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Exercise-based cardiac rehabilitation in twelve European countries results of the European cardiac rehabilitation registry☆

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ABSTRACT

Aim: Results from EuroCaReD study should serve as a benchmark to improve guideline adherence and treatment quality of cardiac rehabilitation (CR) in Europe.
Methods and results: Data from 2.054 CR patients in 12 European countries were derived from 69 centres. 76% were male. Indication for CR differed between countries being predominantly ACS in Switzerland (79%), Portugal (62%) and Germany (61%), elective PCI in Greece (37%), Austria (36%) and Spain (32%), and CABG in Croatia and Russia (36%). A minority of patients presented with chronic heart failure (4%). At CR start, most patients already were under medication according to current guidelines for the treatment of CV risk factors. A wide range of CR programme designs was found (duration 3 to 24 weeks; total number of sessions 30 to 196). Patient programme adherence after admission was high (85%). With reservations that eCRF follow-up data exchange remained incomplete, patient CV risk profiles experienced only small improvements. CR success as defined by an increase of exercise capacity >25 W was significantly higher in young patients and those who were employed. Results differed by countries. After CR only 9% of patients were admitted to a structured post-CR programme.
Conclusions: Clinical characteristics of CR patients, indications and programmes in Europe are different. Guideline adherence is poor. Thus, patient selection and CR programme designs should become more evidence-based. Routine eCRF documentation of CR results throughout European countries was not sufficient in its first application because of incomplete data exchange. Therefore better adherence of CR centres to minimal routine clinical standards is requested.

1. Introduction

Cardiovascular (CV) disease is the leading cause of death. It is responsible for almost a quarter of the disease burden in Europe resulting in substantial direct and indirect healthcare costs [1]. However, the enormous engagement in the development and availability of high technology diagnostic and therapeutic procedures for treatment of CV disease in recent decades is associated with increased survival and

☆ Plans for and progress on this project were presented previously at several abstract sessions of the EuroPRevent Congress 2011, 2012 and 2013

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reduced age-adjusted mortality in many European countries [2]. Since CV conditions are chronic and often reflect long-term patterns of unhealthy lifestyles and/or deconditioning of patients, benefit is not automatically achieved through high technology interventions and pharmacological management alone. Several studies suggest that preventive measures are responsible for at least half of the improvement [3]. Therefore patients need to be professionally supported to regain or maintain physical capacity and to achieve changes in lifestyle, risk factor management, better well-being and social and vocational participation [4]. Cardiac rehabilitation (CR) is the structured and multicomponent intervention to deliver these services [5].

Evidence of the benefits of CR has been well established [6–8]. In its consequence CR is categorised as a Class I recommendation in the ACRF/AHA guidelines for the management of patients with ST-elevation myocardial infarction [9], and a Class IIa recommendation in the ESC Guidelines for patients after acute myocardial infarction [10].

Effectiveness of CR, however, strongly depends on minimal standards to be delivered and guaranteed during all day care in clinical practice. Therefore the need for a continuous and interactive quality assurance process is crucial. An effective quality assurance, however, only can be achieved by a regular and structured exchange of institutional and clinical data including their continuous scientific evaluation. The first representative evaluation of CR activities in European Union Member States was the Carinex Survey published in 2002 [11]. In 2008 the EACPR introduced the European Cardiac Rehabilitation Inventory Survey (ECRIS) to investigate the status of CR in European countries [12]. The ECRIS study provided information on the CR structure, legislation, funding mechanisms and national guidelines. However, neither Carinex nor ECRIS was designed to deliver information about baseline clinical variables and outcome data of patients admitted to CR. But the success of CR service provision depends on data collection and quality assessment provided by a common, international core database and data standard across Europe.

Therefore the European Cardiac Rehabilitation Registry and Database (EuroCaReD) was introduced as the next step after Carinex and ECRIS to get information about CR across Europe from a predominantly clinical perspective. Cardiology Audit and Registration Data Standards (CARDS) for Europe and collection of a common core dataset across CR centres in European countries has been promoted earlier [13]. Based on this core dataset EuroCaReD aimed to assess the current CR practice in clinical all day care using a web-based data collection system.

The purpose of the EuroCaReD project was to put together information on the clinical status of CR across European countries by using an electronic case report form (eCRF) to consider how this data match in different countries and what parts of the CR have to be better standardised in accordance with the current guidelines to improve treatment results.

2. Methods

2.1. Study aims and characteristics

The aims were to develop and test the feasibility and practicability of a web-based registry in European countries that routinely provides data on CR settings, contents and interventions, clinical characteristics of patients and outcomes and thereby serves as basis for a regular European quality assessment of CR services and results. Participation to EuroCaReD was voluntary.

EuroCaReD was designed as a central internet database (http://www.eurocared.org) being connected to national registries and local databases of individual CR centres. The database itself was located in the European Heart House, Sophia Antipolis, France, hosted by Solarys IT Company, Götzis, Austria. All data were collected electronically using a web-based data entry system. The datasets were based on the CARDS model [13], and include items reflecting characteristics of the individual institution, patient's characteristics and actual CR performance standards [14].

2.2. Enrolment of study population

All European countries being members of the European Association for Cardiovascular Prevention and Rehabilitation (EACPR) have been invited to be part of the survey and 69 CR centres in 12 European countries could be selected by the national study coordinators to participate. Following the "snapshot" design of this study, for consecutive enrolment of patients undergoing CR a predefined time window of 8 weeks has initially been arranged. Because of insufficient patient inclusion within the first time period, a second prolonged time period of another 24 weeks has been offered to the participating CR centres for data collection. Except of Germany, participating only the second period, all centres collected their data within both time frames (October 1st, 2010 to November 30th, 2010, and October 1st, 2011 to February 28th, 2012). Informed consent of all participating patients was obtained according to the national regulations of the participating country.

2.3. Electronic case report form (eCRF)

The selection of variables aimed to closely mirror CR all day care and included the initiating clinical event (Table 1), demographic details (age, gender, employment status), history of CV risk factors (hypertension, hyperlipidaemia, diabetes, overweight/obesity, smoking, physical inactivity, depression) (Table 2), and CV risk factors as evaluated at the CR start and CR end (blood pressure, LDL-cholesterol, fasting glucose, body mass index, smoking status, watts achieved during exercise testing) (Table 4). Current medication at CR start has also been evaluated (Table 3). All these items have been tested for conformity in the participating countries. A complete overview on all eCRF items is given in Appendix 1.

2.4. Follow-up

Follow-up was limited to the duration of the individual rehabilitation programme, which varied considerably between 3 weeks (Hungary, Germany) and 24 weeks (Greece). Clinical follow-up data entered into the EuroCaReD database at the end of the regular CR programme included clinical events during CR, premature ending of the CR-programme, current risk factors, exercise capacity and medication.

2.5. Testing CR success

Due to limited follow-up time and data acquisition not monitored by an independent clinical research organisation (CRO), CR success could not be evaluated by its effect on clinical prognosis. Moreover, as management of CV risk factors like hypertension, hyperlipidaemia and diabetes already is started by therapeutic attempts preceding CR these items cannot serve as prognostic surrogate parameters. From this background and because all participating centres were offering bicycle exercise training as a major programme content, CR success has retrospectively been defined as "exercise capacity" gained during the CR process. Therefore, CR was regarded to be successful, if the "gain of exercise capacity" during CR was >25 W from CR start. This assumption is based on the experience in clinical practice and the need to reflect a heterogeneous population with a large variety of exercise capacities at baseline.

2.6. Data management

Data were anonymously entered online into the eCRF at each individual study site and stored in the central EuroCaReD database. To maintain patient's anonymity, only the identification number of each study participant was transferred to the central database. Patient's re-identification