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## COMPARISON OF GENERAL CLINICAL DATA FROM TWO INDEPENDENT REGISTERS AMONG MALE SUBJECTS IN ONE AREA TASHKENT CITY

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### SUMMARY

The register is an organized system for collecting information about patients with specific diseases. Functions of registers on acute coronary diseases allow using them to characterize therapeutic approaches and assess their quality. It is with the help of registers that help to identify the status and deficiencies in the management of patients at individual stages of specialized care, you can see the most optimal ways to improve the quality of treatment. Carrying out registers and estimation of their dynamics for today are poorly covered in the literature, and in this connection we conducted a comparative analysis of the database of two independent registers (in 2009 and 2015) in one of the districts of Tashkent (a total of 894 patients with acute coronary syndrome and acute myocardial infarction).

The analysis revealed that the incidence of ACS/AMI in the 2nd register among men younger than 40 years decreased, but the number of obese individuals increased. In the 2nd register, the number of men with HR > 90 beats/min decreased, but the

mean values of blood pressure increased. Among men with ACS/AMI, an increase in the level of triglycerides of blood was registered in the 2nd register, but the percentage of men with hypertriglyceridemia was less. In the 2nd register, the number of troponin determinations has increased, which indicates an increase in the coverage of laboratory studies. The results of the 2nd register on ACS/AMI among males revealed a significant increase in the groups of drugs used in the treatment, not only those included in the basic therapy of IHD, but also the main ones in the treatment of ACS/AMI, which indicates positive qualitative shifts in treatment acute cardiac pathology.

Thus, the use of the population methodologies of the Registers allows the creation of a program for predicting the outcome of the disease, and also to improve the volume and quality of medical care, taking into account individual risk factors and the potential of their interrelationships

**Keywords:** *acute coronary syndrome, acute myocardial infarction, male population, comparative analysis of two registers*

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## RELEVANCE

The term «acute coronary syndrome» (ACS) denotes a period of exacerbation of coronary heart disease (CHD), which is caused by damage to the coronary artery atherosclerotic plaque and the development of intracoronary thrombosis [1]. Typical signs of ACS are the clinical picture of acute myocardial infarction (AMI) with or without ST segment elevation and unstable angina (UA). The urgency of studying the problem is due, first of all, to the fact that ACS is one of the leading causes of mortality from cardiovascular pathology [2].

The epidemiological situation in the Republic of Uzbekistan regarding cardiovascular diseases (CVD) indicates a continuing stable trend of high rates of morbidity and mortality: CVD accounts for 59.1-59.3% of total mortality. The mortality from CVD to 91% is due to CHD and arterial hypertension (AH) in the form of their complications (AMI or cerebral stroke).

Correct and complete treatment of patients with ACS and AMI, described in the current guidelines (European Heart Journal 2008, European Heart Journal 2011) has allowed to significantly reduce inpatient mortality in recent years. At the same time, despite the efforts, the lethality from ACS and AMI in the CIS countries, including in Uzbekistan, remains high. Important reasons for this are the peculiarities in treatment of patients in general medical practice, which often do not comply with existing standards.

An especially important role in assessing the degree of adherence to treatment standards is played by specially organized studies - registers. In the literature in English, various registrational studies are called either «registry» or «survey». The English «registry» or «register» in Russian is translated as «registration», and «survey» is translated as «survey, questionnaire, review». A register is a cohort prospective epidemiological study that includes all persons with studied pathology in a separate region or in a population of a certain age and gender. The register is an organized system for collecting information about patients who have specific diseases, are in a certain state or are receiving/received specific treatment.

The functions of the registers on ACS/AMI allow using them to characterize treatment approaches and assess their quality, timeliness and completeness of using high-tech methods of treatment, isolating and evaluating additional risk factors (RF), forming new strategies for predicting disease outcomes. It is with the help of registers that help to identify deficiencies in the management of patients, it is possible to determine the most optimal ways to improve the quality of treatment [3-6]. However, carrying out of registers for the purpose of a comparative assessment of the dynamics of the state of the problem has not been sufficiently covered in the literature today. Relating to the aforementioned, the goal of this study was to make a comparative assessment of general clinical indicators among men with acute coronary syndrome (ACS) and acute myocardial infarction (AMI) according to two independent registers in one of the districts of Tashkent.

## STUDY MATERIAL AND METHODS

The material of the study was the electronic databases of patients' data that were created and processed in accordance with the developed protocol of the ACS/AMI register, hospitalized in treatment and prophylactic institutions in one of the districts of Tashkent with the diagnosis of ACS/MI (according to the data of service «03» and/or family polyclinics) or those who died from this pathology (according to the Bureau of Forensic Medical Examination and the Registry Office).

For the formation of the search and reference device, an alphabetic card index system was used, containing numbered

«Register Cards» for each examinee, with passport and objective data.

The results of 2 independent registers of ACS/AMI conducted in one of the districts of Tashkent in 2009 and 2015 were studied. The base of the 1st register was 464 (67.9%) men, the 2nd register - 430 (55.0%) men.

The analysis of patients with ACS/AMI in the course of conducting the register assumed the following conditions:

- Patients must meet the inclusion criteria;
- Patients voluntarily signed informed consent to include their data in the registry database;
- Participation of the patient should not influence the approaches to his therapy;
- Inclusion of the patient in the register should be accompanied by its registration in the register database with the filling in of the «Register card» for each patient.

### Inclusion criteria:

The register included patients aged 18 to 70 years who applied to the Emergency Call Service, hospitalized in the relevant hospitals for ACS/AMI.

- ACS and AMI were diagnosed on the basis of generally accepted criteria:
  - a) typical pain syndrome;
  - b) the appearance of a new Q wave on the ECG;
  - c) dynamics of the ST segment and the T wave on the ECG;
  - d) the dynamics of markers of myocardial damage (as the tests are carried out)

### Exclusion criteria:

The age is under 18 and over 70 years old.

Verification of the causes of death was carried out on the basis of the medical certificate of death according to ICD-10 and, if available, the data of the initial survey.

Statistical processing of data was carried out using methods of variation statistics with the calculation of arithmetic mean values, fraction and standard error, mode, median, coefficient of variation. To compare the qualitative parameters, the McNemar coefficient and  $\chi^2$  were used.

## STUDY RESULTS

According to the results of the analysis, it was found that in the 1st register the age of men was younger than in the 2nd register ( $p > 0.05$ ), which was probably due to a larger number of people under the age of 40 (7.3% and 2.9%, respectively, in 1 and in 2 registers,  $p < 0.05$ ). According to the height-weight parameters, in men in the 2nd register there was an increase in weight and, correspondingly, BMI (both  $p < 0.05$ ) (Table 1).

A more detailed analysis of patients by weight characteristics showed that in the 2nd registry the number of men with normal weight decreased by 3.1%, and with excess weight – by 6.3%, however, the number of patients with 1st stage obesity increased by 8.1%; with 2nd stage obesity. – by 0.7%; with 3rd stage obesity – by 0.6% (Figure 1).

Anamnestic data showed an increase in the number of patients with a previous myocardial infarction by 7.3%: 144 (31.1%) in 1st register and 165 (38.4%) in 2nd register ( $p = 0.044$ ,  $\chi^2 = 3.431$ )

After assessing the most frequently reported complaints, it was found that chest pain, dyspnea and weakness were more common in the 2nd register (all  $p < 0.001$ ). On the contrary, complaints about cold sweat and syncope in men with ACS/AMI in the 2nd registry were less often. Of note is the diagnosis of asymptomatic forms of ACS/AMI in 0.7% of cases, which were not recorded in the first register (table 2).

**Table 1. Comparative characteristics of men in two registers by age and height-weight parameters**

Factor	Men of the 1st register, (n=464)	%	Men of the 2nd register, (n=430)	%	p	x <sup>2</sup>
Age, years	56,05±9,53		57,26±8,59		<b>0,047</b>	
< 40 years	34	7,3	12	2,8	<b>0,004</b>	<b>8,505</b>
40-45 years	32	6,9	32	7,4	0,852	0,035
46-50 years	55	11,9	58	13,5	0,526	0,402
51-55 years	67	14,4	60	14,0	0,911	0,013
56-60 years	100	21,6	96	22,3	0,843	0,039
61-65 years	102	22,0	87	20,2	0,577	0,312
66-70 years	74	15,9	76	17,7	0,548	0,361
> 70 years	-	0	9	2,1	<b>0,005</b>	<b>7,823</b>
Weight, kg	81,84±10,08		83,51±11,22		<b>0,019</b>	
Height, cm	172,32±5,34		171,70±5,21		0,080	
BMI, kg/m <sup>2</sup>	27,59±3,35		28,38±3,74		<b>0,000</b>	

Note: n is the number of patients; BMI is the body mass index; p and x<sup>2</sup> – statistical significance of differences between groups

In the course of the study, we also analyzed bad habits, in particular smoking, and found that smoking decreased by 12.9% (p=0.044, x<sup>2</sup>=3.431) (figure 2).

Clinical and laboratory parameters of patients had the following characteristic. The number of men with heart rate (51-90 beats/min) increased by 4% (in percentage terms), while the number of patients with heart rate > 90 beats/min decreased by 1.7% (p<0.001). In our opinion, this phenomenon was caused by an increase in the admission of  $\beta$ -blockers, which will be discussed below. On the contrary, there was a tendency to increase of blood pressure. Namely, mean values of blood pressure increased: systolic blood pressure increased by 8.3 mm Hg. Art. (from 131.2±30.7 mm Hg to 139.6±28.8, p=0.001) and diastolic – by 0.7 mm Hg. Art. (from 84.31±60.04 mm Hg to 85.03±15.25 mm Hg, p=0.854). This is probably due to an increase in the number of people with obesity, as indicated above. In the distribution of patients according to the values of blood pressure, the following picture was observed (figure 3): the hypotension effect was attenuated by 6.9%, and the incidence of AH III degree increased by 6.2% (both p<0.05).

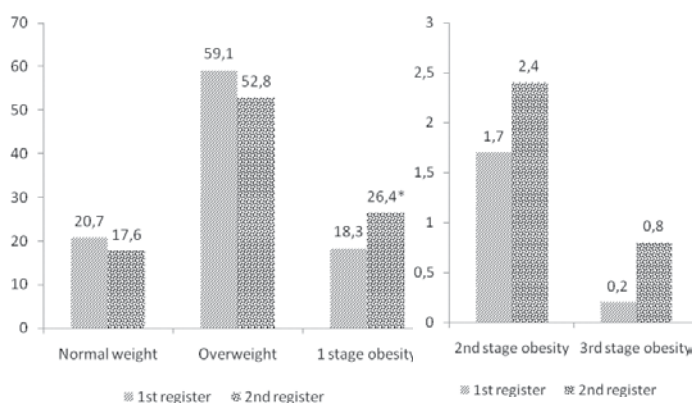
Of the concomitant nosologies, our attention was particularly focused on diabetes mellitus (DM), as one of the most important risk factors. From these positions it was revealed that the number of people with diabetes in the 2nd register, in comparison with the data of the 1st register, did not practically change (28.5% of patients in the 1st register and 27.9% of the patients in the 2nd register, p=0.966, x<sup>2</sup>=0.002). In the distribution of men in groups: patients taking hypoglycemic drugs, insulin-taking respondents,

and patients with newly diagnosed diabetes had a reduction of 5.3% (p=0.194, x<sup>2</sup>=1.687). In general, by groups, there was a decrease in the average blood glucose level from 7.06±3.38 mmol/l in 1 register, to 5.99±2.81  $\mu$ mol/l – in the 2nd register (p=0.026).

The evaluation of lipid metabolism included the determination of total cholesterol (TC) and triglyceride (TG) levels. It was found that hypertriglyceridemia prevailed in the 2nd register, rather than hypercholesterolemia, although the number of men with a high TG content was lower (32.5% in 2 registries versus 42.2% in 1 register, p>0.05). The average values of TC levels in men in the 1st register were higher than in the 2nd register, and the mean values of blood TG were on the contrary lower (table 3).

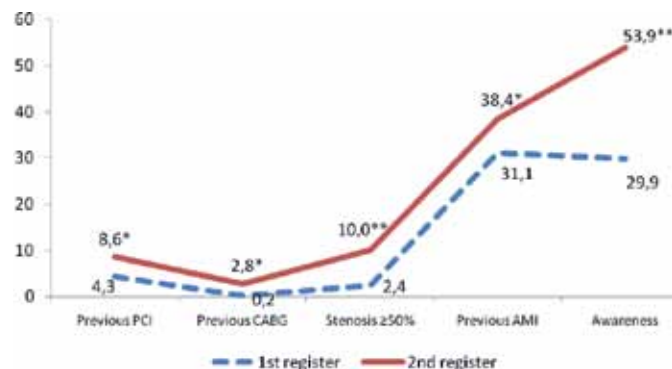
Comparison of hemoglobin level of blood (Hb) revealed a tendency for anemia development among men with ACS/AMI, mean values of Hb of blood in men of 2nd register was 119.56 g/l, which was 12.22 g/l less than in the 1st register. The revealed tendency, in our opinion, was caused by an increase in the number of patients with low Hb blood levels: 46.5% of men – in 2 registers versus 22.2% of men in 1 register (table 3).

Comparative evaluation of the two registers revealed an increase in the level of some markers of myocardial necrosis at the prehospital stage. In particular, early markers of necrosis, such as troponin T (TnT) and troponin I (TnI) in the 2nd register were determined in 6.5% and 9.6%, while in the 1st register, similar indicators were 2.3% and 8.1%; the determination of creatine phosphokinase-MB (CK-MB) in the 2nd register decreased to 3.6% of respondents, while in 5.4% of patients (in all p>0.05) was detected in 1 register.



**Figure 1. Comparison of data on the weight category among men of the 1st and 2nd registers**

Note: the data is presented as a percentage; \* - statistical significance of differences between groups at p<0.05.



**Figure 2. Anamnestic data of compared groups of patients**

Note: Data are presented as a percentage; \* - statistical significance of differences between groups at p<0,05; \*\* - statistical significance of differences between groups at p<0.001.

**Table 2. The most common complaints with ACS/AMI in a comparative aspect according to the data of two registers**

Factor	Men of the 1st register, (n=464)	%	Men of the 2nd register, (n=430)	%	p	$\chi^2$
Retrosternal pain	231	49,8	400	93,0	<b>0,000</b>	<b>198,87</b>
Dyspnea	152	32,7	338	78,6	<b>0,000</b>	<b>187,54</b>
Weakness	218	47,0	368	85,6	<b>0,000</b>	<b>145,53</b>
Cold sweat	107	23,1	78	18,1	0,083	3,00
Syncopes	6	1,3	3	0,7	0,578	0,309
Asymptomatic form	0	-	3	0,7	0,221	1,497

Continuity of patients to adhere to medical recommendations and taking medications was characterized by significant growth, in almost all types of groups of medicines. If aspirin,  $\beta$ -adrenoblockers, ACE inhibitors and nitrates were the most frequently used drugs in 1 register, in addition to these groups of drugs, clopidogrel (by 8.3%), angiotensin II receptor antagonists (by 4, 6%), as well as statins (by 11.5%), all  $p < 0.001$  (Table 4 and Figure 4).

## DISCUSSION

According to the literature [7-8], the incidence of myocardial infarction in the CIS countries is 3-4 people per 1000 population, and at the age of 40-49 years it is 2 per 1000; at the age of 50-59 years - 6 per 1000, at the age of 60-64 – already 17 people per 1000 population. In the results obtained by us, there was also an increase in the development of ACS/AMI as the age of the respondents increased in parallel in both compared registers.

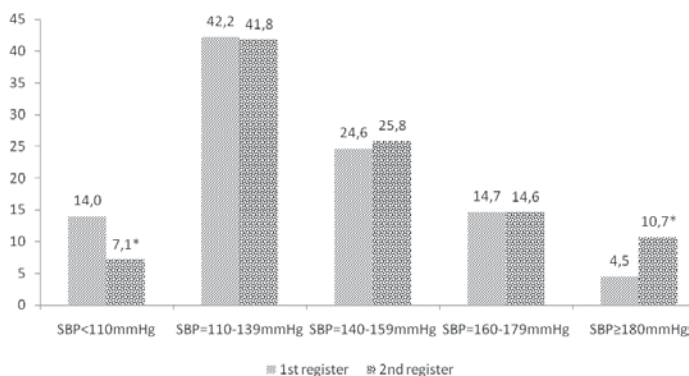
The mechanisms underlying the relationship between blood pressure and heart rate with cardiovascular mortality (CVM) have been studied poorly. Summarizing the results of several published studies, one can say that in none of them has the negative impact of increased heart rate on CVM been refuted. But is this influence always absolutely independent of other risk factors (RF)? Thus, in the work of A. Reunanen et al., who observed more than 10 thousand people for more than 20 years, the inclusion in the design model of blood pressure changed the statistical significance of the relationship between heart rate and CVM to the non-significant [9]. The researchers concluded that high heart rate is a reliable nonspecific predictor of mortality, but the increased risk of CVM should be explained by the relationship between heart rate and elevated blood pressure. The comparative results of the two registers obtained by us revealed a decrease in the number of men with increased heart rate by 1.7%, but the number of men with grade III AH increased by 6.2%. Thus, the

data obtained by us do not confirm the existence of a relationship between heart rate and AH in men with ACS/AMI. Initial findings about the disappearance of the relationship between increased heart rate and CVD/CVM after the amendment for other RF were made in the Chicago and Paris population studies [10]. A follow-up survey of a Chicago cohort 20 years later confirmed that for men aged 40-59 years, the heart rate is an independent predictor of CVD/CVM [11], which is in tune with our comparative analysis of two independent registries.

According to the literature data [12-13], the occurrence of diabetes as a comorbid state in ACS/AMI ranges from 17.8% to 19.1% of cases. The results of our registries have established that almost one-third (28.5% of patients in the 1st register and 27.9% of patients in the 2nd register) of patients with ACS/AMI have concomitant diabetes. However, in this study we were interested in the comparative aspect of two independent registers. From these positions it was revealed that the number of persons with the presence of diabetes in the 2nd register, in comparison with the data of the 1st register, practically did not change. Proceeding from this, it can be asserted that DM is an independent risk factor of the development of CHD, which accounts for 1/3 of all cases of acute coronary events.

Already in the first reports from the Framingham study, it was shown that in men aged 30-49 years with an TC level of less than 220 mg/dL, the risk of developing CHD was twice less [14]. A positive correlation between the level of blood TC and the risk of developing CHD has been confirmed by many epidemiological studies, the most significant of which was the Multiple Risk Factor Study, where 361,622 participants were involved [15]. In our study, both registries indicate the prevalence of the number of patients with hypercholesterolemia (64.2% and 60.5%, respectively, in the 1st and 2nd registers), but the nature of the lipidogram in the 2nd register shows an increase in the level of blood TG (but not the number of patients with hypertriglyceridemia). The role of TG as an independent RF for atherosclerosis is controversial, and despite the evidence available, there remain doubts about the independent nature of the relationship between the level of TG and the development of atherosclerosis [16].

The results of the registers are, although rather limited, but very representative. Thanks to the conduct of the registers and their subsequent comparative analysis, we managed to establish that 5 years after the 1st register there was a positive trend in terms of infarct-alertness of the medical staff in the primary care. Namely, the detection of early markers of myocardial necrosis (TnT and TnI) in the 2nd register increased (by 4.2% and 1.5%, respectively). A similar positive dynamics was observed in the treatment administration: in particular, the use of ASA increased by 34.7%; Clopidogrel – by 8.3% and nitrates – by 10.4%. Thus, the application of the population-based methods of the Registers, together with the identification of the weakest aspects in the



**Figure 4. Distribution of men by blood pressure (according to the registers)**

Note: the data is presented as a percentage; \* - statistical significance of differences between groups at  $p < 0.05$ .



**Table 3. Comparative characteristics of laboratory indicators of men in the 1st and 2nd registers**

Factor	Men of the 1st register (n=464)	%	Men of the 2nd register (n=430)	%	p	x <sup>2</sup>
<b>Lipid profile</b>						
Average total blood cholesterol, mg/dL	201,04±49,33		173,33±70,57		<b>0,000</b>	
Mean level of triglycerides of blood, mg/dL	190,61±85,68		214,79±196,15		<b>0,016</b>	
Number of patients with hypercholesterolemia (TC> 180 mg/dl)	298	64,2	260	60,5	0,276	1,189
Number of patients with hypertriglyceridemia (TG> 200 mg/dL)	196	42,2	140	32,6	<b>0,004</b>	<b>8,513</b>
<b>Blood Hb</b>						
Average blood Hb, g/l	131,78±19,55		119,56±12,73		<b>0,000</b>	
The number of patients with normal blood Hb levels (≥ 120 g/l)	361	77,8	230	53,5	<b>0,000</b>	57,802
Number of patients with low Hb blood content (<120 g/l)	103	22,2	200	46,5	<b>0,000</b>	57,802
<b>Troponins</b>						
<b>Troponin T</b>	<b>n=261</b>		<b>n=230</b>			
Not measured	255	97,7	190	82,6	<b>0,000</b>	31,045
Increased	1	0,4	9	3,9	<b>0,015</b>	5,969
Not increased	5	1,9	6	2,6	0,832	0,045
Unknown	-	-	25	10,9	<b>0,000</b>	27,685
<b>Troponin I</b>	<b>n=261</b>		<b>n=229</b>			
Not measured	240	91,9	180	78,6	<b>0,000</b>	16,684
Increased	5	1,9	11	4,8	0,124	2,371
Not increased	16	6,2	11	4,8	0,657	0,197
Unknown	-	-	27	11,8	<b>0,000</b>	30,342
<b>CK-MB</b>	<b>n=261</b>		<b>n=220</b>			
Not measured	247	94,6	188	85,5	<b>0,001</b>	10,598
Increased	6	2,3	5	2,3	0,774	0,082
Not increased	8	3,1	3	1,3	0,349	0,879
Unknown	-	-	24	10,9	<b>0,000</b>	27,981

**Table 4. Comparative characteristics of the intake of drugs among men in the 1st and 2nd registers**

Medications	1st register (n=464)	%	2nd register (n=430)	%	p	x <sup>2</sup>
Aspirin	154	33,2	292	67,9	<b>0,000</b>	<b>106,21</b>
Clopidogrel	21	4,5	55	12,8	<b>0,000</b>	<b>18,550</b>
Ticlopidine	3	0,6	5	1,2	0,643	0,215
B-blockers	112	24,1	221	51,4	<b>0,000</b>	<b>69,778</b>
ACE Inhibitors	90	19,4	179	41,6	<b>0,000</b>	<b>51,384</b>
ARA-II	8	1,7	27	6,3	<b>0,000</b>	<b>11,128</b>
Statins	34	7,3	81	18,8	<b>0,000</b>	<b>25,359</b>
Non-statin lipid-lowering drugs	4	0,8	7	1,6	0,463	0,539
Nitrates	95	20,5	133	30,9	<b>0,000</b>	<b>12,298</b>
Ca channel blockers	20	4,3	27	6,3	0,243	1,364

system of epidemiological, medical and diagnostic measures and the development of ways to eliminate them using statistical-mathematical methods in a certain population, allows the creation of a program for predicting the outcome of the disease, the quality of care, taking into account individual risk factors and the potential of their interrelationships.

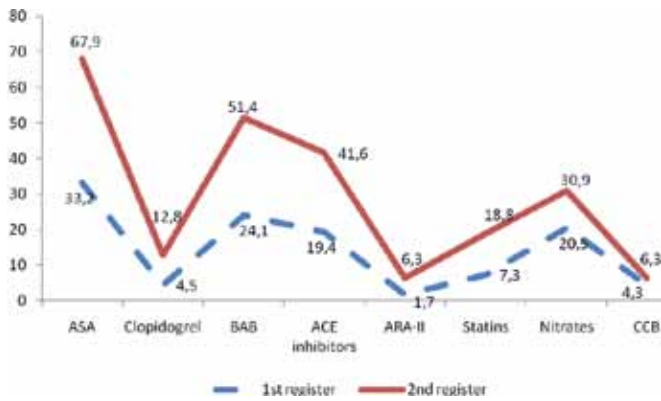
#### CONCLUSIONS:

- The incidence of ACS/AMI in the 2nd register among men younger than 40 years has decreased, but the number of obese individuals has increased. In the 2nd register, the number of men with HR> 90 beats/min decreased, but the mean values of blood pressure increased. Among men with ACS/AMI, an increase in the

average level of triglycerides of blood was recorded in the 2nd register, but the number of men with hypertriglyceridemia was less. In the 2nd register, the number of troponin measurements has increased, which indicates an increase in the coverage by laboratory studies.

- The results of the 2nd register on ACS/AMI among males revealed a significant increase in the groups of drugs used in the treatment, not only those included in the basic therapy of CHD, but also the main ones in the treatment of ACS/AMI, which indicates positive qualitative changes in treatment of acute cardiac pathology.

- The presented comparative analysis of two independent registers determines the need for further improvement of secondary prevention measures, taking into account the patient's compliance,



**Figure 4. Comparative evaluation of medication**

Note: data are presented as percentages

as well as constant monitoring of compliance and implementation of international standards in the context of medical care provided by primary health care personnel, which once again proves the relevance of this type of research. This strategy, especially in the comparative aspect, contributes to the improvement of the quality of treatment activities and, accordingly, to the reduction of disability and mortality among the able-bodied population.

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