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Italian survey on CArdiac RehabilitatiOn and Secondary prevention after cardiac revascularization: ICAROS study. A survey from the italian cardiac rehabilitation network: rationale and design

Studio ICAROS: survey sulla cardiologia riabilitativa e preventiva dopo rivascolarizzazione coronarica in Italia. Il razionale ed il disegno dello studio

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ABSTRACT: ***Italian survey on CArdiac RehabilitatiOn and Secondary prevention after cardiac revascularization: ICAROS study. A survey from the italian cardiac rehabilitation network: rationale and design. R. Griffo, F. Fattirolli, P.L. Temporelli, R. Tramarin.***

In this paper, the Italian Association for Cardiac Prevention and Rehabilitation (GICR) presents the rationale and design of the "Italian survey on CArdiac RehabilitatiOn and Secondary prevention after cardiac revascularization (ICAROS)". The survey is a prospective, longitudinal, multicentric survey, with a on-line web-based data collection. Its design corresponds to the survey's goal, i.e. to describe accurately in the Italian cardiological setting, through a representative number of cardiac rehabilitation centers belonging to the GICR national network, the characteristics, content and effects in the medium term of cardiac rehabilitation (CRP) inpatient or outpatient programs offered to patients after coronary artery bypass (CABG) or percutaneous revascularization (PTCA). The primary aims of the study are: a) to define the principal clinical characteristics of patients who have undergone PTCA or CABG and have been admitted to a CRP program; b) to identify the components of the CRP programs in terms of diagnostic procedures and assessment tests performed, treatments administered, educational programs and physical exercise interventions employed; c) to identify and analyze drug treatments prescribed at discharge from the acute facility and those prescribed at the end of the CRP program; d) to verify the clinical outcome during the course of the CRP program and at 6 months and 1 year after the end of the post-acute CRP program, as well as patients' adherence to the prescribed pharmacological therapy and to the recommended life styles, and the achievement and maintenance of the targets in relation to the modifiable risk factors; e) to define the consumption of major healthcare resources (major cardiac events, hospital re-admission, emergency care access, specialist visits) during the first year following a CRP program.

The survey population will consist of all patients consecutively discharged in the period November 3 - 30, 2008 at the end of an inpatient, day-hospital or outpatient CRP programme after CABG (isolated or associated to valve or ascending aorta surgery) or PTCA (rescue, primary or elective). There are no age, sex or other patient selection criteria. Based on ISYDE 2008 data analysis, we plan to recruit approximately 1300-1400 patients, 75% of whom with post CABG diagnosis and 25% with post PTCA diagnosis. Preliminary results of the survey are expected in the late winter 2009.

Keywords: cardiac rehabilitation, guidelines, survey, prevention.

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Background

Cardiac Rehabilitation and Prevention (CRP) is widely recognized as the standard model for the global treatment of patients with heart disease in post-acute phase and it represents the most care- and cost-effective model for the implementation of an adequate medium-long term strategy of secondary prevention [1-5].

CRP programs, with a flexible mode of delivery (outpatient or inpatient) but always targeted to the individual, are based on a series of integrated interventions that include:

1. care and pharmacological treatment aimed to achieve clinical stability,
2. evaluation of the global cardiovascular risk,
3. identification of specific goals for the control of each risk factor,

4. planning and implementation of an individual care project including therapeutic interventions aimed at risk reduction, structured educational programs aimed to bring about an effective change of life style (smoking cessation, appropriate diet, weight control, psychological well-being), and a prescribed program of physical exercise to reduce the disability consequent from heart disease, improve functional capacity and promote the patient's social and occupational reintegration, plus planning of a follow-up program aimed at consolidating and maintaining the results and at promoting adherence in the long term.

Despite the large body of scientific evidence documenting the effectiveness of CRP programs in terms of total mortality, cardiovascular mortality, and quality of life, important elements of discrepancy in the real world emerge from a number of major prospective observational studies. In particular, the overall number of cardiac patients who are admitted to a comprehensive CRP program after acute events is unsatisfactory, i.e. less than 30% of those appropriately indicated for such a program, both in the USA [6] and in Europe [7] and in our own country [8]. According to the latest data available, in Italy approximately 70% of patients after coronary or valvular heart surgery are admitted to CPR programs, but only 15% of patients following an acute myocardial infarction (AMI), whether or not treated with percutaneous revascularization (PTCA) and less than 5% of patients who have undergone elective PTCA [9]. Therefore, many patients are referred directly to primary care upon discharge and often (due to the progressively shorter length of stay in acute wards) they are discharged without an adequate assessment of the residual risk of coronary heart disease and progression of atherosclerosis, with incomplete treatment (as regards the therapeutic targets defined by current scientific evidence) and without any structured intervention to ensure the long term adherence to treatment and maintenance of adequate life styles.

Furthermore, concerning the role of CRP in the management of patients with ischemic heart disease after revascularization, there are no data, at least in our country [10], on which patients, after aorto-coronary bypass (CABG) but particularly after primary or elective PTCA, are admitted to a CRP program. In other words, it is not known if in clinical practice a management bias exists that reserves structured CRP intervention only to a specific subgroup of patients (those with complications? with comorbidities? male gender? younger patients? elderly?).

Similarly there are no data on whether patients admitted to CRP receive treatment with respect to the current guidelines and whether they are discharged in a more adequate condition to achieve an effective secondary prevention in the short-medium term. Recently the GOSPEL study carried out on more than 3,000 patients after recent AMI (65% of whom underwent revascularization: 41% PTCA and 27% CABG) showed, after a comprehensive CRP program (including a series of contacts and monthly clinical controls in the first 6 months, followed by 6-monthly controls for 3 years), an improvement in functional capacity and quality of life, a better adherence to pharmacological treatment and life style modifications, and a reduction in the global cardiovascular risk profile and subsequent coronary events, i.e. a significant reduction of AMI [11]. The results of this study however refer to a healthcare model that is not adopted in current clinical practice (and, realistically speaking, is not feasible), and the results of the few studies in the literature on the short and medium term effects of a CRP intervention on the same end-points are controversial [12-17].

Finally, data are also controversial on the short-medium term efficacy and sustainability of various post intensive rehabilitation care models, ranging from the "spot" model in post-acute care without any follow-up reinforcement program, to one with a periodic follow-up carried out at a rehabilitation center [11-18].

In the light of these considerations, following on the heels of the Italian Survey on Cardiac Rehabilitation (ISYDE-2008) carried out by the Italian Association for Cardiac Prevention and Rehabilitation (Gruppo Italiano di Cardiologia Riabilitativa e Preventiva - GICR) and following the call for action of the European Society of Cardiology (ESC) on the implementation of guidelines of cardiovascular prevention, the GICR considers it useful to conduct a survey to systematically gather accurate information aimed to define in the "real world" the characteristics of ischemic heart disease patients with coronary revascularization who are admitted to CRP programs, and what interventions and treatments are carried out, to verify in the short-medium term the adherence to such treatments and to what extent the recommended targets are pursued, and evaluate the correlation of these aspects with events and healthcare costs. The survey does not intend to modify the models of intervention and follow-up adopted by the single participating centers.

Methods

Study design

The Italian survey on cardiac rehabilitation and secondary prevention after cardiac revascularization (ICAROS) is a prospective, longitudinal, multicentric survey, with on-line web-based data collection. Its design corresponds to the survey's goal, i.e. to describe accurately in the Italian cardiological setting, through a representative number of CR centers belonging to the GICR national network, the characteristics, content and effects in the medium term of CRP inpatient or outpatient programs offered to patients after CABG or PCTA. The survey does not involve any experimentation of drugs or any diagnostic tests, care interventions or pharmacological treatments that are not part of the clinical practice and rehabilitation protocols routinely adopted by each single cardiologist/participating center (and which will be registered in the data base). Patients' anonymity will be guaranteed.

Aims

The primary aims of the study are:

1. to define the principal clinical characteristics of patients who have undergone PTCA or CABG and have been admitted to a CRP program;
2. to identify the components of the CRP programs in terms of diagnostic procedures and assessment tests performed, treatments administered, educational programs and physical exercise interventions employed (from individual treatments aimed at the recovery of functional autonomy to physical training);
3. to identify and analyze drug treatments prescribed at discharge from the acute facility and those prescribed at the end of the CRP program;
4. to verify the clinical outcome during the course of the CRP program and at 6 months and 1 year as well as patients' adherence to the prescribed pharmacological therapy and to the recommended life styles, and the achievement and maintenance of the targets in relation to the modifiable risk factors;
5. to define the consumption of major healthcare resources (major cardiac events, hospital re-admission, emergency care access, specialist visits) during the first year following a CRP program.

Population

The survey population will consist of all patients consecutively discharged in the period November 3 - 30, 2008 at the end of an inpatient, day-hospital or outpatient CRP program after CABG (isolated or associated to valve or ascending aorta surgery) or PTCA (rescue, primary or elective).

There are no age, sex or other patient selection criteria. In order to evaluate in the clinical praxis the real distance from the revascularisation procedure and access to CPR, there will be no limitation of time from the index event. Patients who died during the course of rehabilitation or were transferred-hospitalized for acute clinical recurrences (data will in any case be collected), patients after combined valvular and coronary surgery for preoperatory detection of asymptomatic coronary heart disease, patients with unfavorable prognosis at 1 year for any reason, and finally patients who did not give their informed consent to participate will be excluded from the survey.

Selection of participating centers

The process of identification of the CR centers invited to participate in the ICAROS study was based on the results of the study ISYDE-2008 [8] and the selection criteria applied were as follows:

– analysis of the core components of the center's rehabilitation program in conformity with national CRP guidelines [3],
– the center's recruitment potential, quantified as at least 15 patients who completed the inpatient, day-hospital or outpatient CRP program in the two-week study period of ISYDE-2008.

In selecting the Centers attention was paid to ensure an adequate representativity in terms of hospital organization, territorial distribution (metropolitan or not; north, central or southern Italy) and care setting (inpatient, day-hospital, outpatient).

Sample size

In view of the study design it is not possible to determine the sample size *a priori*. However, based on ISYDE 2008 [8] data analysis, we plan to recruit approximately 1300-1400 patients, 75% of whom with post CABG diagnosis and 25% with post PTCA diagnosis. This sample size is adequate from a statistical point of view with respect to the study aims and methods of data analysis.

Methods and mode of data collection and data quality control

ICAROS is a prospective survey with a duration of 4 weeks that will collect data on patients consecutively discharged after a first cycle of rehabilitation following surgical or percutaneous revascularization. A follow-up contact at 6 and at 12 months is planned. Data collection will be through completion of an electronic survey form (e-CRF) on-line in a dedicated section of the GICR website www.gicr.it. Access to the electronic survey forms will be restricted to the investigators previously identified by the study's Executive Committee according to the indications of the director of each participating center. The on-line data collection instrument is available for use round-the-clock and the data required for patients can be inserted in real-time, at any moment during the course of the survey.

The data collection masks will be structured with questions and multiple choice answers pre-ordered and with obligatory exits, in order to optimize the classification of the various items, reserving for a later detailed analysis the evaluation of less typical or less frequently observed situations. An on-line guide for the compilation of the fields is envisaged.

An on-line and telephone help-desk will also be available throughout the duration of the study to resolve or clarify any technical or clinical problems.

The Executive Committee is responsible for the control of data quality, and will generate eventual enquiries related to questions of incomplete or inconsistent data.

Data collection is structured in such a way as to prevent in any way tracing the identity of the subjects whose rehabilitation course is described in the survey. Concerning the structural and organizational data of the participating Centers, the GICR and its corresponding administrative office will manage the ownership and treatment of the data collected in full respect of the current national privacy act.

Data collection form and follow-up (Table 1)

The e-CFR form is designed to cater for the collection and analysis of data regarding both the participating centers (each center's structural and organizational characteristics) and patients: i.e. each patient's anthropometric, demographic and social data,

Table 1.

DATA COLLECTION FORM

1. Structural and organizational data of the recruiting Center.
2. Clinical setting (inpatient, day hospital, outpatient).
3. Patient's sex, age, and educational level.
4. Patient's weight and height at entry.
5. Patient's psychosocial and living conditions.
6. Name and telephone number of General Practitioner.
7. Index event (date and diagnosis): rescue, primary or elective PTCA, POBA and/or stent (specify DES or BMS); CABG, isolated or associated to other interventions.
8. Therapy at discharge from acute phase (active agents, dosage, note eventual contraindications or adverse events that compromise the use or efficacy).
9. Complications of the index event (acute phase): atrial fibrillation (AF)/atrial flutter(AFL), severe ventricular hyperkinetic arrhythmias, temporary or permanent pacemaker, perioperative AMI, type 1 neurological damage (stroke/TIA) or type 2 (cognitive impairment/decline), peripheral nerve damage, acute kidney failure or worsening of chronic kidney failure (increase of serum creatinine >1.0 mg/dl), liver/pancreas failure, sternal revision, complications of the arteries, thoracentesis, pericardiocentesis, pneumothorax, reintervention, inotropic/mechanical support, respiratory support, pulmonary embolism, systemic infection, transfusions.
10. Starting date of rehabilitation treatment.
11. Comorbidities: diabetes, chronic kidney failure (MDRD or calculated glomerular filtration rate), chronic obstructive pulmonary disease, chronic respiratory failure, previous non index AMI/PTCA/CABG, permanent atrial fibrillation, significant carotid vasculopathy (at least one stenosis of 50%), peripheral vasculopathy (documented or symptomatic or submitted to previous revascularization), previous TIA/stroke, gastro-esophageal disease, liver disease, metabolic syndrome, neoplasia, orthopedic/osteoarticular/rheumatic/immune diseases.
12. Anamnestic risk profile of atherosclerosis progression: familiarity, current smoker or quit smoking <1 year prior; arterial hypertension in pharmacological treatment, hypercholesterolemia (total and LDL) or chronic treatment with statins, sedentary life style (assessed with a specific scale), habitual consumption or not of fruit/vegetables/wine.
13. Risk profile of events: left ventricular ejection fraction (evaluated by echocardiography), presence of severe ventricular arrhythmias (evaluated by Holter/telemetry), presence/absence of residual ischemia (at rest or during exercise).
14. Instrumental examinations and assessments performed: echocardiogram, 6-minute walking test (entry, discharge, unable to be carried out), ergometric test or cardiopulmonary exercise test (entry, discharge, unable to be carried out), Holter ECG, ambulatory blood pressure monitoring, CT scan, nuclear scan, MRI, EEG, internal ultrasound, vascular Doppler, Barthel Index score (if performed).
15. Therapeutic procedures performed: pharmacologic or electric cardioversions, transfusions, thoracentesis, parenteral nutrition, intravenous drugs or infusions.
16. Content of the rehabilitation program: number and type of structured health education sessions aimed to modify life style (smoking cessation, appropriate diet, weight control, psychological intervention, physical activity).
17. Complications during the rehabilitation phase: AF/AFL, severe ventricular hyperkinetic arrhythmias, temporary or permanent pacemaker, perioperative AMI, type 1 neurological damage (stroke/TIA) or type 2 (cognitive impairment/decline), peripheral nerve damage, anemia, acute kidney failure or worsening of chronic kidney failure (Delta >1 creatinine), liver/pancreas failure, sternal revision, complications of the arteries, thoracentesis, pericardiocentesis, pneumothorax, re-surgery, inotropic/mechanical support, respiratory support, pulmonary embolism, systemic infection, transfusions.
18. At discharge: precise values of blood pressure (BP), heart rate (HR), BMI, weight, waist measurement, lipid profile, fasting glucose, glycosylated hemoglobin (in diabetics).
19. Pharmacological treatment at discharge from the Rehabilitation Center (active agents, dosage, incidental contraindications or adverse events that emerged during the hospital stay).
20. Date of discharge.
21. Mode of discharge.
22. Proposed follow-up program as per the Center's routine practice.

Follow-up

At 6 and 12 months (±15 days) the following information will be collected from the same patients, by telephone interview with each patient, conducted according to a standard relational model and not linked to other eventual visits that may be programmed by the Center:

1. Life style: smoking habit, dietary habit (measured with a specific scale), physical activity (measured by means of a specific scale).
2. Target: knowledge or not and usual values of BP < 140/90 (and <= 130/80 in diabetic subjects), LDL <100 (and <80), glycosylated hemoglobin in diabetics <7%.
3. In the case of a subsequent visit to the Center: precise values of BP, HR, BMI, waist measurement, lipid profile, fasting glucose, glycosylated hemoglobin in diabetics.
4. Pharmacological therapy: active agents, dosage, incidental contraindications and adverse events influencing the non prescription/withdrawal from treatment, qualitative assessment of adherence (evaluated with a specific questionnaire).
5. Events:
   - Death for any cause
   - Cardiovascular death
   - Non-fatal AMI
   - new (including "programmed") revascularization
   - re-hospitalization for cardiovascular causes (heart failure, angina, pacemaker, ICD and RCT)
   - fatal and non fatal cerebrovascular events
   - Emergency Care access without subsequent hospital admission
   - visits carried out/planned by the Center's follow-up program.
6. Diagnostic procedures: echocardiogram, exercise test, Holter ECG or blood pressure monitoring, nuclear scan, coronary angiography, coronary multislice-CT.
7. Drop-outs (i.e. patients lost to follow-up).

comorbidities and global risk profile, clinical data (related to the index event and rehabilitation phase) as regards complications, physical examination, and treatment, exercise training and pharmacological care. Information is gathered also on the duration of the post-acute rehabilitation program and on the type of follow-up program routinely adopted by the center.

At 6 and 12 months, information will be collected from the patients, through telephone interview conducted according to a standard relational model and not linked to other visits programmed by the Center, on: life styles adopted, the achievement or not of the therapeutic targets [blood pressure (BP), lipid profile, body mass index (BMI], pharmacological treatment (active agents and adherence), cardiovascular events, and on the healthcare resources consumed.

Statistical considerations

Apart from the overall analysis of end-points, data will be analyzed according to the revascularization strategy (CABG or PTCA), the sex and age of patients, the rehabilitation setting and the follow-up time intervals.

Ethical aspects and good medical practice

The protocol will be submitted for approval to the local Ethical Committee of each center participating in the Survey.

Notwithstanding the purely observational design of study, an informed consent will be obtained from each patient to authorize the treatment, in total anonymity, of patients' clinical data held in a centralized data-base.

ICAROS Study Investigators

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Informatics support

Website of the GICR www.gicr.it, Segno & Forma SpA Milano, Italy.

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ICAROS

ITALIAN SURVEY ON CARDIAC REHABILITATION AND SECONDARY PREVENTION AFTER CARDIAC REVASCULARIZATION

3-30 Novembre 2008

E-mail: icaros@gicr.it

SAVE THE DATE

3 Novembre 2008

Dopo lo studio ISYDE-2008, un'altra survey web-based del GICR.

Studiamo il contenuto e gli effetti nel medio termine dei programmi di Cardiologia Riabilitativa e Preventiva degenziali o ambulatoriali offerti a pazienti dopo un intervento chirurgico e percutaneo di rivascolarizzazione coronarica.

Parteciperanno allo studio circa 60 centri italiani di Cardiologia Riabilitativa che in un mese potranno arruolare nello studio circa 1200 pazienti con esiti di PTCA o di CABG.

IL PROTOCOLLO DI STUDIO ICAROS

Presentazione dello studio ICAROS:

a. Background
b. Disegno dello Studio
c. Obbiettivi
d. Popolazione
e. Centri partecipanti
f. Raccolta dati e data-base
g. Statistica
h. Aspetti etici
i. Bibliografia
j. Composizione del gruppo di ricerca
k. Cronoprogramma

DOCUMENTAZIONE PER I COMITATI DI ETICA

I-001 Lettera di notifica ai Comitati di Etica Locali
NB: Deve essere "personalizzato" con il nome del ricercatore e del Centro
>>> Scarica modulo

I-002 Consenso Informato
NB: Deve essere "personalizzato" con il nome del ricercatore e del Centro
>>> Scarica modulo

I-003 Informativa Privacy
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I-004 Lettera informatica per il Medico Curante
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>>> Scarica modulo

Protocollo dello studio ICAROS
>>> Scarica documento

Scheda di raccolta dati
>>> Scarica documento

CRONOPROGRAMMA

Maggio 2008	Stesura protocollo, selezione dei Centri
10 Giugno 2008	Evento start-up
1 Luglio 2008	Materiali per comunicazioni al Comitato Etico completati
31 Luglio 2008	Scadenza per invio Comitati Etici/Direzioni Mediche
Settembre 2008	Realizzazione e-CRF on-line sul sito e beta-test Invio del protocollo per pubblicazione sulla Rivista del GICR (Monadi Archives for Chest Disease) e ad una rivista di una società scientifica cardiologica non di settore
23 Ottobre 2008	Congresso GICR, simposio e incontro tra gli sperimentatori
3 Novembre 2008	START ARRUOLAMENTO e inserimento dati e-CRF
30 Novembre 2008	STOP ARRUOLAMENTO
Maggio-Giugno 2009	Follow-up sei mesi e inserimento dati e-CRF
Novembre-Dicembre 2009	Follow-up un anno e inserimento dati e-CRF
Gennaio 2010	Controllo e-CFR
Primo Trimestre 2010	Analisi dei risultati e pubblicazione

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