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COHORT PROFILE

Cohort profile: the ESC EURObservational Research Programme Non-ST-segment elevation myocardial infraction (NSTEMI) Registry

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Aims The European Society of Cardiology (ESC) EURObservational Research Programme (EORP) Non-ST-segment elevation myocardial infarction (NSTEMI) Registry aims to identify international patterns in NSTEMI management in clinical practice and outcomes against the 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without ST-segment-elevation.

Methods and results Consecutively hospitalised adult NSTEMI patients ($n = 3620$) were enrolled between 11 March 2019 and 6 March 2021, and individual patient data prospectively collected at 287 centres in 59 participating countries during a two-week enrolment period per centre. The registry collected data relating to baseline characteristics, major outcomes (in-hospital death, acute heart failure, cardiogenic shock, bleeding, stroke/transient ischaemic attack, and 30-day mortality) and guideline-recommended NSTEMI care interventions: electrocardiogram pre- or in-hospital, pre-hospitalization receipt of aspirin, echocardiography, coronary angiography, referral to cardiac rehabilitation, smoking cessation advice, dietary advice, and prescription on discharge of aspirin, P2Y12 inhibition, angiotensin converting enzyme inhibitor (ACEi)/angiotensin receptor blocker (ARB), beta-blocker, and statin.

Conclusion The EORP NSTEMI Registry is an international, prospective registry of care and outcomes of patients treated for NSTEMI, which will provide unique insights into the contemporary management of hospitalised NSTEMI patients, compliance with ESC 2015 NSTEMI Guidelines, and identify potential barriers to optimal management of this common clinical presentation associated with significant morbidity and mortality.

Keywords NSTEMI • Prospective • Observational • Non-interventional • EORP • Registry

[†] The NSTEMI Investigator Group is in the Appendix.

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Introduction

Non-ST-segment elevation myocardial infarction (NSTEMI) is a leading cause of emergency hospitalisation across Europe.[1] For example, it accounts for over 50 000 admissions to hospitals each year in the National Health Service of England and Wales.[2] Long-term mortality rates for patients hospitalised for NSTEMI are high,[3] and the incidence of NSTEMI is increasing across many countries as populations age, and become more comorbid.[4]

Despite substantial improvements in the treatment of NSTEMI, the burden and variation of NSTEMI care and outcomes persist.[5–7] Clinical outcomes from NSTEMI may be improved through adherence to evidence-based care for NSTEMI.[8,9] However, between and within European country variation in the delivery and outcomes from NSTEMI suggest that the potential to reduce the burden of cardiovascular disease has not been realised.[1,8–10] Measuring recognised standards of care is a mechanism by which geographic variation in the use of guideline-indicated treatments for NSTEMI may be addressed and, therefore, cardiovascular outcomes improved.[11–13]

Following the addition of standardised quality indicators in 2016 to the European Society of Cardiology (ESC) guidelines for the care of patients presenting for NSTEMI from 2015, we had the opportunity to measure the quality of care we provide in the context of NSTEMI.[14,15] External validation studies have suggested greater attainment of the ESC standards of NSTEMI care is associated with better clinical outcomes.[16,17] We therefore designed and implemented the EORP NSTEMI registry to identify patterns in NSTEMI care and outcomes across the entire spectrum of patients admitted with NSTEMI in the heterogeneous context of ESC countries.

Aim of the EURObservational Research Programme Non-ST-segment elevation myocardial infarction registry

The aim of the EORP NSTEMI registry is to collect individual patient data for NSTEMI to foster the improvement of clinical outcomes of patients hospitalised for NSTEMI through the identification and reporting of contemporary delivery of guideline-recommended care. Specifically variation in care by country-income classification, hospital classification, age, sex, diabetic status, chronic kidney disease presence and severity, and risk scores will be investigated.

Quality of care interventions

Using an electronic case report form (eCRF), individual patient data were collected across guideline-recommended NSTEMI interventions. Since the EORP NSTEMI Registry aims to capture real-world NSTEMI management patterns as undertaken in routine clinical practice, local NSTEMI evaluation, management and/or treatment management strategies were not pre-specified by the study protocol.

Setting

The EORP NSTEMI registry is an international prospective, multicentre, and observational study of patients presenting to hospitals for NSTEMI. All the ESC country members through the 56 National Cardiac Societies and 43 affiliated countries (as there were at time of design of the registry) were invited to participate.

Participating centres were appointed by the respective national coordinator. National coordinators in conjunction with local centres, or participating centres, managed the approvals of national or regional ethics committees, or Institutional Review Boards, according to local regulations.

Centres were chosen in an attempt to allow representation of each category of hospital in proportion to the distribution of the different types of acute centres in the individual country, and to, as far as possible, respect geographical criteria within each country.

Population and consent

The overall patient enrolment period in the study spanned from 11 March 2019 to 6 March 2021, and each centre was limited to two consecutive weeks within the study enrolment period. Participating centres were requested to enrol all consecutive eligible adult patients admitted with a final diagnosis of NSTEMI; that is, patients with Universal Definition acute myocardial infarction, type 1 myocardial infarction, and who did not have persistent ST segment elevation (Table 1).[15,18] All participating patients received detailed written

Table 1 Definitions used for inclusion of adult patients in the EORP NSTEMI registry

The Universal Definition of acute myocardial infarction is:
A combination of the detection of an increase and/or decrease of a cardiac biomarker, preferably high-sensitivity cardiac troponin, with at least one value above the 99th percentile of the upper reference limit and at least one of the following:
(1) Symptoms of ischaemia.
(2) New or presumed new significant ST-T wave changes or left bundle branch block on 12-lead ECG.
(3) Development of pathological Q waves on ECG.
(4) Imaging evidence of new or presumed new loss of viable myocardium or regional wall motion abnormality.
(5) Intracoronary thrombus detected on angiography
The ESC definition of NSTEMI is:
Of those with Universal defined acute myocardial infarction, patients with acute chest pain, but no persistent ST-segment elevation. ECG changes may include transient ST-segment elevation, persistent or transient ST-segment depression, T-wave inversion, flat T waves or pseudo-normalization of T waves or the ECG may be normal.
The definition of Type 1 myocardial infarction is:
Atherosclerotic plaque rupture, ulceration, fissure, erosion, or dissection with resulting intraluminal thrombus in one or more coronary arteries leading to decreased myocardial blood flow and/or distal embolization and subsequent myocardial necrosis. The patient may have underlying severe coronary artery disease but, on occasion, there may be non-obstructive coronary atherosclerosis or no angiographic evidence of coronary artery disease.

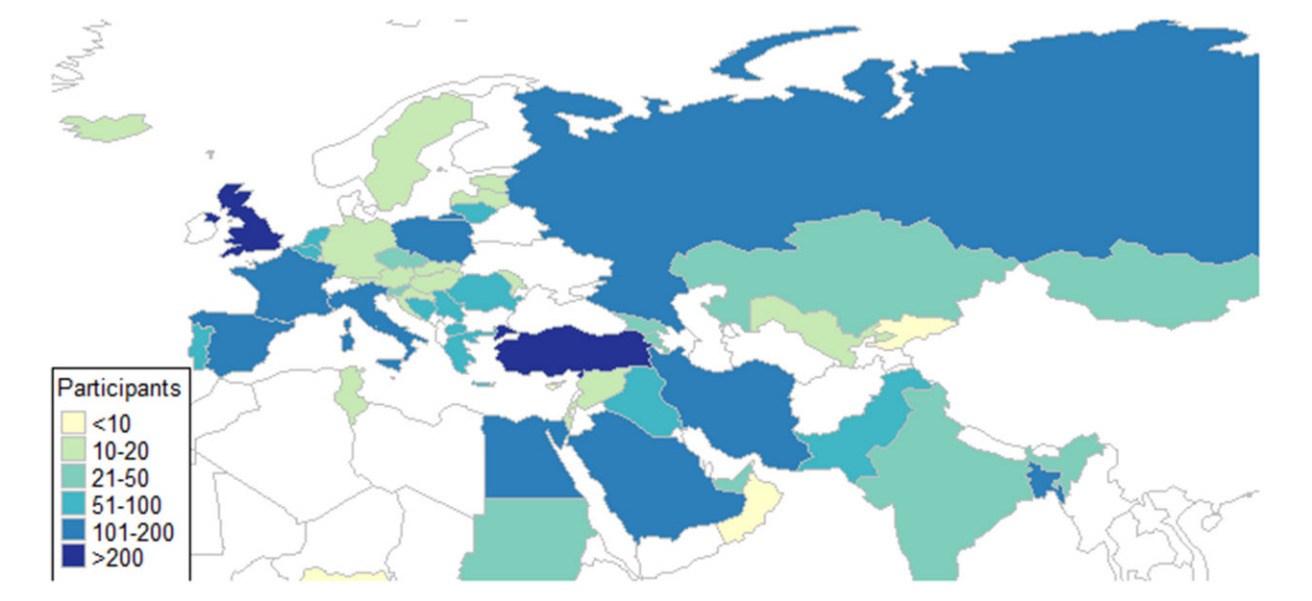

Figure 1 The EURObservational Research Programme participating countries and their colour-coded contribution. EORP, EURObservational Research Programme.

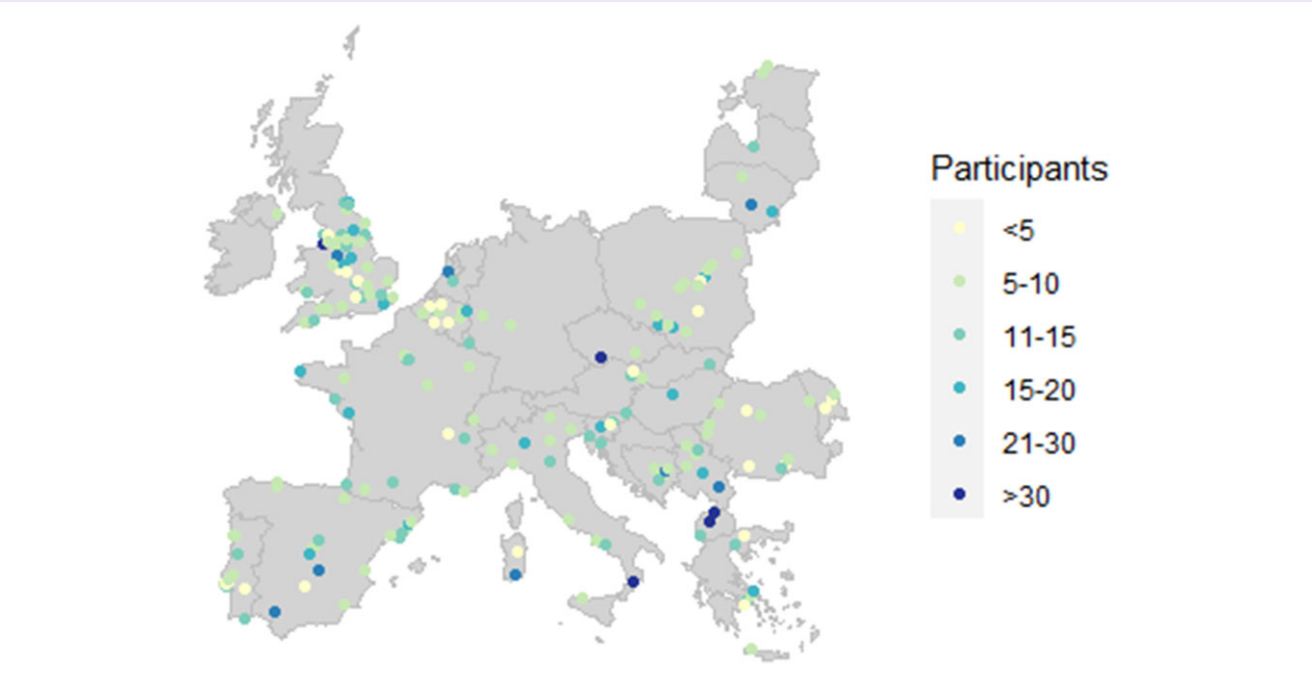

Figure 2 Centre distribution per country and number of patients included per centre.

information concerning the study and signed informed consent. Patients <18 years and those unwilling or unable to give consent were not included.

In total, 3620 patients were enrolled from 287 centres in 59 countries (Figures 1 and 2). Of 2947 patients that formed the analytical cohort (excluding patients who did not meet the period inclusion criteria, had inadequate data completeness or other exclusions) 30.8% were women, 79.3% Caucasian, and the median age was 66 years (interquartile range 57 to 75 years).

Patient identification

Potential participants were identified from admission to hospitals managing patients with NSTEMI and each patient was given a unique study number.

Start points

During the study (and centre) enrolment period, consecutive patients aged ≥18 years, hospitalised with a final diagnosis of NSTEMI were included, in whom type 1 myocardial infarction was confirmed.

Baseline and follow-up data

Baseline data included the enrolment setting, patient demographics, cardiovascular risk factors, mode of admission, therapeutic methods, time delays to reperfusion, risk stratification, adverse events, and medications during admission and at discharge. Quality of care was evaluated based on guideline-recommended NSTEMI care interventions including electrocardiogram pre- or in-hospital, pre-hospitalization receipt of aspirin, echocardiography, coronary angiography, referral to cardiac rehabilitation, smoking cessation advice, dietary advice, and prescription on discharge of aspirin, P2Y12 inhibition, angiotensin converting enzyme inhibitor (ACEi)/angiotensin receptor blocker (ARB), beta-blocker, and statin. Follow-up for clinical events and life status was recorded at 30 days.

Data capture and storage

Data were manually entered by investigators or data collecting officers at the participating centres in the registry-specific online eCRF that is accessible using the individual's unique username and password distributed by the EORP team. Collected patient data are pseudononymous and only a unique code identifies a patient in the EORP database. Pseudononymized data are stored in the registry-specific central database with limited access protected by individual passwords. The EORP NSTEMI Registry database is stored at the EORP Department, European Heart House, 2035 route des Colles, 06 903 Sophia Antipolis, France.

Data quality

The EORP NSTEMI registry database is designed, managed, controlled, and validated according to the ESC EORP standards. The EORP NSTEMI eCRF has numerous built-in automatic cross-checks for data completeness, internal consistency, and validity that automatically raises alerts in case of data incompleteness or inconsistency, thus enabling investigators to resolve such issues during data entry. In addition, data were regularly assessed and validated by the EORP-NSTEMI Data Management Team, according to the Data Validation Plan, no formal source data verification was undertaken.

Endpoints and linkage to other data

Adherence to guidelines during the inpatient stay and subsequent 30-day all-cause mortality will be investigated. Secondary outcomes include in-hospital episodes of acute heart failure, cardiogenic shock, use of mechanical circulatory support, bleed (BARC Type ≥ 3),[19] stroke/transient ischaemic attack, and recurrent myocardial infarction. These endpoints will be directly entered in the eCRF, as reported by the participating investigators and supported by pertinent medical records. It is anticipated that the EORP NSTEMI registry could provide a legacy platform for future NSTEMI data capture.

Access to data

Direct access to the Registry dataset is limited to the EORP NSTEMI Data Management and Statistical Analysis teams. Country-specific datasets may be provided to the national cardiology societies/national coordinators for subsequent analysis of the country-specific data.

Conclusions

The EORP NSTEMI Registry is an international, prospective registry of care for and outcomes of patients treated for NSTEMI across a wide sample of ESC and ESC-affiliated countries. This registry will provide insights into the patterns of NSTEMI management, implementation of ESC 2015 NSTEMI guidelines in routine practice, and potential barriers to optimal management of this common clinical presentation associated with significant morbidity and mortality. Data will be reported as research publications and health reports to the wider ESC community, and provide the opportunity for interventions to increase guideline implementation in practice.

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Declaration of Helsinki

The study complies with the Declaration of Helsinki, that the locally appointed ethics committee has approved the research protocol and that informed consent has been obtained from the subjects (or their legally authorized representative).

Data availability

The data underlying this article are subject to an embargo of 12 months from the publication date of the article. Once the embargo expires, the data will be available upon reasonable request to the EORP NSTEMI Executive Committee Chair, with the approval of the EORP Oversight Committee.

Conflict of interest: H.B., K.H., M.L., P.L., R.N., V.K., and Y.A. report no conflict of interest.

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Signed COIs available for all authors.

Appendix 1

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