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## Changes in Blood Pressure in Patients with Breast Cancer during Polychemotherapy with Anthracyclines

**Introduction.** Arterial hypertension (AH) is the most common comorbid condition, occurring in approximately 40.0 % of all cancer patients [8]. Changes in blood pressure (BP) in oncology may be due to the type, localization, and stage of cancer, as well as its therapy [2, 5].

Doxorubicin and epirubicin, which belong to the group of anthracyclines, are recommended for the treatment of many types of cancer, in particular breast cancer (BC) [3]. It has been established that anthracyclines, in addition to their antitumor effect, cause cardiac and vascular dysfunction [5, 7].

Anthracyclines are effective cytostatics, but their cytotoxicity leads to an increase in BP due to endothelial dysfunction, oxidative stress and kidney damage [3, 7]. On the other hand, it is known that in patients receiving anthracyclines, AH is a moderate risk factor for cardiovascular toxicity [6, 8]. Elevated baseline BP is recognized as a significant risk factor for cardiotoxicity, as it creates additional stress on the heart, making it more vulnerable to the effects of chemotherapy [7]. Given this, current national and international guidelines for the management of patients with breast cancer recommend that all patients monitor BP before chemotherapy, especially anthracycline therapy, and that treatment should not be initiated or should be postponed if BP exceeds 180/120 mm Hg [6,7]. Researchers believe [11] that special attention should be paid to patients with elevated BP (systolic pressure: 120-139 mm Hg or diastolic pressure: 80-89 mm Hg), since this category is often overlooked by physicians, although it has an increased risk of cardiovascular complications.

Despite existing literature, a significant gap persists in understanding the impact of complex therapeutic regimens involving anthracyclines combined with cyclophosphamide on blood pressure (BP) regulation. This knowledge deficit provided the primary justification for the present investigation.

**The aim of the study.** The principal objective of this research was to investigate fluctuations in blood pressure levels during multi-agent chemotherapy incorporating anthracyclines, cyclophosphamide, and paclitaxel in individuals diagnosed with mammary carcinoma.

**Materials and methods.** This investigation employed a prospective observational design, carried out between 2024 and 2025. The study was conducted within the outpatient chemotherapy department of the consultative polyclinic, affiliated with the Center for Reconstructive and Restorative Medicine (University Clinic), Odesa National Medical University (ONMedU). All procedures adhered to the ethical principles outlined in the Declaration of Helsinki. The study protocol received official endorsement from the Ethics Committee of ONMedU, operating under the purview of the Ministry of Health of Ukraine. Voluntary informed consent was secured from every participant prior to enrollment.

The study comprised (included) 86 female, ranging in age from 46 to 71 years, who had been diagnosed with mammary carcinoma, specifically stages T2-3-4, N0-1, M0. These participants were undergoing either neoadjuvant or adjuvant multi-agent chemotherapy - polychemotherapy (PCT). Diagnosis of mammary carcinoma was confirmed in accordance with established medical care guidelines. Standard of Medical Care - "Breast Cancer" [4].

**Inclusion criteria for the study.** Participants must meet the following criteria to be eligible for the study. Individuals aged between 35 and 74 years, inclusive. Confirmed diagnosis of specific breast cancer subtypes: luminal B (HER2-negative), HER2-positive, or triple-negative, with documented disease staging of T2-4, N0-1, M0. Presence of elevated systolic blood pressure (SBP) ranging from 120.0 to 130.0 mm Hg and/or diastolic blood pressure (DBP) ranging from 80.0 to 89.0 mm Hg. Absence of any conditions specified in the exclusion criteria. Voluntary provision of written informed consent. Capacity to adequately comply with study pro-

cedures and requirements. Exclusion criteria for the study. Individuals will be ineligible for participation if they present with any of the following conditions. Diagnosis of primary hypertension (Stages I-III). Presence of secondary or malignant forms of hypertension. A history of significant cardiovascular or cerebrovascular events, including myocardial infarction, invasive or non-invasive cardiac interventions, or cerebrovascular disorders. Clinically significant cardiac dysrhythmias. Heart failure with reduced ejection fraction, categorized as NYHA functional class III or IV. Stable ischemic heart disease. History of pulmonary embolism. Chronic renal failure beyond Stage III severity. Decompensated hepatic dysfunction. Significant mental or psychiatric disorders that could impair study participation. Current pregnancy or lactation. Documented hypersensitivity or allergic reaction to any components of the study therapy. Concurrent participation in other clinical research trials.

According to the Standard of Medical Care "Breast Cancer" [4], medical history was collected from all patients, body weight and height were measured, body mass index (BMI) was calculated, an objective examination was performed, and office blood pressure and heart rate were measured. All patients underwent general clinical blood and urine tests and a biochemical blood test. During the biochemical blood test, liver enzymes (aspartate aminotransferase - AST, alanine aminotransferase-ALT, creatine phosphokinase - CPK) and creatinine levels were determined, followed by calculation of glomerular filtration rate (GFR) using the CKD-EPI formula. Serum electrolytes (potassium, sodium, calcium, magnesium), fasting glucose levels, and serum lipid metabolism were assessed. Instrumental studies included electrocardiography (ECG) and transthoracic echocardiography (TTE) [4]. Blood pressure was measured using an Omron M10 device (Japan) before the start of intravenous drug administration and immediately after completion of the chemotherapy procedure. SBP and DBP were recorded on the same arm in a sitting position three times at 1-2-minute intervals, and the average value of the last two measurements was calculated [9].

Depending on the anthracycline used, the patients were divided into 2 groups. The first group (44 patients), according to the standard for the treatment of breast cancer [4], received neoadjuvant PCT with doxorubicin (60.0 mg/m<sup>2</sup>) and cyclophosphamide (600.0 mg/m<sup>2</sup>) administered intravenously every 3 weeks. The second group (42 patients) received neoadjuvant PCT with epirubicin (90.0 mg/m<sup>2</sup>) and cyclophosphamide (600.0 mg/m<sup>2</sup>) administered intravenously every 3 weeks. After 4 courses according to the "anthracycline + cyclophosphamide" protocol, patients continued chemotherapy with paclitaxel (80.0 mg/m<sup>2</sup>) weekly for 12 weeks. All patients found to have increased blood pressure after CT procedures were recommended to follow non-drug measures for hypertension prevention in accordance with national and international guidelines [2, 9, 11].

According to the main clinical characteristics, age, and sex, patients in both groups were comparable (Table 1).

Table 1

Characteristics of patients included in the study  
(M ± m, n, p)

Indicator	Group I (n = 44)	Group II (n = 42)	p
Females, n	44	42	
Age, M + m, years	51.5 + 3.9	54.0 ± 4.8	> 0.05
Office SBP, M + m, mm Hg	123.3 + 2.3	125.1 + 2.6	> 0.05
Office DBP, M + m, mm Hg	81.3 + 1.4	82.7 + 1.1	> 0.05
BMI (kg/m <sup>2</sup> )	28.0 ± 3.5	27.3 ± 2.8	> 0.05

**Notes:** Quantitative data are presented as (M + m) - mean value + standard deviation of the mean. Blood pressure; DBP - diastolic blood pressure; BMI - body mass index; SBP - systolic blood pressure.

Statistical processing of the obtained data was carried out using Microsoft Excel (Microsoft Corporation, USA, 2016) and Statistica 12.5 (StatSoft, version 12.5.192.7). The Fisher criterion was used to assess the normal distribution of groups of patients. With normal distribution, parametric methods of statistical processing of the obtained data were applied. The average values were denoted as M, and the standard error as m. Indicators are presented as mean + standard error of the mean (M + m). The probability of the differences in relative indicators was calculated using the  $\chi^2$  test and the Student's t-test for normally distributed values. Differences were considered statistically significant at  $p < 0.05$  [1, 10].

**Results and discussion.** As shown in Table 1, before treatment initiation, the average values of systolic and diastolic blood pressure met the criteria for elevated blood pressure [9], i. e. were within 120-130/80-89 mm Hg.

Monitoring of blood pressure during chemotherapy showed that most patients experienced an increase in blood pressure during parenteral drug administration, which was reflected in significant changes in mean values in both the doxorubicin and epirubicin groups (Table 2).

Table 2

Changes in blood pressure in patients with breast cancer during polychemotherapy with doxorubicin, epirubicin and cyclophosphamide (M ± m mm Hg, n)

Indicators	BP indicators	
	Doxorubicin + cyclophosphamide, n = 44	Epirubicin + cyclophosphamide, n = 42
SBP, mm Hg: before infusion after infusion	123.1 + 1.8 132.3 + 2.4	122.7 + 2.7 135.6 + 2.3
p	0.001	0.002
DBP, mm Hg: before infusion after infusion	82.3 + 1.3 86.7 + 1.5	81.9 + 1.7 85.7 + 1.8
p	0.04	0.13

**Notes:** BP - blood pressure; DBP - diastolic blood pressure; SBP - systolic blood pressure. The significance of the difference between the indicators between the 1st and 2nd visits is indicated by p.

As shown in Table 2, the subjects had a significant increase in mean systolic blood pressure after infusion of doxorubicin ( $p < 0.001$ ) and epirubicin ( $p = 0.002$ ). In the vast majority of patients (88.9 %) after infusion of doxorubicin combined with cyclophosphamide, and in 83.3 % after infusion of epirubicin combined with cyclophosphamide, systolic blood pressure increased. In most cases, the systolic blood pressure after the procedure increased from 122.5 to 141.5 mm Hg. Only one patient had a systolic blood pressure of 150 mm Hg after doxorubicin infusion. In 2 (4.6 %) patients receiving doxorubicin-based therapy, SBP decreased insignificantly, on average from 120.5 to 119.5 mm Hg. In complex epirubicin-based therapy, SBP did not change in 4 (9.5 %) patients, and decreased in three (7.1 %) patients by an average of 1.33 mm Hg.

Mean DBP values after the procedures also increased in patients of both groups (Table 2). On average, DBP increased by 4.4 mm Hg (95.0% CI: 0.5-15.1 mm Hg) in the doxorubicin group and by 3.8 mm Hg (95.0% CI: 1.8-12.4 mm Hg) in the epirubicin group. DBP remained unchanged in 4 (9.0 %) patients in the first group and 5 (11.9 %) patients in the second group. According to the protocol, after 4 courses of anthracycline and cyclophosphamide therapy, patients continued weekly paclitaxel chemotherapy for 12 weeks. During paclitaxel therapy, post-infusion blood pressure increases were less pronounced (Table 3).

Table 3  
Changes in blood pressure in patients with breast cancer during paclitaxel therapy (M ± m mm Hg, n)

Indicators	BP indicators	
	Group I, n = 44	Group II, n = 42
SBP, mm Hg: before infusion after infusion	124.8 ± 2.5 131.9 ± 2.7	126.7 ± 2.7 133.1 ± 2.2
<i>p</i>	0.06	0.07
DBP, mm Hg: before infusion after infusion	80.7 ± 1.6 83.3 ± 1.7	83.1 ± 1.4 86.7 ± 1.6
<i>p</i>	0.28	0.11

**Notes:** BP - blood pressure; DBP - diastolic blood pressure; SBP - systolic blood pressure. The significance of the difference between the indicators between the 1st and 2nd visits is indicated by *p*.

Table 3 shows that during paclitaxel chemotherapy, patients in the first group tended to have increased systolic blood pressure ( $p = 0.06$ ), while the increase in mean DBP was not statistically significant ( $p = 0.28$ ). Similar changes were observed in patients in the second group - there was also a tendency toward increased systolic blood pressure ( $p = 0.07$ ), with no significant change in DBP ( $p = 0.11$ ). Analysis showed that an increase in blood pressure ( $> 5$  mm Hg) during procedures at the beginning of paclitaxel treatment in the first group was observed in 37 (84.1 %) patients; by the end of treatment, this proportion decreased by 18.2 % to 29 (65.9 %) women ( $\chi^2=0.049$ ,  $p > 0.05$ ). In the second group, it was observed in 34 (80.9 %) patients initially and in 22 (52.4 %) patients at the end of treatment ( $\chi^2 = 0.006$ ,  $p < 0.05$ ). This may indicate, firstly, that

paclitaxel infusions do not have as pronounced effect on hemodynamic parameters in patients with elevated blood pressure compared to anthracycline and cyclophosphamide therapy. Secondly, non-pharmacological measures in accordance with the National and International Guidelines [2, 9,12], recommended to all patients with elevated BP at the beginning of PCT. In a quarter of patients in the first group and a third of the second group, hemodynamic reactivity was reduced by the end of PCT. Thus, doxorubicin is characterized by an increase in blood pressure in most patients with PAD, but it rarely exceeds 11.0 % compared to baseline levels. It should be noted that in no case of PCT did the BP increase persist for a prolonged period, lead to clinical deterioration, or require discontinuation of therapy.

Non-pharmacological measures included lifestyle modification, moderate physical activity, adherence to dietary recommendations, and smoking cessation and were recommended for patients with high cardiovascular risk ( $> 10.0$  %) [2, 9, 12].

High cardiovascular risk according to SCORE 2 and SCORE 2OP ( $> 10.0$  %) before chemotherapy was found in 26 (59.1 %) patients in the first group and in 23 (54.8 %) in the second group.

Non-pharmacological measures and lifestyle behaviour factors were highly variable and were mostly self-reported. Physical activity was assessed by self-reported amount of time spent on different levels of intensity of activities per day, week, or month. Daily food intake according to the eight-component Dietary Approaches to Stop Hypertension (DASH) pattern, including high intake of fruits, vegetables, nuts and legumes, whole grains, low-fat dairy products, and low intake of sodium, red and processed meats, and sweetened beverages [12]. Self-reports showed that dietary recommendations were followed by 35 (79.5 %) patients in the first group and 32 (76.2 %) in the second, and physical activity was increased by 15 (34.1 %) and 10 (23.8 %) patients, respectively.

The empirical data collected indicate that within the context of polychemotherapy (PCT) regimens incorporating anthracyclines and cyclophosphamide, a substantial proportion of patients presenting with pre-existing elevated blood pressure, yet without a documented history of hypertension, consistently exhibit elevations in both systolic and diastolic arterial pressure. These findings corroborate the perspective articulated by L. J. Philip et al. [11], underscoring the imperative for diligent blood pressure surveillance in individuals undergoing anthracycline-based therapeutic interventions and emphasizing the necessity of timely antihypertensive interventions aimed at mitigating the risk of chemotherapy-associated cardiotoxicity.

**Conclusions.** During complex multi-agent chemotherapeutic regimens involving anthracyclines and cyclophosphamide, a significant proportion of patients exhibiting baseline elevated blood pressure consistently manifest increased systolic and diastolic arterial pressures. Conversely, the sequential administration of paclitaxel, succeeding anthracycline-centric polychemotherapy, was not associated with a statistically significant augmentation of blood pressure parameters across the cohorts investigated.

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## Changes in Blood Pressure in Patients with Breast Cancer during Polychemotherapy with Anthracyclines

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**Introduction.** Elevated blood pressure (BP) during treatment with anthracyclines, which include doxorubicin and epirubicin, may be a factor in polychemotherapy (PCT)-related cardiotoxicity, which necessitates monitoring and adjustment of BP in these patients.

**The aim of the study.** The principal objective of this research was to investigate fluctuations in blood pressure levels during multi-agent chemotherapy incorporating anthracyclines, cyclophosphamide, and paclitaxel in individuals diagnosed with mammary carcinoma.

**Materials and methods.** The investigation enrolled 86 female patients diagnosed with breast cancer (T2-4, N0-1, M0). These individuals were subsequently randomized and underwent a neoadjuvant PCT. The treatment involved the administration of anthracyclines in conjunction with cyclophosphamide, delivered 3-weekly for 4 cycles. Upon the conclusion of this twelve-week anthracycline-based therapeutic course, participants proceeded to receive weekly infusions of paclitaxel.

**Results.** Blood pressure monitoring during PCT showed that the subjects had a significant increase in mean systolic blood pressure after infusions in the doxorubicin group (from  $123.1 \pm 1.8$  to  $132.3 \pm 2.4$  mm Hg,  $p < 0.001$ ) and the epirubicin group (from  $122.7 \pm 2.7$  to  $135.6 \pm 2.3$  mm Hg,  $p = 0.002$ ). Diastolic blood pressure in the doxorubicin group increased by an average of 4.4 mm Hg (95.0 % CI: 0.5-15.1 mm Hg) and by 3.8 mm Hg (95.0 % CI: 1.8-12.4 mm Hg) in the epirubicin group. Paclitaxel treatment procedures did not lead to a significant increase in blood pressure in patients in either group. Non-pharmacological measures did not significantly affect changes in blood pressure during PCT with anthracyclines in combination with cyclophosphamide and paclitaxel in the majority of patients.

**Conclusions.** The administration of combination chemotherapy, specifically involving anthracyclines and cyclophosphamide, is associated with a substantial post-procedural elevation in mean blood pressure. Paclitaxel infusions were not accompanied by significant changes in mean blood pressure during procedures.

**Keywords:** breast cancer, elevated blood pressure, anthracyclines, paclitaxel, chemotherapy.

## Зміни підвищеного артеріального тиску у хворих на рак молочної залози під дією поліхімієтерапії антрациклінами

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**Вступ.** Підвищений артеріальний тиск (АТ) під час лікування антрациклінами, до яких відносять доксорубіцин і епірубіцин, може бути чинником кардіотоксичності поліхімієтерапії (ПХТ), що зумовлює необхідність моніторингу і коригування АТ.

**Мета.** Дослідити зміни підвищеного артеріального тиску під час лікування антрациклінами у комплексній терапії з циклофосфамідом і паклітакселом у хворих на рак молочної залози.

**Матеріали й методи.** У дослідженні обстежено й рандомізовано 86 жінок віком 46–71 рік із діагнозом рак молочної залози T2-3-4, N0-1, M0, яких лікували неoad'ювантною або ад'ювантною ПХТ антрациклінами (доксорубіцин або епірубіцин) у поєднанні з циклофосфамідом кожних три тижні, чотири процедури на курс. Після завершення курсу лікування антрациклінами упродовж 12 тижнів пацієнтки щотижня отримували інфузії паклітакселу.

**Результати.** Моніторинг АТ під час ПХТ показав, що у пацієток спостерігали достовірне підвищення середнього показника систолічного АТ після інфузій у групі доксорубіцину (зі  $123,1 \pm 1,8$  до  $132,3 \pm 2,4$  мм рт. ст.  $p < 0,001$ ) та епірубіцину (зі  $122,7 \pm 2,7$  до  $135,6 \pm 2,3$  мм рт. ст.,  $p = 0,002$ ). Показники діастолічного АТ в групі доксорубіцину зросли в середньому на 4,4 мм рт. ст. (із  $82,3 \pm 1,3$  до  $86,7 \pm 1,5$  мм рт. ст.,  $p = 0,04$ ) і на 3,8 мм рт. ст. (із  $81,9 \pm 1,7$  до  $85,7 \pm 1,8$  мм рт. ст.,  $p = 0,13$ ) – в групі епірубіцину. Лікування паклітакселом не призводило до достовірного підвищення АТ у пацієток обох груп. Немедикаментні заходи суттєво не впливали на зміни АТ під час ПХТ антрациклінами в комплексі з циклофосфамідом у більшості обстежених.

**Висновки.** Поліхімієтерапія антрациклінами у поєднанні з циклофосфамідом супроводжується достовірним підвищенням середніх показників артеріального тиску після процедур. Інфузії паклітакселу не супроводжувались достовірними змінами середніх показників артеріального тиску під час процедур. Немедикаментних заходів замало для корекції підвищеного артеріального тиску під час поліхімієтерпії у більшості пацієток.

**Ключові слова:** рак молочної залози, підвищений артеріальний тиск, антрацикліни, паклітаксел, хімієтерапія.

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