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Prospective observational study of acute coronary syndromes in China: practice patterns and outcomes

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Short Title: Management of acute coronary disease in China.

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ABSTRACT

Objective:

To describe the investigation and management of patients admitted to hospitals in China with suspected ACS and to identify potential areas for improvement in practice.

Design:

A multi-centre prospective survey of sociodemographic characteristics, medical history, clinical features, in-hospital investigations, treatment practices and major events among patients with suspected ACS.

Setting:

Large urban public hospitals.

Patients:

Consecutive patients admitted to in-patient facilities with a diagnosis of suspected acute myocardial infarction (MI) or unstable angina pectoris.

Main outcome measures:

Myocardial infarction/re-infarction, heart failure, death.

Results:

Between September 2004 and May 2005, data were collected prospectively from 2973 patients admitted to 51 hospitals in 18 provinces of China. An initial diagnosis of ST elevation myocardial infarction, non-ST elevation MI and unstable angina was made in 43%, 11% and 46% of patients, respectively. Diagnosis was inconsistent with objective measures in up to 20% of cases. At both tertiary and non-tertiary centres, there was little evidence that clinical risk stratification was used to determine the intensity of investigation and management. The mortality rate during hospitalisation was 5% overall and similar in tertiary and non-tertiary centres, but reported in-hospital re-infarction rates (8%) and heart failure rates (16%) were substantially higher at non-tertiary centres.

Conclusions:

This study has identified a number of areas in the management of ACS patients, including diagnosis and risk stratification, which deviate from current guidelines. These findings will help inform the introduction of widely used quality improvement initiatives such as clinical pathways.

Introduction

In China, coronary heart disease has emerged as a leading cause of morbidity and premature death. More than 700,000 deaths each year, one quarter of all deaths, are due to coronary events.^{1,2} As it is for other countries, the challenge for China is to provide evidence-based care to acute coronary syndrome (ACS) patients in a timely and cost-effective fashion. However, anecdotal reports and a limited number of smaller national surveys³ suggest that significant gaps exist between best evidence and practice. This is despite the fact that a number of treatments⁴⁻¹¹ have been shown to be effective in substantially improving patient prognosis and have been widely incorporated into national Chinese guidelines.

Unlike clinical trials, appropriately designed disease registries and surveys provide valuable information about the “real-world” spectrum of clinical management practices and their impact in a diverse population group. The Clinical Pathways for Acute Coronary Syndromes in China (CPACS) study was devised to provide information about patients admitted with acute coronary syndromes to public hospitals in China, and to identify gaps in evidence-based practice which might ultimately be addressed through implementation of quality improvement initiatives. Here, we report the survey findings relating to the in-hospital management of nearly 3000 patients admitted to Chinese hospitals with a provisional diagnosis of ACS.

Methods

CPACS is a multi-centre prospective registry of patients admitted to hospital with suspected acute coronary syndromes in China. Approval to conduct the study was obtained from a central ethics committee at FuWai Heart Hospital in Beijing and from The University of Sydney Human Research Ethics Committee.

Participating hospitals and study patients

Using the Chinese Society of Cardiology, a national body with a broad overview of cardiological centres in China, 51 hospitals were identified and invited to participate in the study. The hospitals were selected to ensure broad geographic spread and representation of the spectrum of clinical facilities assessing patients with ACS, as highlighted by quality standards proposed for registries and surveys.¹² Hospitals in China are classified as Level 1 (community hospitals with only the most basic facilities and very limited inpatient capacity), Level 2 (hospitals with at least 100 inpatient beds providing acute medical care and preventative care services to populations of at least 100 000); or Level 3 institutions (major tertiary referral centres in provincial capitals and major cities).¹³ CPACS included only Level 2 and Level 3 institutions as the study focus was in-hospital management of ACS patients. Invitation of centres to participate in the study was also designed to maximise the likelihood of approximately equal contribution from each type of hospital. None of the invited hospitals declined participation.

Consecutive patients with a diagnosis of suspected acute myocardial infarction (MI) or unstable angina pectoris (UAP) admitted to the in-patient ward of participating centres were invited to participate in the study. A log of all consecutive eligible patients was maintained by study staff at each hospital. Inclusion of at least 50 patients from each participating hospital was sought and recruitment of consecutive patients stopped once each hospital had reached their quota. Written informed consent was obtained from each individual. Only 5% of patients refused to participate in the study.

Data collection

Hospitalisation data were collected for each patient using standardised case report forms. Paper case report forms were completed by trained centre staff. These were then forwarded in batches to a central coordinating centre in Beijing where data were entered directly into a secure database using an Internet-based interface. During the patient recruitment phase, participating centres were audited by coordinating centre staff to check the data accuracy and completeness, and to evaluate responses to data queries. Data collected during the index hospitalisation included sociodemographic characteristics, medical history, features of the presenting condition, electrocardiographic (ECG) and plasma biomarker findings, treatment practices and major in-hospital events.

In addition to this patient level questionnaire, each hospital was asked to complete a centre-level questionnaire. Data collected as part of this survey included hospital type (level, location, institutional affiliations), total and ACS patient admission numbers and the availability of resources allocated to the investigation and management of ACS (enzyme testing, functional testing, specialised staff, coronary care units, cardiac catheterisation laboratories).

Follow-up patient questionnaires were planned for 6 and 12 months following each patient's index admission. These follow-up data will be reported separately.

ACS diagnosis and outcome definitions

In keeping with the study aim to collect information reflecting actual practice, the diagnoses of ACS and other in-hospital events were those assigned by the managing clinician. ECG and biomarker findings were used to evaluate the likely accuracy of the practitioner-assigned final diagnosis. In addition, physicians were asked to specify the criteria (symptoms alone; symptoms and/or ECG changes; symptoms and/or ECG changes *with* positive biomarker findings) used to confirm the diagnosis of each subsequent myocardial infarction (or re-infarction) reported during hospitalisation.

Statistical analysis

Unpaired t-tests or Wilcoxon rank sum tests were used for continuous variables, and chi-square tests were used for binomial variables in comparisons between patients admitted to different hospital types. No adjustment for multiple comparisons was made.

The Global Registry of Acute Coronary Events (GRACE risk) model¹⁴ provides a predictive score for in-hospital mortality based on Killip class, systolic blood pressure, age, serum creatinine level, cardiac arrest at admission, ST segment deviation, and elevated cardiac enzymes. To estimate baseline risk, each patient was assigned a modified GRACE risk score (serum creatinine measurements and information about cardiac arrest at admission were not available, however, the median baseline creatinine value from the GRACE registry¹⁵ and applied to each patient). Receiver operator characteristic (ROC) curve analysis performed on the combined outcome of in-hospital death and re-infarction confirmed that this model provided good risk discrimination (i.e. ranking of risk) in the CPACS population, with an area-under-the-curve of 0.74.¹⁶

Results

Between September 2004 and May 2005, hospitalisation data were collected for 2973 patients admitted with suspected ACS to 51 hospitals throughout China (Figure 1).

Hospital characteristics

Of the 51 participating hospitals, one third (34%) were located in the largest cities in China (municipality cities). The remaining two-thirds were from provincial capitals or other major cities. Only 3 hospitals were from smaller townships. Participating hospitals were widely distributed across the country (Figure 1); 14 were in Beijing, the remaining 37 hospitals were spread across 17 different provinces.

The largest hospital in the study recorded a total of 4,300 beds and 3,000 cardiology admissions in the previous year. Most other hospitals admitted between 200 and 800 cardiology patients a year, around half of whom were classified as having an ACS. All but two hospitals were public institutions and the majority (80%) was level 3. Level 3 centres were all equipped with facilities for conducting continuous ECG monitoring, measurement of cardiac enzymes, exercise testing, nuclear imaging and percutaneous coronary intervention (PCI). Furthermore, 94% also had the capacity to perform on-site coronary artery bypass grafting (CABG). Of the level 2 hospitals, around half were equipped with cardiac catheterization laboratories but none were performing CABG onsite. All hospitals employed specialist staff involved in the management of ACS patients including cardiologists, coronary care nurses and cardiac technicians.

Characteristics of the patients

The mean age of patients was 64 years and approximately two-thirds were male (Table 1). Despite their older mean age, 57% of patients were still in paid employment with manual labour jobs accounting for around one third of listed occupations. The average annual household income was RMB 11,000/yr (\$USD 1,450/yr) and just over half (57%) of all patients held medical insurance. A history of established vascular disease, or at least one major known risk factor for CHD (known hypertension, dyslipidaemia, diabetes or current smoking) was present for most patients. Sociodemographic characteristics differed according to the type of hospital to which patients initially presented; those presenting to level 3 hospitals in general earned higher incomes, had attained higher levels of education and were more likely to be working in professional jobs or be retired than those presenting to level 2 hospitals.

Diagnosis of ACS

Of the 2973 enrolled patients, an initial (working) diagnosis of STEMI was made in 1287 (43%). The corresponding figures for NSTEMI and UAP were 322 (11%) and 1360 (46%) respectively. The final discharge diagnosis changed among 3% of patients with an initial diagnosis of STEMI, 15% of patients with an initial diagnosis of NSTEMI and 11% patients with an initial diagnosis of UAP. A total of 63 patients (2%) were assigned a final discharge diagnosis indicating absence of ACS. The final physician-assigned diagnosis was inconsistent with the reported ECG and / or biochemical findings in 19% of patients diagnosed with STEMI and 16% of patients diagnosed with NSTEMI (Figure 2).

In-hospital investigations and management

Among patients with STEMI, primary reperfusion therapy (thrombolysis or percutaneous coronary intervention [PCI] within 12 hours of symptom onset) was received by 36% patients

admitted to hospitals with cardiac catheterization laboratories and 31% of patients admitted to those without such facilities. The corresponding proportions of patients with STEMI undergoing PCI within 12 hours of symptom onset were 16.3% and 6.6%. For those receiving thrombolysis, the median door-to-needle time was 55 minutes (interquartile range 30-100 minutes) for level 2 hospitals and 61 minutes (26-120) for level 3 hospitals. For those undergoing PCI, the median door-to-balloon time was 51 minutes (30-180) in level 2 hospitals and 90 minutes (60-175) in level 3 hospitals. The use of other major in-hospital investigations and interventions is shown in Table 2. Exercise testing was very infrequent, regardless of initial diagnosis. As expected, echocardiography, cardiac catheterisation and PCI were utilised more extensively in Level 3 hospitals, compared with Level 2 hospitals. In general, use of these investigations and treatment modalities was greatest for patients diagnosed initially with STEMI or UAP, and lowest for those with suspected NSTEMI. Coronary artery bypass grafting (CABG) was uncommon, particularly among patients admitted to Level 2 facilities.

Standard investigations and interventions for ACS were examined according to patient baseline in-hospital mortality risk (stratified by thirds) as determined by a modified GRACE risk model (Table 2). The analysis suggested an *inverse* relationship between baseline risk and the intensity of investigation or intervention such that patients were more likely to undergo cardiac catheterisation if they exhibited lower GRACE risk scores.

Medical treatment on admission or during hospitalisation and at discharge from hospital is described in Table 3. A high percentage of patients were treated with and discharged on therapies of proven effectiveness for the prevention of recurrent events.

Outcomes

Overall, in-hospital mortality was 5% (Figure 3). Non-fatal MI occurred among 8% of patients during the period of hospitalisation. The physician-assigned diagnosis of MI/ReMI after admission was reported to have been based on symptoms and/or ECG changes *with* elevation of biochemical markers of myocardial injury in 85% of patients. A diagnosis of heart failure during hospitalisation was particularly frequent in level 2 hospitals, occurring in 17%, compared with 11% in level 3 centres. A gradient of risk was demonstrated by initial diagnosis (high for MI and low for UAP), and by the modified GRACE model risk score (Figure 3).

Discussion

The CPACS study is the largest survey to date of the spectrum of acute coronary syndrome patients admitted to hospitals throughout China. As such, it highlights a number of features of management practice previously unrecognised or underestimated. The most striking finding is that patient risk appears to be inversely related to the likelihood of receiving an invasive management strategy with similar proportions of patients with a diagnosis of UAP and MI undergoing cardiac catheterisation. In tertiary level hospitals, almost 40% of all UAP patients underwent PCI.

Guidelines derived from the ACC/AHA are widely upheld in China and recommend revascularisation for moderate or higher risk patients, but not for low risk patients. However, the findings from this study indicate a clear departure from these recommendations. These observations are not unique to China; recent results from other registries in European and North American^{17 18-20} also suggest PCI procedures are more likely to be performed in low than medium or high risk patients and that the selection of patients for revascularisation is not primarily determined by the likelihood of clinical benefit. However, as the CPACS population included patients with “suspected ACS” and therefore many low risk individuals, direct comparisons should be made with caution.

In theory, clinical decisions about the management of ACS patients follow the accurate diagnosis and stratification of patients according to baseline level of risk. Compared with international registry data, a relatively low proportion of CPACS patients were initially diagnosed as NSTEMI (12% and 10% in level 2 and 3 hospitals respectively) and a comparison between the final stated diagnosis and objective electrocardiography and biomarker measurement revealed inconsistencies in up to 20% of cases. Centre-level data suggest enzyme testing, including troponin measurement, was widely available at all participating hospitals and at a comparable cost, making lack of resources an unlikely explanation. Furthermore, less than 5% of all UAP patients and only around 1% of NSTEMI patients received stress tests, despite the availability of facilities and appropriately trained staff at most hospitals. This low level of functional testing is consistent with failure to base treatment decisions on risk stratification.

The survey indicated close compliance with guideline recommendations with regard to the medical management of ACS patients. Approximately three-quarters of patients included in CPACS were discharged on what may be considered an optimum combination of an antiplatelet drug, at least one blood pressure lowering agent (β -blocker, ACE-I or ARB) and a statin. These levels are consistent with or even exceed reported rates from international registries.²¹⁻²³ Given the known persisting 3-5% annual risk of death among those experiencing a vascular event,^{24,25} follow-up data will offer important insights about the longer term adherence to recommended therapies.

Although the unadjusted risk of death during hospitalisation in CPACS was broadly comparable with that reported in the GRACE registry, rates of re-infarction and heart failure were substantially higher in CPACS, particularly at level 2 hospitals. Clinical trial^{10,11,26} and observational data²⁷ suggest that an early interventional approach among high-risk ACS patients is associated with less recurrent ischaemia and fewer adverse outcomes. It is possible, therefore, that differences in re-infarction and heart failure rates may have been attributable to substantially

lower use of revascularisation among high-risk patients with MI, although any such conclusions are difficult in the absence of a standardised definition of outcomes. Despite median door-to-needle and door-to-balloon times being relatively short, approximately two-thirds of patients with an initial diagnosis of STEMI did not receive primary reperfusion therapy within 12 hours of symptom onset.

While this study provides a unique perspective on the contemporary management of ACS in China, one limitation of the study is that centres invited to participate in the study were not selected at random. Although this may limit the generalizability of results to the wider Chinese population, the findings are likely to accurately reflect the situation within urban centres where very large numbers of individuals increasingly have access to hospitals with more advanced facilities. The level of representativeness of the study population is indirectly supported by income and medical insurance data which correspond closely to current population estimates^{28,29}. One further limitation is that treatment practices may have been influenced by study participation, however, concerted efforts were made to ensure the treating physicians were not involved in collection of data for the study.

The first phase to the CPACS study has focussed attention on a number of disparities between best-evidence and practice which are potentially amenable to intervention. Globally, closing evidence-practice gaps have centred on individual clinician and institutional approaches, including the use of clinical pathways and public reporting of performance indicators^{20,30,31}. In China, such initiatives could include the implementation of diagnostic pathways and pathways to ensure appropriate risk stratification. However, careful elucidation of the barriers to guideline adherence, analysis of follow-up data, and close consultation with the cardiological community is required in advance of the introduction of proposed pathways.

Over the coming years, China faces rapidly rising numbers of patients developing and presenting to hospitals with ACS, and major challenges to ensuring availability of evidence-based, cost-effective care for all her citizens. In addition to approaches directed at promoting guidelines adherence at the level of the institution and the individual clinician, health care systems reform is likely key to any future success.

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Figure Legends

Figure 1 – Geographical distribution of patients included in CPACS.

Figure 2 – Diagnosis of ACS

Figure 3 - Proportion of patients with in-hospital death or non-fatal MI, stratified by hospital type (level 2 or level 3): A. According to initial diagnosis, B. According to baseline (unadjusted) risk as defined by the modified GRACE risk model score.

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Table 1: Patient characteristics at hospital admission, mean(sd) or proportion.

Characteristic	N=2973
<i>Sociodemographic characteristics</i>	
Mean age, years (SD)	64.4 (12)
Male	67
Completed high school	18.7
Manual labourer	30.0
Business / professional / clerical work	17.7
Retired	42.8
Annual income, x1000 renminbi* (IQR)	11.0 (6-20)
Medical insurance held	57.1
<i>Medical history and risk factors</i>	
Prior history of myocardial infarction	13.7
Prior diagnosis of coronary artery disease	42.4
Prior history of stroke	12.3
Prior history of heart failure	9.3
Known hypertension	59.7
Treated	83.2
Known diabetes	21.2
Known dyslipidaemia	32.9
Smoking status	
Current	28.9
Former	23.4
<i>Presenting condition</i>	
Systolic blood pressure, mmHg	133.2 (27.3)
Diastolic blood pressure, mmHg	79.1 (15.5)
Heart rate, beats per minute	78.7 (17.7)

Table 2: Inpatient investigation of patients with suspected ACS

Treatment	Initial diagnosis ¹			Baseline risk ²		
	STEMI N=1287	NSTEMI N=322	UAP N=1360	Higher risk N=933	Intermediate N=896	Lower risk N=994
Level 2 hospitals	N=531	N=142	N=488	N=380	N=361	N=351
Exercise test, %	0.0	1.4	3.7	0.0	0.8	4.6
Echocardiogram, %	39.0	46.5	55.1	36.5	50.9	48.7
Cardiac catheterisation, %	27.5	19.7	27.7	14.7	30.5	31.0
Percutaneous coronary intervention, %	22.2	14.8	18.4	9.7	21.6	25.1
Coronary artery bypass grafting, %	0.2	0.7	3.1	0.5	1.1	2.0
Level 3 hospitals	N=756	N=180	N=872	N=553	N=535	N=643
Exercise test, %	0.1	1.1	3.1	0.0	1.1	3.1
Echocardiogram, %	66.5	63.9	68.3	64.3	68.6	67.8
Cardiac catheterisation, %	56.8	45.0	56.0	41.0	59.6	63.0
Percutaneous coronary intervention, %	52.7	38.9	38.1	35.5	49.0	47.5
Coronary artery bypass grafting, %	3.2	3.3	4.8	2.5	3.6	5.5

¹ Initial diagnosis information missing for 4 (0.1%) patients

² Data contributing to modified GRACE risk scores missing for 150 (5%) patients

Table 3: Medical management of patients with suspected ACS

Treatment (%)	On admission or during hospitalisation		At discharge home	
	Level 2	Level 3	Level 2	Level 3
Unfractionated heparin	21.6	15.5	-	-
Low molecular weight heparin	67.2	79.9	-	-
Aspirin	95.5	98.1	94.1	92.7
Clopidogrel	36.5	63.0	30.8	53.9
Other antiplatelet agent	6.1	7.5	5.4	6.0
Beta-blocker	77.0	74.7	74.0	70.3
ACE inhibitor	76.1	76.4	70.0	68.7
Angiotensin receptor blocker	6.8	10.8	5.8	9.6
Calcium antagonist	34.4	40.4	29.8	31.4
Statin	79.0	88.5	78.2	83.6
Antiplatelet + [β -blocker or ACE inhibitor or ARB] + statin	72.2	83.3	71.1	75.8
Antiplatelet + β -blocker + [ACE inhibitor or ARB] + statin*	56.6	60.0	48.2	49.1

* among patients with final diagnosis of myocardial infarction (STEMI or NSTEMI)

ARB – angiotensin receptor blocker; ACE – angiotensin converting enzyme

Figure 1

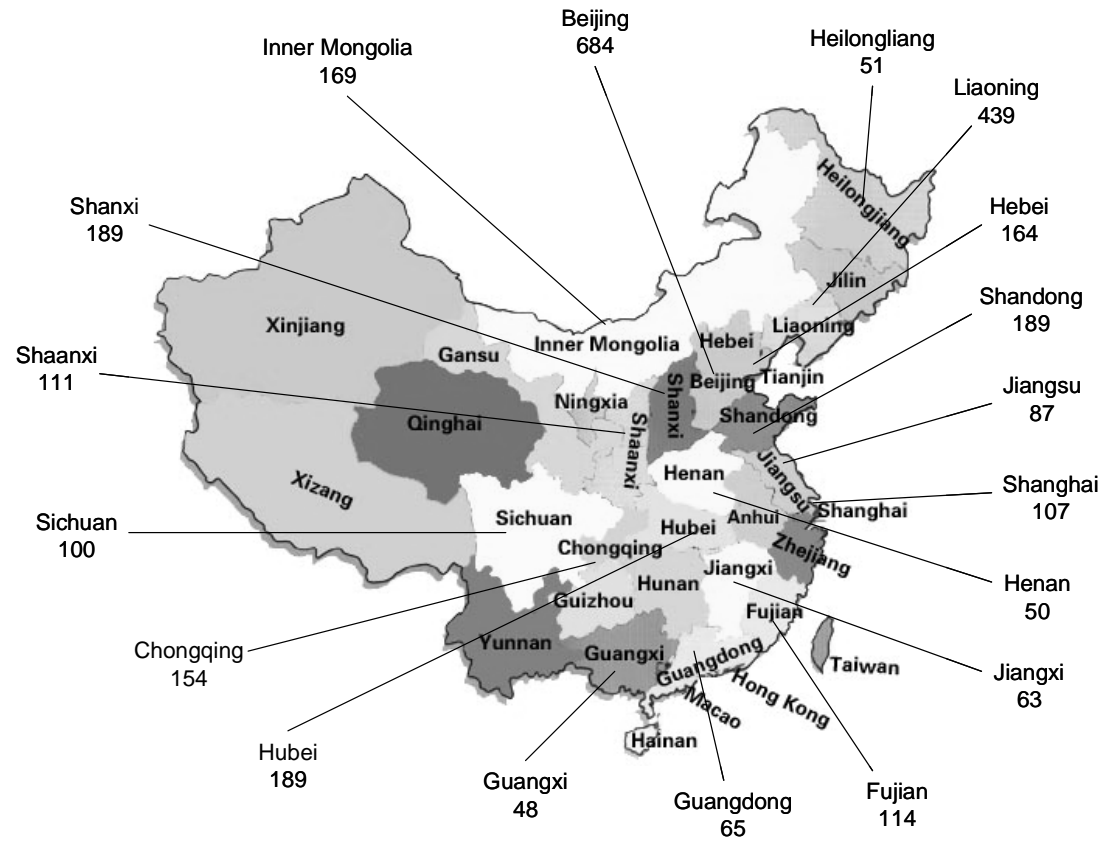


Figure 2

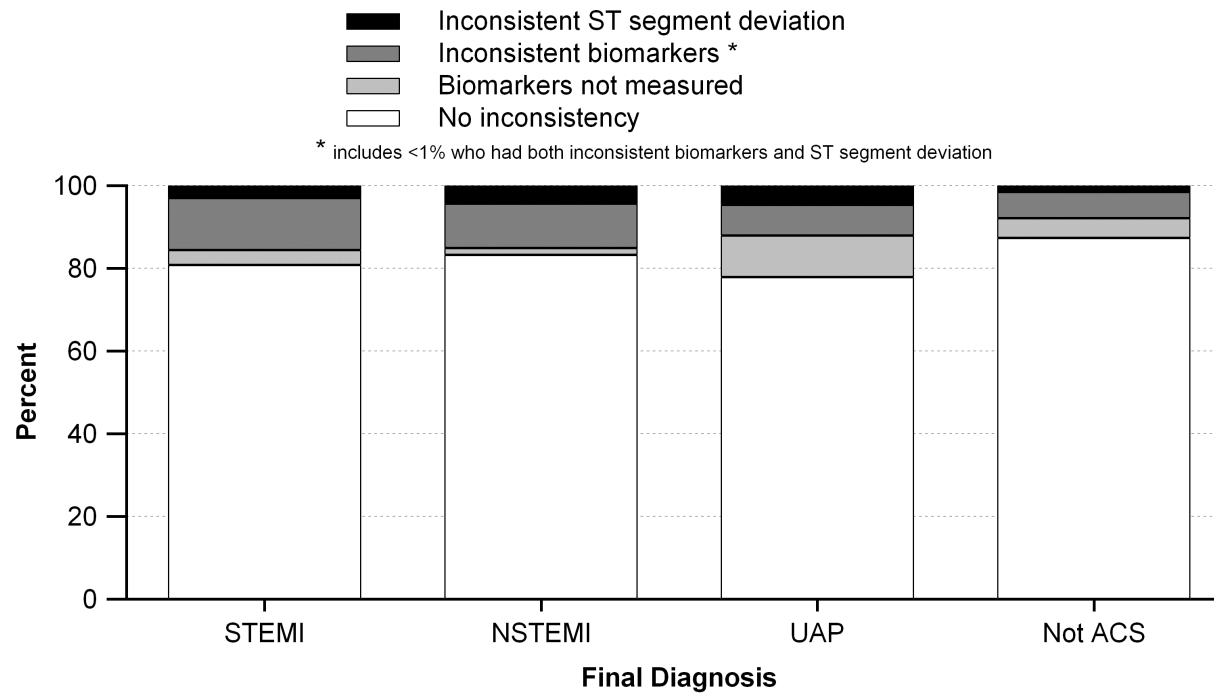
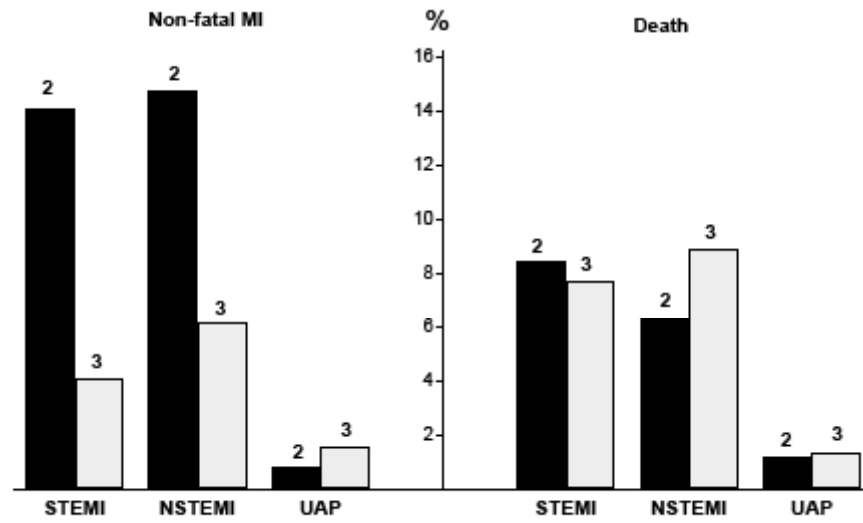


Figure 3

3A



3B

