, the difference between the two subgroups was statistically significant: $p < 0.001$.

The mean diastolic blood pressure in the "Diabetes mellitus type 2 normotensive ESC/ESH (2018)" subgroup was 75.5 mmHg (95% CI 74.53; 76.44), while the mean diastolic blood pressure in the "Diabetes mellitus type 2 hypertension ESC/ESH (2018)" subgroup was 91.5 mmHg (95% CI 90.34; 92.67). Thus, the difference between the two subgroups was statistically significant: $p < 0.001$.

The mean diastolic blood pressure in the "Diabetes mellitus type 2 normotensive ACC/AHA (2017)" subgroup was 68.5 mmHg (95% CI 67.55; 69.49), while the mean diastolic blood pressure in the "Diabetes mellitus type 2 hypertension ACC/AHA (2017)" subgroup was 87.5 mmHg (95% CI 86.52; 88.53). Thus, the difference between the two subgroups was statistically significant: p <0.001.

In the Type 2 diabetes group, according to the diagnostic criteria of ESC/ESH (2018), normotension was found in 43.6% (95% CI 38.97; 48.14) of the group, while arterial hypertension was found in 56.4% (95% CI 48.14; 61.03).

Based on the diagnostic criteria of ACC/AHA (2017), normotension was found in 15.8% (95% CI 12.41; 19.15) of the type 2 diabetes group, while arterial hypertension was found in 84.2% (95% CI 80.85; 87.59). The prevalence of arterial hypertension in the type 2 diabetes group according to the diagnostic criteria of ACC/AHA (2017) was significantly higher compared to the ESC/ESH (2018) criteria (p<0.0001).

Cardiovascular risk assessment in normal carbohydrate metabolism, prediabetes, and type 2 diabetes

In the CG group, patients were divided into three subgroups to determine the effect of blood pressure on cardiovascular risk:

- "Ideal Normotension" subgroup (n = 40): Patients with blood pressure in the range of 120-129/70-79 mmHg.
- "Intermediate Blood Pressure" subgroup (n = 32): Patients with blood pressure in the range of 130-139/80-89 mmHg.
- "Ideal Hypertension" subgroup (n=27): Patients with blood pressure ≥140/90 mmHg.

A statistical comparison between the "Ideal Normotension" and "Intermediate Blood Pressure" subgroups showed significant differences in all cases. When applying the PCE risk scale (0.7% vs 2.4%), the minimal difference was statistically significant (p<0.05), while the maximal difference was observed using the lipid profile-based Framingham risk scale (1.8% vs 5.0%) and the body mass index-based Framingham risk scale (2.7% vs 6.3%), with both showing p<0.001. However, when applying the PROCAM risk scale, the difference between these subgroups was not statistically significant (p>0.05).

A significant statistical difference ($p<0.001$) was found bet-ween the "Ideal Normotension" and "Ideal Hypertension" sub-groups. Furthermore, the difference between the "Intermediate Blood Pressure" and "Ideal Hypertension" subgroups was not statistically significant in terms of ASCVD (2.4% vs 4.1%) and PCE risk scales ($p>0.05$). However, a statistically significant dif-ference was found when applying the lipid profile-based Fra-mingham risk scale (5.0% vs 8.8%) ($p<0.05$) and the body mass index-based Framingham risk scale (6.3% vs 11.1%) ($p<0.01$). The difference between the "Inter-mediate Blood Pressure" and "Ideal Hypertension" subgroups was statistically significant ($p<0.05$) when applying the PCE risk scale (3.5% vs 6.0%).

The complex application of all the above risk scales in the CG group resulted in the following average cardiovascular risk values "Ideal Normotension" subgroup: 1.4% (95% CI 1.26; 1.61); "Inter-mediate Blood Pressure" subgroup: 3.7% (95% CI 3.07; 4.41); "Ideal Hypertension" subgroup: 6.7% (95% CI 5.76; 7.61).

The differences between the subgroups were highly statistically significant ($p<0.001$).

The complex and seperately application of cardiovascular risk scales, in individuals with normal carbohydrate metabolism demon-strated that an increase in systolic blood pressure to 130-139 mmHg and/or diastolic blood pressure to 80-89 mmHg resulted in an eleva-ted cardiovascular risk. Further increases in blood pressure exacer-bated this risk.

In the prediabetes group, patients were divided into three subgroups to determine the effect of blood pressure on cardiovas-cular risk:

- "Ideal Normotension" subgroup (n = 7): Patients with blood pressure in the range of 120-129/70-79 mmHg.
- "Intermediate Blood Pressure" subgroup (n = 9): Patients with blood pressure in the range of 130-139/80-89 mmHg.
- "Ideal Hypertension" subgroup (n = 31): Patients with blood pressure ≥140/90 mmHg. When assessing the risk between the "Ideal Normotension", "Intermediate Blood Pressure", and "Ideal Hyper-tension" subgroups (using corresponding risk scales), no statistically significant differences were observed ($p>0.05$). However, a signi-ficant difference was found between the "Ideal Normotension" and

“Ideal Hypertension” subgroups when applying the Framingham body mass index-based risk scale and Framingham lipid profile-based risk scale ($p<0.01$).

Complex application of all risk scales in the prediabetes group resulted in the following cardiovascular risk values: “Ideal Normotension” subgroup: 3.1% (95% CI 2,76; 3,44); “Intermediate Blood Pressure” subgroup: 6.2% (95% CI 5,44; 6,96); “Ideal Hypertension” subgroup: 9.3% (95% CI 8,57; 10,12). Significant statistical differences were observed between “Ideal Normotension” and “Intermediate Blood Pressure”, as well as between “Intermediate Blood Pressure” and “Ideal Hypertension” subgroups ($p<0.01$). The difference between “Ideal Normotension” and “Ideal Hypertension” was highly statistically significant ($p<0.001$).

Conclusion for Prediabetes: The complex application of cardiovascular risk scales in the prediabetes group indicated that a rise in systolic blood pressure to 130-139 mmHg and/or diastolic blood pressure to 80-89 mmHg resulted in an increase in cardiovascular risk. Further increases in blood pressure exacerbated this risk.

In the Type 2 Diabetes group, patients were divided into three subgroups to assess the effect of blood pressure on cardiovascular risk:

- “Ideal Normotension” subgroup (n = 71): Blood pressure in the range of 120-129/70-79 mmHg.
- “Intermediate Blood Pressure” subgroup (n = 125):
- Blood pressure in the range of 130-139/80-89 mmHg.
- “Ideal Hypertension” subgroup (n=254): Blood pressure ≥140/90 mmHg.

There was a significant statistical difference between the “Ideal Normotension” and “Intermediate Blood Pressure” subgroups in all cases. For instance, applying the PCE risk scale showed a minimal difference (6.0% vs 9.1%) ($p<0.01$), lipid profile-based Framingham risk (10.7% vs 16.5%) ($p<0.01$), and body mass index-based Framingham risk scale (12.1% vs 26.5%) ($p<0.05$). The difference between “Ideal Normotension” and “Ideal Hypertension” subgroups was also significant ($p<0.001$). There was a significant difference between the “Intermediate Blood Pressure” and “Ideal Hypertension” subgroups in terms of lipid profile-based Framingham risk scale

(16.5% vs 23.0%), ASCVD risk scale (9.1% vs 12.6%), PROCAM risk scale (12.1% vs 16.1%), PCE risk scale (9.1% vs 12.6%), and QRISK 2 risk scale (13.4% vs 17.2%) ($p<0.01$), with the body mass index-based Framingham risk scale showing a more significant difference (26.5% vs 17.4%) ($p<0.001$).

Complex application of all risk scales in the Type 2 Diabetes group resulted in the following cardiovascular risk values: "Ideal Normotension" subgroup: 8.5% (95% CI 7.80; 9.28), "Intermediate Blood Pressure" subgroup: 12.9% (95% CI 12.32; 13.51), "Ideal Hypertension" subgroup: 18.0% (95% CI 17.43; 18.55). The differences between the subgroups were highly statistically significant ($p<0.001$). Conclusion for Type 2 Diabetes: The complex and seperately application of cardiovascular risk scales in Type 2 Diabetes patients showed that an increase in blood pressure to 130/80 – 139/89 mmHg resulted in an increase in cardiovascular risk. Further increases in blood pressure exacerbated this risk. It is well known that, in addition to blood pressure, other factors also influence cardiovascular risk. Individuals in the CG, prediabetes, and type 2 diabetes groups differed in terms of lipid profile, body mass index, height, age, and gender composition. It is undeniable that these factors affect cardiovascular risk indicators to varying degrees. Thus, besides blood pressure indicators and carbohydrate metabolism status, the need arose to neutralize the influence of other factors in the CG, prediabetes, and type 2 diabetes and to demonstrate the impact of arterial hypertension diagnostic criteria on cardiovascular risk.

Creation of a virtual risk model to neutralize the impact of factors other than blood pressure and carbohydrate metabolism status on cardiovascular risk

The PROCAM risk scale determines cardiovascular risk ba-sed on the following indicators: age, presence of diabetes, smoking, family history of myocardial infarction, low-density lipoprotein cho-lesterol, high-density lipoprotein cholesterol, triglycerides, and systolic blood pressure. The Framingham risk scale based on lipid profile evaluates cardiovascular risk based on indicators such as age, sex, systolic blood pressure, treatment of arterial hypertension, current smoking, presence of diabetes, total cholesterol, and high-density lipoprotein cholesterol levels. The Framingham risk scale based on body mass index, like the Framingham risk scale based on lipid profile, analyzes indicators such as - age, sex, systolic blood pressure, treatment of arterial hypertension, current smoking, and presence of diabetes. In this scale, the body mass index is used instead of total cholesterol and high-density lipoprotein cholesterol levels. The QRISK2 scale evaluates cardiovascular risk with the following indicators: age, sex, ethnicity (in our study, only the European ethnicity was investigated), smoking, presence of diabetes, first-degree relatives with myocardial infarction or angina, stage 4-5 chronic kidney disease, presence of atrial fibrillation, treatment of arterial hypertension and rheumatoid arthritis, body mass index, systolic blood pressure, total cholesterol/high-density lipoprotein cholesterol ratio. The ASCVD risk scale evaluates cardiovascular risk with indicators such as age, sex, ethnicity, smoking, presence of diabetes, treatment of arterial hypertension, systolic and diastolic blood pressure, total cholesterol, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol. The PCE risk scale uses indicators such as age, sex, ethnicity, smoking, presence of diabetes, treatment of arterial hypertension, systolic blood pressure, total cholesterol, and high-density lipoprotein cholesterol for analysis.

A virtual risk model and corresponding virtual groups (VG) were created to neutralize the impact of factors other than blood pressure and carbohydrate metabolism status on cardiovascular risk indicators. These groups include: "Normal Carbohydrate Metabolism VG", "Prediabetes VG" and "Type 2 Diabetes VG". To design the mentioned virtual risk model, six international risk scales were also used: the PROCAM risk scale, lipid profile-based Framingham risk scale, body mass index-based Framingham risk scale, QRISK 2 scale, ASCVD risk scale and PCE risk scale. To neutralize the gender factor, risk assessment was performed twice: first, with participants of the VG corresponding to the real gender prototype, and second, by including the opposite gender's corresponding indicators and changing the gender. For each member of the listed VGs, the following parameters were generalized as zero:

The following parameters were generalized as zero for each member of the listed VGs:

- family history of myocardial infarction;
- presence of myocardial infarction or angina in first-degree relatives under the age of 60;
- atrial fibrillation;
- presence of rheumatoid arthritis;
- presence of stage 4-5 chronic kidney disease;
- treatment of arterial hypertension;
- smoking.

All participants in the VGs were considered to be of European descent.

Table 1 presents the indicators of women in the three VGs.

It should be noted that these indicators are presented as the average indicators for each VG and were applied to each female member of the respective VG. Furthermore, these indicators varied not only within each VG but also between the VGs. Within each VG, the arterial pressure indicator of each woman was equal to the arterial pressure of her real prototype.

Table 1.

Indicators of women in the "Normal Carbohydrate Metabolism VG," "Prediabetes VG," and "Type 2 Diabetes VG" virtual groups

Indicator	Virtual Groups		
	Normal carbohydrate metabolism VG	Prediabetes VG	Type 2 Diabetes VG
Age (years)	46	58	58
Presence of Diabetes	no	no	yes
Height (cm)	160	158	159
Body Weight (kg)	74	83	82
Body Mass Index (kg/m²)	29	33	32,4
Total Cholesterol (mg/dL)	176	200	201
Low-Density Lipoprotein Cholesterol (mg/dL)	78	102	113
High-Density Lipoprotein (HDL) Cholesterol (mg/dL)	61	56	47
Triglycerides (mg/dL)	180	205	207

Table 2 presents the indicators of men in the three VGs:

It should be noted that these indicators are presented as the average indicators for each VG and were applied to each male member of the respective VG. Furthermore, these indicators varied not only within each VG but also between the VGs. Within each VG, the arterial pressure indicator of each man was equal to the arterial pressure of his real prototype. According to the data from the 6 risk scales, cardiovascular risk data were presented across 9 VGs:

1. Ideal normal arterial pressure (<130/80 mmHg) + Normal Carbohydrate Metabolism (n=80);
2. Ideal normal arterial pressure (<130/80 mmHg) + Prediabetes (n=14);
3. Ideal normal arterial pressure (<130/80 mmHg) + Type 2 Diabetes (n=142);
4. Intermediate arterial pressure (systolic blood pressure 130-139 mmHg and/or diastolic blood pressure 80-89 mmHg) + Normal Carbohydrate Metabolism (n=54);
5. Intermediate arterial pressure (systolic blood pressure 130-139 mmHg and/or diastolic blood pressure 80-89 mmHg) + Prediabetes (n=14);
6. Intermediate arterial pressure (systolic blood pressure 130-139 mmHg and/or diastolic blood pressure 80-89 mmHg) + Type 2 Diabetes (n=250);
7. Ideal arterial hypertension (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg) + Normal Carbohydrate Metabolism (n=64);
8. Ideal arterial hypertension (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg) + Prediabetes (n=62);
9. Ideal arterial hypertension (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg) + Type 2 Diabetes (n=508).

In the figure, the cardiovascular risk was assessed as a result of the complex application of the relevant risk scales in the VGs.

Table 2.

Indicators of men in the "Normal Carbohydrate Metabolism VG," "Prediabetes VG," and "Type 2 Diabetes VG" virtual groups

Indicator	Virtual Groups		
	Normal Carbohydrate Metabolism VG	Predia-betes VG	Type 2 Diabetes VG
Age (years)	43	55	54
Presence of Diabetes	no	yes	yes
Height (cm)	173	173	172
Body Weight (kg)	83	86	89
Body Mass Index (kg/m²)	28	29	30.0
Total Cholesterol (mg/dL)	189	189	208
Low-Density Lipoprotein (LDL) Cholesterol (mg/dL)	90	93	115
High-Density Lipoprotein (HDL) Cholesterol (mg/dL)	57	56	44
Triglycerides (mg/dL)	211	197	243

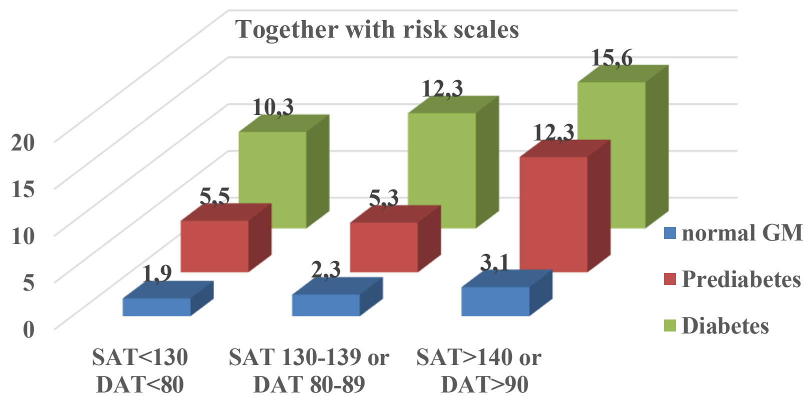

Image. Results of cardiovascular risk assessment in participants of 3 VGs as a result of the complex application of risk scales

It is clear from the figure that, during the complex application of the relevant risk scales in the VGs, the following trends were observed:

- In the VGs with ideal normal arterial pressure (<130/80 mmHg), minimal cardiovascular risk was observed: Normal Carbohydrate Metabolism VG – 1.9%, Prediabetes VG – 5.5%, Type 2 Diabetes VG – 10.3%.
- In the VGs with intermediate arterial pressure (130-139/80-89 mmHg), cardiovascular risk was as follows: Normal Carbo-hydrate Metabolism VG – 2.3%, Prediabetes VG – 5.3%, Type 2 Diabetes VG – 12.3%.
- According to the diagnostic criteria of the ESC/ESH (2018), in the VGs with arterial hypertension, the cardiovascular risk was 3.1% in normal carbohydrate metabolism, 8.3% in prediabetes, and 15.6% in type 2 diabetes mellitus. The analysis of the three variations of arterial pressure in type 2 diabetes mellitus VGs also showed a statistically significant difference ($p<0.001$ in all cases). Similarly, the analysis of normal carbohydrate metabolism VGs and the three variants of arterial pressure also showed a statistically significant difference ($p<0.001$ in all cases).
- According to the diagnostic criteria of ESC/ESH(2018), risk indicators in the prediabetes arterial hypertension VG showed higher statistically significant results compared to the normal and intermediate arterial pressure VGs ($p<0.001$ in all cases). It is important to note that the difference between normal arterial pressure and intermediate arterial pressure in prediabetes VGs was not statistically significant ($p>0.05$).

The frequency of high cardiovascular risk (≥10.0%) based on arterial pressure and carbohydrate metabolism status in the VGs was also studied.

The increase in arterial pressure from “ideal normal” to “intermediate” in the normal carbohydrate metabolism VG did not cause a statistically significant increase in the frequency of high cardiovascular risk indicators (from 0.0% to 0.6%; $p>0.05$). A similar situation was observed in the prediabetes VG (from 10.7% to 11.9%; $p>0.05$). Based on the obtained data, the increase in the frequency of high cardiovascular risk was observed only in the “ideal arterial hypertension” cases in both normal carbohydrate metabolism VG ($p<0.05$) and prediabetes VG.

Additionally, the increase in arterial pressure from "ideal normal" to "intermediate" caused a statistically significant rise in the frequency of high cardiovascular risk (≥10%) in the type 2 diabetes mellitus VG, from 46.0% (95% CI 40,56; 51,34) to 62.8% (95% CI 57,62; 67,98) ($p<0.001$).

We believe that these findings allow us to propose the following points:

– According to the ACC/AHA (2017) diagnostic criteria, systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 80 mmHg confirms arterial hypertension in type 2 diabetes mellitus.

– Even if this proposal is not accepted by our country's cardiology society, systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 80 mmHg should be considered a signal to initiate pharmacological treatment for arterial hypertension in type 2 diabetes mellitus.

The significance, effectiveness, and safety of this recommendation are based on the results of the ADVANCE study - a large-scale trial conducted in 215 clinical centers across 20 countries, involving 11,140 patients. This study demonstrated that the use of the perindopril/indapamide combination in type 2 diabetes is safe even in patients with normal blood pressure and effectively reduces cardiovascular complications.[9;10]

RESULTS

1. The prevalence of arterial hypertension, according to the diagnostic criteria of ESC/ESH (2018), was lower compared to the ACC/AHA (2017) diagnostic criteria, with the following percentages for individuals with normal carbohydrate metabolism, prediabetes, and type 2 diabetes mellitus, respectively: normal carbohydrate metabolism: 32.3% (95% CI 23.06; 41.58) vs. 59.6% (95% CI 49.88; 69.31) ($p<0.0001$); prediabetes: 66.0% (95% CI 52.26; 79.65) vs. 85.1% (95% CI 74.82; 95.40) ($p<0.05$); type 2 diabetes mellitus: 56.4% (95% CI 51.86; 61.03) vs. 84.2% (95% CI 80.85; 87.59) ($p <0.0001$) [7].

2. The application of six international accepted cardiovascular risk scales (PROCAM risk scale, lipid profile-based Framingham risk scale, body mass index-based Framingham risk scale, QRISK 2 scale, ASCVD risk scale, Pooled Cohort Equations risk scale) demonstrated that an increase in systolic blood pressure to 130-139 mmHg and/or diastolic blood pressure to 80-89 mmHg resulted in an increase in average cardiovascular risk indicators [8; 9; 10; 12]:

- normal carbohydrate metabolism: from 1.4% (95% CI 1.26; 1.61) to 3.7% (95% CI 3.07; 4.41) ($p<0.001$)
- prediabetes: from 3.1% (95% CI 2,76; 3,44) to 6.2% (95% CI 5,44; 6,96) ($p<0.01$)
- type 2 diabetes mellitus: from 8.5% (95% CI 7.80; 9.28) to 12.9% (95% CI 12.32; 13.51) ($p < 0.001$)

3. The application of the six cardiovascular risk scales indicated that an increase in systolic blood pressure to ≥ 140 mmHg and/or diastolic blood pressure to ≥ 90 mmHg resulted in the maximal increase in average cardiovascular risk indicators [8; 9; 10; 12]:

- normal carbohydrate metabolism: from 1.4% (95% CI 1.26; 1.61) to 6.7% (95% CI 5.76; 7.61) ($p<0.001$)
- prediabetes: from 3.1% (95% CI 2,76; 3,44) to 9.3% (95% CI 8,57; 10,12) ($p < 0.001$)
- type 2 diabetes mellitus: from 8.5% (95% CI 7.80; 9.28) to 18.0% (95% CI 17.43; 18.55) ($p <0.001$)

4. A virtual risk model was created to neutralize the effects of other factors influencing cardiovascular risk, aside from arterial pressure and carbohydrate metabolism status [11].

5. Based on the developed virtual risk model, an increase in systolic blood pressure to 130–139 mmHg and/or diastolic blood pressure to 80–89 mmHg in type 2 diabetes significantly increased the prevalence of high cardiovascular risk (≥10%), rising from 46.0% (95% CI 40,56; 51,34) to 62.8% (95% CI 57,62; 67,98) ($p < 0.001$). However, in individuals with normal carbohydrate metabolism and prediabetes, no statistically significant increase in the prevalence of high cardiovascular risk (≥10%) was observed ($p > 0.05$) [11].

PRACTICAL RECOMMENDATIONS

1. Cardiovascular risk assessment is essential for optimizing treatment in patients with type 2 diabetes and should be a routine element of medical examinations.

2. In patients with type 2 diabetes, based on the diagnostic criteria of ACC/AHA (2017) and more specifically ESC/ESH (2018), the presence of arterial hypertension increases the prevalence of high cardiovascular risk (≥10%). This necessitates the inclusion of pharmacological treatment aimed at optimizing blood pressure as part of complex pharmacological therapy.

3. In patients with type 2 diabetes, if systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥ 80 mmHg are present, the initiation of pharmacological treatment is considered safe according to literature. However, if the cardiovascular risk is <10%, the decision to start pharmacological treatment should be based on the overall assessment of the patient.

4. In type 2 diabetes patients without associated arterial hypertension, an association with high cardiovascular risk (≥10%) has been noted. In this case, complex treatment is required to reduce cardiovascular risk.

5. In prediabetes, according to the diagnostic criteria of ACC/AHA (2017) and ESC/ESH (2018), if arterial hypertension is present, it is essential to determine the cardiovascular risk level. If the cardiovascular risk is ≥10%, treatment should be initiated to optimize blood pressure. If the cardiovascular risk is <10%, the decision regarding pharmacological treatment for blood pressure should be individualized.

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ABBREVIATIONS AND CONDITIONAL SIGNS

ESC/ESH (2018)	– Guidelines for the management of arterial hypertension developed by the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH) in 2018.
ACC/AHA (2017)	– Guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults, developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) in 2017.
ASCVD	– Atherosclerotic Cardiovascular Diseases
CI	– Confidence interval
CG	– Control Group
QRISK	– QRESEARCH Cardiovascular Risk Scale
PROCAM	– Prospective Cardiovascular Risk Scale
PCE	– Pooled Cohort Equations Risk Scale
VG	– Virtual Group

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