SPECIAL CONTRIBUTIONS

Standardized Reporting Guidelines for Studies Evaluating Risk Stratification of ED Patients with Potential Acute Coronary Syndromes

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Researchers evaluating patients with potential acute coronary syndromes (ACS) have incorporated a wide range of eligible patients, historical factors, and outcome parameters into their studies. This has led to difficulty comparing results and conclusions of diagnostic and prognostic studies. The patient selection criteria, time intervals, and positive test and outcome definitions vary greatly between studies and investigators. As a result, Emergency Medicine Cardiac Research and Education Group - International (EMCREG-I) initiated an effort to standardize operational definitions and reporting of studies involving emergency department (ED) patients with potential ACS. These recommendations balance scientific rigor with practicality in an effort to increase the likelihood of obtaining scientifically valid data that may impact care of emergency cardiac patients. *The goal of this group was not to develop an ideal study. It was to convene a multidisciplinary consensus panel to develop standardized reporting criteria that would more easily allow for comparison of studies.*

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Received July 23, 2004; accepted August 12, 2004.

This article was approved by the SAEM Board of Directors in July 2004 and is being published simultaneously in the December 2004 issue of *Annals of Emergency Medicine*.

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doi:10.1197/j.aem.2004.08.033

DEVELOPMENT OF THE CRITERIA

Members of the Standardized Reporting Criteria Working Group of EMCREG-I first met in October 2001 to draft an initial set of criteria to be considered for incorporation into this document. The draft document was circulated to members of the working group and continually modified prior to a face-to-face meeting in May 2002. During this meeting, committee members methodologically discussed each proposed criterion and how critical knowledge of the individual parameter would be to interpretation of individual studies. After discussion, the working group determined whether each criterion should be considered a core reporting criterion, considered a supplemental reporting criterion, or not further considered.

Ten broad areas were defined, and a subcommittee was assigned to further review the core and supplemental designations and prepare supporting documentation for the consensus recommendations. The document was then distributed to the full EMCREG-I working group and was discussed in detail at a face-to-face meeting in May 2003. The document was distributed to Society for Academic Emergency Medicine (SAEM), the American College of Emergency Physicians (ACEP), the American Heart Association (AHA), and the American College of Cardiology (ACC). Representatives were named from each of the four respective organizations. Organizational representatives and members of EMCREG-I formed the Multidisciplinary Standardized Reporting Criteria Task Force and met face to face to discuss and finalize the Standardized Reporting Guidelines for Studies Evaluating Risk Stratification of ED Patients with Potential

Acute Coronary Syndromes. The Standardized Reporting Guidelines document was then submitted to Society for Academic Emergency Medicine, the American College of Emergency Physicians, the American Heart Association, and the American College of Cardiology for endorsement. All of the aforementioned organizations endorsed the document.

INTEGRATION WITH OTHER KEY PUBLICATIONS

In constructing these reporting guidelines, every effort was made to review consensus documents and organizational publications that might overlap with these guidelines. We did not attempt to define all of the variables that we recommend reporting. The American College of Cardiology has previously defined Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes.[1] The Standardized Reporting Guidelines is complementary to the American College of Cardiology Key Data Elements document. The Standardized Reporting Guidelines document is intended to guide authors who are reporting research on ED patients with potential ACS, while the American College of Cardiology Key Data Elements document provides definitions for aspects of clinical management and outcomes on known ACS patients. Thus, the two documents are complementary, each with a different focus.

The Standardized Reporting Guidelines complements the American College of Cardiology Key Data Elements by emphasizing which elements should be reported. In this manner, the Standardized Reporting Guidelines are somewhat analogous to the Utstein criteria for reporting of cardiac arrest studies[2] and the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting of randomized controlled clinical trials.[3]

PROPER USE OF THIS DOCUMENT

Items in bold print are core components. These items should be reported in essentially all risk-stratification studies of ED patients. Investigators planning clinical studies that involve risk stratification of ED patients with ACS should report the items that are considered core components. These items are those that represent the minimal amount of information necessary to allow readers to compare studies with respect to patient enrollment, patient description, and clinical outcomes. Peer reviewers evaluating studies for potential publication are encouraged to utilize these criteria to determine whether investigators have reported sufficient information so that the reader can place the study in the appropriate context and compare results with other studies of similar topics. Finally, practicing clinicians should familiarize themselves with the core criteria and utilize these items to determine whether patients reported in clinical studies are similar to the patients that they treat in their daily practice. This will facilitate appropriate incorporation of study results into medical practice.

Items not in bold print are supplemental (optional) items. When available, they should be reported. These criteria were not considered essential to interpretation of all ED risk-stratification studies. However, these supplemental items may be critical to a particular study or specific topics of investigation and, as such, should be included as appropriate. Investigators should consider the additional cost that might be associated with collection of the supplemental information and whether there would be additional benefit from collecting and reporting this information with any given study.

There are several additional goals that this document may help fulfill. Standardized definitions and reporting will allow better comparison of trials as well as facilitate meta-analysis of studies. It may also facilitate identification of important registry data that could be used to supplement clinical trial data. Standardized data collection and/or registry information can be invaluable tools for quality improvement and performance assessments.

1. Inclusion/Exclusion Criteria

Investigators must adequately describe the population studied, so that the reader will be able to understand the study population. The performance of diagnostic and prognostic evaluations is dependent on the prevalence of the disease in the study population. Thus, a thorough understanding of the study population is essential to interpretation of the data.

1.1. Specific ages for inclusion and exclusion should be stated

1.2. Report how study subjects were identified

1.2.1. By the type of symptoms at presentation (chest pain, ischemic equivalents, etc.)

1.2.1.1. The specific symptoms used for inclusion/exclusion

1.2.1.2. Time of onset of symptoms used as inclusion/exclusion criteria

1.2.2. By ED discharge diagnosis

1.2.2.1. Primary versus secondary diagnoses used to identify study patients

1.2.3. By hospital discharge diagnosis

1.2.3.1. Primary versus secondary diagnoses used to identify study patients

1.2.4. By use of diagnostic testing (patients received electrocardiogram [ECG], stress test, etc.)

1.2.4.1. By results of diagnostic testing (for example, positive cardiac markers)

1.3. Account for patients included and excluded from study

1.3.1. Develop flow sheet to account for all patients
1.3.2. Report total ED census for study institution(s)
1.3.3. Report ED volume of potential patients (for example, number of chest pain patients seen annually)

2. Demographic Patient Characteristics

A description of the study population and of the study sample is necessary to understand the relevance of the study to specific populations. The following characteristics of the subject population should be reported.

2.1.1. Age with measure of age distribution

2.1.1.1. Distribution of age by decade

2.1.2. Sex

2.1.3. Race and ethnicity (as defined by the patient)

2.1.3.1. The standards for presenting data on race and ethnicity are derived from the U.S. guidelines for federal reporting. The standards include two ethnic categories: Hispanic or Latino and non-Hispanic or Latino. There are five racial categories: American Indian or Alaskan Native; Asian; Black, or African American; Native Hawaiian or Other Pacific Islander; and White. Mixed races should be reported as such. At a minimum, race should be reported as Black, White, or Other.

2.1.4. Insurance status
2.1.5. Mode of arrival

2.1.5.1. Self-transport
2.1.5.2. Ambulance
2.1.5.3. Transfer from other facility

3. Presence or Absence of Cardiac Risk Factors and Method of Evaluation

In the ED setting, most physicians will not have access to detailed medical records and therefore the emergency physician typically has to rely upon patient self-report. Therefore, in ED-based studies, it is acceptable to rely upon patient self-report of cardiac risk factors. However, the investigators must report the method of evaluation.

3.1. Hypertension previously diagnosed and treated with diet modification, exercise, or antihypertensive medication

3.2. Family history of ACS (acute myocardial infarction [AMI], angina, or sudden cardiac death in a direct blood relative younger than 55 years old)

3.3. Diabetes mellitus (regardless of duration of disease or use of specific medications)

3.3.1. Type of diabetes mellitus (diet, oral agents, insulin alone, or insulin with or without oral agents)

3.4. Tobacco use

3.4.1 Current (past week)/former <1 year/former >1 year/never

3.5. Hypercholesterolemia or hyperlipidemia

3.5.1. Diagnosed by a health care provider and treated with either medications or diet

3.6. Cocaine or amphetamine use

3.6.1. Current (past week)/former <1 year/former >1 year/never
3.6.2. Results of toxicology testing

3.7. Renal insufficiency

3.7.1. Elevated creatinine level (>2.5 mg/dL for men; >2.0 mg/dL for women)
3.7.2. Reduced creatinine clearance
Preferred measure is Cockroft–Gault formula: creatinine clearance (mL/min) = [(140 − age) × weight (kg)]/72 × serum creatinine (mg/dL) (×0.85 for women)

3.8. Presence of obesity

4. Presence or Absence of Prior Cardiac Events/Diagnosis

4.1. AMI

If the prior AMI is confirmed through medical record review and meets the European Society of Cardiology/American College of Cardiology criteria, this should be noted.[4] If the history of AMI cannot be confirmed to meet European Society of Cardiology/American

College of Cardiology criteria, then it should be recorded as "self-reported history of AMI."

4.2. Known cardiovascular disease

4.2.1. Known coronary artery disease
If the presence of coronary artery disease is documented in the medical record through objective criteria, this should be noted. Objective criteria include cardiac catheterization with demonstration of at least one 50% stenosis; demonstrated electrocardiographic changes, perfusion defects, or wall motion abnormalities on exercise; pharmacologic or rest imaging studies or prior documentation of AMI. Otherwise, it should be reported as "self-reported history of CAD."

4.2.2. Revascularization (percutaneous coronary intervention, coronary artery bypass graft)
4.2.3. Heart failure
4.2.4. Ventricular tachycardia
4.2.5. Cardiac arrest
4.2.6. Atrial fibrillation
4.2.7. Peripheral vascular disease
4.2.8. Cerebrovascular events (stroke)
4.2.9. Automatic internal cardioverter defibrillator (AICD)
4.2.10. Pacemaker

4.3. Prior objective evaluations of coronary artery disease

4.3.1. Cardiac catheterization results

4.3.1.1. Time interval from testing to ED visit

4.3.2. Exercise or pharmacologic stress test results

4.3.2.1. Type of test
4.3.2.2. Time interval from testing to ED visit

4.4. Preventative measures and pretreatments

4.4.1. Current medications
Medications should be reported as current therapy if the patient reports their use within 7 days prior to ED presentation.

4.4.1.1. Aspirin
4.4.1.2. Clopidogrel
4.4.1.3. Beta-blockers
4.4.1.4. Calcium channel blockers
4.4.1.5. Nitroglycerin
4.4.1.6. Angiotension-converting enzyme (ACE) inhibitors
4.4.1.7. Angiotension receptor blockers (ARBs)
4.4.1.8. Anticoagulants
4.4.1.9. Lipid-lowering drugs

5. ED Presentation

The nature of the chief symptom and other symptoms associated with ACS are incompletely understood. In order to compare patient populations across studies, some measure of patient presentation must be reported. At a minimum, the primary symptom leading to presentation and time from symptom onset to presentation should be described. Depending upon the specific study being performed, more detailed description may be desired. When evaluating new risk-stratification tools, descriptions of the specific items included in previously described tools should be reported. For example, individual items in the Goldman algorithm[5] or TIMI risk[6] score would be important to report when comparing different risk-stratification tools.

5.1. Character of chief complaint

5.1.1. Presence of chief complaint at time of ED arrival (for example, persistent pain)

5.1.2. Chest discomfort or pain description

5.1.2.1. Typical or atypical characteristics
5.1.2.2. Pressure
5.1.2.3. Heavy
5.1.2.4. Sharp

5.1.3. Anatomic location/radiation of symptoms
5.1.4. Symptom intensity
5.1.5. Symptom similarity to previously diagnosed ischemia
5.1.6. Activity at symptom onset
5.1.7. Onset of symptoms—gradual versus abrupt
5.1.8. Single or multiple (constant versus stuttering) episodes of symptoms in the 48 hours prior to presentation
5.1.9. Other chief complaint

5.2. Associated symptoms

5.2.1. Shortness of breath
5.2.2. Weakness
5.2.3. Nausea or vomiting
5.2.4. Syncope
5.2.5. Palpitations
5.2.6. Diaphoresis

5.3. Time course of symptom complex

5.3.1. Time of onset of symptoms responsible for presentation

5.3.2. Duration of symptoms

5.3.3. Pattern of prior episodes of symptoms and similarity to current episodes

5.4. Vital signs at time of presentation

5.4.1. Blood pressure
5.4.2. Heart rate
5.4.3. Respiratory rate
5.4.4. Pulse oximetry

5.5. Evidence of heart failure and how defined

5.5.1. Rales
5.5.2. S3
5.5.3. Other signs of heart failure
5.5.4. Laboratory testing or diagnostic imaging for heart failure

6. ECG Interpretation

The ECG is central to the clinical classification and triage of patients with chest pain and possible ACS. Therefore, all studies of ED patients with potential ACS must report sufficient electrocardiographic information for the readers to evaluate the study population. Studies should include the following ECG characteristics as core data and present them as part of the description of the study population and subpopulations in the manuscript.

6.1. Report who interpreted the ECGs

6.1.1. Report if the clinician, unblinded investigator, blinded investigator, or core laboratory interpreted the ECG

6.2. ECG analysis should be reported in terms of specific findings suggestive of ACS

6.2.1. Rate
6.2.2. Rhythm

6.2.3. ST-segment elevation and depression (and unit of deviation and location of measurement in the ST segment)

The measurement of ST deviation identifies patients who differ in risk, prognosis, and prospective diagnosis of ACS. Measurements should take into consideration the isoelectric baseline used to determine ST deviation, the degree of ST deviation, and the reference point used to measure ST deviation from the baseline. We recommend that ST-segment deviation be measured using the TP segment as a reference for the isoelectric baseline unless tachycardia or artifact precludes this measurement. Then, the PQ junction (intersection of the PR segment and QRS complex) is used. ST-segment deviation (ST-segment depression or ST-segment elevation) is classified as <0.05 mV, 0.05–1.0 mV, and >1.0 mV deviation. To be considered ST-segment deviation, the ECGs should demonstrate changes in at least two contiguous leads. The degree of ST-segment deviation should be measured 0.06 seconds from the J point (intersection of QRS and ST segment) from the reference baseline.

6.2.3.1. Should be reported as "known to be old" or "not known to be old"

6.2.4. T-wave inversion (should report standardized depth)

T-wave inversion is nonspecific and not diagnostic of ischemia. However, ischemia as an etiology of nonspecific T-wave inversion is increased in the subgroup of patients presenting with chest pain. We recommend that T-wave inversion is classified as ≥ 0.2 mV or <0.2 mV when it is found in two or more contiguous leads with dominant R waves (abnormal QRS/T-wave axis).

6.2.4.1. Should be reported as "known to be old" or "not known to be old"

6.2.5. Left bundle branch block (presence or absence)

6.2.5.1. Should be reported as "known to be old" or "not known to be old"

6.2.6. Right bundle branch block (presence or absence)

6.2.6.1. Should be reported as "known to be old" or "not known to be old"

6.2.7. Pathological Q waves

6.2.7.1. Should be reported as "known to be old" or "not known to be old"

6.2.8. Report overall categorization of the ECG

6.2.8.1. Normal
6.2.8.2. Nonspecific ST/T-wave changes

6.2.8.3. Abnormal but not diagnostic of ischemia

6.2.8.4. Infarction or ischemia known to be old

6.2.8.5. Ischemia or prior infarction not known to be old

6.2.8.6. Consistent with AMI (ST-segment elevation or new left bundle branch block)

This ECG classification system has high interrater reliability.[7] Previous studies have assigned definitions to each category as follows: normal, no possible evidence for ischemia; nonspecific, accepted deviation from the norm with the lowest likelihood of ischemia (e.g., inverted T-wave axis in III or V1; or sinus tachycardia); abnormal but not diagnostic of ischemia, prolonged PR, QRS, QTc intervals, bundle branch blocks, left ventricular hypertrophy with strain; ischemia or prior infarction not known to be old, ST-segment depression more than 0.1 mV measured 40–80 milliseconds from the J point, inverted T waves more than 0.1–0.3 mV, or Q waves at least 30 milliseconds in duration; ischemia or prior infarction known to be old, or consistent with AMI, ST elevation >0.1 mV measured 40–80 milliseconds from the J point in two or more contiguous leads, with or without reciprocal ST depressions.

6.3. Report results of presenting ECG

6.4. Report results of out-of-hospital ECG

6.5. Report results of serial in-hospital ECGs

6.6. Report use of dynamic ECG analysis

6.7. Time intervals from symptom onset to first and subsequent ECGs

6.8. Time from arrival until ED ECG acquisition

7. Biochemical Marker Performance

The specifics listed here are intended to provide a reporting framework without identifying any specific markers or their outcome variables. They are consistent with guidelines from other organizations.[1,8–13]

7.1. Identify the cardiac marker(s) studied

7.2. Identify the specific assays used

7.2.1. Manufacturer (name and location of offices)

7.2.2. Platform used to run assay (proprietary name)

7.2.3. Description of the platform characteristics (for example, point of care)

7.2.4. Assay method and generation (for example, chemiluminescent, calorimetric, etc.; competitive versus noncompetitive assay system)

7.3. Report characteristics of assays used

7.3.1. Reference levels, when they are already determined

7.3.2. Report established cutoffs for normal values (at site laboratory) for established outcomes (may be different for AMI, ACS, or other outcomes)

7.3.3. Define 99th percentile at what specific coefficient of variation

7.4. Specimen collection and handling procedures

7.4.1. Date and timing of assay relative to key clinical parameters (e.g., time from chest pain onset or ED admission to blood draw)

7.4.2. Detailed method of sample handling and compliance with manufacturer recommendations

7.4.2.1. Phlebotomy tubes used (reagent), centrifugation, etc.

7.4.2.2. Assay performed individually or batched, run at time of blood draw or delayed

7.4.2.3. Location (for example, at bedside, ED stat laboratory, off-site research laboratory, etc.)

7.4.2.4. Storage (for example, sample frozen [within how many hours of draw], flash frozen on liquid nitrogen, freezing temperature, length of time frozen, etc.)

7.5. Investigators should report marker performance relative to prospectively defined outcomes using. This is a core requirement if the primary objective of the investigation is assessment of marker function; otherwise, it is a supplemental criterion.

7.5.1. Sensitivity, specificity, positive predictive value, negative predictive

value, and likelihood ratios with 95% confidence intervals)

7.5.2. Receiver operating characteristic data along with predictive properties for optimum cutoff if multiple outcomes are reported or new assays are being described

7.6. Report any relevant confounders to the assay being used

7.6.1. Report percentage of patients with renal insufficiency (see 3.7)

8. Patient Course

8.1. Medications/procedures prior to hospital arrival (at home or by out-of-hospital providers)

8.1.1. ASA
8.1.2. Nitroglycerin (specify route)
8.1.3. Beta-blockers
8.1.4. Morphine
8.1.5. Fibrinolytic agents
8.1.6. Low-molecular-weight heparins
8.1.7. Amiodarone
8.1.8. Epinephrine
8.1.9. Lidocaine
8.1.10. Atropine
8.1.11. Cardiopulmonary resuscitation
8.1.12. Synchronized cardioversion
8.1.13. Defibrillation
8.1.14. Intubation
8.1.15. Other

8.2. Medications given in ED

8.2.1. Aspirin
8.2.2. Clopidogrel
8.2.3. Antithrombins (heparin, low-molecular-weight heparin, direct thrombin inhibitors)
8.2.4. Nitroglycerin
8.2.5. Beta-blockers
8.2.6. Calcium channel blockers
8.2.7. Glycoprotein IIb/IIIa inhibitors
8.2.8. Fibrinolytic agents
8.2.9. Morphine
8.2.10. ACE inhibitors
8.2.11. ARBs
8.2.12. Dopamine
8.2.13. Dobutamine
8.2.14. Nesiritide
8.2.15. Other

8.3. Medications given during hospitalization

8.3.1. Aspirin
8.3.2. Clopidogrel
8.3.3. Antithrombins (heparin, low-molecular-weight heparin)
8.3.4. Nitroglycerin
8.3.5. Beta-blockers
8.3.6. Calcium channel blockers
8.3.7. Glycoprotein IIb/IIIa inhibitors
8.3.8. Fibrinolytic agents
8.3.9. Morphine
8.3.10. ACE inhibitors
8.3.11. ARBs
8.3.12. Dopamine
8.3.13. Dobutamine
8.3.14. Nesiritide
8.3.15. Other

8.4. Disposition

8.4.1. Discharge
8.4.2. Observation unit or observation protocol
8.4.3. Admission

8.4.3.1. Cardiac catheterization laboratory
8.4.3.2. Operating room
8.4.3.3. Cardiac/intensive care unit
8.4.3.4. Telemetry monitored bed
8.4.3.5. Nonmonitored floor bed

8.4.4. Transferred
8.4.5. Left ED against medical advice
8.4.6. Expired in ED

8.5. Evaluation for ACS

The absolute number and percentage of study patients receiving an evaluation should be reported. This information is critical to determining the validity of the outcome measures. It is important for the reader to be able to discern how the final diagnosis has been determined, especially in the cohorts of patients with a final diagnosis of unstable angina or a nonischemic etiology of their presenting symptoms. Specifically, the number of patients who did not receive testing to confirm either an ischemic or nonischemic etiology of their symptoms should be noted.

8.5.1. Serial markers and timing
8.5.2. Serial ECGs and timing
8.5.3. Pharmacologic or exercise stress tests

8.5.3.1. Type of study
8.5.3.2. Timing of the studies

8.5.4. Resting imaging studies

8.5.4.1. Type of study
8.5.4.2. Timing of the study

8.5.5. Coronary angiography

8.5.5.1. Timing of the study

8.6. Interventions during hospital course

8.6.1. Intraaortic balloon counterpulsation
8.6.2. Temporary pacemaker placement
8.6.3. Intubation (other than for surgical procedures requiring anesthesia)
8.6.4. Pulmonary artery catheter (other than for monitoring during surgical procedures)

9. Defining Outcomes

9.1. Mortality

9.1.1. Cardiovascular mortality

9.1.1.1. Specific definition used

9.1.2. Noncardiovascular mortality
9.1.3. Death by unknown means

9.1.3.1. Specify if classified as cardiovascular or noncardiovascular

9.1.4. All-cause mortality (including noncardiovascular causes)

9.2. AMI

9.2.1. Use European Society of Cardiology/American College of Cardiology definition[4]

9.2.2. AMI type

9.2.2.1. ST-segment elevation myocardial infarction
9.2.2.2. Non–ST-segment elevation myocardial infarction
9.2.2.3. Indeterminate
The AMI should be classified as STEMI, non-STEMI, or indeterminate (left bundle branch block or paced rhythm obscuring assessment of the ST segment). Use of Q-wave or non–Q-wave classification is less relevant to initial risk stratification because it is not easily extrapolated to ECG appearance at the time of ED presentation.

9.2.3. AMI location

9.2.3.1. Inferior
9.2.3.2. Anterior
9.2.3.3. Lateral
9.2.3.4. Posterior
9.2.3.5. Other

9.3. Non-AMI ACS

9.3.1. The specific definition of ACS should be noted. ACS should include unstable angina.

9.3.2. Definition should be objective, not based upon clinical judgment alone
The definition should include clinical signs and symptoms consistent with acute ischemia and objective evidence for ischemia or coronary artery disease.

9.3.2.1. Transient or new ST-segment changes >0.5 mm
9.3.2.2. Transient or new T-wave changes
9.3.2.3. Coronary artery disease >70% stenosis or a culprit lesion (ulcer or thrombus) in at least one vessel on cardiac catheterization
Report >70% even if you use >50% for your outcome to facilitate comparison with other studies
9.3.2.4. Reversible ischemia on provocative testing
9.3.2.5. New perfusion defects or wall motion abnormalities on imaging studies
9.3.2.6. Cardiac marker release not high enough to meet definition of AMI, if not using European Society of Cardiology/American College of Cardiology criteria or site laboratory has a gray zone
An objective definition of ACS identifies a different subset of patients than clinical judgment and can alter results of clinical trials. Therefore, all investigators should use objective definitions rather than clinical diagnosis.
9.3.2.7. Patients without objective data supporting a definitive diagnosis
Patients who do not undergo diagnostic testing and/or are without clinical follow-up should ideally be reported separately. They cannot definitively be labeled as ACS or non-ACS. They should not automatically be included in the non-ACS category. If these

patients are included in the overall study results, the specific number without clinical follow-up or diagnostic testing should be reported. In addition, any significant differences in clinical characteristics from the total study group should be described as well.

9.3.2.8. Report basis for objective diagnosis of ACS
Since each of the above criteria that can be used to define ACS represents a different level of evidence regarding the final diagnostic assignment of ACS versus non-ACS, it is recommended that authors report the basis for the diagnosis of ACS, when possible.

9.4. Revascularization

9.4.1. Percutaneous coronary interventions

9.4.1.1. Emergent
9.4.1.2. Urgent
9.4.1.3. Elective

9.4.2. Coronary artery bypass graft

9.5. Additional adverse events and procedures
If the primary purpose of the investigation is to determine the incidence of adverse events, the investigator should report the frequency of adverse events. The investigator should define the adverse events that they report.

9.5.1. Recurrent infarction

9.5.1.1. Timing of the event

9.5.2. Recurrent ischemia based upon objective testing

9.5.2.1. Timing of the event

9.5.3. Heart failure
9.5.4. Ventricular tachycardia
9.5.5. Ventricular fibrillation
9.5.6. Cardiac arrest
9.5.7. Synchronized cardioversion
9.5.8. Defibrillation
9.5.9. High-degree atrioventricular block requiring treatment
9.5.10. Cardiogenic shock
9.5.11. Emergency percutaneous intervention

9.5.11.1. Define difference between emergency and elective intervention

10. Follow-up Period
Emergency medicine is less concerned with therapies involving secondary prevention than acute therapies that assure optimum short-term outcomes. Conversely, readmissions, recurrent ischemia, and death within one month are important in ED patients who are often admitted for abbreviated therapy or observational diagnostic protocols. This may be even more relevant in patients discharged from the ED. In trials involving short-term diagnostics and risk stratification, short-term follow-up periods of 48 hours to 14 days may be considered ample to evaluate some initial disposition decisions and provide sufficient time for patients to comply with referrals to primary care providers or specialists. Conversely, trials of pharmacologic interventions may require 12 months or longer to demonstrate a durable effect of therapy. Based on these concerns, the committee felt that a 30-day time interval would be a core recommendation for reporting of clinical ED based studies. Shorter or longer time frames can *also* be reported depending upon the primary study design.

10.1. Define follow-up methods

10.1.1. Telephone contact

10.1.1.1. Primary versus proxy contact

10.1.2. Patient reassessment and examination
10.1.3. Medical record review
10.1.4. Autopsy and National Death Index search

10.2. Use in hospital and 30-day outcomes (relative to index presentation) as standard for comparison

10.2.1. Two- to 14-day outcomes for diagnostic and risk-stratification studies
10.2.2. Three-, six-, and 12-month outcomes for longer-term treatment studies

11. Risk-stratification algorithms or scoring systems

11.1. Goldman risk score
11.2. ACI-TIPI
11.3. TIMI Risk Score
11.4. Neural network output
11.5. Others

References

1. ACC Writing Committee for Acute Coronary Syndromes Clinical Data Standards. American College of Cardiology key data elements and definitions for measuring the clinical

management and outcomes of patients with acute coronary syndromes. J Am Coll Cardiol. 2001; 30:2114–9.
2. Cummins RO, Chamberlain DA, Abramson NS, et al. Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein Style. A statement for health professionals from a task force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council. Circulation. 1991; 84:960–75.
3. Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA. 1996; 276:637–9.
4. Thygesen K, Alpert JS, Garson A, et al. Myocardial infarction redefined-a consensus document of the Joint European Society of Cardiology/American College of Cardiology committee for the redefinition of myocardial infarction. J Am Coll Cardiol. 2000; 36:959–69.
5. Lee TH, Juarez G, Cook EF, et al. Ruling out myocardial infarction: a prospective multicenter validation of a 12-hour strategy for patients at low risk. N Engl J Med. 1991; 324: 1239–46.
6. Antman EM, Cohen M, Bernink PJ, et al. The TIMI risk score for unstable angina/non-ST elevation MI: a method for prognostication and therapeutic decision making. JAMA. 2000; 284:835–42.
7. Weber JE, Shofer FS, Larkin GL, Kalaria AS, Hollander JE. Validation of a brief observation period for patients with cocaine associated chest pain. N Engl J Med. 2003; 348: 510–517.
8. Apple FS, Wu AHB, Jaffe AS. European Society of Cardiology and American College of Cardiology guidelines for re-definition of myocardial infarction: how to use existing assays clinically and for clinical trials. Am Heart J. 2002; 144:981–6.
9. Wu AHB, Apple FS, Gibler WB, et al. National Academy of Clinical Biochemistry Standards of Laboratory Practice: recommendations for the use of cardiac markers in coronary artery diseases. Clin Chem. 1999; 45:1104–21.
10. Braunwald E, Antman EM, Beasley JW, et al. ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction: executive summary and recommendations. Circulation. 2000; 102:1193–209.
11. Ryan TJ, Antman EM, Brooks NH, et al. 1999 update: ACC/AHA Guidelines for the Management of Patients With Acute Myocardial Infarction: Executive Summary and Recommendations: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 1999; 100:1016–30.
12. Bruns DE, Huth EJ, Magid E, Young DS. Toward a checklist for reporting of studies of diagnostic accuracy of medical tests. Clin Chem. 2000; 46:893–5.
13. Zweig MH, Campbell G. Receiver-operating characteristic (ROC) plots: a fundamental evaluation tool in clinical medicine. Clin Chem. 1993; 39:929–35.