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The aspects of the therapy of hypertension in women in menopause

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Abstract:

The aspects of the therapy of hypertension among women in menopause is not studied in wide ranged therefore the treatment of the hypertension in women in the menopause is still under study. The search for effective ways to increase the adherence of therapy in patients with high-risk hypertension is the most important task in terms of reducing morbidity and mortality from cardiovascular diseases. Presented are modern data on the problem of adherence to antihypertensive therapy in postmenopausal women with high cardiovascular risk. Identification of factors associated with adherence will justify the implementation of a number of measures to increase the effectiveness of the treatment of patients with arterial hypertension.

Objective: to study the effectiveness and adherence to HT of postmenopausal women.

It was revealed that in women of the older age group, the onset of early menopause is associated with the presence of previous hypertension, including gestational. Hypertension in this category of women is characterized by significantly higher blood pressure, a violation of the circadian rhythm of blood pressure, an increased frequency of obesity, impaired lipid and carbohydrate metabolism, clinical manifestations of lesions of target organs (significant systolic and diastolic LV dysfunction, concentric LV hypertrophy, etc.) and the presence of associated clinical conditions (IHD, type 2 diabetes mellitus, etc.) with a high probability of their complications. The factors associated with high adherence to AHT were identified: dynamic control (BP, heart rate, taking drugs), increasing the proportion of patients' responsibility, AH duration, awareness of the risks of complications, etc. One of the effective methods of increasing adherence to therapy is keeping a diary of self-monitoring of blood pressure, reflecting both the dynamics and the effectiveness of the therapy used. To increase adherence to therapy, it is recommended that the frequency of treatment regimen changes be minimized. The appointment of rational treatment regimens is not sufficient to achieve control of hypertension, it is necessary to increase the share of responsibility of patients themselves for observing the correct regimens by regularly maintaining a diary of self-monitoring, thereby reducing the risk of a degree of mistrust of patients to doctors.

Keywords: arterial hypertension, high risk, adherence to therapy, postmenopause, gestational arterial hypertension.

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Introduction. Arterial hypertension (AH) is not only one of the most common diseases of the cardiovascular system, but also the main predictor of the occurrence of cardiovascular catastrophes [1, 5, 7, 8, 10]. In 30% of the adult population of developed countries of the world, an elevated level of blood pressure (BP) is determined and in 12-15%, persistent arterial hypertension is observed. About 50% of all deaths from cardiovascular diseases (CVD) are in hypertension [12, 14, 15].

Therefore, the timely appointment of adequate antihypertensive therapy, allowing patients with hypertension to reach and maintain the target blood pressure for the longest possible time, is the most important condition for ensuring a reduction in the risk of CVD and mortality [1, 2, 9, 10].

Despite the fact that a large number of antihypertensive drugs are currently available, both in the form of monotherapy and in the form of fixed combinations, the situation with hypertension control remains difficult: among 40% of the adult population suffering from hypertension, only 23% achieve the target numbers AD [2, 5, 7, 15]. The reasons for this situation with blood pressure control are very diverse. Some of them may be associated with medical tactics for determining hypertension: irrational choice of drugs and / or their combinations, fear of using combination therapy due to a possible excessive decrease in blood pressure, lack of desire to achieve the recommended target numbers for blood pressure [11, 14]. Another group of reasons includes factors related to patients: their non-compliance with the doctor's recommendations regarding lifestyle changes and drug therapy: low adherence to therapy [4, 6, 9, 10]. Also, concomitant diseases that require an individual approach to the choice of hypertension (for example, kidney diseases, metabolic disorders, diabetes mellitus, etc.) can complicate the control of blood pressure. In addition, in recent years more and more attention has been paid to gender-related differences in the clinical picture, course of CVD, the effectiveness and safety of treatment [5, 7, 8, 10].

Data from the Framingham Study and some other epidemiological studies have shown that, contrary to the belief that has existed for many years, the risk of CVD in women is at least consistent with that in men, and in some cases exceeds it [12, 13]. Since the 80s of the twentieth century in developed countries, cardiovascular mortality among men began to decrease markedly. In women, on the contrary, there is a tendency to its growth. The first step towards solving this problem is to identify the most significant CVD risk factors for women and to find methods for their correction [1, 2, 9, 10]. Risk factors for the development of CVD can be divided into non-specific (common for men and women) and specific (characteristic only for men or only for women). Despite the commonality of risk factors, there are differences in the features of their influence on the formation of CVD pathology in men and women [10, 11]. Practitioners pay less attention to CVD risk factors specific for women and men [9, 10].

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AH is widespread and is observed in 41.1% of women. Complications of this disease occupy the first place in the structure of mortality in the female population. In women with hypertension, the risk of developing coronary heart disease is 3.5 times higher than in women with normal blood pressure [1, 2, 9, 10].

In 2018, experts from the European Society of Cardiology and the European Society for Hypertension significantly revised the approach to AHT: it was recommended to strive to achieve lower target BP values in all categories of patients, as well as to start AH therapy in most patients with combined AH drugs, mainly fixed [12]. These recommendations should contribute to a more effective reduction in blood pressure and faster achievement of target numbers in patients with hypertension and, most importantly, an effective reduction in the risk of cardiovascular complications and mortality [1, 3, 5, 7].

The choice of antihypertensive drugs, their doses, monitoring the effectiveness and safety of treatment in women also has its differences, due to the physiological characteristics of the female body [6]. They affect the pharmacokinetic parameters of the drug, therefore, the effectiveness and safety of drug therapy [8].

We can distinguish the following features that should be considered when using drugs in women:

women have less body mass index and size of internal organs, more relative amount of fat; the water content in a woman's body varies depending on the phase of the menstrual cycle (estradiol delays sodium and water); women have lower glomerular filtration rate and creatinine clearance; the menstrual cycle, menopause, pregnancy are accompanied by fluctuations in the content of sex hormones, changes in the water content in the body; the female sex is a risk factor for the development of undesirable drug reactions, which develop in this case 50–70% more often than men; adherence to therapy is lower in women than in men [1-10].

For patients with hypertension, adherence to therapy is 50-60%, i.e. taking only half of the prescribed AGS [4, 5]. The lack of adherence to therapy is associated with an increase in the risk of loss of blood pressure control by 41%, with an increase in the risk of myocardial infarction by 15%, and an increase in the risk of stroke by 22% [10]. Due to these complications, the cost of managing the patient increased by 43.7% [10]. With a commitment to antihypertensive therapy of less than 50% compared with a commitment of more than 80%, mortality and hospitalization increased by 1.4 times [9].

Some patients (16-60%), especially those with newly diagnosed hypertension, stop taking AGS within a year. When observed for 5-10 years, less than 40% of patients continue to take antihypertensive drugs [5].

Given the above factors, informing doctors about modern approaches to the treatment of hypertension and optimal tactics of hypertension and the study of adherence to therapy in women is of great importance. This was the purpose of this

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study: the study of the effectiveness and adherence to AHT of postmenopausal women.

Materials and research methods. According to the goal of the study, we studied the structural and functional features of CVS, clinical and laboratory parameters in women (n = 200) in postmenopausal women with arterial hypertension. Based on the reproductive history and the fact of an increase in blood pressure, hyperglycaemia, and other risk factors during pregnancy, women were divided into two groups of dynamic observation, i.e. patients with a history of hypertension (increased blood pressure and / or preeclampsia) during pregnancy, group 1 (n = 104) cf. age - 62.19 ± 0.40 years and without increasing blood pressure during pregnancy, 2-group (n = 96) cf. age - 63.45 ± 0.32 years; any pregnancies accompanied by hypertension (not necessarily the last) were taken into account. Induced menopause was an exclusion criterion. The analysis was carried out on the basis of records in outpatient cards (archival materials) at the place of residence. The groups were comparable by age, the number of births in the anamnesis, while in the group with a history of gestational hypertension, the average age of menopause corresponded at n = 45 (43.3%) to 46.4 ± 2.6 years, and at n = 40 (38.5%) 44.3 ± 3.5 years, which corresponds to early menopause. Patients had a duration of hypertension (on average 15.3 ± 2.5 years), while the frequency of occurrence of hypertension in women with a history of hypertension was 2.1 years longer than in women without hypertension during pregnancy. It should be noted that awareness of the presence of the disease and the need to control blood pressure in women with a history of hypertension was higher than in women without a history of hypertension. It is important to note that the study involved patients who, at the time of inclusion, did not receive effective AHT (the therapy used was not regular, target blood pressure levels were not reached or were occasionally treated), in addition, patients did not take statins and aspirin. Women of both groups had comparable BMI values (27.9 ± 0.4 kg / m2 versus 27.7 ± 0.4 kg / m2, p <0.1) (Table 1.). Analysis of anamnestic data showed that women of both groups noted the appearance of clinical complaints associated with an increase in blood pressure, as well as an increase in body weight with the onset of menopause on average 1.5 years from the onset of irregular menstrual reactions. It is important to indicate that women with obesity were 2.1 times more likely to have type 2 diabetes, and women with gestational diabetes were 1.6 times more likely than women without a history of gestational diabetes. It is necessary to indicate that the data of obstetric and gynaecological history in patients of both groups by the number of pregnancies and childbirth, the beginning of sexual activity and other factors were generally comparable, except for the only fact that among the patients of the 2nd group prevailed multiparous women (2.2 times more giving birth to 5 or more living children), which is evidence of relatively favourable reproductive health.

Table 1.

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Comparative analysis of risk factors in women in postmenopausal depending on the presence of AH in history

Indicator	Women			
	1-group		2-group	
	n	%	n	%
Normal body weight (up to 25 kg / m2)	34	32,7	31	32,3
Obesity I-st. (25.9-29.9 kg / m2)	48	46,2	49	47,1
Obesity II-III-Art. (30 and more kg / m2)	22	21,1*	16	16,6
Type 2 diabetes	15	14,4*	9	9,3
Ischemic heart disease	34	32,7*	24	25
Total	104	100	96	100

Notes: significance between observation groups * -p <0.05;

According to the analysis of age groups at 5-year intervals, taking into account the presence of a hypertensive history during pregnancy and without it, of the total number of patients included in the study, it was found that in patients with hypertension during pregnancy, an increase in blood pressure prevails in the age period 55- 60 years in 40 (38,%) women and in the age of 61-65 years old in 39 (37.5%), i.e., 3.7 years earlier than the average world data, according to published in the recommendations of the EAG (2013-2018) Moreover, in women without hypertension during gestation, the onset of clinical manifestations associated with an increase in blood pressure is more likely to occur at the age of 61-65 years, 49 (51%) versus 19 (19.8%) women aged 55-60. At the same time, a relatively similar incidence of hypertension is observed in the age range of 66-69 years - 25 (24%) versus 28 (29.2%) included postmenopausal women in both groups.

Thus, it should be noted that in the group of postmenopausal patients with a history of hypertension in the gestational period, the incidence of CVD risk factors is 1.6 times more likely than in the group of postmenopausal patients without hypertension in the gestational period.

An important research question was the assessment of the effectiveness of AHT, which was determined after 12 weeks of therapy, the criteria were indicators of achieving the target blood pressure values, restoration of the daily profile and blood pressure variability according to the ABPM, dynamics of clinical and biochemical parameters, and regression (tendency) of target organ damage. AHT was prescribed to all patients, which included the use of per valsartan 80 mg / day, after 2 weeks with insufficient effect, the dose was increased to 160 mg / day, after 4 weeks in the absence of dynamics of a decrease in blood pressure, a fixed combination of valsartan was used - 80 mg with amlodipine 10 mg , or valsartan -160 mg, amlodipine 5 mg, along with AHT, all women were prescribed aspirin at a dose of 75 mg / day, statins

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(rosuvastatin 20 mg / day) under the control of clinical and biochemical parameters. For the target value of blood pressure was taken the value of SBP ≤130 mm Hg, DBP ≤80 mm Hg.

For each patient, an individual dynamic observation card (diary) was filled out, in which the patient daily recorded the results of blood pressure and heart rate measurements, complaints, and also noted the time of taking the drug and side effects from the treatment (if any). Compliance was assessed using the Moriski-Green test, which determines compliance with treatment [2, 3, 5]. A study of adherence to AHT in postmenopausal patients was carried out, which was evaluated on the Moriski-Green compliance scale: 1. Have you ever forgotten to take drugs? (well/no); 2. Do you sometimes not care about the hours of medication? (no/Yes); 3. Do you skip taking medications if you feel good? (no/Yes); 4. If you feel unwell after taking the medicine, do you miss the next dose? (no/ Yes). Each item is evaluated on a yes-no basis, with yes being 0 points, 1 no. Adherent (compliant) were considered patients who scored more than 3 points, scored less than 3 points are not committed [2, 5]. Patients filled out diaries for monitoring blood pressure, heart rate and taking AGT, according to these records, they evaluated the effectiveness of therapy and determined adherence to therapy after 3 months of observation.

Statistical data processing was carried out on a personal computer using the program “Statistica 6.0 for Windows”. To provide the data, the following indicators were used: mean value, standard error of the mean, standard deviation, or the median and interquartile range, percent and frequency. The reliability of differences between the compared indicators was evaluated by paired t-student test. The result was considered reliable with a probability of error ($p < 0.05$), according to t-test. The relationship between the studied parameters was evaluated using the correlation analysis with the determination of the correlation coefficient (r) and its significance level (p) according to the Pearson method, they were considered reliable at $p < 0.05$, highly reliable at $p < 0.0001$.

Results and discussion. Based on the data of primary medical documentation and entries in self-monitoring diaries, an analysis of the regularity of treatment and preservation of the treatment regimen was performed as components of adherence to AHT. Under the change in the AGT regimen, we understood the discrepancy between the therapy regimen recommended by us and the one used at the time of the re-examination of the change in the regimen of hypertension according to its content (trade names of drugs / international nomenclature names and their dosages). Evaluation of the effectiveness of AHT was carried out on the basis of the dynamics of clinical and laboratory parameters, achievement of target blood pressure values, restoration of the circadian rhythm of blood pressure, and also adherence to the conducted AHT was assessed.

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An important research question was the assessment of adherence to AHT on the Moriski-Green scale. Thus, the results of data analysis showed that the total score in patients of the 1st group during the visit after 1 month averaged 2.7 ± 1.4 points, and in the 2nd group 1.8 ± 1.3 points (p <0, 01), this generally reflects a low adherence to therapy. The tactics of AHT in the studied groups included the use of combination therapy — a fixed combination of valsartan with amlodipine in doses of 80/5 mg, with titration to the maximum dose (Table 2).

All patients were recommended to cover diaries for controlling blood pressure, heart rate, and taking medications. It should be noted that regularly during the 1st month the diaries of 46 (44.2%) patients of the 1st group, 41 (42.7%) of the women of the 2nd group were filled, in the remaining cases there were gaps, which shows approximately the same adherence to treatment in both groups.

Table 2.

Antihypertensive therapy in those included in the study history of postmenopausal women with and without gestational hypertension.

Therapy	Women			
	1 -group		2-group	
	n=104	%	n= 96	%
Valsartan / Amlodipine 80/10 mg / day	52	50	48	50
Valsartan / Amlodipine 160/5 mg / day	52	50	48	50
Rosuvastatin 20 mg / day	100	96,2	93	96,9
Aspirin 75 mg / day	94	90,4	88	91,7

It is important to emphasize that more than half of patients in both groups are not motivated not only to comply with treatment recommendations, but also demonstrate a “not serious” attitude towards self-control when filling out diaries. According to patients, the most common reasons for skipping medications were well-being and lack of complaints in 37 (35.6%) cases in the 1st group, in 28 (29.2%) in the second group, forgetfulness (30.9% and 29 , 2%), in 9 (8.7%) and 6 (6.3%), respectively, they were afraid of drug dependence or the lack of effect of 1.6% and 0.9%, respectively, of respondents in both groups. that is, controlled factors. The adherence to therapy in the groups was comparable, with an equally low compliance with statins and aspirin in patients of both groups. A repeated analysis of compliance with AHT was evaluated after 3 months of therapy (Table 3), by the 3rd visit (after 3 months of therapy). The survey data showed that 58 (55.8%) patients of the 1st group and 50 (52.1%) of the 2nd group regularly monitored blood pressure, heart rate, took drugs and filled out diaries, and in other cases the diaries remained the same empty since inclusion in the study. Nevertheless, in general, adherence reached high values of 3.8 ± 2.2 and 4.1 ± 0.8 points, respectively, in both groups when using the fixed

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combination of valsartan / amlodipine 160/5 mg / day, taking the combination of valsartan / amlodipine 80/10 mg / day, the most common side effects. Of the side effects, tachycardia, an increase in the number of hot flashes were most often noted, a similar situation is possibly due to the action of amlodipine (10 mg). Significantly increased adherence to statins and aspirin (table. 3).

Table 3.

The dynamics of adherence to hypertension in postmenopausal women.

Therapy	**1- group (n=104)**		**2- group (n=96)**	
	After 1 months	**After 3 months**	**After 1 months**	**After 3 months**
Valsartan / Amlodipine 80/10 mg / day	3,1±1,7	3,4±2,1	3,4±1,3	3,6±1,1*
Valsartan / Amlodipine 160/5mg / day	3,7±1,6	3,8±2,2	3,9±1,1	4,1±0,8
Rosuvastatin 20mg / day	2,5±1,6	3,1±1,6*	3,4±0,9	3,6±1,4
Aspirin 75 mg / day	2,8±1,3	3,4±1,3*	3,3±0,9	3,6±0,8*

Note: reliability before and after treatment * -p <0.01

Despite the recommended rational AHT regimens, an uncontrolled increase in blood pressure was recorded in 37.7% of patients within 3 months after our initial consultation, and the frequency of achieving the target blood pressure was only 28.7%. After 3 months, 74.9% of respondents regularly took antihypertensive drugs. Analysis of AHT adherence by the component of preservation of the recommended treatment regimen showed that only 25.1% of patients after 3 months maintained the treatment regimen for AH, 8.9% refused treatment completely, and 66.0% of patients changed the treatment regimen. Among patients who changed the pattern of AHT / refused treatment of AH, 56.0% did it on their own, without the recommendation of a doctor, and the main reason for changing the treatment regimen / stopping medical correction of AH in 46.9% of cases was the fear of side effects and / or the fear of addiction .

According to patients, the main causes of omissions in taking ACS are the absence of disease symptoms (52.3%) and forgetfulness (31.2%). In 5% of cases, patients indicated a lack of confidence that treatment could help, in 1.6% - distrust of the doctor or lack of money, in 0.8% - the absence of the effect of antihypertensive therapy. 10.4% of patients indicated two or more reasons leading to a change in ACS intake.

Factors were identified that statistically significantly correlate with the administration of AHT as the position of patients (among pensioners, adherence is higher than among workers) ($r = 0.2$; $p < 0.05$), the presence of arterial hypertension

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in close relatives (r = 0.42; p < 0.05), the duration of the disease is less than 5 years (r = 0.54; p <0.05), the risk of developing cardiovascular complications in hypertension (r = 0.32; p <0.05). A positive correlation was revealed between taking AHT and conducting combination therapy (r = 0.33; p <0.05), the number of AHT taken (r = 0.64; p <0.05), and treatment with ACE inhibitors (r = 0.62; p <0.05), BAB (r = 0.24; p <0.05), AK (r = 0.2; p <0.05). These correlations indicate better adherence when taking several antihypertensive drugs, as well as taking ACE inhibitors, BAB, and AK. Correlation analysis showed that in patients who independently control their blood pressure, adherence is also higher (r = 0.8; p <0.05).

The highest effectiveness of hypertension control, assessed by achieving target blood pressure according to the results of self-monitoring, was noted in the group of patients who regularly took hypertension and did not change the treatment regimen for 3 months (47.4%), with insufficient adherence to one / both components, the frequency of achieving target blood pressure ranged from 9.4% to 26.5%.

Thus, in women of the older age group, the onset of early menopause is associated with the presence of previous hypertension, including gestational. Hypertension in this category of women is characterized by significantly higher blood pressure, a violation of the circadian rhythm of blood pressure, an increased frequency of obesity, impaired lipid and carbohydrate metabolism, clinical manifestations of lesions of target organs (significant systolic and diastolic LV dysfunction, concentric LV hypertrophy, etc.) and the presence of associated clinical conditions (IHD, type 2 diabetes mellitus, etc.) with a high probability of their complications. The factors associated with high adherence to AHT were identified: dynamic control (blood pressure, heart rate, taking drugs), an increase in the proportion of patients' responsibilities, duration of AH, awareness of the risks of complications, etc.

Factors associated with high adherence in the women included in the study, the duration of the disease is more than 5 years, keeping a diary for monitoring blood pressure and taking AGS, medical examination at the doctor's office for arterial hypertension, the presence of concomitant coronary heart disease, myocardial infarction and / or stroke, several antihypertensive drugs, as well as taking ACE inhibitors, □-blockers, calcium antagonists.

One of the effective methods of increasing adherence to therapy is keeping a diary of self-monitoring of blood pressure, reflecting both the dynamics and effectiveness of the therapy used. To increase adherence to therapy, it is recommended that the frequency of treatment regimen changes be minimized. The appointment of rational treatment regimens is not sufficient to achieve control of hypertension, it is necessary to increase the share of responsibility of patients themselves for observing the correct regimens by regularly maintaining a diary of

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self-monitoring, thereby reducing the risk of a degree of mistrust of patients to doctors.

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