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An introduction to the Global Registry of Acute Coronary Events: GRACE

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Acute coronary syndromes, which comprise AMI, non-Q-wave MI and UA, are a major cause of mortality and morbidity in the western world. Each year, approximately 6.3 million people worldwide suffer an AMI, up to 25% of whom die as a result. In the USA in 1995, over 2 million patients were admitted to hospital with AMI, and more than 250 000 others died within 1 hour of the onset of symptoms, before they could reach a hospital.

Despite the importance of ACS in public health terms, and the escalation of research efforts into UA and non-Q-wave MI, remarkably little reliable data are available about the prevalence and routine management of ACS. Much of the existing data originate from clinical trials or are restricted by geographic region, and the patients do not represent the population as a whole. Furthermore, it is difficult to compare clinical trials because inclusion criteria and definitions of UA vary from one study to the next. There is therefore a need for an international observational registry covering the full spectrum of ACS, to allow comparison of management practices and outcomes of patients hospitalized with ACS at the local, national and multinational level.

Registry studies

Several registry studies have been conducted in patients with UA and AMI (Table). The MONICA Project sponsored by the World Health Organization, has produced valuable data from across the world, but is restricted to patients with AMI.^{1,2} The OASIS registry included patients with UA and non-Q-wave MI from 95 hospitals in six countries.³ However, the centers participating in this study were not representative of the countries as a whole. The PRAIS-UK study examined data from patients with UA or NSTEMI at 56 hospitals in the UK.^{4,5} Data from throughout Europe have also been collected by the ENACT survey.⁶ This registry was designed to provide a 'snapshot', based on patients admitted over a 7-day period, and no longitudinal data were collected.

None of the registry studies of patients with UA or non-Q-wave MI have provided insight into the various therapeutic options

used, the relationship between the process of care and outcomes, or the clinical decision-making process. Furthermore, data from randomized clinical trials cannot be extrapolated to the 'real-world' population because trials are, by their very nature, selective, and patients known to be at high risk are often excluded.

GRACE

The GRACE study is a multinational, prospective, observational study of clinical management practices and patient outcomes across the full spectrum of ACS. By describing treatment practices and providing data to cardiologists, GRACE aims to enhance understanding of patient management and outcomes, both on an individual hospital level and from a global perspective.

Study design

GRACE uses a unique cluster design to ensure that the registry reflects the sociodemographic makeup of the community. Each cluster represents a population of 150 000–300 000, and the total enrollment target is 10 000 patients per year. The feasibility of this design was validated in a pilot study involving 18 cluster sites, five in the USA and 13 in Europe, Argentina, Brazil and Australia. Approximately 100 hospitals from 14 countries take part in the full study.

GRACE is an observational study, collecting data on 'real-life' patient management, with the patient's physician determining the type of treatment administered. Patients aged over 18 years are eligible for enrollment, and participating hospitals are required to enroll the first 20 consecutive patients each month who meet the inclusion criteria. Individuals who are transferred from another hospital or from a registry hospital to another hospital within 24 hours of the onset of symptoms are included. At centers adopting a community-based approach to the study, only patients residing within a specified geographic area are eligible for inclusion.

Data collection

Information relating to demographic characteristics, medical history, time of presentation, presenting symptoms, clinical and treatment characteristics and in-hospital outcomes are collected by trained study coordinators. The case report form includes information collected during the patient's stay in various hospital departments. In some cases data may be collected at discharge, using hospital records. Patients are followed up approximately 6 months after discharge from hospital to provide information about specific longer-term outcomes.

Conclusions

GRACE is the first large observational registry to collect data on the full spectrum of patients with ACS from a multinational perspective. With data collected each year from around 10 000 ACS patients, GRACE has the potential to contribute greatly to our understanding of current management practices and outcomes. Furthermore, by providing a benchmark for current practice, GRACE will allow clinicians to measure the impact of randomized clinical trial results on future patterns of clinical practice.

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Registry	Clinical target	Number of centers	Number of countries	Period of interest	Limitations
ENACT ⁶	UA or MI	389	29	In-hospital	No longitudinal data
GRACE	UA or MI	100	17	In-hospital, 6 months after discharge	
MONICA ²	MI	38	21	28 days	Restricted to AMI patients
NRMI ^{7,8}	STEMI	1073	USA only	In-hospital	Restricted to USA and STEMI patients
OASIS ³	UA or NSTEMI	95	6	In-hospital and 6 months	Not population-based
PRAIS-UK ^{4,5}	UA or NSTEMI	56	UK only	In-hospital	Restricted to UK

Table.

Characteristics of registry studies in UA and AMI