MAEDICA – a Journal of Clinical Medicine
2019; 14(3): 191-195
https://doi.org/10.26574/maedica.2019.14.3.191

MÆDICA - a Journal of Clinical Medicine

ORIGINAL PAPER

The Romanian National Registry of non-ST Elevation Acute Coronary Syndromes – Design and Rationale

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ABSTRACT

Introduction: *Non-ST segment elevation acute coronary syndromes (NSTE-ACS) form a large part of the number of annual emergency admissions in the Cardiology Departments in Romania, representing a significant burden on the health care system resources. The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of NSTE-ACS patients represent ideal standards, which are difficult to implement, given the significant differences in the socio-economic climates of the various European Union countries, as the access to modern reperfusion techniques for NSTE-ACS patients, including Romania, is usually suboptimal.*

Objectives: *The evaluate the current implementation state of the ESC recommended protocols for the diagnosis and treatment of NSTE-ACS patients in Romania. There are no data regarding the number of patients who benefit from modern revascularization techniques, the time intervals between symptom onset, positive diagnosis and revascularization procedures, and the impact of these strategies on in-hospital and one-year mortality.*

Materials and methods: *We support the development of an online National Registry of NSTE-ACS patients, in which data obtained from the in-hospital medical records of patients undergoing invasive management will be prospectively recorded. The platform will initially be accessible to 11 interventional centers, and will include patients diagnosed and treated according to local protocols. Patient status at one year after the acute event will also be recorded. The Registry will eventually be accessible to any center in Romania caring for NSTE-ACS patients. The recorded variables will be based on those with a significant impact on the time from symptom onset to the positive diagnosis, type of clinical presentation, appropriate treatment initiation and the type of applied treatment.*

Eexpected outcomes: *Local clinical expertise, the number of treated patients and center-level technical barriers are expected to significantly influence the reported diagnostic and therapeutic measures. The performance of the various local in-hospital guidelines and transfer protocols between non-interventional and interventional centers will be analyzed, based on which recommendations and objectives can be defined in order to optimize the ESC guidelines implementation.*

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Article received on the 2nd of September 2019 and accepted for publication on the 27th of September 2019.

Conclusion: *The National Registry of non-ST elevation acute coronary syndromes will provide an essential tool that facilitates the implementation of optimal ESC guideline-driven diagnostic and treatment measures, by adapting its recommendations to the socio-economic status in Romania and ensuring the best possible outcomes for the NSTE-ACS patient.*

Keywords: ischemic heart disease, non-ST elevation acute coronary syndromes, unstable angina, myocardial infarction, registry, Romania.

INTRODUCTION

Cardiovascular disease is the main worldwide cause of mortality and disability (1). At a European level, the incidence and prevalence of cardiovascular disease, including all types of myocardial infarction, are lower in Western and Southern Europe, but significantly higher in high-risk countries, such as those in Eastern Europe, including Romania (2).

Non-ST segment elevation acute coronary syndromes (NSTE-ACS) form a large part of the annual number of Emergency Room admissions in the Cardiology Departments, representing a significant burden on the health care system resources. Almost a third of all myocardial infarction hospital admissions in 2015 in Romania were due to non-ST elevation myocardial infarction (NSTEMI) (3), without counting unstable angina (UA) patients.

BACKGROUND

The European Society of Cardiology (ESC) periodically updates the guidelines for the diagnosis and treatment of NSTE-ACS patients, the latest dedicated guideline published in 2015 setting clear recommendations regarding the timing and type of every diagnostic and treatment strategy, tailored to different patient types depending on the assessed individual risk score on admission (4). These recommendations were reinforced and updated by the 2018 ESC/EACTS Myocardial Revascularization Guidelines (5). On the other hand, such ideal standards are difficult to implement given the significantly different socio-economic climates in the various European Union countries.

The net benefit on in-hospital and 30-day mortality of timely reperfusion therapy has been well documented in ST elevation myocardial infarction (STEMI) patients (6), and confirmed by the data collected in the Primary PCI Romanian Registry of STEMI Patients after the introduction of the nationwide timely primary reperfusion programme in 2010 (7). In one year after starting the programme, in-hospital mortality of STEMI patients dropped from 13.5% in 2010 to 9.93% in 2011.

A routine invasive strategy in NSTE-ACS patients has, also, improved outcomes, including mortality, especially in patients with high-risk features (4, 8-10). Unfortunately, access to modern reperfusion techniques for NSTE-ACS patients in middle income countries is usually suboptimal. Also, the use of other modern diagnostic devices indicated stable coronary artery disease and in selected NSTE-ACS cases during the invasive management (11-13), such as optical coherence tomography, intravascular ultrasound and fractional flow reserve measurement, is rather limited, mostly due to costs.

Interestingly, the medium and long-term mortality in the case of NSTE-ACS is comparable or worse than in STEMI, at 12 to 18% at one year for NSTEMI and about 10% for STEMI patients (14-16). Previous reported data state that, besides the limited access to modern treatment, the higher mortality can also be explained by the fact that NSTE-ACS usually occurs at an older age, in the presence of multiple comorbidities and diffusely diseased coronary arteries. Also, NSTE-ACS patients are more likely to have non-specific symptoms, which lead to a significant delay in starting appropriate therapy, as well as short- and long-term undertreatment (17). ❑

OBJECTIVES

The current implementation state of the recommended protocols for the diagnosis and treatment of NSTE-ACS patients in Romania is unclear. There are no data regarding the number of patients who benefit from modern revascu-

larization techniques, on top of optimal medical treatment, the time intervals between symptom onset, positive diagnosis and the revascularization procedures, and the impact of these strategies on in-hospital and one-year mortality.

The quantification of these parameters is essential for identifying the limiting factors in the prehospital/in-hospital settings that prevent efficient guideline-driven strategies of care, and thus, offering the opportunity to generate recommendations related to optimizing the diagnostic and treatment of NSTE-ACS patients and consequently improving short and long-term prognosis. ❑

MATERIALS AND METHODS

Coordinated by the Romanian Academy of Medical Sciences and the European Regional Development Fund, we support the development of an electronic online National Registry of NSTE-ACS patients, which, through a user-friendly graphical interface, will facilitate the entry of patient data obtained from the in-hospital medical records of NSTE-ACS patients undergoing invasive management. The patient recruitment would be undertaken in a prospective, consecutive manner and prior to any data collection, the patient would sign the approved informed consent form.

This platform will initially be accessible to 11 centers capable of invasive management that will record per patient data, diagnosed and treated according to local protocols. At the same time, data relating to patient follow-up at one year after the acute event will be recorded. The Registry will eventually be accessible to any center in Romania treating NSTE-ACS patients in order to form a near to real-life picture.

The included variables will be based on those with a significant impact on the time from symptom onset to the positive diagnosis, appropriate treatment initiation and the type of applied treatment. Several demographic, risk factor and comorbidity variables will be requested, such as: age, gender, living conditions (urban/rural), known hypertension, smoking, diabetes, dyslipidemia, obesity, family history of relevant premature cardiovascular disease, previous myocardial infarction, stroke/transient ischemic attack, peripheral artery disease, chronic kidney di-

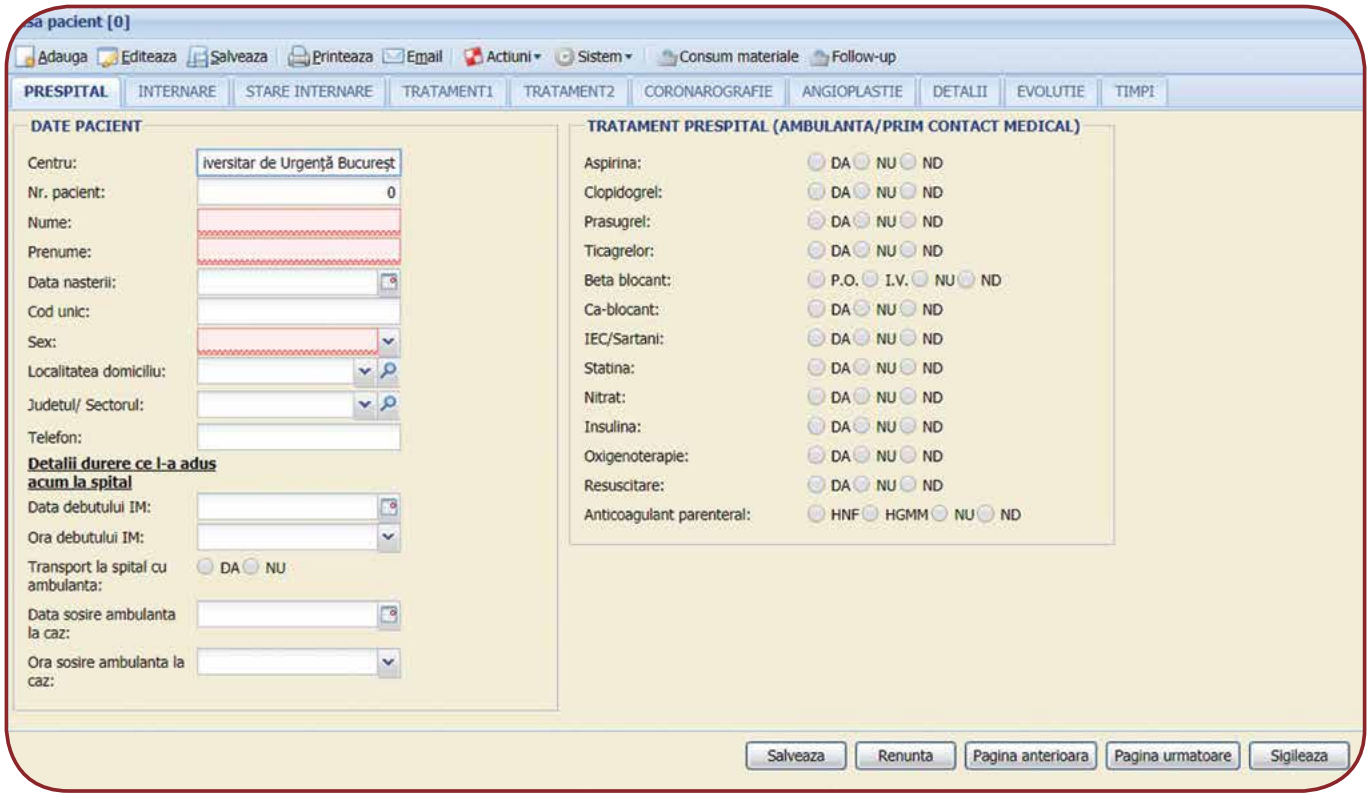

FIGURE 1. Example of Registry data entry page – anonymized personal information, symptom onset data, prehospital management

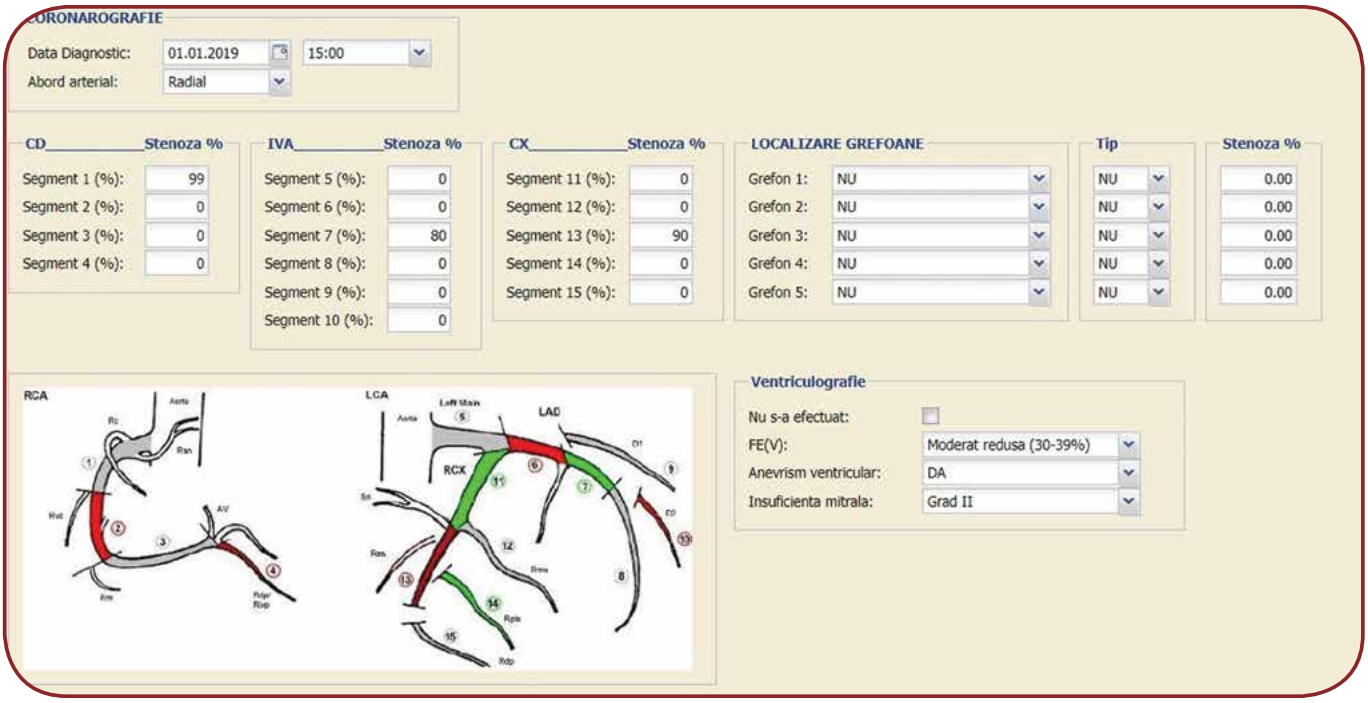

FIGURE 2. Example of Registry data entry page – coronary angiogram information (date/time/vascular access/coronary anatomy/presence and severity of coronary stenosis)

sease, chronic obstructive pulmonary disease and others.

Several other categories of interest will be recorded: chronic medication prior to the event, prehospital/at admission/in-hospital medication, clinical presentation, various test results (ECG, myocardial necrosis markers, left ventricle ejection fraction, renal function tests and others), time intervals between symptom onset, first medical contact (report page as seen in Figure 1), time of presentation in the Emergency Department, admission time in the Cardiology Department, coronary angiogram (report page as seen in Figure 2) and revascularization procedures, length of hospital stay, complications, clinical status at discharge and long term treatment.

The data requested at one year after the event will include: patient status (alive/deceased), the number of cardiovascular hospital admissions, angina and heart failure symptoms, revascularization procedures and clinical examination parameters.

An internal redundancy check algorithm will be implemented in the Registry, which will generate error messages if the data entered is invalid or mismatched.

The data will be periodically analyzed and the participant centers will be informed regarding the number of included patients, data quality and, if relevant to clinical practice, preliminary results regarding optimizing diagnostic and treatment protocols of their NSTE-ACS patients. ❑

EXPECTED OUTCOMES

Local clinical expertise, the number of treated patients, their risk stratification and center-level technical barriers are expected to significantly influence the reported diagnostic and therapeutic measures.

The current per patient transfer protocols for NSTE-ACS patients between non-invasive centers and invasive ones can be highlighted and the major causes for delays in invasive management can be identified and analyzed, taking into account the type of center that initially admits the patient in the Cardiology Department, the type of clinical presentation and the several variables known to be associated with an increased risk of complications and high mortality.

Depending on the results of the data analysis, several recommendations and short, medium and long-term objectives will be defined. The ultimate goal of the Registry is to provide a tool that facilitates optimal ESC guideline-driven diagnostic and treatment measures, by adapting

the recommendations to the socio-economic status in Romania and ensuring the best possible outcomes for the NSTE-ACS patient.

The Registry data will be compared with several other national/international NSTE-ACS registries from medium to high income countries, as well as low income countries, pinpointing the common issues in the management of these patients, as well as regional-specific problems. ❑

CONCLUSION

The Romanian National Registry of non-ST elevation acute coronary syndromes will render an overview of the diagnostic and treatment strategies of NSTE-ACS patients in invasive management centers, which is essential for assessing the ESC guidelines implementation at a national level. The main goal of the Registry is to identify factors that prevent the application of the current recommendations considered ideal and to propose solutions to overcome these obstacles and ultimately improve patient outcomes. ❑

Conflicts of interest: none declared.
Financial support: none declared.
Acknowledgement: The authors were supported by the Romanian Academy of Medical Sciences and European Regional Development Fund: Funding Contract 2/Axa 1/31.07.2017/SMIS 107124.

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