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# Remote Monitoring of the QT Interval During Polychemotherapy

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| *Aim* | To evaluate the incidence of prolonged corrected QT interval (QTc) by remote single-channel electrocardiogram (ECG) monitoring in primary oncological patients with elective polychemotherapy (PCT). |
| *Material and Methods* | This study included 49 oncological patients with elective PCT. A single-channel portable CardioQVARK electrocardiograph was used to record single-channel, one-lead ECG between the first and second courses of PCT. |
| *Results* | Analysis of QTc interval detected a prolonged QTc interval >500 msec in 8.2% of cases, prolonged QTc > 480 msec in 18.3% f cases, and prolonged QTc interval >60 msec compared to baseline in 12.2% of cases. |
| *Conclusion* | Remote recording of single-channel ECG using a portable electrocardiograph is an effective method for recording and detecting various forms of heart rhythm disorders. |

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| *Keywords* | Chemotherapy; cardiotoxicity; prolonged QT interval; remote single-channel electrocardiogram |
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## Introduction

Survival rates of cancer patients have grown significantly as chemotherapy treatments have evolved. However, cardiovascular complications associated with anticancer therapy are becoming more clinically significant and are one of the causes of death [1]. The incidence and intensity of cardiotoxicity vary widely and depend on applied regimens and classes and doses of administered chemotherapeutic drugs [2].

Cardiotoxicity manifests among other disorders with arrhythmias, such as tachyarrhythmia and bradyarrhythmia, supraventricular and ventricular arrhythmias, conduction disorders, particularly, QT prolongation in electrocardiogram (ECG) [3]. QT prolongation causes ventricular arrhythmias, including polymorphic ventricular tachycardia, the so-called torsade de pointes. The clinical picture varies from minimal symptoms, such as irregular heartbeats, to sudden cardiac death (SCD) [4].

Anticancer drugs of different classes can cause QT prolongation. These include arsenic trioxide, anthracyclines, antimetabolites, tyrosine kinase inhibitors, histone deacetylase inhibitors, and protein kinase C inhibitors [5]. However, QT prolongation in ECG can be nonspecific when chemotherapy drugs are administered and can be caused by metabolic imbalance and depend on cardiotoxicity risk factors (RFs). The 2016 ESC Position Paper on cancer treatments and cardiovascular toxicity identified curable RFs (electrolyte imbalance, particularly, hypokalemia (≤ 3.5 mEq/L), hypomagnesemia (≤ 1.6 mEq/L), and hypokalemia (≤ 8.5 mEq/L)) and non-curable RFs (familial history of SCD, elderly age, female sex, myocardial infarction, severe kidney and liver dysfunction) [6].

The corrected QT interval (QTc) is commonly determined by the Bazett formula ($QTc = QT/\sqrt{RR}$ in heart rate (HR) of 60–100 bpm) or the Frederick formula ($QTc=QT/3\sqrt{RR}$ in HR of < 60 bpm and > 100 bpm) [7]. In the ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of SCD, QTc intervals of > 450 ms for male patients and > 460 ms for female patients are considered the upper limit of normal for the baseline electrocardiography [8]. QTc prolongation of > 500 ms and/or a change from the baseline interval by > 60 ms is a predictor of life-threatening arrhythmias. In case of QTc prolongation of > 500 ms or by > 60 ms from the baseline, anticancer treatment should be discontinued, and possible predisposing factors should be eliminated [6, 7].


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It is not known for sure whether monitoring is needing to detect QT prolongation at baseline in cancer patients. However, outpatient ECG monitoring is extremely difficult during chemotherapy treatment. Digital technology is being actively implemented in medicine, including remote monitoring of patients, for example, using smartphones. Moreover, the possibility of their use in different areas is actively studied: QT interval monitoring, heart rhythm in paroxysmal atrial fibrillation (AF), systolic myocardial function, blood pressure [9–11]. Using smartphones to record ECGs for the QT interval measurement is quite effective. Garabelli et al. [12] demonstrated a high sensitivity of QTc interval determination compared to standard ECG recording in patients with sinus rhythm.

A Russian study was published, in which the single-channel electrocardiograph CardioQVARK was shown to be effective in patients receiving anti-tuberculosis chemotherapy for the detection of QT prolongation [13].

Given the above, a study is conducted in the University Clinical Hospital No. 1 under the Sechenov University to monitor cardiac arrhythmias and conduction disorders in cancer patients.

## Objective

Estimate of the frequency of QTc prolongation using remote single-channel ECG monitoring in primary cancer patients with scheduled polychemotherapy.

## Material and Methods

This study is an analytic part of the open-label, prospective, interventional trial including 49 cancer patients with scheduled polychemotherapy admitted to the anticancer treatment department the University Clinical Hospital No. 1 under the Sechenov University. The study was conducted following the Good Clinical Practice and the Declaration of Helsinki. The study protocol was approved by the local ethics committee (Minutes #34–20 dated 09/12/2020). All patients signed the informed consent form before being included in the study.

*Inclusion criteria*: age of 18 years and older; signed informed consent; scheduled polychemotherapy.

The study did not include patients who received radiation therapy; patients with initially arrhythmias and/or conduction disorders, including complete right or left bundle branch block; patients with upper limb motor dysfunction; patients with dementia; patients with severe hepatic and/or renal failure; patients with a minimum life expectancy of less than 1 month; pregnant patients.

*Exclusion criteria*: withdrawal of informed consent; poor-quality single-channel ECG recording with the CardioQVARK device (hand tremor, movement during ECG recording, ECG record of less than 1 min); inadequate records and/or of poor quality for QTc analysis; polychemotherapy intolerance due to noncardiac cause.

The endpoint was to record prolongation of QTc interval of >500 msec and/or by >60 msec from the baseline.

The study design is shown in Figure 1.

The collected data were processed using Python v 3.8. The distribution of quantitative indicators was estimated using the Shapiro-Wilk test; the mean values and the standard deviations or the medians and the interquartile ranges were used depending on the type of data distribution. The percentages and absolute values were determined for the categorical and qualitative variables. Comparative analysis of normally distributed quantitative variables was performed using the Welch t-test (between 2 groups) or ANOVA (between more than 2 groups) followed by pairwise group comparison, and the Mann-Whitney U-test (between 2 groups) or the Kruskal-Wallis test (between more than 2 groups) were used for non-normally distributed quantitative variables. The comparative analysis of categorical and qualitative data was conducted using Fisher's exact test. The differences were statistically significant with p value being less than 0.05.

The influence of factors on the endpoint was assessed using the LASSO regression algorithm. Categorical factors are represented as binary variables (one-hot-encoding), quantitative traits are normalized. The above procedures allowed determining the standardized coefficients for each factor and select the largest in absolute values. The LASSO regression algorithm allowed us to set coefficients to 0 for the factors with little effect on the endpoint variability.

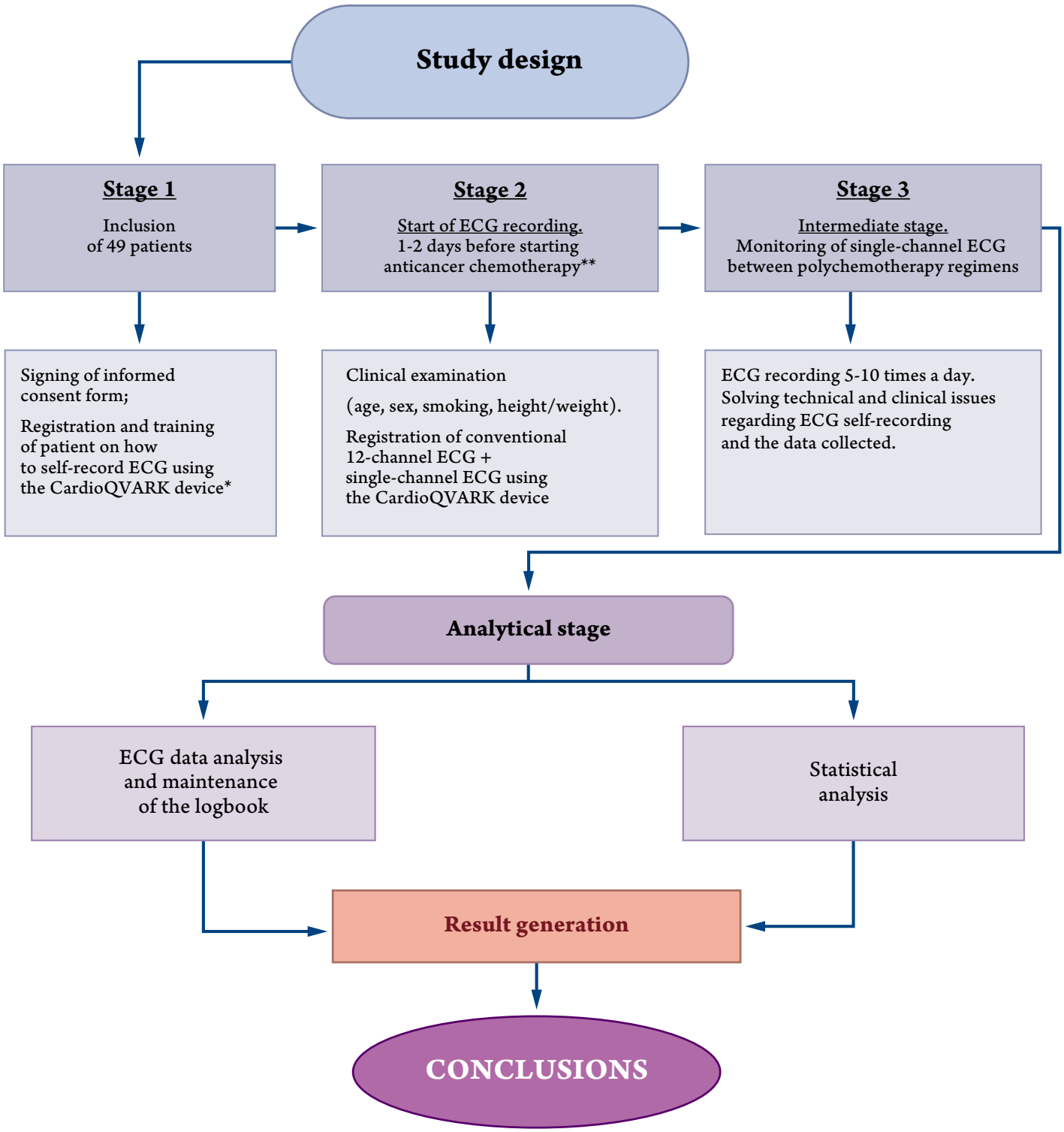
## Results

Characteristics of the study subjects are detailed in Tables 1–3.

QTc interval in 1 minute single-channel ECGs recorded using the CardioQVARK electrocardiograph was analyzed in 49 patients between the first and second regimens of polychemotherapy: the minimum number of ECG records per patient was 20, a mean of 46 records per patient was analyzed. Mean QTc prolongation was 27.9 ms. QTc interval of > 500 msec was detected in 8.2% of cases, QTc interval of > 480 msec in 18.3%, and QTc prolongation by >60 msec compared to the baseline in 12.2% of cases.

QTc interval of >500 msec was recorded in 4 (8.2%) patients (Table 4), 2 patients of this group had QTc interval prolonged by >60 msec compared to the baseline. Patients in this group were statistically significantly older (p=0.027). QT prolongation was significantly more often detected in patients with type 2 diabetes mellitus (DM) and higher blood glucose levels before chemotherapy (p=0.002 and p=0.023, respectively). In this group, patients had esophageal cancer, bladder cancer, gastric cancer, and soft

**Figure 1.** Дизайн исследования




* 1-min single-channel ECGs were recorded in all patients using the CardioQVARK cardiomonitor. The CardioQVARK device is a portable electrocardiograph in the form of a smartphone case used to record data on the bioelectric activity of the heart in standard lead I with possible data transfer to a remote server. It should be noted that QTc intervals are not the same in different leads. Historically, QT interval duration is measured in standard lead II and leads I and aVF [14]. The 2009 AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram propose measuring QT interval with the largest QT interval (V2, V3) [15]. The comparison of QTc intervals measure by the conventional 12 lead ECG and single-channel ECG (CardioQvark) was conducted by two independent functional diagnosticians.

** The CardioQVARK electrocardiograph was handed out to each included patient for outpatient ECG self-recording in the period between the first and second polychemotherapy regimens.

*** The period between regimens is determined by the anticancer treatment standard recommended by experts of oncology communities and varies depending on anticancer regimen; it was 14–21 days in our study.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tissue sarcoma and received TPF, GemCis, FLOT, and AI regimens. The percentage of chemotherapy was distributed in this group as follows: docetaxel – 20%, cisplatin – 20%, 5 fluorouracil – 20%, doxorubicin – 10%, ifosfamide – 10%, gemcitabine – 10%, oxaliplatin – 10%. It should be noted that each of the four polychemotherapy regimens included a chemotherapeutic agent of the antimetabolite group (5 fluorouracil, ifosfamide, gemcitabine).

QTc interval of > 480 msec was recorded in 9 (18.3%) patients (Table 4), 4 of whom had QTc interval prolongation by >60 msec. As in the QTc >500 msec group, the prolongation of the QTc interval in this group was statistically significantly more common in patients with type 2 DM (p=0.037). Attention is drawn to a significant QTc prolongation in patients with bladder cancer who received the GemCis regimen (p=0.031). The percentage of chemotherapy was distributed in this group as follows: docetaxel – 14.3%, cisplatin – 14.3%, 5 fluorouracil – 14.3%, capecitabine – 9.5%, oxaliplatin – 19%, gemcitabine – 9.5%, doxorubicin – 9.5%, ifosfamide – 4.8%, cyclophosphamide – 4.8%.

In the follow-up period, 3 new-onset AF paroxysms of > 30 seconds were detected in patients with (6.3%) under TPF and XELOX chemotherapeutic regimens. High-grade ventricular extrasystoles were not detected.

The univariate regression analysis identified the RFs associated with QTc prolongation of > 500 msec, including statistically significant risk factors (hazard risk (HR) 1.15; 95% confidence interval (CI) 0.99–1.33; p<0.05): pre-polychemotherapy QTc interval (HR 1.09; 95% CI 1.01–1.17; p<0.01), fasting glucose levels (HR 8.19; 95% CI 1.20–55.5; p<0.05), type 2 DM (HR 64.49; 95% CI 4.46–931.8; p=0.002), a history of chronic heart failure and/or cardiac disorder (coronary artery disease, postinfarction cardiosclerosis) (HR 9.1; 95% CI 0.97–84.72; p=0.05), presence and/or onset of AF during polychemotherapy (HR 13.6; CI 1.39–134.1; p=0.025).

The univariate regression analysis determined RFs associated with QTc prolongation of > 480 ms,

**Table 1.** Baseline patient characteristics (n=49)

| Parameter | Value |
|---|---|
| Age, years | 62.0 ± 10.8 |
| **Sex, n (%)** | |
| Male | 23 (46.9) |
| Female | 26 (53.1) |
| Smoking, n (%) | 21 (42.9) |
| **BMI, kg/m²** | |
| Normal weight (BMI 18.5–24.9 kg/m²), n (%) | 14 (28.6) |
| Overweight (BMI 25.0–29.9 kg/m²), n (%) | 21 (42.9) |
| Obesity stage I (BMI 30.0–34.9 kg/m²), n (%) | 14 (28.6) |
| Hypertensive heart disease, n (%) | 25 (51.0) |
| Atrial fibrillation, n (%) | 2 (4.1) |
| Chronic heart failure and/or cardiac diseases (CAD, PICS), n (%) | 12 (24.5) |
| Diabetes mellitus type 2*, n (%) | 5 (10.2) |
| Drug therapy for cardiovascular diseases, n (%) | 14 (28.6) |
| Creatinine, μmol/L | 82.9 ± 21.2 |
| Glucose, fasting, mmol/L | 5.8 ± 0.7 |

The data are expressed as the means and standard deviations (M±SD), if not otherwise specified. BMI, body mass index; PICS, postinfarction cardiosclerosis. * Patients received continuous glucose-lowering therapy prescribed by endocrinologist

**Table 2.** Localization of tumor and polychemotherapy regimen

| Tumor localization | Number of patients | Tumor detection rate, % | Polychemotherapy regimen | Frequency of administration of the corresponding polychemotherapy regimen, % |
|---|---|---|---|---|
| Lungs | 3 | 6.1 | EP[1] | 6.1 |
| Stomach | 3 | 6.1 | FLOT[2] | 6.1 |
| Pancreas | 4 | 8.2 | FOLFIRINOX[3] | 8.2 |
| Oral cavity | 2 | 4.1 | PF[4] | 4.1 |
| Esophagus | 4 | 8.2 | TPF[5] | 8.2 |
| Intestine (rectosigmoid) | 15 | 30.6 | XELOX[6]<br>FOLFOX[7]<br>FOLFIRI[8] | 16.2<br>8.2<br>6.2 |
| Urinary bladder | 2 | 4.1 | GemCis[9] | 4.1 |
| Breast | 12 | 24.4 | AC[10] | 24.4 |
| Soft tissue sarcoma of lower limb including hip | 3 | 6.1 | AI[11] | 6.1 |
| Body of uterus | 1 | 2.1 | PC[12] | 2.1 |

[1] etoposide + cisplatin; [2] docetaxel + oxaliplatin + 5 fluorouracil; [3] irinotecan + 5 fluorouracil + oxaliplatin; [4] cisplatin + 5 fluorouracil; [5] docetaxel + cisplatin+ 5 fluorouracil; [6] oxaliplatin + capecitabine; [7] oxaliplatin + 5 fluorouracil; [8] irinotecan + 5 fluorouracil; [9] gemcitabine + cisplatin; [10] doxorubicin + cyclophosphamide; [11] doxorubicin + ifosfamide; [12] paclitaxel + carboplatin.

**Table 3.** Frequency of administration of chemotherapeutic drugs Number of chemotherapeutic drugs used to treat patients in this study (n = 13)

| Chemotherapeutic agent | Percentage of an individual chemotherapeutic drug among the polychemotherapy regimens administered, % | n= number of patients receiving chemotherapeutic drugs |
|---|---|---|
| Docetaxel | 14.35 | 7 |
| Irinotecan | 14.35 | 7 |
| Paclitaxel | 2.05 | 1 |
| Carboplatin | 2.05 | 1 |
| Capecitabine | 16.4 | 8 |
| Etoposide | 6.15 | 3 |
| Oxaliplatin | 38.9 | 19 |
| Cisplatin | 22.5 | 11 |
| 5 fluorouracil | 41 | 20 |
| Gemcitabine | 4.1 | 2 |
| Doxorubicin | 30.7 | 15 |
| Cyclophosphamide | 24.6 | 12 |
| Ifosfamide | 6.15 | 3 |

including statistically significant risk factors: QTc before polychemotherapy (HR 1.10; 95% CI 1.03–1.17; p = 0.003), type 2 DM (HR 9.49; 95% CI 1.30–69.19; p = 0.026).

## Discussion

The world literature details the effect of chemotherapeutic agents of our interest on the likelihood of electrophysiological changes, including a wide range of arrhythmias, such as QTc prolongation and AF, the incidence of which varies from 16% to 36% [3, 4].

The actual incidence of QTc prolongation induced by anticancer drugs is unknown and may be underestimated. In the systematic review of 173 papers by Porta-Sánchez et al. (2017) [4], the incidence of QTc prolongation ranged from 0% to 22%.

Comparable data are published in the Russian literature in the review by Vasyuk et al. [16], who showed that QT prolongation associated with chemotherapy occurs in 3–20% of patients.

**Table 4.** Incidence of QTc prolongation in primary cancer patients under the first polychemotherapy regimen

| Parameter | QTc prolongation > 500 ms (n = 49) | | | QTc prolongation > 480 ms (n = 49) | | |
|---|---|---|---|---|---|---|
| | Patients without QTc prolongation | Patients with QTc prolongation | p | Patients without QTc prolongation | Patients with QTc prolongation | p |
| Patients, n (%) | 45 (91.8) | 4 (8.2) | – | 40 (81.6) | 9 (18.4) | – |
| Age, years | 61.04 ± 10.6 | 73.0 ± 5.79 | 0.027 | 60.67 ± 10.52 | 68.0 ± 9.96 | 0.085 |
| **Sex** | | | | | | |
| • Male, n (%) | 21 (46.7) | 2 (50.0) | 1.000 | 19 (47.5) | 4 (44.4) | 1.000 |
| • Female, n (%) | 24 (53.3) | 2 (50.0) | 1.000 | 21 (52.5) | 5 (55.6) | 1.000 |
| Smoking, n (%) | 19 (42.2) | 2 (50.0) | 1.000 | 18 (45.0) | 3 (33.3) | 0.714 |
| Hypertensive heart disease, n (%) | 24 (53.3) | 1 (25.0) | 0.099 | 22 (55.0) | 3 (33.3) | 0.436 |
| Cardiac disorders*, n (%) | 9 (20.0) | 3 (75.0) | 0.099 | 8 (20.0) | 4 (44.4) | 0.436 |
| Diabetes mellitus type 2, n (%) | 2 (5.0) | 3 (75.0) | 0.002 | 2 (5.0) | 3 (33.3) | 0.037 |
| Glucose at baseline, fasting, mmol/L | 5.71 ± 0.69 | 6.59 ± 0.4 | 0.023 | 5.74 ± 0.69 | 5.97 ± 0.79 | 0.459 |
| Creatinine at baseline, baseline, μmol/L | 82.55 ± 21.87 | 86.25 ± 9.68 | 0.281 | 83.68 ± 22.48 | 79.2 ± 13.27 | 0.979 |
| HR before polychemotherapy, bpm | 73.87 ± 8.21 | 67.75 ± 6.76 | 0.170 | 74.17 ± 8.14 | 69.78 ± 7.87 | 0.544 |
| HR after polychemotherapy, bpm | 83.87 ± 10.69 | 81.25 ± 13.5 | 0.762 | 82.31 ± 10.92 | 83.9 ± 10.69 | 0.915 |
| Atrial fibrillation, n (%) | 3 (6.8) | 2 (50.0) | 0.049 | 3 (7.7) | 2 (22.2) | 0.231 |
| **Cancer, n (%)** | | | | | | |
| • Esophageal cancer | 3 (6.7) | 1 (25.0) | 0.297 | 3 (7.5) | 1 (11.1) | 0.569 |
| • Pancreatic cancer | 4 (8.8) | 0 | 1.000 | 4 (10.0) | 0 | 1.000 |
| • Intestinal cancer | 15 (33.4) | 0 | 0.298 | 13 (32.5) | 2 (22.2) | 0.702 |
| • Lung cancer | 3 (6.7) | 0 | 1.000 | 3 (7.5) | 0 | 1.000 |
| • Bladder cancer | 1 (2.3) | 1 (25.0) | 0.158 | 0 | 2 (22.2) | 0.031 |
| • Breast cancer | 12 (26.6) | 0 | 0.560 | 11 (27.5) | 1 (11.1) | 0.420 |
| • Soft tissue sarcoma | 2 (4.4) | 1 (25.0) | 0.230 | 2 (5.0) | 1 (11.1) | 0.464 |
| • Gastric cancer | 2 (4.4) | 1 (25.0) | 0.230 | 1 (2.5) | 2 (22.2) | 0.083 |
| • Oral cancer | 2 (4.4) | 0 | 1.000 | 2 (5.0) | 0 | 0.569 |
| • Uterine cancer | 1 (2.3) | 0 | 1.000 | 1 (2.5) | 0 | 1.000 |

The data are expressed as the means and the standard deviations (M ± SD), if not otherwise specified. HR, heart rate, * cardiac disorder: CAD, PICS, chronic heart failure. CAD, coronary artery disease; PICS, postinfarction cardiosclerosis.


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Our findings are consistent with the world literature: QTc interval of > 500 msec in 8.2% of cases, QTc interval of > 480 msec in 18.3%, and QTc prolongation by >60 msec compared to the baseline in 12.2% of cases.

At the same time, cardiovascular diseases (CVDs) are closely correlated with DM. CVDs are the leading cause of death and disability in patients with DM [17]. The risk of developing CVDs increases as fasting plasma glucose levels elevate, even before reaching the levels used for diagnosing DM [18]. Many patients with DM have QTc prolongation and other electrocardiographic markers of abnormal repolarization and the risk of arrhythmic death, such as T-wave microvoltage abnormalities [19]. Esins et al. [20] showed in their study the role of glycated hemoglobin and DM in the increased risk of QTc prolongation: the frequency of detecting transient QTc prolongation was 77% in patients with type 1 DM. The levels of glycated hemoglobin of > 7% were associated the average daily QTc prolongation by 10.8 ms male patients and by 4.72 ms in female patients.

In our study, the incidence of QTc prolongation in patients with DM was 75% in the group of QTc prolongation of >500 ms and 33% in the group of QTc prolongation of >480 ms, which correlates with the data published in the world and Russian literature.

### *Limitations*

ECG recording mainly depended in this part of the study on the mental and physical capabilities of the patients.

Conduction disorders, such complete right or left bundle branch blocks, were not evaluated in our study, since there is no data in the world literature on the reliability of the analysis of QTc prolongation in combination with complete bundle branch block using a portable electrocardiograph and a smartphone.

Levels of glycated hemoglobin were not estimated in our study.

The effect of drugs used in the treatment of CVDs was not assessed in this part of our study.

## Conclusions

1. Combination anticancer regimens increase the risk of cardiac arrhythmias and electrophysiological changes in the electrocardiogram.
2. Remote recording of single-channel electrocardiogram using a portable electrocardiograph is an effective method of recording and identifying various cardiac arrhythmias.
3. Patient age, diabetes mellitus, and elevated blood glucose levels are risk factors for QTc prolongation and cardiovascular complications in cancer patients.

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*No conflict of interest is reported.*

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