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ABSTRACT

of the dissertation submitted for the degree of Doctor of Philosophy

OCCURRENCE AND DEVELOPMENT OF CHRONIC KIDNEY DISEASE DURING TYPE 2 DIABETES: RISK FACTORS AND PROTECTIVE FACTORS

Specialization: 3216.01 – Endocrinology

Field of science: Medicine

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INTRODUCTION

Relevance of the topic and degree of development. According to the data of the World Health Organization, the number of patients with diabetes mellitus in the world in 1980, there were 108 million people worldwide, which increased to 422 million in 2014, i.e. the prevalence of diabetes mellitus among the elderly population increased from 4.7% to 8.5%[1]. In 2021, the number of diabetes mellitus patients was already 537 million. people. However, it is predicted that by 2045 the number of patients with diabetes mellitus will increase to 783 million. people. According to the 10th edition of the IDF Diabetes Atlas, in 2021 there were 397.1 thousand diabetic patients aged 20 to 79 in Azerbaijan, the prevalence of the disease was 5.6%[2]. Thus, 145.2 thousand individuals were unaware of their condition. This indicator corresponds to the data that every second person in the world is unaware of their diabetes mellitus[2].The increase in the number of patients is due to the increase in risk factors for diabetes, the most important of which are overweight and obesity[3].

Diabetes mellitus was the cause of 6.7 million deaths worldwide in 2021. This is more than the number of deaths from malaria, tuberculosis and the Human Immunodeficiency Virus combined[2]. Also, in countries with low per capita income, people are more likely to get diabetes and die from this disease more often[1].

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[1]World Health Organization / Global Report on Diabetes. 2016, -88 p.

[2] IDF Diabetes Atlas. Tenth Edition // International Diabetes Federation. –Brussels. -2021, -10, -141 p.

[3] Şəkərli diabetin diaqnostikası, profilaktikası və tibbi yardım üzrə standartları // Azərbaycan Respublikası Endokrinologiya, Diabetologiya və Terapevnik Təlimat assosiasiyası. –Bakı: "Azərdiab". – 2017. -134 s

According to the International Diabetes Federation, the number of deaths related to diabetes in our country that year was 7,577 people[2].

The majority of patients with diabetes mellitus are patients with type 2 diabetes mellitus[4;5].

The medical and social significance of diabetes mellitus is mainly due to its complications (macroangiopathies, microangiopathies, neuropathies, etc.)[6]. Their development is largely due to delayed diagnosis and inadequate control of metabolic processes[7].

All this significantly increases the costs of healthcare organizations and patients themselves[2]. Diabetic nephropathy is one of the main complications of diabetes mellitus.

In 2002, experts from the KDOQI (Kidney Diseases Outcomes Quality Initiative) group of the US National Kidney Foundation briefly and honestly expressed the concept of "chronic kidney disease" (CKD) in order to create a methodological basis for an effective system of assistance to patients with kidney diseases and terminal renal failure. This concept replaced the concept of "chronic renal failure", which did not have precise and universal criteria,

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emphasized only the late stages of kidney diseases, making it unsuitable for primary and secondary prevention programs[8].

Chronic kidney disease (CKD) poses a serious problem for the population and healthcare organizations of our country[9;10].

In diabetes mellitus, CKD can be both a manifestation of true diabetic nephropathy, and a consequence of arterial hypertension, bladder neuropathy, urinary tract infection, or macroangiopathy[2].

According to data, CKD occurs in one in five people with diabetes in the UK.[11] In the US, 40% of patients with diabetes develop CKD, and 19% of patients have symptoms of stage 3 or higher of the disease.[12] A study conducted in 54 countries shows that in 80% of cases, the end-stage of chronic kidney disease occurs as a result of diabetes, arterial hypertension, or their combination. Chronic kidney disease on end-stage renal disease related to diabetes alone is 12-55%. Moreover, the incidence of end-stage chronic kidney disease in patients with diabetes mellitus is 10 times higher than in those without diabetes mellitus.[13] Diabetes mellitus, arterial hypertension and renal failure are closely interconnected.

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[13] United States Renal Data System. International Comparisons. In United States Renal Data System. 2014 USRDS annual data report: Epidemiology of kidney

On the one hand, type 2 diabetes mellitus is the leading cause of renal failure and can be aggravated by hypertension, on the other hand, arterial hypertension often precedes chronic kidney disease and leads to the development of renal pathologies.

Hyperglycemia causes hyperfiltration, which is a predictor of the development of renal diseases. However, subsequent morphological changes in the structure of the kidneys lead to a decrease in their filtration capacity.

Financial costs in the case of clinically expressed chronic kidney disease are 50% higher than in cases without it, and treatment with hemodialysis leads to a 2.8-fold increase in financial costs[14].

Currently, effective prevention of chronic kidney disease and remission in its early stages are possible[15]. However, in order to achieve this, it is necessary to clearly clarify which of the risk factors for the development of chronic kidney disease and the factors protecting against the development of chronic kidney disease are more important. Since it has been proven that the development of complications of diabetes mellitus has a genetic basis, the significance of various factors may vary in different populations.

Object and subject of the study: the study group included 117 patients aged 21-81 years (mean age 56.0±12.25) with type 2 diabetes mellitus duration of 6.9±6.45 years (46.2% men and 53.8% women). The significance of the following factors was analyzed:

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gender, age, duration of disease with type 2 diabetes mellitus, age at diagnosis of diabetes mellitus.

The purpose of the study: to study the frequency of occurrence of various stages of chronic kidney disease in patients with type 2 diabetes mellitus and to analyze the factors that cause and prevent the occurrence and development of this disease.

Objectives of the study:

1. To determine the optimal method for calculating glomerular filtration rate in patients with type 2 diabetes;
2. To determine the frequency of chronic kidney disease and its various stages in patients with type 2 diabetes in routine outpatient practice;
3. To identify factors that cause and prevent the occurrence of chronic kidney disease in patients with type 2 diabetes;
4. To identify factors that cause and prevent the development of chronic kidney disease in patients with type 2 diabetes;

Research methods:

Registering patients and obtaining passport data: gender, age, smoking, physical activity, use of alcoholic beverages.

The duration of type 2 diabetes mellitus and the treatment received due to diabetes mellitus (with a record of the groups of hypoglycemic drugs taken), the presence of diabetic ketoacidosis and/or hyperosmolar state, the presence of hypoglycemia in the anamnesis, the presence of arterial hypertension in the past and its treatment (with a record of the groups of antihypertensive drugs taken), the received antidyslipidemic treatment, the received antithrombotic treatments were recorded.

The main provisions presented for the defense:

1. Comparative analysis of glomerular filtration rate calculated by applying the Cockroft D.W., Gault M.H. and CKD-EPI formulas in patients with type 2 diabetes mellitus and chronic kidney disease.

2. The onset of diabetes mellitus at the age of 45 and younger and glycated hemoglobin of 8.0% and higher in patients with type 2 diabetes mellitus can be considered as risk factors for the development of chronic kidney disease.

3. Type 2 diabetes mellitus onset after the age of 55, maintaining blood pressure within normal limits, taking angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in the treatment of arterial hypertension, and having a glycated hemoglobin level below 7.0% can be considered protective factors in relation to the occurrence of chronic kidney disease.

4. Risk factors for the development of chronic kidney disease in patients with type 2 diabetes mellitus can be considered: age of the patient 65 and older; diagnosis of type 2 diabetes mellitus at the age of 55 and later; duration of type 2 diabetes mellitus for 15 years and more; obesity; systolic blood pressure of 140 mm.c.s. and higher; glycated hemoglobin level of 8.0% and higher.

Scientific novelty of the study:

– The optimal method for calculating glomerular filtration rate in patients with type 2 diabetes mellitus was determined;
– The occurrence and prevention of chronic kidney disease in patients with type 2 diabetes mellitus Statistically significant risk factors for the development of chronic kidney disease and protection from its development were identified;
– Statistically significant risk factors for the development of chronic kidney disease in patients with type 2 diabetes mellitus and protection from its development were identified.

Theoretical and practical significance of the study:

– Calculation of glomerular filtration rate in patients with type 2 diabetes mellitus according to EPI-CKD increases the accuracy of the diagnosis of chronic kidney disease and its stages, and the effectiveness of using Internet resources in calculating this indicator was shown;

– In routine outpatient settings, a high incidence of chronic kidney disease was found in patients with type 2 diabetes mellitus, and the incidence of various stages of chronic kidney disease in patients with type 2 diabetes mellitus was shown. This should direct the attention of practicing physicians to the issues of primary and secondary prevention of chronic kidney disease in patients from this category;
– Information was obtained that allows optimizing the primary prevention of chronic kidney disease in patients with type 2 diabetes mellitus;
– Information was obtained that allows optimizing the secondary prevention of chronic kidney disease in patients with type 2 diabetes mellitus.

Approbation of the work. Separate fragments of the dissertation were discussed at the following scientific and practical conferences: II Azerbaijan Diabetes Congress (December 14, 2018, Baku, Azerbaijan). Modern Medicine: New Approaches and Current Research (2022, Moscow, Russian Federation);

The initial discussion of the dissertation was held at the II Interdepartmental Meeting of Internal Medicine of the AMU (December 25, 2023, protocol No. 08).

The dissertation was approved and discussed at the scientific seminar of the FD 2.11 Dissertation Council operating under the Azerbaijan State Institute of Advanced Training of Doctors named after A. Aliyev (24.06.2024, protocol No. 4).

Publications. 12 works were published based on the dissertation materials. Of them, 8 articles (2 foreign) and 4 theses (1 foreign) in journals and publications designated by the AAK.

The organization where the dissertation was carried out. The results obtained from the research were practically applied at the M.A. Efendiyev Khatai Medical Center and "Istanbul Clinic" LLC.

Application of the research results. The results of the research were applied in the practical activities of the Azerbaijan

Medical University, Department of Internal Medicine II and Azer Turk Med Clinic.

Structure and volume of the dissertation. The dissertation consists of 152 pages typed on a computer. It is structured into the following sections: "Introduction" (10404 characters), "Literature Review" (55245 characters), "Materials and Methods" (18928 characters), "Results and Discussion" (66196 characters), "Conclusion" (16779 characters), "Findings" (2349 characters), "Practical Recommendations" (1249 characters), and "References."

The work is illustrated with 29 figures, 26 tables, and 4 formulas. The reference list includes 291 sources: 12 in Azerbaijani, 34 in Russian, and 245 in other languages. The total number of characters is 171150.

MATERIALS AND METHODS OF THE STUDY

All patients with diabetes mellitus who applied to the "AzerTurkMed Clinic" from September 01, 2016 to August 31, 2017 were involved in the study. The patient's compliance with the following requirements is the criterion for inclusion in the study:

- Having type 2 diabetes mellitus;
- Having passport data, data on anamnesis vitae and anamnesis morbi;
- Having anthropometric indicators (height, body mass, body mass index);
- Having determined blood pressure data;
- Having biochemical examination data including glycated hemoglobin, creatinine, general urine analysis, and urine microalbuminuria analysis.

The absence of any of the specified criteria led to the exclusion of the patient from the study.

117 patients with type 2 diabetes mellitus who met the inclusion criteria for the study were included in the final study group,

of which 46.2% were men and 53.8% were women. The year of birth of the patients was between 1936 and 1996. The age of the patients included in the study group ranged from 21 to 81 years, with a mean of 56.0±12.25 years (95% CI 53.780-58.220). Of these, the age of women (n=63) ranged from 31 to 81, with a mean age of 57.3±13.00 years (95% CI 54.090-60.510), while the age of men (n=57) ranged from 32 to 70, with a mean age of 54.5±11.25 years (95% CI 51.499-57.501), which was less than that of women. The pa of patients participating in the study was as follows: The following age groups were presented:

– up to 45 years;
– from 45 to 65 years;
– 65 years and older.

The distribution of women (n=63) by age group is characterized by indicators close to the general group:

– up to 45 years – 12 patients (19.0%, 95% CI 9.35 – 28.74);
– from 45 to 65 years – 32 patients (50.8%, 95% CI 38.45 – 63.14);
– 65 years and older – 19 patients (30.2%, 95% CI 18.83 – 41.49).

The distribution of men (n=54) by age group was as follows:

– up to 45 years – 11 patients (20.4%, 95% CI 9.63 – 31.11);
– 45 to 65 – 29 patients (50.8%, 95% CI 40.40 – 67.00);
– 65 and older – 14 patients (30.2%, 95% CI 14.24 – 37.61).

There was no significant difference in the distribution of women and men by age group. The $\chi 2$ criterion was 0.2578 ($p>0.05$) in the 6-digit table.

In the general study group (n=117), the mean age of patients under 45 (n=23) was 37.1±5.46 years (minimum age 21, maximum age 44). In the 45 to 65 age group (n=61), the mean age of patients was 55.6±5.13 years (minimum age 45, maximum age 64). The mean age of patients in the 65 and older age group (n=33) was 69.8±4.55 years (minimum age 65, maximum age 81).

Of the women in the study group (n=63), the mean age of patients under 45 years of age (n=12) was 37.2±6.74 years (minimum age 21, maximum age 44). The mean age of women in the 45 to 65 age group (n=32) was 56.3±4.77 years (minimum age 45, maximum age 64). The mean age of women in the 65 and older age group (n=19) was 71.6±5.09 years (minimum age 65, maximum age 81).

The mean age of patients (n=11) under 45 years of age (n=54) included in the study group was 37.0±3.95 years (minimum age 32, maximum age 44). The mean age of male patients in the 45 to 65 age group (n=29) was 55.0±5.49 years (minimum age 45, maximum age 63). The mean age of female patients in the 65 and older age group (n=14) was 67.3±1.82 years (minimum age 65, maximum age 70).

In the final study group (n=117), the duration of diabetes mellitus type 2 was 6.9±6.45 years (95% CI 5.731 – 8.069).

In women (n=63), the duration of type 2 diabetes was 7.3±6.24 years (95% CI 5.759 – 8.841). In men (n=54), the duration of type 2 diabetes was 6.9±6.45 years (95% CI 5.307 – 8.493). The difference between the duration of type 2 diabetes in women and men was statistically significant ($p<0.05$).

In the last group of the study (n=117), the duration of type 2 diabetes was up to 5 years in 53 patients (45.3%, 95% CI 36.28 – 54.32). In 22 patients (18.8%, 95% CI 11.72 – 25.88), the duration of diabetes was from 5 to 9 years. 25 patients (21.4%, 95% CI 13.94 – 28.79) had been suffering from diabetes for 10 – 14 years. 17 patients (14.5, 95% CI 8.14 – 20.92) had been suffering from diabetes for 15 years or more.

Among women (n=63), the duration of suffering from diabetes type 2 was up to 5 years in 26 patients (41.3%, 95% CI 29.11 – 52.43). In 14 patients (22.2%, 95% CI 11.96 – 32.49) the duration of suffering from diabetes was from 5 to 9 years. In 13 patients (20.6%, 95% CI 10.64 – 30.63), the duration of diabetes was between 10 and 14 years. In 10 patients (15.9, 95% CI 6.85 – 24.90) diabetes was

present for 15 years or more. In men (n=54), the duration of diabetes mellitus type 2 was up to 5 years in 27 patients (50.0%, 95% CI 36.66 – 63.34). In 8 patients (14.8%, 95% CI 5.34 – 24.29), the duration of diabetes was 5 to 9 years. In 12 patients (22.2%, 95% CI 11.13 – 33.31), the duration of diabetes was 10 to 14 years. 7 patients (13.0, 95% CI 4.00 – 21.92) suffered from diabetes mellitus for 15 years or more.

The distribution frequencies of diabetes mellitus duration between women and men did not differ statistically significantly. When determining the χ^2 indicator for an 8-digit table, χ^2=1.5415 ($p>0.05$).

The following data were collected from the patients participating in the study:

– Obtaining passport data by registering patients:

• Sex

• Age

– Anamnesis vitae with the following data

• Smoking

• Physical activity

• Alcohol consumption

– Obtaining the following anamnestic data:

• Duration of type 2 diabetes mellitus and treatment received due to diabetes mellitus – with a note on the groups of hypoglycemic drugs taken;

• The presence of diabetic ketoacidosis and/or hyperosmolar state;

• History of hypoglycemia;

• History of arterial hypertension and its treatment – with a note on the groups of antihypertensive drugs taken;

• Antidyslipidemic treatment taken;

• Accepted antithrombotic treatment.

According to the International Classification adopted by WHO for the detection of overweight in patients, the body mass index of patients was assessed according to the following criteria:

- Underweight: body mass index < 18.50 kg/m^2;
- Normal body weight: body mass index in the range of 18.50 – 24.99 kg/m^2;
- Overweight (pre-obesity): body mass index in the range of 25.00 – 29.99 kg/m^2;
- Grade I obesity: body mass index in the range of 30.00 – 34.99 kg/m^2;
- Grade II obesity: body mass index in the range of 35.00 – 39.99 kg/m^2;
- Grade III obesity: body mass index ≥ 40.00 kg/m^2

Blood pressure was determined according to generally accepted standards.

Since the modern classification of chronic kidney disease is based not on creatinine, but on the glomerular filtration rate, we also performed its determination in our study. The calculation of the glomerular filtration rate was carried out using the Cocroft D., Gault M. formula. Since this widely used formula gave elevated results in a number of cases, the glomerular filtration rate was also calculated using the CKD-EPI formula. The calculations were performed online in a universal calculator designed to calculate creatinine and glomerular filtration rate.

Glomerular filtration rate values of 60 ml/min/1.73m^2 and higher were considered normal. The degree of chronic kidney disease was determined in accordance with the recommendations given in the table.

During the study, the average, minimum and maximum indicators of the analyzed sample were determined. The standard deviation of the sample and the error of the mean value were calculated. Statistical processing was performed on a computer using the Microsoft Excel program.

In the text of the dissertation, the mean values are presented together with the standard deviation (M±SD). The confidence interval (CI) of the mean values was determined for the 95% level of probability using the online "Confidence Limits for Mean Calculator". In addition to the above indicators, the error of the mean value and the percentage were calculated. The statistical significance of the difference between the proportions was determined using the χ^2 criterion and the "Fisher's exact test". The statistical significance of the difference between the proportions was determined online using the "Fisher's exact method". The χ^2 criterion was also applied using the "MEDCALC" calculator to determine the statistical accuracy of the difference between the proportions. Also, the confidence interval of the proportion of the symptom in the total sample was determined.

Table. Stages of chronic kidney disease

Degree	Description	GFR, ml/dəq/1,72m^2
1	Normal GFR, signs of nephropathy	> 90
2	Slight decrease in GFR, signs of nephropathy	60 – 89
3A	Moderate decrease in GFR	45 – 59
3B	Marked decrease in GFR	30 – 44
4	Severe decrease in GFR	15 – 29
5	Terminal chronic renal failure	< 15

Since the modern classification of chronic kidney disease is based on data on glomerular filtration rate, there is always a need to calculate this indicator in conservative practice. Previously, the Cockroft D.W., Gault M.H. formula was widely used for this purpose. However, recently, since data on obtaining relatively high

results when applying the Cockroft D.W., Gault M.H. formula have been shown, it is more appropriate to apply the CKD-EPI formula.

In this part of our study, our goal is to compare the results of CKD-EPI and Cockroft D.W., Gault M.H. in patients with type 2 diabetes mellitus with chronic kidney disease. The glomerular filtration rate is assessed by applying the formulas. When the maximum indicator of the GFR calculated by the Cockroft D.W., Gault M.H. formula was 183 ml/min/1.73m^2, the value of this indicator calculated by the CKD-EPI formula was 122 ml/min/1.73m^2. When the minimum indicator of the glomerular filtration rate calculated by the Cockroft D.W., Gault M.H. formula was 22 ml/min/1.73m^2, the value of this indicator calculated by the CKD-EPI formula was 29 ml/min/1.73m^2. When the glomerular filtration rate was determined by the Cockroft D.W., Gault M.H. formula, the average result of this indicator was 94.2±27.23 ml/min/1.73m^2. When this indicator was also determined by the CKD-EPI formula, the average value of this indicator was 83.8±19.12 ml/min/1.73m^2. Also, the difference between the indicators was statistically significant (p<0.001) (figure).

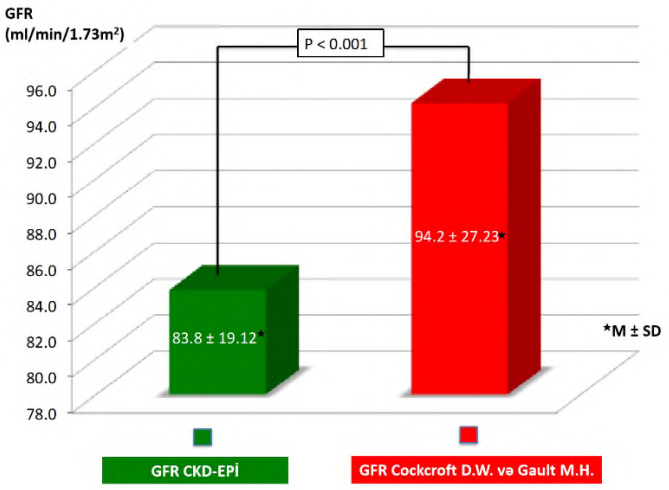

Figure. Average indicators calculated by the GFR CKD-EPI and Cockroft D.W., Gault M.H. formulas in the study group.

When the glomerular filtration rate indicator was calculated by the Cockroft D.W., Gault M.H. formula, only in 6 cases was the indicator below 60 ml/min/1.73m^2 and in 94 cases it was above 60 ml/min/1.73m^2. The indicator of glomerular filtration rate CKD-EPI formula When determined by, this indicator was found to be below 60 ml/min/1.73m^2 in 11 cases and above 60 ml/min/1.73m^2 in 89 cases. When calculating the glomerular filtration rate using the Cockroft D.W., Gault M.H. and CKD-EPI formulas, the indicator was equal to or higher than 60 ml/min/1.73m^2 in 88 cases.

When calculating the glomerular filtration rate using both formulas, the indicator was below 60 ml/min/1.73m^2 in 5 patients. Thus, in 93 out of 100 patients, the calculation of the glomerular filtration rate did not depend on the formula. However, the glomerular filtration rate calculated by Cockroft D.W., Gault M.H. In 6 patients, the indicator was equal to or higher than 60 ml/min/1.73 m^2 when calculated by the formula, but this indicator was lower than 60 ml/min/1.73 m^2 when calculated by the CKD-EPI formula. In another 1 case, the indicator of the GFR was lower than 60 ml/min/1.73 m^2 when calculated by the Cockroft D.W., Gault M.H. formula, but this indicator was equal to or higher than 60 ml/min/1.73 m^2 when calculated by the CKD-EPI formula. The obtained result revealed a statistically significant ($p<0.05$) difference between the calculations made by both formulas.

Thus, the conducted study allows us to say that in patients with CKD diabetes mellitus type 2, the Cockroft D.W., Gault M.H. The application of the formula gives “overestimated” results compared to the values calculated by the CKD-EPI formula. Also, such “overestimated” results affect the timely detection of a decrease in GFR and the quality of diagnosis. The results obtained are in good agreement with the diagnostic value of the glomerular filtration rate

previously calculated by Cockroft D.W., Gault M.H. and CKD-EPI formulas in non-diabetic populations.

A comparative analysis was performed between the results of the following groups:

– A group of patients with type 2 diabetes mellitus without kidney damage (n=17) – will serve as a control group in the study and will be indicated as DM2-N in the notes;
– A group of patients with type 2 diabetes mellitus with chronic kidney disease (n=100) – will be indicated as DM2-CKD in the following notes.

In routine outpatient practice, the incidence of chronic kidney disease in patients with type 2 diabetes was 85.5%. Among patients with type 2 diabetes included in the study, the absence of chronic kidney disease was found in 14.5% of cases. The difference between the indicators was 71% (95% CI 60.384 – 78.425) and was statistically significant (χ^2=117.455, p<0.0001).

According to our study, the incidence of chronic kidney disease is 85.5%, and this indicator is consistent with the results of studies in other countries.

The study showed that 35% of chronic kidney patients had stage 1 of the disease, 54% had stage 2, 8% had stage 3A, 2.0% had stage 3B, and 1% had stage 4. Extrapolation of these results to the general population of patients with type 2 diabetes in Azerbaijan allows us to estimate the number of patients with more severe chronic kidney disease (stages 4-5 of chronic kidney disease) in the country from 1294 to 1681.

In the DM2-CKD group, MAU was detected in 79 patients (79%) and proteinuria in 21 patients (21%). The difference between the indicators was 58% (95% CI 48.344 – 67.049) and was statistically significant (χ^2=78.38, p<0.0001).

No cases of MAU were observed in the DM2-N group (n=17). The incidence of MAU in the DM2-CKD and DM2-N groups was 79% and 0%, respectively (p<0.0001).

Proteinuria was also not observed in the DM2-N group. The incidence of proteinuria in the DM2-CKD and DM2-N groups was 21% and 0% ($p<0.05$).

While the mean glomerular filtration rate in the DM2-N group was 97.0±13.63, in the DM2-CKD group this figure was 83.8±19.12 ($p<0.001$).

Thus, the results obtained in our study indicate a high incidence of chronic kidney disease. This figure also allows us to predict a high incidence of chronic kidney disease in patients with type 2 diabetes and requires sufficient attention to the realistic analysis of the situation. In order to identify risk factors for the occurrence of diabetic nephropathy (chronic kidney disease) in patients with type 2 diabetes, we conducted a comparative analysis between the indicators of the stage 1 subgroup of chronic kidney disease (n=35) of the DM2-N (n=17) group and the DM2-CKD (n=100) group. In our future notes, we will indicate the stage 1 subgroup of chronic kidney disease of the DM2-CKD group as DM2-CKD1 for the sake of simplicity.

The selection of these 2 populations is conditioned by the fact that diabetic nephropathy (chronic kidney disease) is not found in the DM2-N group, while in the DM2-CKD1 group, chronic kidney disease only has its initial manifestations. What is found? In such a case, the difference between the group indicators may indicate the occurrence and/or protective factors of chronic kidney disease.

The index of albuminuria in the DM2-CKD1 group was 252.5± 582.34 mg/l, and in the DM2-N group it was statistically significantly higher ($p<0.001$). However, albuminuria in the DM2-N group was in the range of 0 – 28 mg/l, and in the DM2-CKD1 group it was in the range of 30 – 300 mg/l.

Creatinine levels in the DM2-N group varied within the range of 0.60 – 1.00 mg/dl, with a mean of 0.809±0.1395 mg/dl, while in the DM2-CKD1 group the creatinine levels varied within the range of 0.45 – 1.00 mg/dl, with a mean of 0.777±0.1253 mg/dl ($p>0.05$).

In the DM2-N group, the mean result of the glomerular filtration rate (CKD-EPI) was 97.0±13.63 ml/min/1.73 m2, while in the DM2-CKD1 group this indicator was 103.8±8.48 ml/min/1.73 m^2 ($p<0.001$).

The obtained results reflect reality quite accurately. Because the DM2-N group consists of patients without diabetic nephropathy, and the DM2-CKD1 group includes patients with stage 1 chronic kidney disease, characterized by kidney damage (albuminuria) and increased GFR.

In total, we analyzed 54 factors (taking into account the degrees). The analysis did not allow us to detect the influence of factors such as the patient's gender, age, and duration of illness with type 2 diabetes.

The age of diagnosis of type 2 diabetes in the DM2-N group was 48.0±11.30 years, and this indicator was statistically significantly higher ($p<0.001$) than in the DM2-CKD1 group, which was 41.7±7.93 years.

While the incidence of type 2 diabetes under 45 years of age was 41.1% in the DM2-N group, this indicator was 71.4% in the DM2-CKD1 group. The difference in the indicators by groups was 30.2% ($\chi^2=4.324$, $p=0.0376$). Thus, the difference between the groups was not random and was statistically significant ($p<0.05$).

Cases of type 2 diabetes mellitus at the age of 55 and older were found in 29.4% of patients in the DM2-N group and 5.7% in the DM2-CKD1 group. The difference between the group indicators was 23.7%; $\chi^2=5.416$; $p=0.0200$. Thus, the difference in the incidence of type 2 diabetes mellitus at the age of 55 and older between the DM2-N and DM2-CKD1 groups was statistically significant ($p<0.05$).

The results obtained allow us to consider the occurrence of type 2 diabetes mellitus at the age of 45 years and younger as a risk factor for the development of chronic kidney disease, and the occurrence of type 2 diabetes mellitus at the age of 55 years and

older as a protective factor, i.e., a factor of protection against the development of chronic kidney disease.

At the same time, the share of patients with normal arterial pressure (regardless of whether they had arterial hypertension) was 76.5% in the DM2-N group, and 45.7% in the DM2-CKD1 group. The difference between the indicators by groups was 30.8% (χ^2=4.316, p=0.0378) (p<0.05).

Among the DM2-N group patients, 66.7% of patients (n=6) received ACEI or ARBs treatment due to arterial hypertension, and 20.0% of patients in the DM2-CKD1 group (n=15). The difference between the groups was 46.7% (χ^2=4.005, p=0.0454) and the difference was statistically significant (p<0.05).

The mean glycated hemoglobin level was statistically significantly lower in the DM2-N group at 6.99±1.015% compared to 8.67±1.365 in the DM2-CKD1 group (p<0.001).

The glycated hemoglobin range "<7.0%" was more frequent in the DM2-N group at 52.9% compared to 8.6% in the DM2-CKD1 group (p<0.001), indicating better control of diabetes. Similarly, the glycated hemoglobin range of "≥ 8.0%", indicating poor glycemic control, was found in the 11.8% DM2-N group compared to the 57.1% DM2-CKD1 group (p<0.01).

Thus, the results obtained strongly support the role of elevated glycated hemoglobin levels (8.0% and above) in patients with type 2 diabetes as a risk factor for the development of chronic kidney disease and good diabetes control as a protective factor against chronic kidney disease with a glycated hemoglobin level below 7.0%.

In order to identify risk factors for the development of chronic kidney disease in patients with type 2 diabetes, we conducted a comparative analysis of the DM2-CKD1 group indicators and the subgroup indicators of patients with type 2 diabetes with more pronounced stages of chronic kidney disease 2, 3 and 4. As previously mentioned, there were no patients with stage 5 chronic

kidney disease in the study. In our future notes, the above subgroup will be referred to as the "DM2-CKD234 group". The selection of DM2-CKD1 and DM2-CKD234 groups is conditioned by the fact that the DM2- CKD1 group included only primary diabetic nephropathy, while the DM2- CKD234 group was characterized by more pronounced manifestations of chronic kidney disease.

DM2-CKD1 The albuminuria index in the DM2-CKD34 group was 252.5±582.34 mg/l, and statistically significantly lower ($p<0.001$) than the DM2-CKD1 group, which was 342.4±706.53 mg/l. However, the albuminuria level varied within the range of 30–300 mg/l in both the DM2-CKD1 and DM2-CKD234 groups.

Creatinine level varied within the range of 0.45–1.00 mg/dl in the DM2-CKD1 group, with an average value of 0.777±0.1253 mg/dl, while in the DM2-CKD234 group it ranged within the range of 0.70–2.80 mg/dl, with an average value of 0.975±0.3137 mg/dl. The difference between the group indices was statistically significant ($p<0.05$).

While the mean value of the CKD-EPI index in the DM2-CKD1 group was 103.8±8.48 ml/min/1.73 m^2, this index was significantly lower in the DM2-CKD234 group - 73.0±13.80 ml/min/1.73 m^2 ($p<0.001$).

The results obtained reflect that chronic kidney disease is more pronounced in the DM2-CKD234 group than in the DM2-CKD1 group.

The age of the patients in the DM2-CKD1 group was in the range of 30–70 years, and the mean age was 47.3±10.48 years. In the DM2-CKD234 group, the age of the patients varied between 42–81 years and was statistically significantly higher than the mean index in the DM2-CKD1 group (61.9±9.28; $p<0.001$).

The incidence of patients under 65 years of age was 97.1% in the DM2-CKD1 group and 53.8% in the DM2-CKD234 group. The difference between the groups was 43.3% ($p<0.0001$). The "age 65

and older" range was found in 2.9% of cases in the DM2-CKD1 group and 46.2% in the DM2-CKD234 group ($p<0.0001$).

According to the results, the average duration of type 2 diabetes mellitus in the DM2-CKD1 group was 5.7±5.47 years. In the DM2-CKD234 group, it was 8.4±6.89 years ($p<0.001$).

In the DM2-CKD1 group, the duration of diabetes mellitus type 2 disease was recorded in 48.6% of patients, and in the DM2-CKD234 group, it was recorded in 35.4% of patients ($p>0.05$).

The duration of type 2 diabetes mellitus was recorded in 51.4% of patients in the DM2-CKD1 group, and in 64.6% of patients in the
DM2-CKD234 group ($p>0.05$).

The duration of type 2 diabetes mellitus was recorded in 10 years or more in 31.4% of patients in the DM2-CKD1 group, and in 44.6% of patients in the DM2-CKD234 group ($p>0.05$).

In the DM2-CKD1 group, the duration of type 2 diabetes mellitus for "15 years or more" was recorded in 5.7% of patients, and in the DM2-CKD234 group, it was recorded in 21.5% of patients ($p<0.05$).

Thus, the duration of type 2 diabetes mellitus for "15 years or more" can be considered as a risk factor for the development of CKD.

The mean age of patients in the DM2-CKD1 group at the time of diagnosis of diabetes mellitus was 41.7±7.93 years. In the DM2-CKD234 group, the mean age of patients at the time of diagnosis of type 2 diabetes mellitus was 53.4±10.44 years ($p<0.001$).

In the DM2-CKD1 group, 71.4% of patients were diagnosed with diabetes mellitus at the age of 45 and younger. In the DM2-CKD234 group, diabetes mellitus was diagnosed in only 20.1% of patients in the same age range ($p<0.0001$).

Diabetes mellitus was diagnosed in the 45-55 age range in the DM2-CKD1 group in 22.9% of patients and in the DM2-CKD234 group in 33.8% of patients ($p>0.05$).

In patients over the age of 55, diabetes mellitus was diagnosed in 5.7% of patients in the DM2-CKD1 group and in 46.2% of patients in the DM2-CKD234 group ($p<0.0001$).

Thus, the fact that the patient was younger than 45 years old at the time of diagnosis of type 2 diabetes mellitus can be considered as a protective factor against the development of chronic kidney disease in patients with type 2 diabetes mellitus. However, being over 55 years old at the time of diagnosis of type 2 diabetes can be considered a risk factor for the development of chronic kidney disease.

The mean height of patients in the DM2-CKD1 and DM2-CKD234 groups was 165.3±10.07 cm and 164.2±9.01 cm, respectively ($p>0.05$).

The mean body mass of patients in the DM2-CKD1 group was slightly lower than that in the DM2-CKD234 group, 86.2±16.86 kg and 87.6±17.62 kg, respectively ($p>0.05$).

The mean BMI of patients in the DM2-CKD1 group was 31.7±6.59 kg/m^2, which was slightly lower than the mean BMI of the DM2-CKD234 group ($p>0.05$).

In the DM2-CKD1 group, 8.6% of patients and in the DM2-CKD234 group, 4.6% of patients had normal body mass, i.e. BMI <25.0 kg/m^2 ($p>0.05$).

BMI changes within the range of 25.0–29.9 kg/m^2 were observed in 40.0% of cases in the DM2-CKD1 group and in 23.1% of cases in the DM2-CKD234 group. The difference between the proportions was 16.9% ($p>0.05$).

The incidence of BMI over 30.0 kg/m^2 (obesity) was recorded in 51.4% of patients in the DM2-CKD1 group and 72.3% of patients in the DM2-CKD234 group ($p<0.05$). The incidence of “no obesity” (BMI <29.9 kg/m^2) was recorded in 48.6% of patients in the DM2-CKD1 group and 27.7% of patients in the DM2-CKD234 grop ($p<0.05$).

Thus, there was a statistically significant difference between the frequencies of normal body mass and excess body mass indicators in the DM2-CKD1 and DM2-CKD234 groups. q was not detected. However, obesity was found to be statistically significantly more common in the DM2-CKD234 group ($p<0.05$), while its absence (normal body mass and excess body mass) was found in the DM2-CKD1 group. Thus, obesity can be considered a risk factor in the development of chronic kidney disease in type 2 diabetes, and its absence can be considered a protective factor.

The results are in good agreement with the literature data on the interaction between obesity and chronic kidney disease and with the indications that obesity may be a risk factor in the development of chronic kidney disease in the general population.

The mean systolic blood pressure in the DM2-CKD1 group was 133.4±16.89 mm Hg, which was statistically significantly lower ($p<0.01$) than in the DM2-CKD234 group, which was 135.9±14.79 mm. Hg. If we look at the average values of diastolic arterial pressure, we can see that here too the indicator in the DM2-CKD1 group was 84.6±12.21 mm. Hg. It was statistically significantly lower ($p<0.001$) than the indicator in the DM2-CKD234 group, which was 87.0±8.23 mm. Hg. Systolic arterial pressure of 140 mm. Hg and higher was observed in 34.3% of patients in the DM2-CKD1 group and in 60.0% of patients in the DM2-CKD234 group ($p<0.05$). Diastolic arterial pressure of 90 mm. Hg. and higher was recorded in 37.1% of patients in the DM2-CKD1 group and in 53.8% of patients in the DM2-CKD234 group ($p>0.05$). 42.9% of patients in the DM2-CKD1 group and 30.8% of patients in the DM2-CKD234 group were receiving treatment due to arterial hypertension ($p>0.05$). The share of patients with arterial hypertension was 5.7% in the DM2-CKD1 group and 73.8% in the DM2-CKD234 group ($p>0.05$). Regardless of the presence of arterial hypertension, the share of patients with normal arterial pressure was 45.7% in the DM2-CKD1 group and less - 26.2% in the DM2-CKD234 group ($p<0.05$).

The results obtained revealed the following:

- The role of increased systolic arterial pressure as a risk factor in the development of chronic kidney disease in patients with type 2 diabetes mellitus, which is the first manifestation of chronic kidney disease;
- The protective effect of "normal AP" factor in relation to the development of chronic kidney disease.

The results obtained on the basis of these data are in good agreement with the data on the relationship between arterial hypertension and the prognosis of chronic kidney disease.

The mean level of glycated hemoglobin in the DM2-CKD1 group was statistically significantly lower at 8.67±1.365 compared to 9.27±1.639 in the DM2-CKD234 group ($p<0.001$).

The range of glycated hemoglobin "<7.0%" was more common in the DM2-CKD1 group (8.6%) and 1.5% in the DM2-CKD234 group ($p>0.05$).

The glycated hemoglobin range "7.0% - 7.9%" was found in 34.3% of cases in the DM2-CKD1 group and in 20.0% of cases in the DM2-CKD234 group ($p>0.05$).

The generalized glycated hemoglobin range "< 8.0%" was recorded in 42.9% of cases in the DM2-CKD1 group and in 21.5% of cases in the DM2-CKD234 group. The difference between the indicators was – 21.4% ($p<0.05$).

The glycated hemoglobin range "≥ 8.0%" was found in 57.1% of cases in the DM2-CKD1 group and in 78.5% of cases in the DM2-CKD234 group ($p<0.05$).

The results strongly suggest that elevated glycated hemoglobin levels (8.0% and above) in patients with type 2 diabetes mellitus are a risk factor for the development of chronic kidney disease and that optimal diabetes control (glycated hemoglobin levels below 8.0%) is a protective factor against chronic kidney disease, and are in good agreement with current views on the etiopathogenesis of diabetes complications and recommendations for glycemic control.

It can be noted that the following can be considered as risk factors for the development of chronic kidney disease in patients with type 2 diabetes mellitus:

- age of the patient 65 years or older ($p<0.0001$);
- diagnosis of type 2 diabetes mellitus at age 55 years or older ($p<0.0001$);
- duration of diabetes mellitus 15 years or more ($p<0.05$);
- obesity ($p<0.05$);
- systolic blood pressure of 140 mm Hg and higher ($p<0.05$);
- glycated hemoglobin level of 8.0% and higher ($p<0.01$).

Protective factors for the development of chronic kidney disease can be considered:

- age of the patient with type 2 diabetes mellitus less than 65 years ($p<0.0001$);
- diagnosis of type 2 diabetes mellitus at the age of 45 and younger ($p<0.0001$);
- absence of obesity ($p<0.05$);
- onset of diabetes mellitus at the age of 55 and older ($p<0.05$);
- normal level of systolic blood pressure (<140 mm. Hg.) and normal level of diastolic blood pressure (<90 mm. Hg.) ($p<0.05$);

Glycated hemoglobin level below 8.0% ($p<0.05$).

RESULTS

1. In people with type 2 diabetes mellitus and chronic kidney disease, the application of the Cockroft D.W., Gault M.H. formula gives “elevated” results compared to the values calculated by the CKD-EPI formula, and also the results are “elevated” presence affects the timely detection of glomerular filtration rate decline and the quality of diagnostics [6,10].

2. The incidence of chronic kidney disease in the patients examined by us was 85%. However, 35% of people with chronic kidney disease had stage 1 of the disease, 54% had stage 2, 8% had stage

3A, 2.0% had stage 3B, and 1% had stage 4. Extrapolation of these results to the general population of patients with type 2 diabetes in Azerbaijan allows us to estimate the number of patients with type 2 diabetes with chronic kidney disease in the country from 129,402 to 168,064 people. Also, the number of patients with a more severe stage of the disease (stages 4-5 of chronic kidney disease) was from 1,294 to 1,681 people
[3].

3. In patients with type 2 diabetes, the onset of diabetes at the age of 45 and younger ($p<0.05$) and glycated hemoglobin of 8.0% and higher ($p<0.01$) can be considered as risk factors for the development of chronic kidney disease. The onset of type 2 diabetes after the age of 55 ($p<0.05$), maintaining blood pressure within normal limits ($p<0.05$), taking angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in the treatment of arterial hypertension ($p<0.05$), and glycated hemoglobin level below 7.0% ($p<0.0004$) can be considered as protective factors for the development of chronic kidney disease [7].

4. The following can be considered as risk factors for the development of chronic kidney disease in patients with type 2 diabetes: patient age 65 and older ($p<0.0001$); diagnosis of type 2 diabetes at age 55 and later ($p<0.0001$); duration of type 2 diabetes for 15 years and more ($p<0.05$); presence of obesity ($p<0.05$); systolic blood pressure 140 mm.Hg. and higher ($p<0.05$); glycated hemoglobin level 8.0% and higher ($p<0.05$). Protective factors against the development of chronic kidney disease can be considered: patient age less than 65 ($p<0.0001$); diagnosis of type 2 diabetes at age 45 and younger ($p<0.0001$); absence of obesity ($p<0.05$); arterial pressure at normal level (systolic arterial pressure <140 mm.Hg., diastolic arterial pressure <90 mm.Hg.) ($p<0.05$); glycated hemoglobin level below 8.0% ($p<0.05$) [8,9].

PRACTICAL RECOMMENDATIONS

1. In patients with type 2 diabetes mellitus with chronic kidney disease, it is more appropriate to use the CKD-EPI formula when calculating glomerular filtration rate, because it provides accuracy in determining the stage of chronic kidney disease;
2. Using websites on the Internet for quick calculation of glomerular filtration rate makes the doctor's work easier;
3. Since chronic kidney disease is more common in patients with type 2 diabetes mellitus, it is appropriate to perform early diagnostics by determining microalbuminuria. Thus, treatment measures taken at the stage of microalbuminuria may lead to the opposite development of the pathological process;
4. Maintaining normal blood pressure, prescribing angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in the treatment of arterial hypertension, maintaining glycated hemoglobin levels below 7%, and also prevention (or effective treatment of obesity) are important conditions for protecting patients with type 2 diabetes from the development of chronic kidney disease;
5. Early diagnosis of type 2 diabetes, lack of obesity, normal blood pressure levels (systolic <140 mm.Hg., diastolic <90 mm.Hg.), and strict control of glycemia prevent the development of chronic kidney disease in patients with type 2 diabetes.

LIST OF PUBLISHED SCIENTIFIC WORKS ON THE TOPIC OF THE DISSERTATION

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LIST OF CONVENTIONAL ABBREVIATIONS

ACE – angiotensin converting enzyme inhibitors
ARBs – angiotensin II receptor antagonists
BMI – body mass index

CI – confidence interval
CKD-EPI – method for calculating the glomerular filtration rate
CKD – chronic kidney disease
DM- diabetes mellitus
GFR – glomerular filtration rate
HDL – high-density lipoprotein
KDOQI – Kidney Disease Outcomes Quality Initiative
LDL – low-density lipoprotein
χ^2 – Chi-square test (or its equivalent) results of application)

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