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Analysis of Clinic Indicators and Ambulatory 24-Hour Blood Pressure Monitoring as a Subject of Special Attention to Assess the Effectiveness of Treatment of Arterial Hypertension in Patients with Type 2 Diabetes Mellitus

Mavlonov N. X.
Bukhara state medical institute

Abstract: Effective blood pressure (BP) control is critical to reducing the risk of cardiovascular complications in patients with arterial hypertension (AH) and type 2 diabetes mellitus (DM). As a rule, routine monitoring is limited to measuring blood pressure at a doctor's appointment (office measurement), which does not always reflect the true state of hemodynamics.

Purpose of the study– to analyze the indicators of office and ambulatory 24-hour blood pressure monitoring (ABPM) in hypertensive patients without diabetes and with type 2 diabetes.

Material and methods. The study included 83 outpatients with hypertension who received antihypertensive therapy, of which 36 (43.4%) had concomitant type 2 diabetes. All of them underwent a clinical examination with assessment of office blood pressure indicators, as well as laboratory examination (clinical and biochemical analysis of blood, urine) and instrumental examination (ABPM, echocardiography).

Results. According to office monitoring data, achievement of target blood pressure values was noted in 31.9% of patients without diabetes and 8.4% of people with type 2 diabetes. According to ABPM results, ineffective hypertension control was registered in 70.2 and 80.6% of patients, respectively. Patients with type 2 diabetes were more likely to have uncontrolled hypertension with a significant increase in systolic blood pressure (SBP) and pulse blood pressure (PBP) at night. The degree of nocturnal decrease in SBP significantly correlated with the duration of type 2 diabetes, and the average daily PBP correlated with the level of fasting blood glucose and glycated hemoglobin.

Conclusion. Despite comparable adherence to antihypertensive therapy in both groups, patients with type 2 diabetes were less likely to achieve target blood pressure values both during office measurements and ABPM. Almost every seventh person with type 2 diabetes had a disturbance in the daily blood pressure profile according to the Knight-Picker type, which requires special attention when managing this category of patients.

Keywords: arterial hypertension, type 2 diabetes mellitus, office blood pressure, 24-hour blood pressure monitoring.

Timely diagnosis and effective control of arterial hypertension (AH) are important components of reducing the risk of cardiovascular diseases (CVD) and death and are of paramount importance in individuals from high and very high cardiovascular risk (CVR) groups, which include patients with diabetes mellitus. diabetes (DM) type 2 [1]. It has been proven that in patients with type 2 diabetes, effective control of blood pressure (BP) helps reduce the likelihood of developing micro- and macrovascular complications, as well as death [1–3].

Underestimation of the severity and characteristics of the course of hypertension leads to inadequate control, which currently remains quite common [4]. As a rule, routine monitoring is limited to measuring blood pressure at a doctor's appointment (office measurement), which does not always reflect the true state of hemodynamics and, therefore, leads to an underestimation of CV risk. In accordance with the recommendations for the management of patients with hypertension of the

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European Society of Cardiology in 2018 [2] and the Russian Society of Cardiology in 2020 [3], to improve the situation, out-of-office blood pressure measurement is recommended: home self-monitoring and 24-hour monitoring (ABPM). Out-of-office BP measurement is important for identifying hidden hypertension treatment failure in patients receiving antihypertensive therapy.

Among the hypertension phenotypes, insufficient reduction in blood pressure at night and nocturnal hypertension, which make a significant contribution to the development of cardiovascular complications, deserve special attention. Residual nocturnal hypertension is a significant factor in CV risk even with normal clinical blood pressure measured at a doctor's appointment. It is no coincidence that the 2023 recommendations of the European Society of Hypertension emphasize the unique potential of ABPM [5]. According to the data obtained, ABPM helps to identify patients with unrecognized hypertension, underestimated or overestimated degree of its severity, and assess the effectiveness of therapy [3, 5–7]. However, to date, the usefulness and informativeness of most ABPM indicators, as well as their clinical interpretation in high and very high risk groups, are still widely debated.

In this regard, the purpose of our study was to analyze the indicators of office BP and ambulatory ABPM in hypertensive patients without diabetes and with concomitant type 2 diabetes.

Material and methods

The study included 83 patients with hypertension of the first – third degree, aged 40 to 60 years. The average age of patients was 54.0 [48.0; 58.0] years. Duration of hypertension – 5.0 [2.0; 10.0] years.

Among the study participants, there were 51.8% men and 48.2% women.

Criteria for inclusion in the study:

essential hypertension of the first – third degree;

sinus rhythm;

signed informed consent.

Non-inclusion criteria:

symptomatic hypertension, atrial fibrillation, clinically significant coronary heart disease, including myocardial infarction, chronic heart failure of the third and fourth functional class according to the New York Heart Association classification;

severe concomitant somatic diseases;

Type 1 diabetes;

Type 2 diabetes requiring insulin therapy.

The study was approved by the interuniversity ethics committee (protocol dated May 24, 2018 No. 05-18).

All participants included in the study underwent a general clinical examination, clinical and biochemical blood tests (glucose, glycated hemoglobin, total cholesterol (TC) and lipid profile, urea, creatinine with calculation of glomerular filtration rate (GFR) using the CKD-EPI formula), clinical urine analysis, electrocardiogram in 12 conventional leads, transthoracic echocardiography, ABPM using the BPLab Vasotens device according to the generally accepted method for at least 24 hours with a measurement interval of 15 minutes during the day, 30 minutes at night [2]. Based on the results of ABPM, the average daily indicators of daytime and nighttime systolic blood pressure (SBP) and diastolic blood pressure (DBP), variability of SBP and DBP, the degree of nocturnal decrease in blood pressure, the speed and magnitude of the morning rise in SBP and DBP, pulse blood pressure (PBP), maximum and minimum blood pressure were assessed per day.

Depending on the degree of reduction in nocturnal blood pressure, four groups of patients were identified [7]:

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with an optimal decrease in night blood pressure, or dipper, daily index (DI) – 10–20%;

insufficient degree of blood pressure reduction, or non-dipper, SI – 0–10%;

sustained increase in night blood pressure, or night peaker, SI less than 0%;

excessive degree of reduction in night blood pressure, or over-dipper, SI more than 20%.

Statistical processing of the obtained results was carried out using the Statistica 10 software package (StatSoft Inc., USA).

Results

Depending on the presence of type 2 diabetes, the subjects were divided into two groups. The first group included 47 (56.6%) patients with hypertension without diabetes, the second group included 36 (43.4%) patients with hypertension and concomitant type 2 diabetes. The duration of type 2 diabetes was 2.0 [1.0; 4.5] years.

There were no significant differences in age, gender and duration of hypertension in the analyzed groups (Table 1).

Body mass index (BMI) and waist circumference (WC) were significantly higher in patients with type 2 diabetes, while the average values of these parameters in both groups exceeded the optimal ones.

The study groups were also comparable in terms of family history of CVD.

Smoking was more often noted in the group of hypertension without diabetes.

A statistically significant excess of reference values for fasting plasma glucose was expected in the hypertensive group with type 2 diabetes. The average glycated hemoglobin levels in this group were 6.0 [5.8; 7.0].

Despite the absence of significant differences in the analyzed groups in terms of TC levels, its average value exceeded the normative values only in patients with type 2 diabetes.

Lipid profile analysis revealed significantly higher levels of triglycerides (TG). Moreover, in patients with type 2 diabetes it exceeded the normative values.

The values of creatinine, urea and GFR in the study groups did not differ significantly.

In patients with type 2 diabetes, office SBP and DBP values were higher. However, they only reached statistical significance for SBP. Increased values of office SBP and DBP were accompanied by significantly higher values of PBP.\

Heart rate (HR) was comparable in both groups.All patients with hypertension and type 2 diabetes received oral hypoglycemic therapy. 17 (47.2%) patients took metformin as monotherapy, 20 (55.6%) patients took metformin in combination with glibenclamide.

Ten (27.8%) patients with hypertension and type 2 diabetes and one (2.1%) patient with hypertension without diabetes received statin therapy ($p < 0.01$).

At the time of inclusion in the study, all patients had already been prescribed antihypertensive therapy. In both groups, angiotensin-converting enzyme inhibitors (ACEIs) predominated among antihypertensive drugs (Fig. 1). Paradoxically, calcium antagonists were the most rarely used.

There were no significant differences in the frequency of taking different classes of antihypertensive drugs and adherence to therapy in the study groups. 18 (38.3%) patients with hypertension without diabetes and 19 (52.8%) patients with hypertension and type 2 diabetes regularly took such therapy. The majority received combination therapy: in the group of hypertension without diabetes - 33 (70.2%), in the group of hypertension with type 2 diabetes - 30 (83.3%). Fixed combinations were used by 36.4 and 23.3% of patients, respectively.

According to office blood pressure measurements, hypertensive patients without diabetes were significantly more likely to achieve target values – 15 (31.9%) versus three (8.4%) ($p = 0.01$).

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ABPM results indicated that uncontrolled hypertension according to at least one of the recommended indicators [2] occurred in 33 (70.2%) patients without diabetes and 29 (80.6%) individuals with type 2 diabetes.

When comparing the results of office and outpatient daily blood pressure measurements, normal values when assessed using both methods (true normotension) were noted only in the group of hypertension without diabetes. Persistent hypertension (increased rates by two methods) – in 59.1% of patients with hypertension without diabetes and 79.4% of patients with hypertension and type 2 diabetes. This characterized blood pressure control in both groups as low.

Uncontrolled latent hypertension (normal office and elevated ambulatory blood pressure) was more often detected in hypertensive patients without diabetes – 15.9 versus 5.9%, respectively. An isolated increase in office blood pressure, or the white coat effect, was observed in 9.1% of patients with hypertension without diabetes and 14.7% of patients with hypertension and type 2 diabetes.

It should be noted that the presence of type 2 diabetes was associated with a significant increase in SBP values at night according to ABPM. At the same time, the average value of SBP during the daytime in the comparison groups did not differ significantly (Table 2). There was also no significant difference in DBP levels between the groups.

Analysis of the degree of blood pressure reduction at night showed disturbances of the circadian profile in both groups (Fig. 2). Optimal blood pressure reduction at night, as well as insufficient blood pressure reduction (dipper and non-dipper), were equally common in both groups. At the same time, disturbances such as increased blood pressure at night (night peak) were more often found in the group of hypertension with type 2 diabetes. At the same time, no significant differences were obtained in terms of the frequency of detection of various daily blood pressure profiles.

No associations were found between the degree of nocturnal decrease in SBP/DBP and clinical and instrumental parameters in the group of hypertension without diabetes. However, in the group of hypertension with type 2 diabetes, the degree of nocturnal decrease in SBP significantly correlated with the duration of diabetes ($r = -0.66$; $p = 0.01$), BMI ($r = -0.66$; $p = 0.02$), linear ($r = 0.99$; $p = 0.03$) and volumetric ($r = 0.99$; $p = 0.04$) dimensions of the left atrium (LA). The magnitude of the nocturnal decrease in DBP in patients with type 2 diabetes significantly correlated with the value of BMI ($r = -0.54$; $p = 0.04$) and WC ($r = -0.56$; $p = 0.04$).

The variability of SBP and DBP at night and during the day was higher in patients with type 2 diabetes, exceeding the normative values only for SBP during the day (see Table 2). When assessing blood pressure variability, 15/15 mmHg was taken as normative values for SBP. Art. (day/night), for DBP – 14/12 mm Hg. Art. (day/night), exceeding at least one of the four critical values was considered pathological [6]. Individual analysis revealed an increase in blood pressure variability in 13 (27.7%) patients with hypertension without diabetes ($p = 0.01$) and 25 (69.4%) patients with hypertension and type 2 diabetes. No connection was found between increased BP variability and clinical and instrumental parameters in hypertensive patients without diabetes. In patients with hypertension and type 2 diabetes, increased blood pressure variability both during the day and at night was positively correlated with LA volume ($r = 0.37$; $p < 0.05$), E/e' ratio ($r = 0.48$; $p < 0.05$), which characterizes the filling pressure of the left ventricle (LV), is negative - with the average value of the speed of early diastolic movement of the mitral ring (e'av. LV) ($r = -0.35$; $p < 0.05$).

Analysis of data from office BP measurements revealed significantly higher PBP numbers relative to normal values (<60 mm Hg) in patients with type 2 diabetes – 60.0 [54.5; 65.5] versus 53.0 [48.0; 60.0] mm Hg. Art. respectively. Similar differences were obtained when assessing ABPM data. Thus, in the group of hypertension with type 2 diabetes there were significantly higher values of average daily blood pressure with a norm of less than 50 mm Hg. Art. – 54.5 [46.0; 62.0] and 45.0 [42.0; 49.0] mm Hg. Art. respectively.

The values of average daily PAP in hypertensive patients without diabetes correlated positively only with the indexed LV myocardial mass ($r = 0.31$; $p = 0.04$). In patients with hypertension and type 2

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diabetes, the values of average daily blood pressure were positively correlated with age (r = 0.57; p = 0.01), fasting glucose levels (r = 0.56; p = 0.01), glycated hemoglobin (r = 0.47; p = 0.01), indexed LV myocardial mass (r = 0.36; p = 0.04) and negative – with e'sr. LV (r = -0.50; p = 0.01).

The discussion of the results

Despite the progress achieved in recent years in the treatment of hypertension, this pathology remains an important public health problem [1–4].

The combination of hypertension and type 2 diabetes is associated with a significant increase in the likelihood of developing micro- and macrovascular complications, the successful prevention of which depends on an integrated approach to identifying and correcting all modifiable risk factors [1, 8, 9].

Many patients with type 2 diabetes have CVD risk factors even before diagnosis, including hypertension, hyperlipidemia, and excess body weight [8, 9].

In our study, patients with type 2 diabetes had significantly higher BMI, WC, TC and TG values. The incidence of dyslipidemia in both groups was three quarters of the cases and did not have significant differences. At the same time, only 27.8% of hypertensive patients with type 2 diabetes took statins. This fact must be taken into account when prescribing complex treatment in order to achieve maximum control of CV risk factors in such patients. To solve this problem, the recommendations for the management of patients with hypertension in 2023 indicate the advisability of using polytablets - fixed combinations containing two antihypertensive drugs and a statin, and in the case of secondary prevention - adding acetylsalicylic acid to them [5]. However, polytablets have not yet received widespread use in real clinical practice.

According to many experts, one of the leading modifiable factors that reduce the risk of cardiovascular complications and death in patients with type 2 diabetes is hypertension [9–12]. This requires achieving target blood pressure values.

As a consequence, effective treatment of hypertension is a primary goal and the main way to prevent target organ damage, reduce CV risk and the risk of death.

The inconsistency between office (clinical) and ambulatory blood pressure values makes their simultaneous assessment an important component of the diagnosis and treatment of hypertension.

As noted above, to identify hidden ineffectiveness of hypertension treatment, outpatient blood pressure measurement outside a medical facility is necessary. In this case, the daily change in blood pressure during habitual daily physical and emotional stress is more important, since it is this that is most associated with target organ damage, prognosis and overall mortality [7].

One of the tools for monitoring the achievement of target blood pressure values is the comparison of office and outpatient measurements, which are called “BP phenotypes”.

Currently, there are four main phenotypes of AD [2]:

true normotension according to the results of office and outpatient measurements;

white coat hypertension – only office BP is elevated;

latent hypertension – only ambulatory blood pressure is increased;

stable hypertension – both office and ambulatory blood pressure are increased.

In our study, when analyzing blood pressure phenotypes, persistent hypertension was recorded in more than half of the cases in both groups, which indicates insufficient blood pressure control. In the group of hypertension with type 2 diabetes, stable hypertension and white coat hypertension were detected somewhat more often. The prognostic significance of white coat hypertension has not been fully determined. It is assumed that these patients are in an intermediate group between normotensives and stable hypertensives [7].

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It has been established that many adverse cardiovascular events, such as acute myocardial infarction, stroke, arrhythmias, demonstrate circadian rhythmicity. Disturbances in the circadian profile are associated with target organ damage [7]. This is why it is important to maintain target blood pressure values throughout the day.

According to our study, patients with type 2 diabetes were significantly more likely to have nighttime SBP levels that exceeded the norm. When analyzing the 24-hour blood pressure profile in patients with type 2 diabetes, a three-fold increase in the incidence of Knight-Picker circadian profile disturbances was revealed compared to patients without diabetes. An increase in nocturnal SBP in hypertensive patients with type 2 diabetes was also noted by other researchers [12]. It is believed that this condition is associated with autonomic dysfunction and can be used as a clinical marker of diabetic autonomic neuropathy.

Despite the fact that the groups did not differ in the duration of hypertension, patients with type 2 diabetes had significantly higher SBP values at comparable DBP, which was accompanied by significantly higher PBP values. According to recommendations for the treatment of hypertension and the prevention of CVD, PAP is more than 60 mm Hg. Art. is a criterion for damage to the vascular wall (increased arterial stiffness) and is regarded as target organ damage in hypertension [1–3].

According to the results of our study, it was in the group of hypertension with type 2 diabetes that higher numbers of office and average daily blood pressure were recorded. At the same time, the value of the average daily blood pressure significantly correlated with the level of fasting blood glucose and glycated hemoglobin. The data obtained are consistent with the data of other studies assessing impaired carbohydrate metabolism, insulin resistance and hyperinsulinemia, leading to an increase in oxidative stress, endothelial dysfunction, hypertrophy of smooth muscle cells, restructuring of the elastic matrix of blood vessels, the development of arteriosclerosis and ultimately to an increase in the rigidity of the vascular wall associated with increased SBP [10]. A long period of asymptomatic insulin resistance and hyperinsulinemia, even before the diagnosis of diabetes, can cause damage to the vascular wall and an increase in its stiffness, contributing to an increase in SBP [11].

The presence of type 2 diabetes in patients with hypertension is associated with earlier and more pronounced damage to target organs, which is confirmed by the presence of a connection between ABPM and structural and functional parameters of the left heart.

A comparative analysis of our data demonstrated that the presence of type 2 diabetes in patients with hypertension is associated with an increase in the variability of SBP and DBP both during the day and at night, probably due to a violation of regulatory mechanisms leading to autonomic dysfunction (neuropathy). The combination of these pathological conditions is also associated with earlier target organ damage. In particular, if the heart is damaged, cardiopathy may develop. Thus, in our study, an increase in blood pressure variability in patients with type 2 diabetes correlated with impaired LV diastolic function (LA volume, E/e', e'avg ratio).

In accordance with current recommendations for the treatment of hypertension, most patients already at the start require two-component antihypertensive therapy [2, 3]. When prescribing treatment, the emphasis is on its effectiveness. Preference is given to combination therapy with fixed combinations that have a stable effect within 24 hours [5]. However, in real practice this approach is not sufficiently implemented [4].

Analysis of previous therapy of patients included in the study showed that more than 70% of them received combination therapy. At the same time, fixed combinations, which increase adherence and effectiveness of treatment, were used only by 36.4% of patients with hypertension without diabetes and 23.3% of patients with hypertension and type 2 diabetes.

Low adherence of patients to prescribed therapy is a common reason for failure to achieve target blood pressure values [13]. This is confirmed by the results of our study. Thus, 38.3% of patients with hypertension without diabetes and 52.8% of patients with hypertension and type 2 diabetes took medications regularly.

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A significant problem in achieving target blood pressure is also the clinical inertia of doctors, which consists in prescribing inadequate doses of antihypertensive drugs, passivity in prescribing or transferring to fixed combinations.

Conclusion

Arterial hypertension is one of the main modifiable factors of CV risk.

Our data indicate insufficient control of blood pressure and dyslipidemia in hypertensive patients with type 2 diabetes. The population under consideration is characterized by higher values of SBP and PBP both during the day and at night. The average daily blood pressure in such patients is positively correlated with the level of fasting glucose and glycated hemoglobin. In almost every seventh patient with hypertension and type 2 diabetes, a disturbance in the daily blood pressure profile of the Knight-Picker type is detected. Moreover, the degree of nocturnal decrease in SBP significantly correlates with the duration of diabetes. Despite the adherence to antihypertensive therapy comparable to patients with hypertension without diabetes, people with hypertension and type 2 diabetes are less likely to achieve target blood pressure values, both according to office measurements and according to ABPM data, which requires attention from medical personnel regarding the timely detection of treatment ineffectiveness Hypertension and its active correction.

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