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Register of patients with stable coronary artery disease underwent coronary artery bypass grafting surgery (Ricochet program)

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Abstract

Objective. The article presents the analysis of social, demographic and clinical risk factors, perioperative examination parameters, therapy and outcome data in patients with stable coronary artery coronary disease after coronary artery bypass grafting surgery (CABG) in three regions in Russian Federation during 2012 year in the context of Ricochet program. The other aim was to establish a correspondence of the findings to international myocardial revascularization guidelines. **Design and methods.** Altogether 300 patients (100 in each region) were chosen according to the inclusion/exclusion criteria, and all participants were given individual numbers. All data were registered in a special database "A registry of patients with stable coronary artery disease after coronary artery bypass grafting surgery". Phone visits or office visits when necessary were scheduled in 12 months. Response rate was almost 100%. **Results.** It was shown that males dominated among patients. The female CABG rate was three times lower, though the most of them (90%) had myocardial infarction in past in comparison with 73% of patients among male group. The average patient age was 60–64 years and 43% of them were invalids. Work-status analysis of pre- and postoperative periods showed no significant difference. Indications for surgery correspond to current guidelines, however, the preoperative stress test rate was only 36%. **Conclusions.** The majority of patients were treated with evidence-based medicine drugs. A significant number of patients with recurrent angina after CABG, including high functional class, was found. These data indicate the need for an out-patient follow-up system for patients undergoing CABG, including cardiac rehabilitation, therapy correction, and, if necessary, re-intervention.

Key words: register, coronary artery disease, coronary artery bypass grafting surgery

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РегИстр больных, перенесших операцию КОронарного Шунтирования при ишЕмической болезни сердца сТабильного течения (программа РИКОШЕТ)

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Резюме

Цель исследования. В рамках регистра РИКОШЕТ проведен анализ социально-демографических и клинических характеристик, распространенности факторов риска, характера предоперационного обследования, лечебных мероприятий, исходов у пациентов с ишемической болезнью сердца (ИБС), направляемых для планового коронарного шунтирования (КШ) в трех регионах Российской Федерации в период за 2012 год, а также их соответствия международным рекомендациям по реваскуляризации миокарда. **Материалы и методы.** Для участия в исследовании по журналам регистрации были отобраны 300 пациентов (по 100 в каждом регионе), каждому из которых был присвоен уникальный порядковый номер. Все данные вносились в специально разработанную для исследования базу данных «Регистр больных со стабильной ишемической болезнью сердца, перенесших коронарное шунтирование». Через 12 месяцев осуществлялись телефонные интервью, в ряде случаев проводился очный визит. Отклик составил практически 100%. **Результаты.** Проведенный анализ регистра больных, перенесших КШ в трех субъектах Российской Федерации, показал, что в структуре больных регистра преобладали мужчины. Женщины почти в три раза реже, чем мужчины, направлялись для реваскуляризации миокарда, при этом 90% пациенток к этому времени перенесли инфаркт миокарда (ИМ), тогда как среди мужчин число больных, перенесших ИМ, было значимо реже (73%). Более половины больных составляли лица пожилого возраста с преобладанием возрастной категории 60–64 года, 43% пациентов являлись инвалидами. Анализ трудоспособности больных в до- и послеоперационном периоде показал отсутствие какой-либо существенной динамики в структуре работающих пациентов и инвалидов в первый год после КШ по всем трем регионам Российской Федерации.

Выводы. В целом показания к операции КШ по данным регистра соответствовали современным международным руководствам об обоснованности реваскуляризации миокарда, однако частота выполнения функциональных нагрузочных проб до операции составила лишь 36%. Большинству пациентов при выписке назначались препараты с доказанным положительным влиянием на прогноз. Установлено значительное число рецидивов стенокардии после КШ, в том числе, высокого функционального класса, что определяет необходимость создания стабильной системы диспансеризации больных, перенесших КШ, включающей проведение кардиальной реабилитации, коррекцию терапии и при необходимости — повторного вмешательства.

Ключевые слова: регистр, ишемическая болезнь сердца, коронарное шунтирование

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Introduction

Cardiovascular diseases (CVD) are the leading cause of death, hospitalization and disability in the Russian Federation [1–3], and coronary artery disease (CAD) is the leading reason of cardiovascular mortality (397 cases per 100 000 people, or 53 %) [4]. Recently,, myocardial revascularization, especially coronary artery bypass grafting (CABG), has become a routine treatment for CAD, resulting in a significant reduction in mortality and improvement of quality of life in these patients.

Improvement of safety and clinical efficacy of the surgery, as well as surgical technology development led to the expansion of the indications and significant increase in treated patients in the Russian Federation [5]. However, due to the increased availability of high-tech medical care several issues become highly relevant, including patients' selection, surgery appropriateness and physicians' compliance with the international guidelines for myocardial revascularization [6–8].

In recent years, observational studies, including registries and electronic databases, have called more attention, because they are the way to obtain objective to apply in routine clinical practice according to the guidelines [9, 10]. Registries of patients undergoing surgical myocardial revascularization in the Russian Federation are a promising way to collect the information on patients referred to CABG. It appears to be useful for the improvement of the high-tech medical care organization.

The purpose of this study was to investigate social, demographic, and clinical characteristics, risk factor prevalence, type of preoperative examination, treatments, and outcomes in CAD patients sent for routine CABG in three regions of the Russian Federation, and management compliance to the international guidelines based on the Registry data.

Design and methods

We analyzed case reports of patients with stable CAD, consecutively admitted for planned CABG to the cardiology departments in three regions of the Russian Federation (Saint-Petersburg, Samara and Orenburg regions) from 12 January to 30 October 2012. The design was planned as a retro-, prospective, observational cohort study in accordance with the basic registry principles.

Exclusion criteria were the following: acute myocardial infarction (MI) or unstable angina pectoris within less than 6 months before selection, living in other regions, in case when that medical reports were missing, as well as patients who underwent urgent CABG. Altogether 300 patients (100 in each region) were pre-selected, and unique serial numbers were assigned. Data from medical records and follow-up information were entered in a specially developed database "Registry of patients with stable CAD undergoing coronary artery bypass surgery". At 12 months repeated visits were carried out mostly by telephone interview, in some cases, personal visits were performed. When either patient or his/her relatives were not contacted by phone, a letter with a return receipt were sent. To verify lethal cases, the requests were sent to the State Civil Institutions. As a result, 299 were followed up, so the response rate was almost 100 %. In lethal cases, the information was also provided by relatives.

Table 1

AGE OF PATIENTS WITH CORONARY ARTERY DISEASE AFTER CORONARY BYPASS GRAFT SURGERY

Age group	46–49	50–54	55–59	60–64	65–69	70–74	75 and more
Number of patients	32	44	49	83	49	34	8
Rate, %	10.7	14.6	16.4	27.8	16.4	11.4	2.7

Table 2

SOCIAL CHARACTERISTICSOF PATIENTS INCLUDED IN THE REGISTRY

Parameter	Number of patients	Rate, %
Working people	83	27.8
Pensioners	78	26.1
Disable people	127	42.5
Unknown	11	3.7
Total	299	100

Table 3

ФАКТОРЫ РИСКА У БОЛЬНЫХ, ВКЛЮЧЕННЫХ В РЕГИСТР

	Number of patients	Rate, %
Hypertension	249	83.3
Dyslipidemia (high level of total cholesterol or LDL)	224	74.9
Non-smokers (never)	119	40
Gave up smoking	37	12.4
Smoke at present time	101	33.8
Diabetes mellitus or impaired glucose tolerance	52	17.4
Family history of coronary artery disease	99	33.1

Note: LDL — low density lipoproteins.

Table 4

CLINICAL CHARACTERISTICS OF PATIENTS INCLUDED IN THE REGISTRY

Disease	Number of patients	Rate, %
Angina pectoris I–II FC	66	22
Angina pectoris III FC	214	71.6
Angina pectoris IV FC	13	4.3
Stenosis of brachiocephalic arteries	101	33.8
Stroke	3	1
Peripheral artery disease	35	11.7
Chronic pulmonary disease	39	13
Percutaneous coronary intervention in past	22	7.4
Diabetes mellitus or impaired glucose tolerance	52	17.4

Note: FC — functional class.

Table 5

THE OCCURRENCE OF CONGESTIVE HEART FAILURE IN PATIENTS INCLUDED IN THE REGISTRY

	Number of patients	Rate, %
CHF 0–I FC	19	9.1
CHF II FC	147	70.7
CHF III FC	40	19.2
CHF IV FC	2	1
Total	208	100

Note: CHF — congestive heart failure; FC — functional class.

Table 6

DRUG THERAPY BEFORE CORONARY ARTERY BYPASS GRAFT SURGERY

	Antiplatelet	Anticoagulants	Beta-blockers	ACEi	ARB	Calcium antagonists	Nitrates	Statins
Number of patients	251	4	234	204	16	49	163	196
Rate, %	84	1.3	78.2	68.2	5.3	16.4	54.5	65.6

Note: ACEi — angiotensin-converting enzyme inhibitors; ARB — angiotensin II receptor blockers type 1.

Table 7

CHARACTERISTICS OF THE ATHEROSCLEROTIC CORONARY LESIONS IN PATIENTS INCLUDED IN THE REGISTRY

Number of involved arteries	Number of patients	Rate, %
1 coronary artery	33	11.1
2 coronary arteries	82	27.4
3 coronary arteries	184	61.5
Total	299	100
Among them — the involvement of the main left coronary artery	78	26.1

Statistical analysis of the database registry was carried out using software packages Statistica 6.0 and 7.0 by descriptive statistics.

Results

Finally, the registry included 299 patients with stable CAD (236 men and 63 women). The mean age was 59.7 ± 6.5 years (32–77 years) (Table 1).

Elderly subjects (60–75 years) composed almost half of the included patients, and almost one third were older than 65 years. Social characteristics is displayed in Table 2.

Less than a third of the patients were employed, and 42.5 % were disabled. Almost all patients had CVD risk factors (Table 3). However, the levels of total cholesterol (TC) and low density lipoprotein cholesterol (LDL–C) were not assessed in all patients referred to CABG. Thus, total cholesterol was evaluated in 245 people (82 %), LDL–C — in 88 patients (29 %). An increased total cholesterol level (more than 4.5 mmol/L) was found in 63 % of patients, and elevated LDL–C (greater than 2.5 mmol/L) was verified in 43 out of 88 patients (49 %). Medical anamnesis is shown in Table 4.

Angina pectoris of high functional class (FC) was diagnosed in 4/5 of patients, but 6 people had no signs of angina pectoris, and myocardial infarction, left ventricular aneurysm or verified coronary artery (CA) lesions were the indications for CABG.

In total, 79 % of the included patients (236 out of 299) suffered MI in past. In addition, among men referred for CABG myocardial infarction was diagnosed in 73 % (173 of 236), while among women — the rate of MI in past achieved 90 %

(57 out of 63). Recurrent MI was diagnosed in 20 % of patients. Left ventricular aneurysm was verified in 22 patients.

208 patients (69.5 %) had chronic heart failure (CHF), while left ventricular dysfunction (ejection fraction, EF < 40 %) was identified only in 25 subjects out of 234 (10.6 % of all patients with available echocardiography). In the rest of patients EF was above 40 %, and in 189 patients the value exceeded 50 % (Table 5).

Before referral to the surgery, all patients received combination drug therapy, except for 2 patients who had not taken any drugs, and 10 patients who had taken only nitrates (Table 6).

Sinus rhythm was verified in 272 patients, 27 (9.0 %) had atrial fibrillation. Out of 251 patients receiving antiplatelet agents, clopidogrel was prescribed to three of them, and ticlopidine was administered in one case. Four patients got warfarin, and 2 of them showed sinus rhythm. However, 25 out of 27 patients with atrial fibrillation did not get any anticoagulation therapy. 165 (55.2 %) subjects received combination therapy with proven favorable prognostic effects (acetylsalicylic acid, ACE inhibitors, beta blockers, statins).

Exercise tests were performed in 108 patients (36 %) before surgery. The frequency of preoperative performance of functional tests varied significantly: 79 and 29 % in two regions, respectively. In one region, stress tests were not included in the common preoperative examination.

Three CA (anterior interventricular CA, right CA and circumflex CA) were affected in more than half (61.5 %) of the patients. More than a quarter of the patients (26 %) showed the lesions of the main branch of the left coronary artery (LCA) usually associated with the stenosis of 2–3 main arteries.

Combination of clinical and coronary manifestations for considered as indications for revascularization. Clinical indications included angina pectoris I–II FC diagnosed in 66 patients (24 subjects had myocardial infarction in past, 17 had left ventricular aneurysm), angina pectoris III FC was found in 214 patients, and angina pectoris IV FC — in 8 subjects. Six patients ahd survived a myocardial infarction without subsequent angina pectoris, and an aneurysm of the left ventricle without angina pectoris was found in 5 subjects.

Angiographic indications included: lesions of 1–2 main CA with or without stenosis of the main branch of LCA were verified 9 people, lesions of 3 main CA with or without stenosis of the main branch of LCA were identified in 163 patients, isolated involvement of the main LCA — in 5 patients (Table 7).

Table 8

CORONARY ARTERIES OPERATED BY BYPASS GRAFT SURGERY IN PATIENTS INCLUDED IN THE REGISTRY

Coronary artery	Number of patients
Anterior interventricular artery	243
Circumflex artery	141
Right coronary artery	215
Intermediate coronary artery	31
Diagonal coronary artery	69
Dull-edged branch	74
Total	773

Table 9

RECOMMENDED THERAPY AT DISCHARGE IN PATIENTS INCLUDED IN THE REGISTRY

	Antiplatelet	Anticoagu-lants	Beta-blockers	ACEi	ARB	Calcium antagonists	Nitrates	Statins
Number of patients	299	11	233	170	39	23	54	271
Rate, %	100	8	78	57	13	8	18	91

Note: ACEi — angiotensin-converting enzyme inhibitors; ARB — angiotensin II receptor blockers type 1.

Table 10

12-MONTH FOLLOW-UP OF PATIENTS INCLUDED IN THE REGISTRY

	Death	Myocardial infarction	Stroke	Recurrent angina pectoris		Hospitalization	
				1–2 ФК	3 ФК	Angina pectoris	Congestive heart failure
Total, n	3	5	3	97	54	11	4
%	1	1.6	1	32	18	4	1.3

	Congestive heart failure, functional class (n = 208)			Shuntocoronarography	Percutaneous coronary intervention	Coronary artery bypass graft surgery
	0–I	II	III			
Total, n	53	111	44	6	2	0
%	26	53	21	2	0.6	0

Internal thoracic artery was used as a graft in 184 patients, radial artery — in 59, and venous shunts were applied in 273 patients. On average, 2.6 ± 1.0 (1 to 4) shunts were implanted in every patient. Only one surgery was performed off pump. No early lethal cases were registered within 30 days after surgery, all patients were discharged from the hospital (Table 8).

After surgical treatment the following medications were prescribed at higher rate: antiplatelet agents (100 vs. 84 %), statins (65.6 vs. 91 %), angiotensin II receptor type 2 blockers (13 vs. 5.3 %). At the same time angiotensin converting enzyme inhibitors were administered less frequent (57 vs. 68.2 %), and nitrates were not prescribed at regular basis after surgery (Table 9).

Major clinical outcomes at 12-month follow-up after CABG are presented in Table 10.

Revascularization had a favorable impact on CAD leading to lower rates of mortality, myocardial infarction, stroke, hospitalization and lower need for repeat revascularization within 12 months after surgery.

Despite high rate of recurrent angina pectoris (in half of the patients), in the majority of cases (32 %) its severity did not exceed II FC. The rate of CHF II NYHA decreased, while the frequency of CHF III NYHA remained stable, although the rate of hospitalizations due to heart failure reduced.

One year after surgery 87.5 % of patients took aspirin, 4 % received clopidogrel (including 10 % of patients who received both aspirin and clopidogrel), 80.5 % of patients received beta-blockers, 56 % — angiotensin converting enzyme inhibitors or angiotensin II receptor blockers type 2, 82 % took statins, 22 % — nitrates, 7.5 % diuretics, 7 % — mineral corticoid receptor blockers. Warfarin was prescribed only to 3 % of patients.

Discussion

Randomized clinical trials cannot provide the answers to most questions concerning the treatment of heterogeneous groups of patients, as it happens in real clinical practice. Therefore, observational studies — registries and other electronic databases — seem to be an alternative approach to obtain necessary information for further guidelines to apply in everyday medical practice [10].

One of the main purposes of surgery is the restoration of the social status of the patients. Thus, social and demographic characteristics of patients referred for myocardial revascularization are relevant. Moreover, social and demographic characteristics were shown to be closely related to the prognosis in CAD, the severity of clinical manifestation of CVD, and their cumulative effect on life quality and duration [11–15].

Based on the registry data, males were predominant among patients undergoing CABG in two Russian regions. Women are referred for myocardial revascularization 3 times less likely than men, with 9 % of women having suffered myocardial infarction compared to 73 % of men (73 %).

Elderly patients composed (60–64 years old) more than one half of patients, 43 % of patients were disabled. The social characteristics were different in three regions: the proportion of disabled

patients was 70; 56 and 17 %, respectively ($p_{1-3} < 0.05$), the proportion of patients aged 60 years and older — 70; 60 and 40 %, respectively ($p_{1-3} < 0.05$). A similar trend with an increase in the rate of surgery among elderly patients has previously been described by L.A. Efros based on the data from the long-term registry of patients operated in the Chelyabinsk Region in 2000–2009 [11].

On the one hand, the differences in social and demographic characteristics can be associated with the lack of attention to the young people and women before the occurrence of the myocardial infarction. On the other hand, it can be explained by the improvement of technology and cardiac care, as well as the opportunity to perform surgical treatment in elderly patients age those at high cardiovascular risk.

The rates of working people before and after surgery were comparable during the first year post-surgery. However, restoration and maintenance of the ability to work is an important social and economic health care parameter. However, this problem is observed elsewhere. In recent years, despite successful restoration of somatic status after surgical treatment, less than two thirds of patients return to their professional activity [14–16].

Therefore, a regular monitoring after coronary artery bypass surgery, follow-up and development of rehabilitation system are required in order to return to work after cardiac surgery [11].

Clinical assessment and risk stratification before myocardial revascularization are highly important, since severe comorbidities and an abrupt decline in myocardial reserves reduce intervention efficiency. On the other hand, an increased number of revascularization is performed in less severe patients, and the impact on the clinical symptoms and prognosis is questionable in this patient cohort [6–8].

Based on our registry, the prevalence of co-morbidities was as following: hypertension — 83.3 %, hyperlipidemia — 74.9 %, atherosclerotic lesions of brachicephalic arteries or peripheral artery diseases — 45.5 %, concomitant diseases of the respiratory system — 13 %, diabetes mellitus — 17 %; family history of CVD — 33.1 %, and one third of patients were smokers at the time of admission to the hospital.

In general, our results are consistent with the data from other studies. Thus, the Russian registry REACH [17] showed that the most frequent risk factors are hypertension (82.2 %) and hypercholesterolemia (52.5 %), multiple atherothrombotic lesions (21 %), although the incidence of diabetes mellitus was lower compared to the general population (18.8 vs. 44.3 %). Smoking prevalence is extremely high comprising 24.9 %.

Since the Registry REACH (2006) was finalized, risk factor prevalence in patients who underwent CABG in 2012, had not changed, indicating a need for secondary prevention improvement in all regions of Russian Federation.

Our register showed some regional differences in the frequency of CHF. The frequency of symptomatic CHF NYHA III was similar in all three regions — 20 %, 9 % and 13 % in Saint-Petersburg, Samara, and Orenburg, respectively. However, CHF NYHA II was diagnosed in 62.7 %, 89 % and 11 % in Saint-Petersburg, Samara, and Orenburg, respectively. Moreover, a significant left ventricular dysfunction (ejection fraction $\leq$ 40 %) was found only in 10.6 %; 2 % and 6 %, respectively. These regional differences seem to be subjective, apparently related to the low compliance with the principles of CHF diagnostics in patients undergoing CABG.

Based on our Registry data, the indications for CABG meet current international guidelines on myocardial revascularization [6–8]. Among patients aged 60 years and older angina pectoris III–IV FC was diagnosed in in 140 (46.8 %), 88.9 % patients had lesions of 2–3 main CA.

One of the key indications for myocardial revascularization is a verified transient myocardial ischemia, since the main purpose is to eliminate ischemia but not just CA lesions themselves. Therefore, data on the functional stress test performance prior CABG are noteworthy. The load tests were performed only in 36 % patients with the significant difference between the regions. Therefore, the main indications for myocardial revascularization included clinical and anatomic criteria.

Exercise stress test is important for risk stratification and referral for coronary angiography, revascularization, as surgical myocardial revascularization is not beneficial in the absence of myocardial ischemia.

Removal of mechanical coronary obstruction does not eliminate CAD, therefore, secondary

prevention remains highly relevant. Our findings confirm that after myocardial revascularization medications with the proven prognostic effects are prescribed to the majority of patients (antiplatelet agents — 100 %, statins — 91 %, angiotensin converting enzyme inhibitors/angiotensin II receptors antagonists — 70 %). However, one year later the rates are slighlty different: antiplatelet agents — 96.5 %, statins — 82 %, angiotensin converting enzyme inhibitors/angiotensin II receptor antagonists — 56 %. Moreover, only 3 % of patients with verified atrial fibrillation were taking warfarin.

Thus, the registry of patients with stable CAD referred to CABG in three regions of Russia in 2012, created within the program RICOCHET, provided information about the main characteristics this cohort, including preoperative management and the results of surgical treatment. The obtained data will contribute optimization of this high-technology medical care in CAD.

Conclusions

In men and women of young and middle age with CAD, an exercise stress test will allow of timely identification of high-risk patients requiring myocardial revascularization.

Social and economic efficiency of CABG remains low, as it does not lead to a reduction in the rate of disabled people.

High incidence of recurrent angina pectoris, including severe cases, indicates a need for a system of post-CABG follow-up with cardiac rehabilitation, treatment update, and re-intervention if necessary.

Based on our registry data, the indications for CABG meet current international guidelines. However, a wider use of functional load tests before CABG would improve the patient selection and the efficiency of myocardial revascularization.

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Conflict of interest
The authors declare no conflict of interest.

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