Trial Designs

Objectives and Design of the Russian Acute Coronary Syndrome Registry (RusACSR)

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ABSTRACT

The Russian Acute Coronary Syndrome Registry (RusACSR) is a retrospective, continuous, nationwide, Web-based registry of patients with acute coronary syndromes (ACS). The RusACSR is a database that uses a secure Web-based interface for data entry by individual users. Participation in the RusACSR is voluntary. Any clinical center that provides health care to ACS patients can take part in the RusACSR. The RusACSR enrolls ACS patients who have undergone care in Russian hospitals from February 2008 to the present. Key data elements and methods of data analysis in the RusACSR are presented in this article. Up to 2015, 213 clinical centers from 36 regions of Russia had participated in the RusACSR. Currently, the database contains data on more than 250 000 ACS patients who underwent care from 2008 to 2015. Some current problems are highlighted in this article. The RusACSR is a perspective project for different epidemiologic studies in Russian ACS patients.

Introduction

There are a number of registries from various countries that include patients with acute coronary syndromes (ACS).[1–11] The main goal of these registries is to fill the gap between probative data of randomized controlled trials and real clinical practice.[12,13] The main functions of the ACS registries are (1) to report on clinical and demographic characteristics of patients with ACS in covered cohorts; and (2) to assess the treatment of ACS in accordance with the current guidelines.

The registries can also be used for epidemiologic studies, original studies, risk modeling, improving the quality of health care, and other objectives. The registry is an ideal tool for studying the real clinical practice, especially when it is necessary to improve the quality of health care.

It is known that the quality of health care in ACS patients, especially revascularization in ACS patients with ST-segment elevation on electrocardiogram (STE-ACS), requires improvement in many countries.[14–16] Within the framework of the Russian Federal Target Program Prevention and Control of Social Diseases (2007–2011) and the All-Russian Vascular Program, in 2008 the Russian Acute Coronary Syndrome Registry (RusACSR; https://federalregistry.ru) was established. This registry is still functioning.

The aim of this article is to describe the objectives and design of the RusACSR. The presented results may be interesting to a wide audience, as the RusACSR is currently the largest registry of ACS patients in Russia.

Description of the Russian Acute Coronary Syndrome Registry

Objectives

The RusACSR has the following main objectives: (1) to create a national database with information on health care in ACS patients treated in Russia; (2) to obtain data on the demographic, clinical, and laboratory characteristics of ACS patients treated in Russia; (3) to identify the national features of associations between the characteristics of ACS and clinical outcomes, including mortality, complications, length of hospital stay, and quality of health care; and (4) to propose a practical guide for improving the quality and efficiency of ACS treatment in each clinical center participating in the RusACSR.

Developers

The Russian Cardiology Research and Production Complex (Moscow, Russia) was responsible for the development of the RusACSR and centralized data analysis at a federal level. The RusACSR was established in 2007 and 2008 by researchers, cardiologists, and information technology specialists from the Saratov Research Institute of Cardiology (Saratov, Russia). The current support of the RusACSR is carried out by the staff of both above-mentioned organizations.

Participation

Participation in the RusACSR is voluntary and free of charge. Any clinical center that provides health care for ACS patients can participate in the RusACSR by sending a request to the technical support staff of the RusACSR. Starting in 2008, most of the main centers participating in the All-Russian Vascular Program were invited to take part in the RusACSR by the Russian Cardiology Research and Production Complex. Up to 2015, 213 clinical centers from 36 regions of Russia had participated in the RusACSR (Figure 1) .[17]

The majority of centers participating in the RusACSR are located in the Central Federal Region of the Russian Federation, and several centers are located in the North-West Federal Region, South Federal Region, Ural Federal Region, and Siberian Federal Region. Thus, registry centers represent federal districts where the majority of the Russian population lives. Of course, these regions are socioeconomically heterogeneous, but an annual public report contains the data on each region separately.[17]

Design of the Russian Acute Coronary Syndrome Registry

The RusACSR is established as a retrospective, continuous, nationwide, Web-based registry operating online (https://federalregistry.ru). The design of the RusACSR is based on the main points of the clinical guidelines on diagnosis and treatment of ACS.[18−21]

Access to the Registry is given to registered members. Each user has a unique identification number and password to log in to the database. The Web forms are designed to be interactive. They limit or exclude certain options to avoid entry of conflicting or spurious data. Wherever possible, the data are entered by selection from drop-down menus to minimize the number of keyboard errors. The purpose of all these measures is to maximize the accuracy of data.

The Web interface of the RusACSR contains 11 Web forms with the following titles: (1) personal data of ACS patients; (2) history of present event of ACS; (3) past history; (4) results of physical examination; (5) results of instrumental examinations; (6) results of laboratory tests; (7) invasive intervention; (8) prior therapy; (9) drug treatment of ACS; (10) recommendations at discharge; and (11) complications and outcomes.

Patients

The RusACSR enrolls patients who were admitted for ACS (ie, unstable angina or myocardial infarction [MI]) and underwent care in hospitals in Russia. Enrollment of patients started in February 2008 and has continued to the present day.

Inclusion criteria comprise any type of ACS (ie, unstable angina or MI) as a presumptive diagnosis, age ≥18 years, finished patient hospital chart, and absence of any exclusion criteria.[22]

The RusACSR exclusion criteria are the following: (1) symptoms considered as consistent with acute cardiac ischemia are absent within the last 24 hours prior to admission; (2) patient was transferred into a registry hospital >24 hours after admission to the initial hospital; (3) patient was transferred out of a registry hospital <24 hours after admission; (4) symptoms considered as ACS at admission were not consistent with acute cardiac ischemia; and (5) ACS accompanied by a significant comorbidity, such as a motor vehicle accident, trauma, or severe gastrointestinal bleeding, and operation or procedure directly before admission.[22]

A flow diagram of patient selection for inclusion in the RusACSR is presented in Figure 2.

Data Elements

The key data elements and definitions of the RusACSR database were developed using the American College of Cardiology (ACC) 2001 Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with ACS[23] and the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) 2011 Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for Electronic Health Records.[24] After 2013, we adopted the RusACSR to the 2013 ACCF/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with ACS and Coronary Artery Disease.[25]

Data on patient demographics, clinical characteristics, previous and hospital drug treatment, and reperfusion therapy are collected. Data on post-hospital treatment of ACS patients are not included in the Registry. There is no capacity to follow patients after hospital discharge. (For details on the key data elements of the RusACSR database, see Supporting Information, Appendix A, in the online version of this article).

Data Collection

The centers participating in the RusACSR were asked to include all patients following inclusion/exclusion criteria
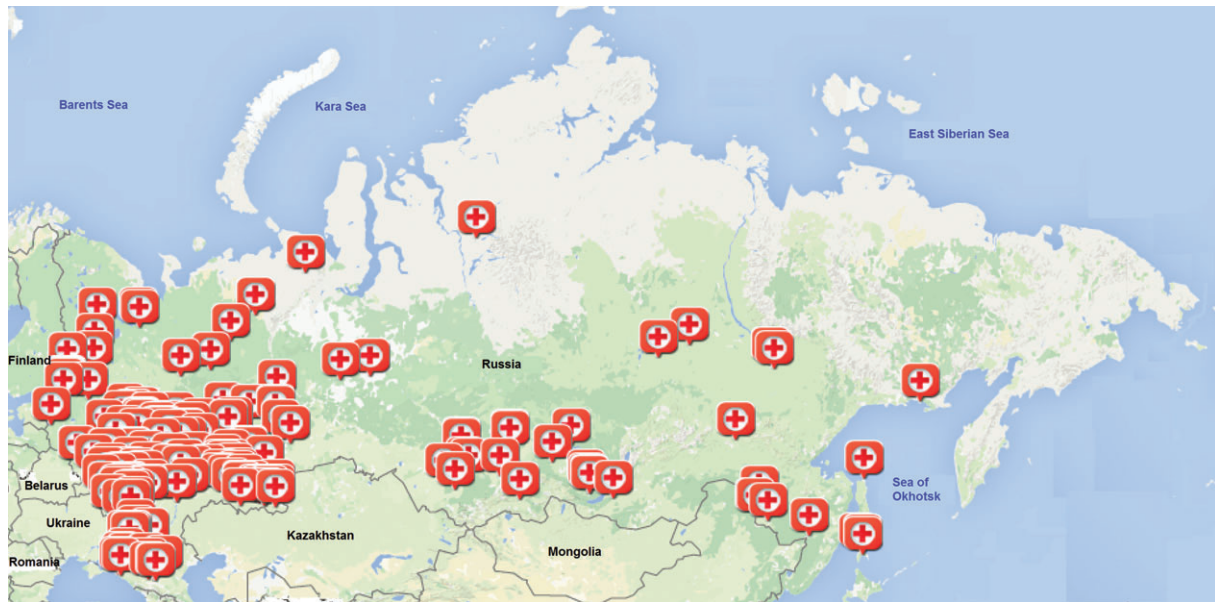
Figure 1. Maps with clinical centers participated in the RusACSR. Abbreviations: RusACSR, Russian Acute Coronary Syndrome Registry.

treated for ACS during the year prior to the year of participation. The source of patient data is the hospital chart. To help the participants, a detailed user manual was developed.[22] This user manual is available on the RusACSR Web site.

The centers are interested in accurate data collection because these data are analyzed further by experts separately for each center and used on-site for health care quality management. In each center, ≥1 physicians have been trained to log patient data into the Registry. The content of data-entry Web forms is intuitive for 88% of untrained users.[26] Each year, experts from the RusACSR check the validity of entered data by reconciling randomly selected records with the data of patients' hospital charts. Currently, the RusACSR contains data on >250 000 ACS patients treated from 2008 to 2015. The main baseline characteristics of patients included in the RusACSR from February 1, 2008, to October 22, 2015, are presented in the Table 1.

As for the proportion of ACS presentations included in the Registry since 2008, we have only an approximate estimation because the public statistics contain only the data on MI, and not on ACS morbidity across Russia. There are about 185 000 MIs per year in Russia. The RusACSR contains data on about 100 000 MI patients.

Data Security

Some of the main features of database and Web security issues should be mentioned briefly. As mentioned above, all users are assigned a unique username/password combination that is used to log on to the RusACSR. In this way, all transactions are recorded automatically in the Web server's log.

All the data are pseudonymously entered into a Web-based database protected by a password on a safe server of the Russian Cardiology Research and Production Complex

using secure sockets layer (SSL) connections. Subject identification is possible only at the local study site, and participating centers are exclusively able to review and modify the patient data. The data on ACS patients added to the RusACSR can be changed but cannot be removed. The transmitted data are stored in the central database on the central server at the Russian Cardiology Research and Production Complex.

The purpose of all the above-mentioned measures is to ensure the confidentiality of the data.

Ethical Aspects

The study protocol including patient information and consent forms has been reviewed and approved by the Ethics Commission of the Russian Cardiology Research and Production Complex.

All patients must give informed consent before inclusion of their personal and clinical data in the RusACSR. The standard informed-consent form is available on the RusACSR Web site. Patients gave their informed consent after transfer from an intensive care unit to a cardiac/coronary care unit. If patients died in the intensive care unit, consent was given by their relatives.

The appropriate measures are used to guarantee maximal data confidentiality. All patient-related clinical data are anonymized locally.

Data Analysis

Within the RusACSR, an analytical module was created for the assessment of health care quality for ACS patients in Russia. The main aim of this analytical module is to implement the system analysis of clinical cases for the development of health care quality indicators for ACS patients to achieve the clinical result (for example, decrease of mortality).
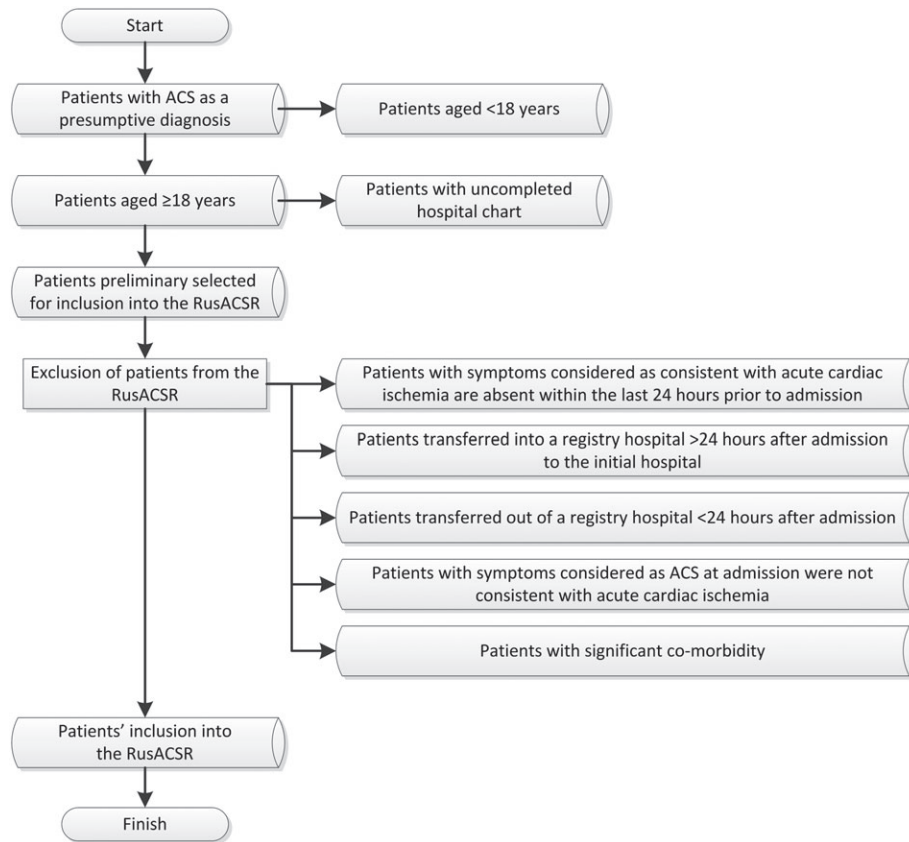
Figure 2. Flow diagram of patients' selection for inclusion to the RusACSR. Abbreviations: ACS, acute coronary syndrome; RusACSR, Russian Acute Coronary Syndrome Registry.

We present the structure of a statistical report on health care in ACS patients that could be calculated in the RusACSR for each clinical center, region, or the whole of Russia (see Supporting Information, Appendix C, in the online version of this article). This report is calculated for any selected date range.

In the RusACSR, the completeness of execution of clinical guidelines in real clinical practice is evaluated using the developed clinical indicators, which are calculated automatically by using the database query for a required cohort of patients (in clinical units, in clinics, in regions of Russia, or in all participating clinics). These indicators were developed according to the ACCF/AHA methodology for the development of quality measures for cardiovascular technology.[27] (For details of clinical indicators, see Supporting Information, Appendix D, in the online version of this article.)

Based on the presented clinical indicators, the quality of care in ACS patients was compared among Russian hospitals. This approach allows us not only to evaluate the quality of care in a particular hospital based on clinical guidelines, but also to carry out a comparative evaluation with other hospitals in the city, region, or whole of Russia.

Discussion

Disease registries allow data to be collected from large patient populations. Currently, the RusACSR is used for different goals by Russian researchers. A number of public reports on the quality of health care in ACS patients have been published recently.[17,28] Some authors already use the data from the RusACSR to assess the mortality[29,30] and appropriateness of percutaneous coronary intervention (PCI) in ACS patients in Russia,[31] to study the quality of health care in ACS patients,[32–37] and to analyze the clinical factors associated with PCI performance in Russia.[30] The results of the RusACSR have caused debate among Russian cardiologists.[38] Some authors reported their comments and suggestions with a view to improving this registry.

Because the RusACSR uses key data elements and definitions recommended by the ACCF/AHA, the results of our study have the potential to be used for cross-country comparison with different registries in other European countries and the United States.

The ACC/AHA have proposed the performance measures for STEMI (ST-segment elevation myocardial infarction) and NSTEMI (non–ST-segment elevation myocardial infarction) patients.[39] The clinical indicators of the RusACSR have a similar goal. But our indicators were proposed in accordance with the national features of health care in ACS patients.

The evaluation of PCI in ACS patients has already become the target of some registries.[40] These registries have provided useful insights regarding the practice of interventional cardiology in various countries. The RusACSR plays a similar role in Russia.

Table 1. Baseline Characteristics of ACS Patients Included in the RusACSR From February 1, 2008 to October 22, 2015

Parameters	Values
Demographic and clinical characteristics (n = 254 584)	
Male sex	49.8
Age, y	67 (58–77)
Prior MI	28.6
Prior chest pain	55.5
Prior PCI	4.5
Prior CABG	<0.1
Prior CHF	43.8
Prior stroke and/or TIA	7.6
PVD	6.3
Family history of CAD	19.9
Hypertension	79.3
Smoking	22.8
DM	15.3
STE-ACS patients	33.6
NSTE-ACS patients	49.2
Heart rate at admission, bpm	76 (68–86)
SBP at admission, mm Hg	140 (120–160)
DBP at admission, mm Hg	85 (80–90)
Killip class at admission (n = 169 007)	
I	71.4
II	21.3
III	4.5
IV	2.8
TC, mmol/L	5.0 (4.2–6.0)
TG, mmol/L	1.4 (1.0–2.0)
Cr, μmol/L	92 (76–111)
Blood glucose, mmol/L	5.6 (4.9–7.0)
ACS patients who underwent PCI	16.6
Prior medical therapy (n = 197 428)	
ASA	45.6
Clopidogrel	9.5
Nitrates	34.6
ACEIs	47.8
ARBs	7.1

Table 1. continued

Parameters	Values
β-Blockers	43.2
Dihydropyridine CCBs	9.1
Non-dihydropyridine CCBs	2.0
Warfarin	1.9
Reperfusion therapy in STE-ACS patients (n = 85 496)	
Fibrinolitic therapy	27.6
Fibrinolitic therapy before hospital arrival	8.0
Time from chest pain (or its equivalent) to fibrinolitic therapy, min (n = 20 544)	180 (120–300)
PCI (n = 85 496)	29.4
Primary PCI (n = 85 496)	24.0
Time from chest pain (or its equivalent) to PCI, min (n = 20 436)	330 (200–750)
Drug therapy in ACS patients (STE-ACS patients, n = 85 496; NSTE-ACS patients, n = 125 228)	
Antiplatelet agents	
STE-ACS patients	97.8
NSTE-ACS patients	97.3
ASA	
STE-ACS patients	96.4
NSTE-ACS patients	95.5
Clopidogrel	
STE-ACS patients	84.4
NSTE-ACS patients	76.4
Anticoagulants	
STE-ACS patients	95.3
NSTE-ACS patients	94.0
β-Blockers	
STE-ACS patients	89.0
NSTE-ACS patients	89.8
Statins	
STE-ACS patients	85.4
NSTE-ACS patients	87.1
ACEIs or ARBs	
STE-ACS patients	82.8
NSTE-ACS patients	87.0

Table 1. continued

Parameters	Values
Outcomes (STE-ACS patients, n = 85 496; NSTE-ACS patients, n = 125 228)	
In-hospital cardiogenic shock	
STE-ACS patients	5.6
NSTE-ACS patients	1.2
Death during hospital stay	
STE-ACS patients	7.3
NSTE-ACS patients	2.1
Death during first day after admission	
STE-ACS patients	3.4
NSTE-ACS patients	0.8
GRACE risk score for in-hospital death (STE-ACS patients, n = 85 496; NSTE-ACS patients, n = 125 228)	
STE-ACS patients with data for calculating GRACE risk of in-hospital death, n (%)	40 214 (47.0)
NSTE-ACS patients with data for calculating GRACE risk of in-hospital death, n (%)	27 896 (22.3)
STE-ACS patients (n = 40 214)	
Low risk	22.2
Medium risk	32.9
High risk	44.9
NSTE-ACS patients (n = 27 896)	
Low risk	26.6
Medium risk	29.8
High risk	43.6

Abbreviations: ACEI, angiotensin-converting enzyme inhibitors; ACS, acute coronary syndrome; ARB, angiotensin II receptor blocker; ASA, aspirin; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CCB, calcium channel blocker; CHF, chronic heart failure; Cr, creatinine; DBP, diastolic blood pressure; DM, diabetes mellitus; GRACE, Global Registry of Acute Coronary Events; IQR, interquartile range; MI, myocardial infarction; NSTE-ACS, non−ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; RusACSR, Russian Acute Coronary Syndrome Registry; SBP, systolic blood pressure; STE-ACS, ST-segment elevation acute coronary syndrome; TC, total cholesterol; TG, triglycerides; TIA, transient ischemic attack.
Data are presented as % or median (IQR), unless otherwise noted.

According to some authors, the employment of ACS registries in small territories (small countries, separate regions, or cities) can improve the quality of health care in ACS patients.[41] The international experience shows that the most complete fulfillment of clinical guidelines in the care of STE-ACS patients is achieved by using STEMI networks.[42,43] In Russia, several regions have already had a positive experience in implementing similar projects. Since 2008, the local STEMI networks based on the independent Samara STEMI Registry have been used successfully in the Samara region of Russia.[44] The RusACSR can become a basis for future development of similar networks in the whole of Russia.

The use of the RusACSR in practical health care is associated with the need to reorganize the workload of staff in centers providing care for ACS patients. Untrained users may have some difficulties with the use of the RusACSR. To solve this problem, we developed a user manual.[22] Another problem with the RusACSR is the formalization of medical information by users during the data transfer from a hospital chart to the Registry database. In our previous study, some problems were identified as the result of a test audit of 26 untrained users of the RusACSR.[26] This study showed that the main errors are the incompleteness of data entry and the semantic content of entered data. The errors relating to incompleteness of data entry were most frequent for heart rate and blood pressure data (33%), results of instrumental examinations (55%), results of laboratory tests (55%), invasive interventions (38%), and advice at discharge on smoking, nutrition, and weight management (28%). The semantic errors were most frequent in data on past history (68%), main symptom at admission (51%), date and time of arrival of ambulance with the patient (49%), electrocardiogram parameters (48%), creatine phosphokinases and troponins (38%), coronary angiography (55%), and advice at discharge on smoking, nutrition, and weight management (50%). It was found that the error rate does not depend on the medical experience of users. After the training, these users entered about 80% of the data correctly. That is why obligatory annual training was organized for all Registry users. However, the problem of human error has still not been completely solved.

Another problem with the RusACSR is covering the Russian population of ACS patients. At first, only clinical centers from the All-Russian Vascular Program participated in the RusACSR. Currently, different centers participate in the Registry. Nevertheless, covering the Russian population of ACS patients is insufficiently representative.[38] The majority of centers that have participated in the RusACSR have quite good quality of health care, whereas most of the centers with low-quality health care do not want to participate in the Registry. Widespread implementation of the RusACSR is the only solution to this problem.

Conclusion

The RusACSR is a perspective project for different epidemiologic studies in Russian ACS patients.

Acknowledgments

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