THE RE-HEART REGISTRY: A PROSPECTIVE, INTEROPERABLE, STANDARDISED CLINICAL REGISTRY OF OUTPATIENTS WITH HEART FAILURE

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Abstract

Purpose: To describe the creation and implementation of the RE-Heart Registry, a prospective, interoperable, highly scalable and standardised clinical registry of outpatients with heart failure (HF). Methods and Results: We carried out the steps, as follows: (1) data standardisation in accordance with national and international data elements. Dataset included all applicable standardised data elements published by the American Heart Association (AHA), American College of Cardiology (ACC) with the National Cardiovascular Data Registry (NCDR) and the Brazilian Cardiovascular Registries, as a reference the BREATHE (I Brazilian Registry of Heart Failure) and PINNACLE (heart failure and atrial fibrillation); (2) development of an initial data collection and clinical research workflow; (3) development of electronic case reports using REDCap and in accordance with the HIPAA privacy rule; (4) pilot test and validation of the data collection and clinical research workflows and CRFs; (5) development of automated data quality reporting using REDCap. Data collection occurs at the outpatient department at the moment of inclusion and every 6 months (phone calls and visits to the outpatients department). Conclusions: The RE-Heart Registry represents a comprehensive database capable to represent real clinical practice favouring clinical research, technology assessment, services management and health policies.

Keywords: heart failure; clinical registry; RE-Heart Registry

Introduction

In 2008, about 17.3 million deaths worldwide were attributed to cardiovascular diseases (CVD), and approximately 80% occurred in low and middle income countries, such as Brazil.[1] By 2030, more than 23 million people will die from the CVD representing a global epidemic, [2] generating more than $39 billion in costs per year for the health care system, in the United States alone. In this context, congestive heart failure (HF) is identified as the first cardiovascular cause of hospitalisation in the USA, representing one of the diseases most rapidly growing in recent times.[3]

The therapeutic approach to these patients is complex, resulting from a series of factors.[4] Accurate data collection becomes essential for understanding the disease, and studying new diagnostic and treatment methods. The implementation of prospective data registries has great potential for defining healthcare practices, health policies, biomedical research and the development of new technologies and health innovation.[5]

In Brazil there has been little work on gathering prospective data records involving follow-up and monitoring of outcomes of these patients, and considering the criteria of quality, data security and information. An HF Registry will serve as a basis for documenting the data in Brazil. Therefore, the objective of the study is to describe the creation and implementation of the RE-Heart Registry, a prospective, interoperable, highly scalable and standardised clinical registry of outpatients with HF.

Methods and Results

The registry has been designed as a longitudinal observational study to document the clinical practice and outcomes of patients with HF in an outpatient setting, at the Cardiology Institute of RS / University

Foundation of Cardiology (IC-FUC). The study was approved by the Institutional Review Board of the Cardiology Institute of RS / University Foundation of Cardiology (IC-FUC) according to local regulatory requirements.

Patients with the diagnosis of HF above 18 years-old are included. For diagnosis, the Boston criteria, shown in table 1, is used. For inclusion in the study, patients must have a score > 7, characterising the diagnosis of definitive HF. Patients who do not agree to participate in the study are excluded.

Table 1. Boston criteria for diagnosis Heart Failure (HF).

Criterion	Point value
Category I: history	
Rest dyspnoea	4
Orthopnoea	4
Paroxysmal nocturnal dyspnoea	3
Dyspnoea while walking on level area	2
Dyspnoea while climbing	1
Category II: physical examination	
Heart rate abnormality (1 point if 91 to 110 beats per minute; 2 points if more than 110 beats per minute)	1 or 2
Jugular venous elevation (2 points if greater than 6 cm H_2O; 3 points if greater than 6 cm H_2O plus hepatomegaly or oedema)	2 or 3
Lung crackles (1 point if basilar; 2 points if more than basilar)	1 or 2
Wheezing	3
Third heart sound	3
Category III: chest radiography	
Alveolar pulmonary oedema	4
Interstitial pulmonary oedema	3
Bilateral pleural effusion	3
Cardiothoracic ratio greater than 0.50	3
Upper zone flow redistribution	2

The following outcomes are evaluated: all-causes mortality, cardiovascular mortality, non-fatal myocardial infarction, stroke, hospital admissions, visits to the emergency department, costs related to the treatment and procedures, and quality of life.

The standardisation of the variables was performed according to the international national references of the area, as recommended by the American Heart Association (AHA), American College of Cardiology (ACC)[8] with the National Cardiovascular Data Registry (NCDR)[9] and the Brazilian Cardiovascular Registries,[10] as a reference the BREATHE (I Brazilian Registry of Heart Failure) and PINNACLE (heart failure and atrial fibrillation). Tables 2 and 3 show the classes, standardisation and selection of variables.

Electronic case report forms (CRF) (Appendix 1) were built using REDCap (Research Electronic Data Capture),[6] which has a secure methodological flowchart and web interface for electronic data collection and management of research. REDCap was developed in accordance with the HIPAA-Privacy Guidelines (The Health Insurance Portability and Accountability Act),[7] strictly complying with the safety and privacy standards for clinical data.

Table 2. Class and Source of Standardisation of Variables.

Variable class	Source of Standardisation
Patient Inclusion	
Patient identification	ACC/AHA[8]/NCDR[9]/ BREATHE
Clinical evaluation	ACC/AHA[8]
Lab exams	ACC/AHA[8]/ NCDR[9]
Image exams	ACC/AHA[8]/ NCDR[9]
Prognostic score	ACC/AHA[8]/ NCDR[9]/ BREATHE/ PINNACLE
Quality of life	Minnesota Living With Heart Failure Questionnaire[11]
Prognostic score	SHFM/HFSS
Quality of life	Minnesota Living With Heart Failure Questionnaire
Outcomes	ACC
Laboratorial exam	ACC/AHA[8]/ NCDR[9]
Procedural and exam	ACC/AHA[8]/ NCDR[9]

(ACC-AHA = American College of Cardiology-American heart Association; CDR= National Cardiovascular Data Registry; III Brazilian Guidelines on Chronic Heart Failure; NYHA= New York Heart Association; BREATHE =I Brazilian Registry of Heart Failure; PINNACLE = heart failure and atrial fibrillation; HFSS=Heart Failure SurvivalScore; SHFM:Seattle heart failure model).

The quality control of the data is insured by the following strategies: Training for data collection; operations manual outlining each step of the electronic CRF protocol in order to prevent incomplete data (mandatory data), inconsistent or non plausible values; central data check - a statistical analysis of the data is performed to verify possible inconsistencies; quarterly reports of screening, recruitment, data quality,

Adherence to the protocol, consistency and completion of data collection forms.

Table 3. Selected variables.

Variable class	Selected variables
Patient Inclusion	
Patient identification	Name, age, sex.
Demographic data of the patients	Address
Clinical evaluation	Patient ID, ethyisis, Diagnosis, comorbidities, disease aetiology, transplant list, smoking habits, Alcoholism, allergies, valve disease, infarct, CABG, NYHA, Dyspnoea, orthopnoea, NPD, cough, syncope, palpitations, Fatigue, chest pain, oedema, hospital admissions, medications, physical exam, vital signs
Laboratorial exam	Leukocytes, Haemoglobin, Creatinine, Urea, Uric acid, Proteinuria, TSH, Troponin I or T, Hs-Troponin I or T, Total cholesterol, Fasting glycaemia, HbA1c, NT-proBNP, Sodium, Potassium, Bilirubin, PCR Ct
Procedures and exams	Chest X-ray, Echo-Doppler, Exercise test - Ergo-Spirometry, VE / VCO2, Holter, Coronary Angiography, cardiac bypass, Electrophysiological study, Transcatheter Ablation, Electric cardioversion, Right heart catheterisation, Myocardial scintigraphy, Endomyocardial biopsy, Intra-aortic balloon, Cardiac Resynchroniser Implantation, Implantation of cardio-defibrillator.
Prognostic score	SHFM/HFSS
Quality of life	Minnesota Living With Heart Failure Questionnaire
Follow-up	
Laboratorial exam	Leukocytes, Haemoglobin, Creatinine, Urea, Uric acid, Proteinuria, TSH, Troponin I or T, Hs-Troponin I or T, Total cholesterol, Fasting glycaemia, HbA1c, NT-proBNP, Sodium, Potassium, Bilirubin, PCR Ct
Procedures and exams	Chest X-ray, Echo-Doppler, Exercise test - Ergo-Spirometry, VE / VCO2, Holter, Coronary Angiography, cardiac bypass, Electrophysiological study, Transcatheter Ablation, Electric cardioversion, Right heart catheterisation, Myocardial scintigraphy, Endomyocardial biopsy, Intra-aortic balloon, Cardiac Resynchroniser Implantation, Implantation of cardio-defibrillator.
Prognostic score	SHFM/HFSS
Quality of life	Minnesota Living With Heart Failure Questionnaire
Outcomes	Death

(CABG = Coronary artery bypass grafting, NYHA = New York Heart Association, NPD = paroxysmal nocturnal dyspnoea, CRP Ct = c protein reactive Ct , TSH = Thyroid-Stimulating Hormone, VE / VCO2 = carbon dioxide production relationship, HFSS=Heart Failure SurvivalScore; SHFM:Seattle heart failure model).

Conclusions

This paper describes the logic and design of the RE-Heart Registry, the first prospective, multicentre clinical registry specific for patients with HF. We believe that the implementation of the RE-Heart Registry allows a better understanding of the Brazilian clinical practice in patients with HF and provides the background for the creation of new therapeutics for this class of patients, also having the potential to generate technologies and innovative research.

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Conflict of interest. The authors declare no conflicts of interest.

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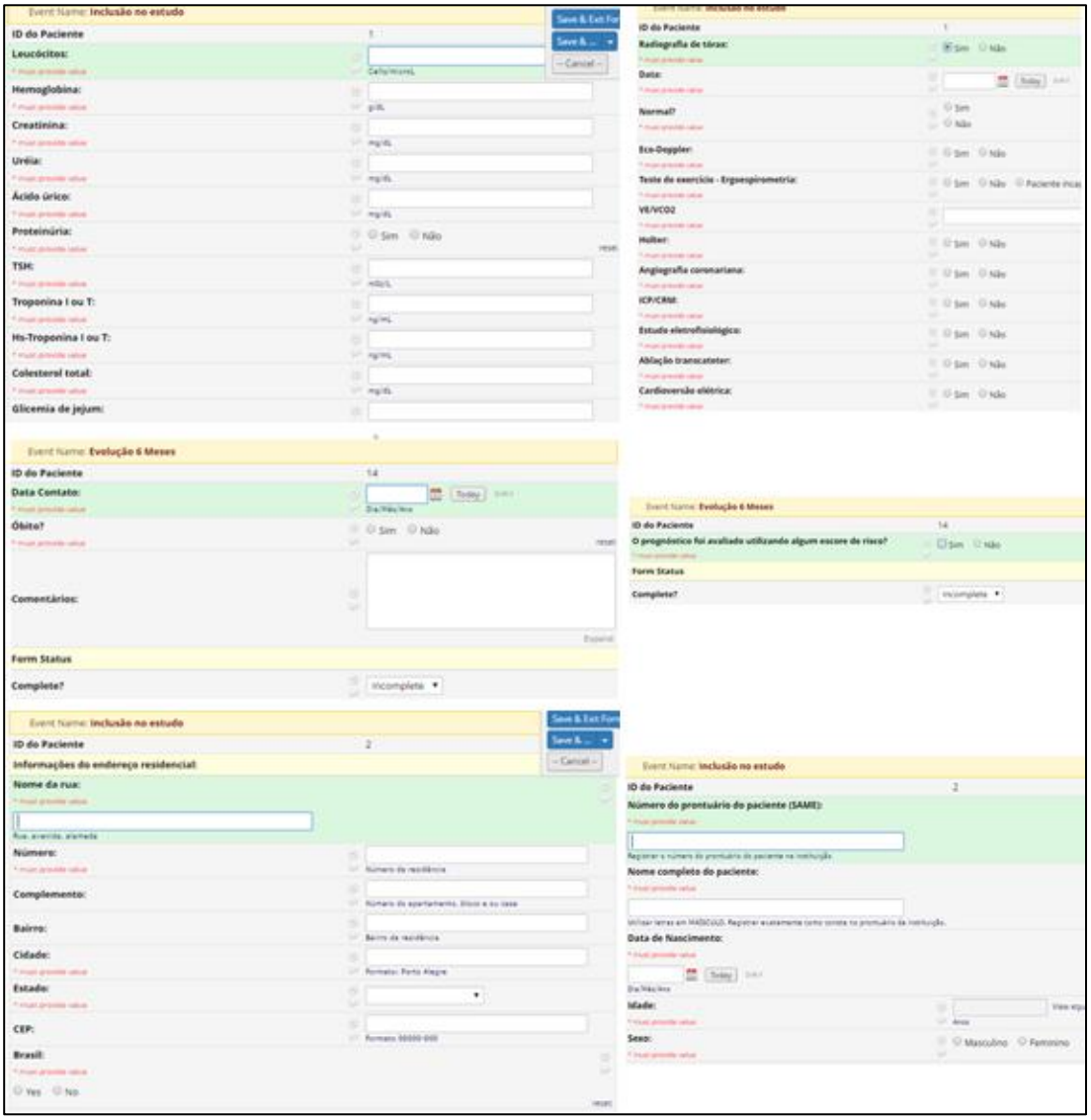
Appendix 1.


Event Name: Inclusão no estudo
ID do Paciente
Leucócitos:
Hemoglobina:
Creatinina:
Ureia:
Ácido úrico:
Proteinúria:
TSH:
Troponina I ou T:
Hs-Troponina I ou T:
Colesterol total:
Glicemia de jejum:
Event Name: Evolução 6 Meses
ID do Paciente
Data Contato:
Óbito?
Comentários:
Form Status
Complete?
Event Name: Inclusão no estudo
ID do Paciente
Informações do endereço residencial:
Nome da rua:
Número:
Complemento:
Bairro:
Cidade:
Estado:
CEP:
Brasil:
Event Name: Inclusão no estudo
ID do Paciente
Radiografia de tórax:
Data:
Normal?
Eco-Doppler:
Teste de exercício - Ergoespirometria:
VE/VCO2
Holter:
Angiografia coronariana:
ICP/CRM:
Estudo eletrofisiológico:
Ablação transcateter:
Cardioversão elétrica:
Event Name: Evolução 6 Meses
ID do Paciente
O prognóstico foi avaliado utilizando algum escore de risco?
Form Status
Complete?
Event Name: Inclusão no estudo
ID do Paciente
Número do prontuário do paciente (SAME):
Nome completo do paciente:
Data de Nascimento:
Idade:
Sexo: