THE RE-ENDO REGISTRY: A PROSPECTIVE, INTEROPERABLE, STANDARDISED CLINICAL REGISTRY OF INFECTIVE ENDOCARDITIS PATIENTS

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Abstract

Purpose: To describe the creation and implementation of the RE-Endo, a prospective, interoperable, highly scalable and standardised clinical registry of patients with infective endocarditis Methods and Results: We developed the RE-Endo through the following steps: i) data standardisation in accordance with national and international standard variables to allow for interoperability among systems; ii) development of an initial data collection and clinical research workflow; iii) development of electronic case reports using REDCap (Research Electronic Data Capture) and in accordance with the HIPAA (Health Insurance Portability and Accountability Act) privacy rule; iv) pilot test and validation of the data collection and clinical research workflows and CRFs; v) development of automated data quality report using REDCap. Data collection occurs at the outpatient department at the moment of inclusion and every 12 months during the follow-up (phone calls and visits to the outpatients department). Conclusions: The RE-Endo Registry represents a comprehensive database capable to represent real clinical practice favouring clinical research, technology assessment, services management and health policies.

Keywords: infective endocarditis, clinical registry, REDCap

Introduction

Infective endocarditis (IE) is a severe disease, associated with high morbidity and in-hospital mortality worldwide.[1-7] Despite improvements in diagnostic and therapeutic strategies, both the incidence and severity of the disease seem to be unchanged. Reasons for this persistent poor prognosis are numerous and include older patients with more severe disease, changes in the epidemiologic profiles and more patients with prosthetic or device related IE.[8-11]

New diagnostic and therapeutic strategies have been developed in order to improve the diagnosis and the prognosis of the disease. The Guidelines on the prevention, diagnosis, and treatment of IE of the European Society of Cardiology (ESC) were published in 2009 and gave new insight into both the diagnostic and therapeutic management of these patients.[12] However, how these recommendations are implemented in real world clinical practice has never been studied.

In this context, the ESC implemented the European Endocarditis Registry, and the main reasons were the following: the epidemiologic profile of IE has changed during the past years, with important differences between countries and increasing numbers of staphylococcal and nosocomial endocarditis cases.[1,8] Along with this initiative and based on the same reasons, we implemented RE-Endo in Brazil, a prospective, interoperable, standardised clinical registry of IE patients.

With RE-Endo, it will be possible to assess if both the implementation of guidelines published in 2009 and the use of early surgery are associated with a reduction in in-hospital and one-year mortality. Therefore, this registry will give us the unique opportunity to assess the characteristics of IE, the current use of imaging techniques, as well as the correct implementation of the guidelines and its consequence in terms of prognosis. All this will help improve the diagnosis and management of IE. The aim of this paper is to describe the creation and implementation of the RE-Endo Registry in Brazil.

Methods and Results

RE-Endo was created and implemented by the Clinical Registries Sector of the Instituto de Cardiologia do RS - Fundação Universitária de Cardiologia, a specialist cardiology referral hospital in Brazil. The registry is planned to expand to other Brazilian centres in 2017. Inclusion criteria are: patients are 18 years old or more, with definite IE according to modified Duke criteria,[13] including native, prosthetic, and cardiac device-related IE, and have signed an informed consent. Patients are excluded if they do not agree to participate in the study, or are already included in another trial.

Data on morbidity and mortality will be recorded at 1 month, 12 months, and 2, 3, and 4 years after the enrolment in the registry. The follow-up data will be collected either by phone call or during an outpatient scheduled visit in centre. Clinical outcomes include all-cause mortality, cardiovascular mortality, recurrence of IE and any other comorbidities will be recording. All patients will be approached by local centre investigators and will be asked for their written informed consent to participate in the registry, if applicable.

To create the RE-Endo, the following steps were undertaken:

1) Data standardisation in accordance with national and international standard variables to allow for interoperability among systems. Our dataset included all applicable standardized data elements such as the Brazilian and European guidelines for IE and the usual local practice terminology; as well as the standard elements proposed by the Endocarditis European Registry (EURO ENDO) to allow for interoperability with international data, and the Brazilian Institute of Geography and Statistics (IBGE). Table 1 presents the classes of variables included in the RE-Endo and the corresponding number of variables.

2) Development of an initial data collection and clinical research workflow. Based on the variables described above, our Clinical Registries Sector developed a first version of a data collection and clinical research workflow to be tested by our team.

3) Development of electronic case report forms (CRF) using REDCap (Research Electronic Data Capture)[14] and in accordance with the HIPAA (Health Insurance Portability and Accountability Act) privacy rule. Figure 1 represents an example of our CRF.

4) Pilot test and validation of the data collection and clinical research workflows and CRFs.

The electronic CRFs of the study was built in REDCap software and is filled and sent by Internet or Web, or using the offline version of REDCap. Electronic signature is used from the access with personal and non-transferable password. Through this, it will be possible to track all the actions performed by the data collectors. This registry is currently in pilot phase and all changes will be made as needed after staff assessment.

5) Development of automated data quality report using REDCap.

Data quality control will occur through several strategies, namely: automatic data quality reports will

Table. Class of variables included in the RE-Endo Registry.

Classes of Variables	Number of variables
Patient personal data	5
Previous endocarditis	5
History of cardiovascular diseases	10
History of valve disease	14
History of valve disease/Intervention	13
Previous cardiac surgery/invasive intervention	6
Risk factors / Clinical conditions	23
Antithrombotic treatment on admission	11
Chronology of symptom / management	5
Clinical examination	15
Complications on admission	4
Electrocardiogram on admission	1
Biochemistry	14
Microbiology on admission	15
Echocardiography	1
Other imaging techniques	9
Antimicrobial therapy	1
Complications under therapy	30
Cardiac surgery or other interventional procedure	6
Type of cardiac surgery/procedure	8
Tissue and material examinations	4
Echocardiography	28
Diagnostic criteria	8
Discharge	9

be generated monthly by REDCap, allowing researchers to identify at an early stage, problems related incomplete data, exemplified by unfilled fields or problems related to inconsistency of information; training of all researchers involved.

Conclusions

We believe the RE-Endo Registry represents a comprehensive database capable to represent real clinical practice favouring clinical research, technology assessment, services management, mortality according the current practice and adherence to the guidelines, the clinical, epidemiological, microbiological, and therapeutic characteristics, number and timing of non-invasive imaging techniques performed and health policies. By using

standardised and reproducible methodologies, the RE-Endo Registry allows for data integration and interoperability among datasets.

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Figure 1. RE-Endo Registry CRF.

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