

The RO-CCI-STEMI registry: rationale and design of a single-centre study of cardiogenic shock and mechanical complications in STEMI

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ABSTRACT

Introduction: In-hospital mortality remains high in patients who develop cardiogenic shock or mechanical complications after ST-elevation myocardial infarction (STEMI), despite primary percutaneous coronary intervention, cardiac surgery, vasoactive therapy, and mechanical circulatory support.

Aims: To present the rationale and design of the Romanian C.C. Iliescu - ST-Elevation Myocardial Infarction (RO-CCI-STEMI) Registry, established to describe the incidence, baseline characteristics, resource use and prognosis of STEMI patients complicated by cardiogenic shock and/or mechanical complications.

Methods: The RO-CCI-STEMI Registry is an observational, retrospective, single-centre study of all consecutive STEMI patients from a large tertiary centre in Romania hospitalized during 2011-2025. Data collection was performed from the patient's electronic health records through an automated process using Python 3. Patients were divided into four mutually exclusive groups.

Registry population: Of 10556 STEMI patients enrolled, 882 had cardiogenic shock alone, 97 mechanical complications alone, 195 both, and 9382 neither. Formal data analysis is due to be performed. The pre-specified statistical analysis plan is reported within this paper.

Conclusion: The RO-CCI-STEMI Registry is designed to address gaps in epidemiology, management and prognosis of these complications after STEMI, and serve as a platform for future analyses in a real-world Eastern European setting.

Keywords: STEMI, cardiogenic shock, myocardial infarction, mechanical complications, registry

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INTRODUCTION

Acute myocardial infarction (AMI) with ST-elevation (STEMI) remains one of the most severe cardiovascular emergencies, with a large variability of in-hospital course [1]. While timely reperfusion through primary percutaneous coronary intervention (PCI) allows favourable recovery in many patients [1], some patients develop catastrophic complications, such as cardiogenic shock (CS) (6-10% [2]) and mechanical complications (MC) (approximately 1% [3]).

Despite comprehensive recommendations issued by professional societies [3-5] and significant advances

in reperfusion strategies, intensive care and pharmacotherapy, outcomes remain poor, with reported mortality rates of approximately 30-60% for CS [6] and nearly 40% for MC [7].

These high mortality rates reflect not only the intrinsic severity of these conditions but also substantial gaps in contemporary evidence regarding their epidemiology, risk stratification, and real-world management. Recent analyses, Lusebrink et al. [8] have highlighted the paucity of robust data, particularly for MC, and the limited generalizability of existing studies to routine clinical practice.

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Rationale

CS and MC following STEMI are rare but devastating events in which further improvements in early detection and management are urgently needed. However, generating high-level evidence in these settings is intrinsically challenging, and randomized controlled trials (RCTs) enrolling patients with MC are virtually non-existent, while other trials in AMI-CS, excluded patients with MC [9]. The acute onset, rapid clinical deterioration, and high early mortality of these conditions markedly limit the feasibility and ethical practicality of RCTs in this clinical setting.

In this context, large sample size, well-structured STEMI registries represent an indispensable source of information that would enable systematic collection of real-world data across the entire clinical spectrum, allowing accurate characterization of epidemiology, temporal trends, precipitating factors, and outcomes of CS and MC. Although, several observational studies [10–12] have already provided valuable information particularly about invasive haemodynamic monitoring [13] or systems-of-care organization [14], larger databases with consecutive enrolment and comprehensive characterization during hospitalization, are strongly needed.

This is essential to bridge existing knowledge gaps, by providing comprehensive epidemiological and clinical data on CS and MC. In addition, this type of registry could support further hypothesis generation, guide quality improvement initiatives, and ultimately inform national health policies aimed to prevention and reduction of mortality associated with these complications.

MATERIALS AND METHODS

Study design

This research is an observational, retrospective, single-centre cohort study, based on the **RO-CCI-STEMI Registry** (Romanian C.C. Iliescu - ST-Elevation Myocardial Infarction), from the Emergency Institute for Cardiovascular Diseases “Prof. Dr. C.C. Iliescu”, Bucharest, Romania, a large tertiary cardiovascular center. The study population comprises all consecutive patients admitted with STEMI, who were enrolled in the registry between 01 January/2011 and 31/December 2025.

Patient population

The list of inclusion and exclusion criteria for the RO-CCI-STEMI Registry, is shown in Table I:

Table I:

Inclusion criteria	Exclusion criteria
- Admission in our institution with STEMI (index hospitalization – unique patients) - Age >18	- Other forms of ACS presentations: NSTEMI, unstable angina, transient ST-elevation or early post-MI angina - Solely evidence/scar of an old MI - Acute aortic syndromes, myocarditis, Takotsubo syndrome

ACS = acute coronary syndrome; NSTEMI = non-STEMI.

MC and CS coexist frequently, so patients were divided into four mutually exclusive groups instead of overlapping the exposure groups: MC only (n=97), CS only (n=882), CS with MC (n=195), and control group with neither complication (n=9382). Consequently, MC was recorded in 292 patients (97+195) and CS in 1077 (882+195). This overlap is illustrated in Figure 2.

We classified all CS patients into SCAI (Society for Cardiovascular Angiography and Interventions) SHOCK stages [5,15] and included only SCAI C, D & E patients in the CS group. Patients with mixed shock (8.6% of total CS patients), were included only if the CS component preceded the septic shock component [16].

Regarding the MC group, the following types of MC have been included: free-wall rupture, ventricular septal rupture, papillary muscle rupture and pseudoaneurysms. True aneurysms have been excluded from the MC group as their acute prognosis is less severe than that of the other MC, and their complication is mainly related to thrombo-embolic events, and less to the risk of fatal MC [7].

Data collection

Patient selection was run through the hospital’s Info World Hospital Manager app. The ICD-10 codes used to identify patients for inclusion are I21.0-I21.3 and I21.9 as the primary discharge diagnosis for transmural MI (I21.4 excluded for “subendocardic MI”). Also, patients with ICD-10 codes as secondary discharge diagnosis have been included, if the AMI hospitalization lead to a severe complication marked as primary discharge diagnosis instead (example for MC or CS: Q21.0, I23.0-I23.9, I51.0-I51.3, I51.5, R57.0).

After patient selection, electronic health records (EHRs) from each patient’s MI hospitalization were ex-

tracted. Data extraction from the EHRs was performed through two distinct methods: 1. Writing an offline algorithm for this project in Python 3 using the Pandas and NumPy libraries, which automatically extracted multiple variables & the 2nd method was manual data entry into a Microsoft Excel database for variables that could not be automated.

Variables and outcomes

We recorded 310 variables per-patient. The primary outcomes include the incidence of CS or MC in patients presenting with STEMI and the in-hospital mortality of these complications (complete list of documented variables and secondary outcomes available in the Appendix).

Statistical analysis plan (detailed version in the Appendix):

- descriptive analysis of baseline characteristics, management and in-hospital outcomes, overall and by group;
- multivariable logistic regression for in-hospital mortality and for development of CS and MC;
- inclusion of clinically relevant variables irrespective of univariable significance;
- assessment of multicollinearity before model construction;
- missing data will be reported for every variable analysed, with imputation applied where appropriate;
- incorporation of calendar year to evaluate temporal trends;
- CS and MC entered as part of the four mutually exclusive groups, allowing the effect of their co-existence to be estimated directly;
- predefined, exploratory subgroup analyses;
- effect estimates reported as odds ratios with 95% confidence intervals; $p < 0.05$ for statistical significance;

Ethics

This research was approved by the Ethics & Research Review Committee of our institution (updated Registration No. 5373/27.02.2026) and is carried out as a PhD thesis by RF within Carol Davila University, Bucharest. Patients signed an informed consent form at hospital admission, including approval for the use of their medical data for academic purposes. Data extraction as variables was undergone into a fully anonymized dataset. The Ethics & Research Review Committee of our institution deemed that the general admission consent signed by the patients is sufficient for the realization of this study.

Registry status and cohort profile

The RO-STEMI program

In the national RO-STEMI program, participating hospitals shared emergency PCI shifts with other centers, based on a “rotating-day algorithm”, with our institution receiving AMI patients from Bucharest and the southeast region of the country [17]. The program started in 2010, with 2011 representing its first full year of operation [18] (Figure 1). Initially, the program included 10 centers across 5 cities, of which 4 were located in Bucharest, providing continuous emergency PCI coverage [18]. Since then, the network has expanded substantially, reaching 21 centers in 13 cities across Romania, explaining part of the drop in admissions at our hospital after 2019, especially after the resolution of the COVID-19 pandemic [19]. It progressed from 4209 primary PCIs in STEMI patients in 2011 to 10382 primary PCIs in 2024 [19]. Despite the addition of new participating hospitals, our institute remains the only center in Bucharest that continues to provide emergency PCI coverage twice weekly [17,19].

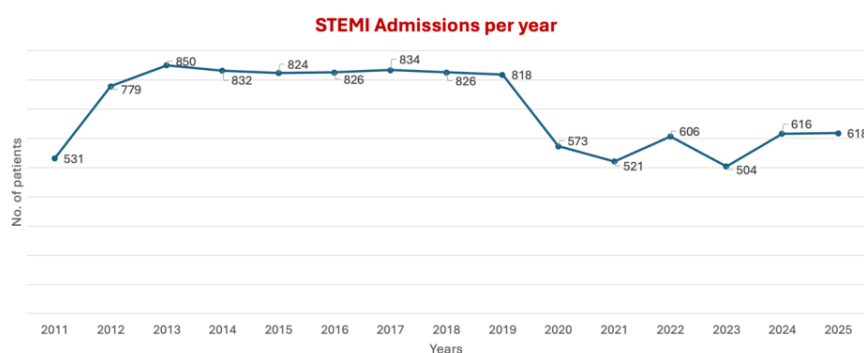


Figure 1. STEMI Admissions per year in the Emergency Institute for Cardiovascular Diseases “Prof. Dr. C.C. Iliescu”, Bucharest, Romania.

Participant flow

During the included study period from 01 January 2011 to 31 December 2025, a total of 10556 individuals were enrolled in the RO-CCI-STEMI Registry. We present, in the Study Flow Diagram (Figure 2), their distribu-

tion across the exposure groups and the control group, as well as the main classifications and interventions. These figures describe enrolment only; no inferential analysis has been performed, and statistical analysis will be reported separately according to the plan above.

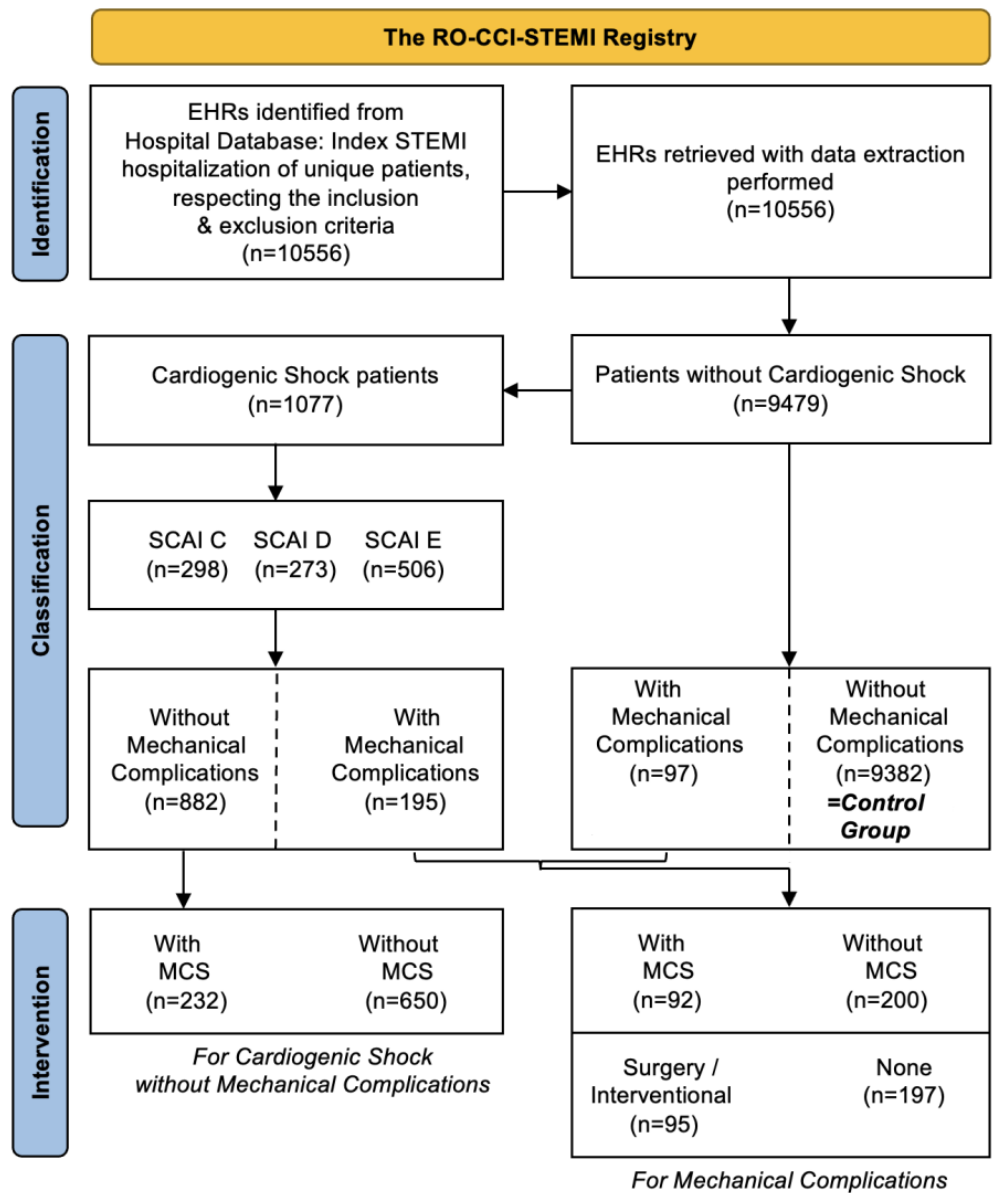


Figure 2. Study Flow Diagram. EHR = electronic health record; MCS = mechanical circulatory support.

DISCUSSION

The RO-CCI-STEMI Registry is a large sample size STEMI/AMI registry including 10556 consecutively enrolled patients, in whom CS and MC were recorded

in 10.2% and 2.7% respectively. Compared to the available data in the literature (Table 2); the RO-CCI-STEMI Registry is the largest single-centre registry in Europe, providing data about both CS and MC.

The RO-CCI-STEMI Registry may support in ad-

Table 2: The RO-CCI-STEMI Registry compared with major registries and cohorts reporting cardiogenic shock (CS) and/or mechanical complications (MC) in STEMI/AMI.

Authors	Year	Title/Observations	Type	Patient Con-secutiveness	Sample Size	Percentage of CS	Percentage of MC
Redfors et al. [20]	2015	SWEDEHEART Registry	National registry (Sweden)	Yes	44,414	8.2% (n=3,654)	NA
Backhaus et al. [21]	2018	Bremen-STEMI Registry	Regional registry (Bremen, Germany)	Yes	7,865	13% (n=981)	NA
Isorni et al. [22]	2018	FAST-MI programme (USIK 1995, USIC 2000, FAST-MI 2005 & 2010)	National registries (France), multicentric	Yes	10,610	5.9% (n=630)	NA
Lanz et al. [23]	2019	Cardiobase Bern PCI Registry	Single-centre registry	Yes	2,508	NA	1.1% (n=26)
Xue et al. [24]	2019	MOODY Registry	Multicentric registry (24 hospitals, China)	NR	9,265	NA	1.6% (n=146)
Ning et al. [25]	2019	CAMI Registry (China Acute Myocardial Infarction)	Multicentric registry (China)	Yes	28,230	8.1% (n=2,273)	NA
Hunziker et al. [26]	2019	AMIS Plus Registry	National multicentric registry (83 Swiss hospitals)	Yes	52,805	7.7% (n=4,090)	NA
García-García et al. [27]/El Ouaddi et al. [12]	2020 / 2023	Ruti-STEMI(-Shock) Registry; MC from 6,033 pts, CS from 7,984 pts	Regional population-based registry (multicentric, ~850,000 inhabitants, North Barcelona, Spain)	Yes	6,033 (MC); 7,984 (CS)	6.2% (n=493)	2.2% (n=135)
Lauridsen et al. [28]	2020	Denmark nationwide medical registries	National database (Denmark)	Yes	101,834	7% (n=7,040)	NA
Bouisset et al. [29]	2021	MODIF Registry	Multicentric national registry (65 centres, France + La Réunion)	Yes	6,185	NA	1.34% (n=83)
Xu et al. [30]	2022	Cangzhou + Tianjin Hospitals	Two-centre retrospective case-control (China)	Yes	22,016	NA	0.9% (n=195)

Authors	Year	Title/Observations	Type	Patient Con-secutiveness	Sample Size	Percentage of CS	Percentage of MC
Vallabhajosyula et al. (CS) [31]; Younes et al. (MC) [32]	2022 (CS); 2025 (MC)	National Inpatient Sample, USA; CS from 4.3 million STEMI, MC from 4,450,219 AMI	National administrative database (USA)	Yes (all-payer NIS)	4.3 million (CS); 4,450,219 (MC)	8.5% (n=368,820)	0.2% (n=7,025)
Yan & Yuan [33]	2025	very elderly (≥75 y) AMI, China	Single-centre retrospective cohort	Yes	2,467	NA	9.6% (n=236)
Filipescu et al.	2026	RO-CCI-STEMI Registry	Single-centre registry	Yes	10,556	10.2% (n=1077)	2.7% (n=292)

Row shading by study type:



AMI = acute myocardial infarction; AMI-CS = AMI-related cardiogenic shock; CS = cardiogenic shock; MC = mechanical complication(s); n = number of patients; NA = not available; NIS = National Inpatient Sample; NR = not reported; PCI = percutaneous coronary intervention; pts = patients; STEMI = ST-segment elevation myocardial infarction; VA-ECMO = veno-arterial extracorporeal membrane oxygenation; y = years
ACS = acute coronary syndrome; NSTEMI = non-STEMI.

addressing persistent knowledge gaps regarding the epidemiology, management, and prognosis of CS and MC following STEMI in the contemporary reperfusion era. By spanning 15 years in a high-volume tertiary cardiovascular center, this registry is designed to offer a unique longitudinal perspective on these catastrophic entities within a real-world Eastern European health-care setting.

One of the major strengths of the registry lies in its ability to evaluate annual trends in the incidence and outcomes of CS and MC [34]. Temporal analyses can provide insight into whether improvements in early reperfusion strategies, critical care organization, and the adoption of MCS have translated into a sustained reduction of mortality, or whether these complications persist at a relatively constant rate despite technological progress. Such data will be particularly relevant given conflicting reports from international registries regarding declining versus stable rates of post-MI MC [12,32], as well as the ongoing debate surrounding optimal timing and patient selection for advanced therapies in CS [6].

From a clinical standpoint, the detailed phenotyping of patients included in the registry will allow for identification of risk factors associated with the development of CS or MC, as well as prognostic markers once these complications occur. This information has direct implications for bedside decision-making, including early recognition of high-risk STEMI presentations, timely escalation of care, referral to surgical or advanced shock centers, and rational use of invasive monitoring and MCS. Moreover, stratification of CS according to SCAI stages facilitates alignment with contemporary shock frameworks and enables meaningful comparisons with other international datasets.

The national epidemiological value of the RO-CCI-STEMI Registry is also substantial. Romania, like many Eastern European countries, remains underrepresented in large cardiovascular datasets, despite differences in population risk profiles, healthcare access, and system organization. A comprehensive national-level registry can inform health policy, resource allocation, and optimization of STEMI networks, particularly regarding transfer pathways for patients with CS or MC.

Finally, beyond hypothesis generation, this registry will provide a pragmatic foundation for future prospective studies and quality-improvement initiatives. In the absence of feasible RCTs, robust national epidemiological data remain essential to guide clinical practice

and ultimately to improve outcomes in this high-risk STEMI population.

Limitations

Limitations may reside in the single-centre design, with retrospective EHR-based data collection, possibly resulting in incomplete/missing variables or potential misclassification related to ICD-10 coding. Temporal changes in STEMI care, MCS availability, ICU practice, definitions, and referral pathways over 15 years may influence the findings. Additionally, limited external generalizability or potential confounding by indication for advanced therapies, including MCS, pulmonary artery catheterization, vasoactive medications, and cardiac surgery should be acknowledged as limitations. The current analysis is limited to in-hospital stay, and future research will collect follow-up data.

CONCLUSIONS

In conclusion, prognosis of STEMI patients greatly improved during the PCI era, and the focus in the present days is on improved prevention, early recognition and management of life-threatening complications, such as MC and CS. We present the rationale and study design of the RO-CCI-STEMI Registry, which is designed to characterize this cohort and to generate evidence aimed at reducing the burden of these pathologies.

AUTHOR'S CONTRIBUTION

RF (Conceptualization; Methodology; Software; Investigation; Writing – original draft; Visualization; Writing – review and editing)

CM (Conceptualization; Investigation; Writing – review and editing)

RR (Conceptualization; Writing – review and editing)

LA (Conceptualization; Writing – review and editing)

OG (Conceptualization; Writing – review and editing)

ES (Conceptualization; Writing – review and editing)

MP (Investigation; Writing – review and editing)

DG (Conceptualization; Writing – review and editing)

DS (Investigation; Writing – review and editing)

AA (Investigation; Writing – review and editing)

DF (Conceptualization; Writing – review and editing)

LP (Conceptualization; Writing – review and editing)

DD (Conceptualization; Writing – review and editing)

OC (Conceptualization; Methodology; Resources; Writing – original draft; Visualization; Writing – review and editing; Supervision; Project administration)

CONFLICT OF INTEREST

All authors report no relevant disclosures.

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