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A study from the Euro Heart Survey Programme of the European Society of Cardiology

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## Summary

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<tr>
<th>Type of study</th>
<th>Prospective, multi-centre observational study</th>
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<tr>
<td>Expected number of patients</td>
<td>3000-5000 patients</td>
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<tr>
<td>Main inclusion criteria</td>
<td>Consecutive patients admitted to ICU with:</td>
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<tr>
<td></td>
<td>1. Suspected acute myocardial infarction (AMI),</td>
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<td>defined by elevated cardiac markers (troponin, CK,</td>
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<td>CK-MB) and ≥1 of the following characteristics:</td>
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<td>▪ Symptoms of myocardial ischaemia</td>
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<td>▪ Development of new Q waves</td>
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<td>▪ Development of ST-T abnormalities</td>
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<td>considered of ischaemic origin</td>
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<td>1. or AMI occurring after non cardiac procedures</td>
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<td>2. having accepted to participate in the study.</td>
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<td>Main goal of the study</td>
<td>To assess the management and hospital outcomes of AMI in the &quot;real world&quot; throughout European countries.</td>
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<td>Main end-points</td>
<td>• management patterns across European regions.</td>
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<td>• characteristics of patients with AMI in Europe across the different European regions</td>
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<td>• in-hospital outcomes according to initial management</td>
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<td>• implementation of current guidelines in a real world setting</td>
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1 STUDY RATIONALE

Although cardiovascular disease is the leading cause of mortality in Europe, and acute myocardial infarction (AMI) represents the principal cause of heart disease, little is known about the epidemiology of patients hospitalised for AMI on the European level.

Acute myocardial infarction
AMI is the most common cause of heart disease and it still carries a high mortality[1, 2, 3, 4, 5]. In the past two decades, considerable progress has been made in its management, thanks to the numerous randomised controlled trials which specifically addressed this question by testing different therapeutic approaches [6, 7, 8, 9, 10, 11, 12, 13]. The results of these studies have been taken into account for setting up and updating guidelines for the management of ST-elevation (STEMI)[14] and non-ST-elevation myocardial infarction (NSTEMI)[15].

Numerous issues, however, are still pending regarding the profile of patients admitted for AMI and the organisation of care. Also, little is known about how guidelines are applied in the real world and it therefore appears essential to identify potential obstacles to their implementation[16].

On the European level, previous surveys from the Euro Heart Survey programme have shown disparities between regions, in terms of patients profile and management[5], but their epidemiologic value has been limited by the lack of representativeness of the participating centres, many countries being represented by only a few voluntary centres. It is, however, known that a North-South and East-West gradient of cardiovascular morbidity and mortality exists in Europe[4].

By setting up a snapshot survey over one week, the European Society of Cardiology hopes to improve the number of participating centres in each country, thereby providing better representativeness for the survey.

STUDY OBJECTIVES

Main objective
To assess the management and hospital outcomes of AMI in the "real world" throughout European countries.

Primary end-point
To determine the profile of patients with AMI in Europe across the different European regions/countries.

Secondary end-points
- Analyse management patterns across European regions/countries.
- Determine how current guidelines are applied in the real world.
• Analyse in-hospital outcomes according to initial management.

POPULATION

Inclusion criteria

Consecutive adult (≥18 years of age), male and female patients admitted to hospital within 48 hours of symptom onset and:

1. Presenting with suspected acute myocardial infarction (AMI), defined by a typical pattern (rise and fall) in cardiac markers (troponin, CK, MB-CK) and ≥1 of the following characteristics:
   ▪ Symptoms compatible with myocardial infarction
   ▪ Development of new Q waves
   ▪ Development of ST-T abnormalities considered of ischaemic origin
2. Or with AMI related to non cardiac procedures according to the universal definition of AMI[17]
3. Having accepted to participate in the study.

Patients dying in the first hours following admission or before blood is drawn, will not require the typical pattern of cardiac markers, provided they have typical symptoms associated with typical ST-T abnormalities and diagnosis of AMI is therefore considered obvious by the investigators. Likewise, and for obvious reasons, informed consent will not be required for patients dying very early after admission.

Participating in the registry will not alter the way the patients are managed throughout the hospital period.

All patients meeting the inclusion criteria will be recruited consecutively over a one-week period at the end of 2009.

In addition, a logbook will be implemented for patients admitted to the ICU during the study period and with an alternative diagnosis; age, sex, main diagnosis and vital status at discharge will be recorded.

Exclusion criteria

Patients meeting the following criteria will not participate in the study:

➢ AMI occurring after percutaneous coronary angioplasty or coronary bypass surgery
➢ Age < 18 years

Participating institutions

In each country, an attempt will be made at identifying all institutions taking care of AMI patients, with the help of National Societies of Cardiology. All institutions will be contacted and asked to participate, whatever the type of institution (academic or non academic, public or private, for profit or non profit)
PRACTICAL CONSIDERATIONS

Type of study
Prospective, multicentre observational study across member countries of the European Society of Cardiology, over a one-week period.

Organisation

Hospital stay
- All patients meeting the inclusion/exclusion criteria will be included consecutively over a one-week period.
- An electronic case record form (e-CRF), will be filled-in for each patient. The e-CRF will record the initial demographic and clinical characteristics of the patients, data on their management, including information on time delays, and clinical events throughout the hospital stay.

Patient follow-up
- There will be no follow-up beyond the hospital stays corresponding to the index event.

Patient management
As the study is purely observational, there will be no change whatsoever in the way the patients are cared for. Consequently, there will be no rule for dropping the patients out of the study.

DATA MANAGEMENT AND STATISTICAL ANALYSES

Data management
- The e-CRF will be filled-in at each participating site under the supervision of the local investigator in charge of the survey.
- Automatic queries will be generated from the e-CRF. Data management will be done at the European Heart House and statistical analyses will be performed once the database is locked.

Statistical analyses
Statistical analyses will be performed under the responsibility of the principal investigator of the survey (N. Danchin).

All conventional descriptive statistics will be used: continuous variables will be described as mean and standard deviation (SD) or median and interquartile range. Categorical variables will be described with absolute and relative frequency distributions. Comparisons between groups will be made using one-
way analysis of variance (ANOVA) or Wilcoxon tests and unpaired t-tests or Mann–Whitney tests for continuous variables and chi-square tests for discrete variables.

Whenever necessary, multivariable analyses, such as binary logistic regression analyses, will be made. P values < 0.05 will be considered significant.

LEGAL AND REGULATORY ASPECTS

Data protection
- The e-CRF is anonymous to provide confidentiality of the data collected.
- Depending on the National laws, the required authorisations will have to be obtained before the survey is launched.

IRB approval
Even though the study is purely observational, IRB approval will be obtained as requested by national regulations.

Study duration
Recruitment will last 7 consecutive days and the patients will be followed until hospital discharge.

Archiving
The protocol, consent forms, and all documents related to the study will be archived in each centre by the local investigator according to national regulations.

PUBLICATION(S)

The study results will be published as articles submitted to peer-reviewed journals. The Executive and Scientific Committees have full responsibility for the main publication. All participants in the study are encouraged to submit proposals for specific research topics to the Steering Committee; proposals will be written according to the following format: objective of the study; scientific context with principal publications related to the proposed topic; expected results; analysis plan including sample size estimation. Beside full publications, submission of abstracts, in particular for the European Society of Cardiology annual congress, will be encouraged.

No publication will be made without approval from the Executive Committee of the survey.
REFERENCES

ANNEX: example of information and consent forms

Patient information
Euro Heart Survey snapshot 2009

Madam, Sir,

This document describes the study you are asked to participate in. It aims at giving you the information necessary for your understanding of the study purpose, as well as what your participation implies. Do not hesitate to ask your doctor if you need any complementary information, or if this document does not seem clear to you.

You have just been admitted to an Intensive Care Unit for a heart condition. The physician in charge, Dr ......................... would like you to participate in an epidemiologic study called "Euro Heart Survey snapshot 2009", the aim of which is to determine how many patients with a similar condition are treated all over Europe and related countries, and how they are treated. To this purpose, data on your current medical condition, risk factors, past medical history, and treatment administered will be collected anonymously.

Participating in this survey will in no way change the way you are treated. Your physician will be free to treat you as he thinks fit. No particular procedure is required for participating in the study. No data will be collected after you are discharged from the hospital.

The survey conforms to national laws. All data collected will be anonymous and confidential. The data collected will be stored at the European Heart House, head office of the European Society of Cardiology.
Doctor ......................................... has proposed me to participate in the above-mentioned study. I have read and understood the information form describing the study. I have had the opportunity to ask all questions that I wished to ask and have received appropriate answers. I have been told that I was totally free to accept or refuse participation in the study and that, whatever the case, I would receive usual care for my heart condition.

My consent does not relieve my doctors from their responsibilities. I accept that the data recorded for this research study be used in a computer database. All data that concern my person will remain strictly confidential. At any time, I will have the possibility to ask Dr ................................ for additional information.

I freely accept to participate in this study.

__________________________________  _________________________
Name / First name  Signature:  Date