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Clinical and Demographic Characteristics of Patients Included in the Registers

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Abstract Sudden cardiac death (SCD) as an irreversible outcome and the result of sudden cardiac arrest reaches 50% among other outcomes in persons 35–50 years old, predominantly male, but recently there has been a tendency to increase the proportion of females, as well as adolescents and young adults. The risk of sudden cardiac death is higher in men and increases with age due to the higher prevalence of coronary artery disease among older people. The number of cases of SCD ranges from 1.4 per 100 thousand person-years (95% CI - 0.95-1.98) in women to 6.68 per 100 thousand person-years (95% CI - 6.24 –7.14) in men. The number of cases of SCD among the younger generation is 0.46–3.7 per 100 thousand person-years, which translates into 1100–9000 deaths in Europe and 800–6200 deaths in the United States each year. Data on the prevalence of SCD in Uzbekistan are limited, including the peculiarities of SCD registration in different countries.

Keywords Arrhythmia, Antithrombotic therapy, Coronary heart disease

1. Annotation

Myocardial infarction is the most frequent cause of the development of rhythm disorders. Structurally, myocardial infarction is characterised by prolonged ischaemia of a single section of heart muscle, the causes of origin of which may be atherothrombotic coronary artery disease, coronary embolism, coronary spasm, prolonged tachyarrhythmia, blood loss, severe anaemia or respiratory failure [3,5]. Ultrastructural changes begin to occur at the 10th minute (has been determined in the human ischemic heart), and include glycogen depletion, myofibril relaxation, sarcolemma rupture, functional abnormalities of mitochodria, and others; these changes are followed in the next few hours by necrosis and programmed types of cell death such as apoptosis and autophagy [2,6].

During ischaemia, the absence of oxygen by one mechanism leads to suppression of oxidative phosphorylation in mitochondria, which is restored by reperfusion of the ischaemic site, but there is also an abrupt release of reactive oxygen species originating from complex I in the electron transport chain. Succinate increases the respiration associated with complex II succinate dehydrogenase, possibly causing an overload of the capacity of the electron transport system and triggering a reverse electron transport to complex I and a further increase in the generation of reactive oxygen species. These phenomena contribute to further mitochondrial dysfunction and damage, which causes cardiomyocyte death and aggravation of myocardial damage [1,7].

Restoration of blood supply to the ischemic area causes dramatic biochemical and metabolic changes that cause ischemia-reperfusion injury based on excessive production of reactive oxygen species, opening of mitochondrial permeability transition pores, decreased ATP production, release of pro-inflammatory signalling molecules, induction of apoptosis and other types of programmed cell death, and other mechanisms [7,9]. Unfavourable consequences of ischemia-reperfusion injury development may include myocardial stagnation and hibernation, phenomenon of no blood flow recovery, ventricular arrhythmias, contractile dysfunction and lethal reperfusion injury. Lethal reperfusion injury represents an additional inducer of cell death distinct from ischaemic injury [8]. In turn, cardiomyocytes possess molecular mechanisms, the induction of which increases their resistance to ischaemic-reperfusion injury - cardioprotection [2,3].

2. Materials and Methods

The work was structured in several stages. At the first stage, data from international and national registers of

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patients with cardiac rhythm disorders were analysed. For this purpose, a search was performed in PubMed and MEDLINE search engines, using the following keywords: arrhythmia, coronary heart disease, rivaroxaban, dabigatran, warfarin, atrial fibrillation, new oral anticoagulants, direct oral anticoagulants, arrhythmia, coronary heart disease, real clinical practice, Rivaroxaban, Dabigatran, Apixaban, Warfarin, atrial fibrillation, new oral anticoagulants (NOACs), direct oral anticoagulants (DOACs). Registries included in the analysis had to fulfil the following criteria: international and national registries of patients with cardiac rhythm disturbances resulting from myocardial ischaemic injury and including information on the presence of antiplatelet therapy. The retrieved studies were analysed according to the following criteria: design, number and characteristics of included patients, risk stratification for stroke, antithrombotic therapy administered.

At the second stage, a retrospective pharmacoepidemiological study was conducted to investigate the pharmacoepidemiology of antithrombotic therapy in heart rhythm disorders. The object of the continuous retrospective pharmacoepidemiological study were medical records of inpatients (form 003/u) with the diagnosis of 'Atrial fibrillation' (ICD-10 code - I48), consecutively admitted to the cardiology department of the MU of Samarkand and Ufa. It was decided to focus on this category of patients due to the high frequency of thromboembolic complications in this group and the highest incidence among other manifestations of rhythm disorders. At this stage, 382 case histories of inpatients were included in the analysis. Inclusion criteria: age of patients older than 18 years, established diagnosis of atrial fibrillation (ICD-10: I48.0, I48.1, I48.2) of ischaemic genesis. Exclusion criteria: Cardiomyopathies of non-ischaemic genesis (I42- I43 according to ICD-10), thyrotoxicosis (E05 according to ICD-10), congenital heart defects (I34- I36 according to ICD-10), rheumatic heart lesions (I01, I05-I09 according to ICD-10), acute coronary syndrome (I20-I24 according to ICD-10), endocarditis (I33 according to ICD-10), myocarditis (I40-I41 according to ICD-10), pericarditis (I30-I32 according to ICD-10), pulmonary embolism (TELA) (I26 according to ICD-10).

For comparison with the indicators of the haemostasis system of healthy volunteers and patients with thrombosis, a sample of patients (n=100) staying in the cardiology department of GBUZ RKB named after G.G. Kuvatov and a control group of healthy volunteers (n=50) was formed, which did not differ in the main criteria from the patient groups. Table 1 presents demographic and clinical parameters of patients included in the prospective part of the study.

3. Result

Clinical and demographic data of patients included in the international registries AFNET, ATRIUM, GLORIA-AF are presented in Table 2.

From the data in Table 2 it is clear that there is no difference in the clinical picture and demographic data presented in the patient registries. The risk of developing thromboembolic complications in patients with atrial fibrillation in the AFNET registry was assessed using the CHADS2 scale, in ATRIUM and GLORIA-AF using the CHADS2 and CHADS2DS2-VASc scales. The mean CHADS2 score was higher in the AFNET registry compared with ATRIUM and GLORIA-AF.

Clinical and anamnestic data of patients included in the international registries GARFIELD-AF, ORBIT-AF I and II are presented in Table 3.

The fundamental difference between the two groups of registers is the fact of the introduction of oral anticoagulants into clinical practice. In all registers, after the introduction of anticoagulants into practice, the risk of developing TEC was assessed using the CHADS scale2DS2-VASc. The analysis showed that the majority of patients with a high risk of thromboembolic complications due to cardiac arrhythmias were in the ORBIT-AF I registry.

Table 1. Clinical and demographic characteristics

Characteristic	Patients in total n=250	Healthy control group, n=50	CAG control group, n=100	R	IHD group with rhythm disturbance, n=100	R
Age, years	58.7±7.4	56.2±8.1	56.9±8.7	0.94	56.1±7.6	0.64
Male gender, abs (%)	97 (38.8)	17 (34.0)	35 (35.0)	0.75	35 (35.0)	0.87
Concomitant pathology of abs (%)						
Diabetes	16 (6.4)	4 (8.0)	6 (6.0)	0.92	6 (6.0)	0.78
Smoking	19 (7.6)	4 (8.0)	7 (7.0)	0.79	8 (8.0)	0.45
Oncology	4 (1.7)	0 (0.0)	2 (2.0)	0.34	2 (2.0)	0.57
Arterial hypertension	4 (1.7)	0 (0.0)	2 (2.0)	0.63	2 (2.0)	0.77
COPD	2 (0.8)	0 (0.0)	1 (1.0)	0.74	1 (1.0)	0.93

Note: p – level of statistical significance in comparison with the control group, CAG – coronary angiography.

Table 2. Clinical and anamnestic data of patients with cardiac arrhythmias in the international registries AFNET, ATRIUM, GLORIA-AF

Index	Register name		
	AFNET (n=9545)	ATRIUM (n=3163)	GLORIA-AF (n=1063)
Patient Demographics			
Average age, years	67±13	71.9±9.2	70
Men, %	60.9	57.9	54.3
History of cardiovascular complications			
Ischemic stroke	5.8	10	10.3
TIA	2.8	10	-
THEM	-	-	9.3
System thromboembolism	-	-	-
Accompanying illnesses			
IHD	25.4	34.5	24.1
AG	69.3	83.6	74.8
DM type 2	21.7	35.1	22.6
Risk of TEC and hemorrhagic complications			
$CHADS_2$,GPA	3.7	2.2	2.0
$CHADS_2$D.S.2-VASc,GPA	-	3.8	3.0

Table 3. Clinical and anamnestic data of patients with cardiac arrhythmias in the international registries GARFIELD-AF, ORBIT-AF I and II

Index	Register name		
	GARFIELD-AF (n=51270)	ORBIT-AF I (n=10132)	ORBIT-AF II (n=11602)
Patient Demographics			
Average age, years	69.7	73.5	70.3
Men, %	55.8	57.6	58.4
ONMK			
Ischemic Stroke	11.4	15.1	10.8
Accompanying illnesses			
IHD	19.4	36	26.6
AG	76.3	83	79.6
DM type 2	22.1	29.4	26.2
Risk of TEC and hemorrhagic complications			
$CHADS_2$D.S.2-VASc=0	2.8	2.2	4.1
$CHADS_2$D.S.2-VASc=1	12.2	7	10.9
$CHADS_2$D.S.2-VASc≥2	85	90.8	85
HAS-BLED<3	88.8	75.7	85

The average age of patients in all registers of the Russian Federation corresponded to the data of European registers. However, it should be noted that the frequency of atrial fibrillation of ischemic etiology in Russian registries and on the territory of the Republic of Uzbekistan is dominant and amounts to more than 95%, while in European registries IHD is recorded in only a third of patients. The most common Cardiac comorbidity in patients with cardiac arrhythmias, regardless of country of residence, is hypertension, which occurs in almost every patient.

The data obtained in international multicentre registries are close to the PROFILE register, where the registration rate of CHD, CHF and AH was 36.4%, 30.3% and 75.7%, respectively.

The incidence of stroke and TIA in the history of patients with cardiac rhythm disturbances in PROFILE did not exceed 15%, which corresponds to the data on the incidence of TEE in the history in international registers. When assessing the risk of TEE development according to the CHA2DS2- VASc scale in the registers REQUASA, REQUASA-Clinic, REQUASA-Kursk, PROFILE, it was revealed that almost all patients with LDC included in the registers had indications for prescription.

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