Outpatient Cardiovascular Rehabilitation Registry in Iran: The First Rehabilitation Registry Experience at EMR

Masoumeh Sadeghi[(1)], **Mohammad Rafatifard**[(1,2)], **Mohammadmahdi Hadavi**[(3)], **Neda Drostkar**[(4)], **Mitra Naderi**[(1)], **Sara Zamani**[(5)], **Safoura Yazdekhasti**[(1)], **Elham Azizi**[(6)], **Habib Rahban**[(7)], **Hamidreza Roohafza**[(3)], **Kasra Shokri**[(1)]

Original Article

Abstract

INTRODUCTION: The collected information includes demographic profile, medical history, physical examination, patient risk factors, anthropometric evaluation, medications, echocardiographic results, and exercise testing of all patients who participated in the outpatient cardiac rehabilitation program in Cardiac Rehabilitation Department since 1996 until now. Each patient was assigned an electronic code by which the patient's information could be identified. Subsequently, standard questionnaires were used, such as International physical activity questionnaire (IPAQ) to assess physical activity, MAC NEW to assess the quality of life, Spielberg to measure anxiety, Beck to assess depression, and nutritional questionnaires.

RESULTS: The findings were recorded, and the data were analyzed by the web and SPSS software. For all patients, the forms were filled based on a number of variables including backgrounds, registration components, type of referral, diagnosis of underlying heart disease, methods of data collection and entry, details of the educational program, return to work, psychiatric condition, drug regimen, clinical condition, echocardiography findings, functional capacity and exercise test response, smoking status, nutritional habits, and finally their 5-year follow-up for events and re-hospitalization.

CONCLUSION: It is necessary for the authors to establish a cardiac rehabilitation registration that can properly display care quality indicators and collect and report standard data from different nations to improve the quality of cardiac rehabilitation services and identify weaknesses.

Keywords: Registries, Cardiac Rehabilitation, Main Variables, Follow-up, Iran

Introduction

Cardiovascular disease (CVDs) is one of the most common causes of death and disability worldwide [1]. In Iran, more than 46% of deaths are due to this disease [2]. CVDs are the leading cause of disability, with 10% of life loss in LMICs (low and middle-income countries) and 18% in high-income countries. With the increasing prevalence of CVDs, the burden of these diseases is growing significantly, especially in LMICs. With the growing health care costs, effective strategies for primary and secondary prevention and risk management of heart disease in this geographical area are needed [3].

1- Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
2- Health Science/ Exercise Physiology, Clinical Research Development Unit, Hajar Hospital, Shahrekord University of Medical Sciences, Shahrekord, Iran
3- Isfahan Cardiovascular Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
4- Interventional Cardiology Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
5- Department of Cardiology, Chamran Cardiovascular and Medical Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
6- Heart Failure Research Center, Cardiovascular Research Institute, Isfahan University of Medical Science, Isfahan, Iran
7- Physician Research Associate, Cardiovascular Research Foundation of Southern California, Southern California Medical Education Consortium, Universal Health System, Isfahan, Iran

Address for correspondence: Mohammad Rafatifard. Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran. E-mail address: rafati2821@yahoo.com

Cardiovascular rehabilitation is one of the treatment and prevention methods recommended by the American Heart Association and the European Heart Association for all patients with coronary heart disease [4, 5]. Several review studies have shown that cardiac rehabilitation (CR) is a cost-effective treatment [6]. Participation in these programs can reduce coronary heart disease mortality and decrease hospital admissions by approximately 25% [7]. CR has been shown to improve the quality of life in patients with heart failure although no significant effect by CR in mortality reduction has been noted [8]. However, in most countries, only a small percentage of heart patients have received cardiac rehabilitation services. In the United Kingdom, only 50 percent of patients, and in Australia and New Zealand, only 25 percent of patients diagnosed with acute coronary syndrome have participated in cardiac rehabilitation programs after discharge [9, 10].

according to clinical guidelines, audition and evaluation are recommended as significant components of CR [5, 11] to improve CR outcomes [12]. Clinical registration centers can be efficient and effective for assessing whether the services are under the clinical guidelines or not and evaluating the effectiveness of these services for people with CVD [13, 14]. In addition, these programs will help to compare clinical, behavioral, and health data with the same ones from other programs [15].

Despite a large number of active Acute Coronary Syndrome Registration Centers and other CVD registries in the world, including the Global Registry of Acute Coronary Events (GRACE) [16] and the National Myocardial Ischemic audit Project [17], there is no national heart rehabilitation registry in many eastern Mediterranean regional office (EMRO) countries, such as Iran. While providing relevant and reliable information through CR registration centers can help improve the quality and increase the use of CR [14].

Concerned with the lack of information about cardiac rehabilitation services and registration centers in Iran, for the first time in 1999, the Cardiac Rehabilitation Center of the Cardiovascular Research Institute of Isfahan University of Medical Sciences created a suitable structure for recording rehabilitation information in Isfahan province area. This information can be an essential way to follow up with the effectiveness of cardiac rehabilitation and monitor the quality of cardiovascular rehabilitation services over time. Also, this system can be effective for improving patient management and the quality and safety of patient care. In addition, it can inspire more provinces to establish their own centers thus resulting in a national database.

This study aimed to introduce a first rehabilitation registration model in the Middle East and its components, the method of collecting and entering data, and long follow up with patients.

Materials and Methods

Design and setting

Patients included in this study had a history of stable angina, myocardial infarction with or without ST-segment elevation, Percutaneous Coronary Intervention (PCI), open-heart surgery, heart failure, congenital heart diseases, peripheral vascular diseases, cardiac arrhythmias with or without resynchronization, and heart transplant. These patients were treated in one of the hospitals and referred to the cardiac rehabilitation department of the Cardiac Rehabilitation Research Center, Cardiovascular Research Institute.

Referrals of these patients to the cardiac rehabilitation center were often made on the advice of a physician, by calling the staff of the rehabilitation center, on the advice of other patients, through virtual groups, or by the patient him/herself. In this center, all patient information was registered, including demographic information, medical records, anthropometric variables, examination and laboratory tests, medications, smoking, alcohol use, ECG, exercise test at the beginning and end of the course, initial and final echocardiography, and nutritional status.

The main task of this center is to provide cardiac rehabilitation services to outpatients. The

outpatient phase is the main stage of cardiac rehabilitation that is performed in patients with cardiac surgery after 6-8 weeks, myocardial infarction after 3-4 weeks, and angioplasty after 1-2 weeks [18]. At this stage, the patients referred by cardiologists and surgeons, after filing and performing biochemical tests, are visited and examined by a sports medicine specialist. Then a cardiologist takes an echocardiography and exercise test from them. Based on the results of the exercise test, echocardiography, lab tests, and clinical examination of the patient, risk stratification was performed according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) protocol. In addition, specific exercise prescription plans and rules for each patient (in terms of intensity and time of exercises and amount of exercise sessions) were established.

Also, educational classes and counseling are organized for all patients with the following topics: healthy lifestyle changes, healthy diet, weight management, quitting smoking and other substances such as opium, control of cardiovascular risk factors such as hypertension (HTN), hyperlipidemia (HLP) and Diabetes mellitus (DM), and control of psychological illnesses such as stress, anxiety, and depression. Standard sports protocols are performed with modern sports equipment and cardiac monitoring during sessions. Figure 1 shows the different steps of data collection and recording.

Data collection
Forms and questionnaires are tools that the clinical teams (cardiologists, sports medicine specialists, nurses, nutritionists, psychiatrists, sports physiologists, and experts trained in this field) have used to record and collect data. Some of this data includes the patient's demographics and medical history, physical examination results, laboratory information, risk factors, anthropometric evaluation, medications, and echocardiographic and exercise testing were all gathered. A code is assigned to each patient and recorded electronically, through which each patient's information can be identified.

The International Physical Activity Questionnaire (IPAQ) for assessing individuals' level of physical activity, the MAC NEW questionnaire for quality of life, the Spielberger questionnaire for anxiety, the Beck for depression, and the Food Frequency questionnaire were used. Hematology and blood chemistry tests were taken by the coagulation method in the laboratory of the Cardiovascular Research Center. After 10 hours of fasting at night, these tests were administered to measure the profile of blood lipids (including triglycerides, total cholesterol, cholesterol with high-density lipoprotein (HDL-C), cholesterol with low-density lipoprotein (LDL-C)), fasting blood sugar, Blood Urea Nitrogen, C-reactive protein, Alkaline Phosphatase, Aspartate transaminase, Alanine aminotransferase, Complete Blood Count, Creatinine, and Uric acid. Blood sampling was repeated according to the initial conditions at the end of the cardiac rehabilitation course.

Exercise testing was performed at the beginning and end of the cardiac rehabilitation course with a treadmill attached to an electronic screen to monitor the patient. The modified Bruce protocol determines a person's physical capacity according to the guidelines [19]. For all patients, this test was the same for accurate comparisons. Systolic and diastolic blood pressure was measured manually with a standard medical blood pressure device. The patient did the exercises until feeling fatigued or having chest pain, ST-T changes, hypotension, or arrhythmia. In addition, a specialist measured myocardial function indices by echocardiography with a VIVID 3 EXPERT device made in Korea, and their information was reviewed and recorded.

As previously mentioned, the International Physical Activity Questionnaire (IPAQ) was used to measure individuals' level of physical activity, such as the amount of light, medium, and heavy activities and the total amount of walking and sitting during the week. Patients' physical activity was defined before and after the rehabilitation program. Psychological tests were used to determine anxiety and depression [20]. The Beck standard questionnaire was used to determine the degree of patients' depression, consisting of 21 four-answer questions with a score of 0-3 for each one.
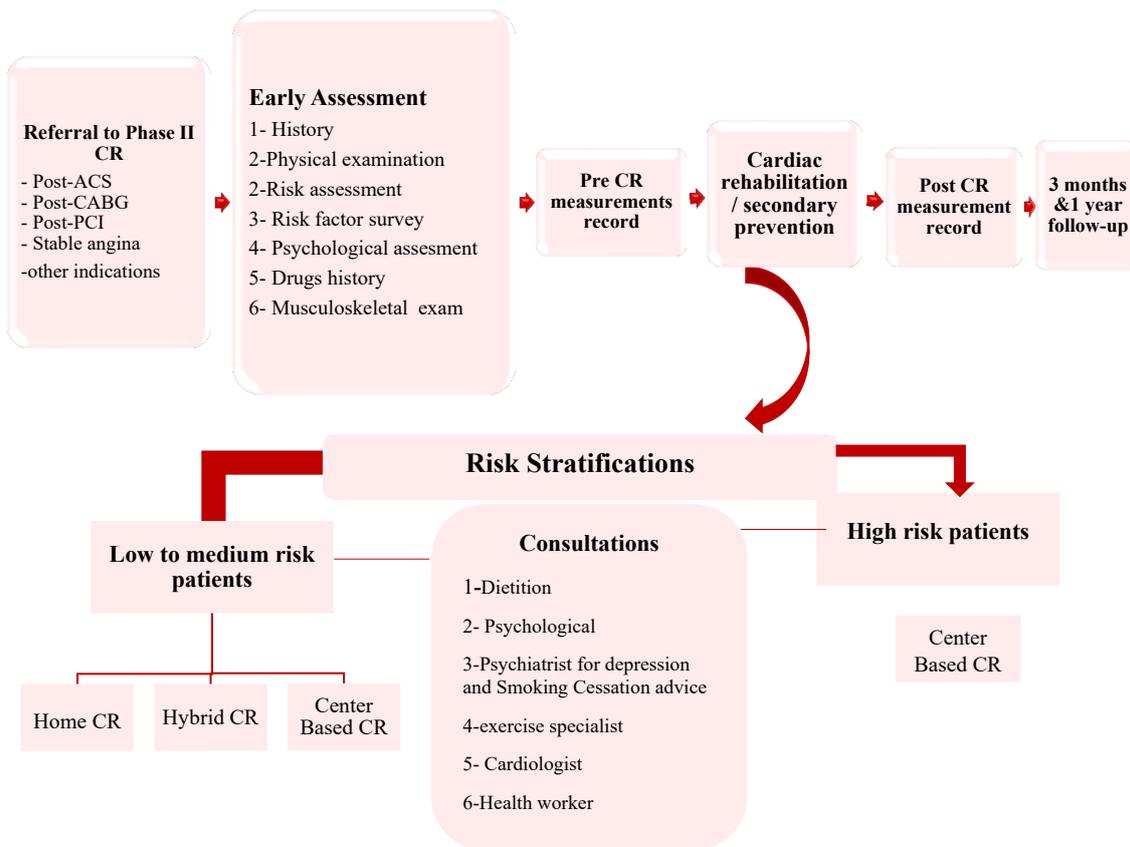
Figure 1. Operational diagram cardiac rehabilitation in Iran/Isfahan.
CABG: coronary artery bypass grafting; CR: cardiac rehabilitation; PCI: percutaneous coronary intervention, ACS: acute coronary syndrome

This questionnaire has been evaluated for validity and reliability in several studies in Iran, and its cut-off has been presented in such a way that the score between zero and 9 is standard, 10 to 19 is mild, 20 to 29 is moderate, and more than 29 is severe [21, 22]. To determine the level of anxiety, patients complete the Spielberger Anxiety Questionnaire, whose validity and reliability have already been confirmed. This questionnaire consists of 40 questions. The first 20 questions assess the state of anxiety in the "current moment of answering," and the second 20 questions measure the anxiety of the general and normal emotions and are scored according to the standards. It can be in the range between 20 and 80. If the total score is between 20-30, it means no or a minor level of anxiety, between 31-42 is mild anxiety, between 53-43 is moderate, and 54 and more is severe anxiety [23].

The Persian form of the MACNew questionnaire determines the quality of life [24, 25]. The total number of questions is 27, divided into three sections, including emotional function with 14 questions, physical function with five questions, and social function with 13 questions. These questions evaluate the symptoms of the disease, such as chest pain, shortness of breath, fatigue, dizziness, and leg pain. Each question can be in one, two, or all three sections. A score of 2-6 in each domain indicates a standard quality of life, and a maximum score of 7 indicates a high quality of life. The lowest score is one, which indicates a low quality of life.

The main variables
The variables that the Cardiac Rehabilitation Registry Center of Isfahan (Iran) has measured are required for the patient file and must be loaded into the system. These variables have

been monitored in several stages to report the progress and results of cardiac rehabilitation (before the start of the rehabilitation program, after the end of the program, three months and one year later, then during a cohort study every year for five years). These variables include risk factors of cardiovascular diseases such as height, weight, body mass index, blood pressure, lipid profile, DM, and lifestyles like nutrition, physical activity, psychological indicators, smoking, and medication use. As presented in Table 1, this data was collected

Table 1. Main variables collected as part of the Cardiac Rehabilitation Registry in Iran/Isfahan

Variable	Description
Sociodemographic	Age, sex, education, marital status, spouse's education level, number of children, current job, number of working hours per day, average household income per month, home ownership status, number of rooms, number of home infrastructure, type of insurance coverage
Reason for referral to cardiac rehabilitation	Myocardial infarction, stable angina, myocardial infarction with and without ST-segment elevation, CABG, heart valve surgery, congenital heart disease, heart failure, peripheral vascular disease, cardiac arrhythmia with or without Resynchronization treatments, heart transplants PCI
Cigarette and substance use status Before / After	Type of substance or tobacco used, sequence and number of times of use, duration of use, amount of use, duration of withdrawal
Alcohol consumption status Before / After	Sequence and amount of use, duration of use, duration of withdrawal
Previous medical records	History of diseases such as diabetes, hypertension, hyperlipidemia, peripheral vascular involvement, heart attack, stroke, kidney problems, lung, sleep apnea, etc. Family history of premature heart disease, diagnostic or interventional procedures of the heart: angiography, angioplasty, Cardiac bypass, valve operation, pacemaker and ICD
Anthropometric variables Before / After	Height, weight, waist circumference, pelvic circumference, body mass index
Physical examination	Head and neck, chest, abdomen, limbs and spine, pulses/ blood pressure, heart rate
Determining the risk level of heart patients	Based on ECG observation, echocardiography, exercise test and clinical findings, patients are divided into three levels: High Risk, Low Risk and Moderate Risk.
Patients taking medications Before / After	Type of medication, drug classification, dosage, frequency of use per day, time of onset and termination of medication that is asked of the patient before the start of rehabilitation and after the end of the course.
Blood biochemistry test results Before / After	CBC. Lipid profile, SGOT, SGPT, ALKP, BUN, CR, Uric Acid, CRP, FBS, HbA1C

Variable	Description
Exercise Test Before/after	Heart Rate (HR) at rest, HR at maximal Exercise, Functional Capacity, Approximate Mets, Total Time, ECG changes during exercise.
Echocardiography results	EF, ESD, EDD Valves (Mitral, Aorta, Tricuspid & Pulmonary) function.
ECG results	Rate, Rhythm, Axis, Hypertrophy, Ischemia
Psychological After / before	Has been screened for depression by questionnaire Beck and anxiety by questionnaire Spielberg
Quality of life After / before	Screened by questionnaire MAC New on initial evaluation and in follow-up.
Physical activity After / before	Counseling about physical activity needs on initial evaluation and in follow-up. using a questionnaire IPAQ
Dietary questionnaire After / before	Counseling with dietitian, using a Food frequency questionnaire (FFQ)
Exercise training	Prescribing a specific prescription (aerobic and resistance exercise) for each patient is based on the findings of the assessment, risk classification, comorbidities (peripheral arterial disease and musculoskeletal conditions) and program goals.
Follow-up (quarterly, one year, then every year for 5-year cohort)	At the time of follow-up, if the patient visits In-person, anthropometric measurements, blood tests, questions related to smoking, physical activity, diet, medication, mental states, whether or not to continue exercise after cardiac rehabilitation are asked. Otherwise, all the above questions will be followed up by phone.
give up smoking	Referral to a quit clinic in smokers
Refer to a psychiatrist	Referral to a psychiatrist clinic if need in the first screening
Back to work	Counseling to get back to work
Educating family members	Training sessions for the patient and the family One session per week
Reasons of cancellation for CR	Investigate the causes of incomplete rehabilitation
Major adverse cardiac event	Follow-up of patients for up to 5 years in terms of readmission for angiography, angioplasty, surgery or use of cardiac devices, any other hospitalization, cardiac and non-cardiac death, stroke,

according to the criteria and guidelines of the World Cardiac Rehabilitation Association to ensure that it can be compared with other countries.

Initially, the rehabilitation data registration system in Iran was launched in 1999 by the Isfahan Cardiac Rehabilitation Research Center in which patient information was recorded manually and on paper. At the same time, a single system was created to record cardiac rehabilitation, which provided information about the structure and services offered in cardiac rehabilitation centers in Isfahan province and compares patients over time.

Follow-up

All registered patients are evaluated annually for five years in terms of main risk factors, behavioral features, medicine use, exercise tests, and training effectiveness. In addition, patients are evaluated for the social consequences of heart disease, hospitalization or death, and its related cause. In case of a patient's hospitalization, files are reviewed by a specialist doctor, the leading cause is recorded. Moreover, in-hospital death cases are also examined, and a verbal autopsy is performed for out-of-hospital death.

Discussion

The establishment of national and international clinical registration centers is evidence of the necessity to access information for health care providers and funding of centers (public or private). Some examples include the National Heart, Lung and Blood Institute New York PCI reporting system (NYPCIRS) and the Australian and American Association of Cardiovascular Surgeons Registry [26, 27].

In the EMRO region, based on the available information, the Cardiovascular Rehabilitation Registration Center of Isfahan Cardiovascular Research Institute is one of the first rehabilitation registry centers. It was established in 2008 with the aim of monitoring and improving the quality of CR program services and promoting better care of cardiovascular patients. The strengths of these centers are improving the quality of training programs, using specialized multidisciplinary teams, and applying the recommendations and instructions of the World Heart Association.

This center is unique due to its direct and simultaneous connection with the administrative department of the hospital. It can be an essential source for monitoring the clinical results of patients, such as the number of admissions and mortality rates, which are directly available.

Data validation using clinical quality records in cardiac rehabilitation centers and clinical follow-up care centers has been introduced as an effective tool to improve clinical performance [28]. In recent years, clinical registration has improved treatment according to guidelines. It provides cost-effective care services [29], and thus essential information about care processes and their consequences to clinicians [30].

Therefore, the development of a national CR registration center that can represent care quality indicators makes it possible to collect and report standard data across the country [31], save more funds [32], and measure the improvement of quality of cardiac rehabilitation services [31].

However, there is a need for a national approach or audit system to standardize and develop the cardiac registry to increase the assessment and monitoring of cardiac rehabilitation centers that are currently providing services in Iran to improve the quality of care and rehabilitation services to cardiac patients.

In addition, establishing registration programs in other countries of the world and the EMRO region seems to be essential for secondary prevention and better control of heart diseases.

Conclusion

Rehabilitation registration and follow-up of these patients for five years is a unique study in the EMRO region. It is currently done for a city and is required to be nationalized it through the country.

Funding

and spiritual support Isfahan University of Medical Sciences.

Authors' contribution

AS and MR initiated the research concept, presented the results and discussions, wrote up of the draft manuscript and is the corresponding author. MH and ND reviewed and finalized the manuscript document. MN and SZ edited the manuscript, and had primary responsibility for the final content of the manuscript. SY, EA, HR and HR contributed to the study conceptualization, and provided constructive feedback on each draft of the manuscript. All authors read and approved the final manuscript.

Acknowledgment

Declarations

Ethics approval and consent to participate: Ethical considerations in this study include obtaining approval of the Ethics Committee (at Isfahan University of Medical Sciences, code: 398975 on 9 August, 2019) for the study protocol before beginning the study and informed consent from the participants, and assuring the participants that every effort would be made to keep their information confidential.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and analyzed during this study are included in the main document of this manuscript.

Competing interests: Authors declare that there is no conflict of interest.

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