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Incidence, management and outcomes of patients with acute chest pain presenting to the emergency departments in China: findings from a prospective multicentre registry

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ABSTRACT

Objectives Early evaluation and treatment of patients with acute chest pain pose a massive challenge to the emergency care system worldwide. This study aims to determine the current burden and early management of acute chest pain presenting to the emergency departments (EDs) in China.

Design The Evaluation and Management of Patients with Acute ChesT pain study is a prospective, multicentre and provincially representative registry of acute chest pain patients in Chinese EDs.

Setting A stratified random sampling design generated the province representative sample of 21 public hospitals with independent EDs in Shandong, China. Each participating site consecutively enrolled patients for at least 12 months from August 2015 to September 2017.

Participants A total of 8349 adult patients presenting with acute chest pain or suspected acute coronary syndrome (ACS) were included.

Primary outcome measures The annual incidence of ED-assessed acute chest pain was estimated. The aetiology, process of care and 30-day major adverse cardiac events (MACE) of included patients were analysed.

Results The estimated annual incidence of ED-assessed acute chest pain was 96.6 (95% CI 95.9 to 97.3) per 100 000 adults, significantly increasing with age. The mean age of included patients was 63.8 years, with 57.9% males. Prehospital delay was a median of 2.8 (IQR, 1.2–10.3) hours, with 17.9% transported by ambulance. About 75.6% of patients received their first ECG within 10 min. Cardiac troponin was tested in 54.2%, with high-sensitivity cardiac troponin in 24.5% and serial troponins in 5.1% during the ED stay. Most (74.0%) were admitted to the inpatient ward, with a median ED stay of 65.0 (IQR, 27.0–385.0) min. Within 30 days, 6.8% experienced MACE. Among included patients, 62.9% were diagnosed with ACS, with specific management varying by ST-segment elevation status.

Conclusions China's first regionally representative registry of acute chest pain revealed a lower incidence of ED-assessed cases but a higher proportion of high-risk patients compared with other countries. Gaps persist in aligning emergency management with guidelines. More programmes and policies are needed to enhance the quality of acute chest pain care in China.

Trial registration number This study was registered at URL: https://www.clinicaltrials.gov (NCT02536677).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A stratified random cluster sampling design was used to select participating sites, and variables were weighted according to the sampling ratio and enrolment duration to produce annual estimates of provincial representativeness.
⇒ Targeted patients in each participating site were consecutively enrolled for at least 12 months to avoid selection bias.
⇒ The preference for outpatient clinics among chest pain patients over emergency department visits may result in an underestimation of incidence and the under-representation of low-risk chest pain.
⇒ The inclusion of only patients who provided written informed consent, rather than consecutively enrolling all eligible patients, may have introduced a potential selection bias.

INTRODUCTION

The management of patients presenting to emergency departments (EDs) with acute chest pain is a global healthcare priority.[1] Early evaluation and timely triage of these patients are important for further treatment and clinical outcomes.[2–6] The correct identification and management of acute coronary syndrome (ACS), a high-risk chest pain with high prevalence, is particularly critical. This work is particularly challenging in emergency practice, where the resources are limited and the workloads are heavy. To date, although some studies have documented the inpatient management of definite ACS,[7 8] little is

known about the incidence, management and outcomes of acute chest pain or suspected ACS at EDs in low- and middle-income countries (LMICs).

As the most populous and largest LMIC in the world, China has experienced rapid economic growth. The emergency medical system also made significant progress with more financial support and more licensed physicians.[9] However, emergency care resources are still relatively strained, as ED visits have tripled in the past decade, reaching a total of 180 million in 2018.[10] The rapid growth of visits has also made overcrowding in the ED a common phenomenon.[11] With limited resources and a tremendous workload, standardised evaluation and treatment of patients with acute chest pain may be challenging for physicians. Therefore, it is necessary to clarify the burden and management of acute chest pain or suspected ACS to rationalise the allocation of limited healthcare resources and improve care quality.

Based on a prospective, multicentre cohort of acute chest pain, the Evaluation and Management of Patients with Acute ChesT pain (EMPACT),[12] we aimed to determine the incidence, characteristics, evaluations, treatments and outcomes of chest pain patients presenting to the ED in China for facilitating the targeting of gaps and quality improvement.

METHODS

Study design and setting

Full details of the study design and methods have been described and published previously.[12] Briefly, the EMPACT is a prospective, multicentre registry with regional representativeness in Shandong province, which is the second most populous (100 million in 2017) province in China. Nearly 40% of the population lives in the countryside, and the GDP per capita was 10 401 dollars in 2017; both parameters were close to those at the national level.[10] We followed a stratified cluster sampling process to generate a representative sample of EDs in Shandong. A total of 846 public hospitals were assessed, and the eligible hospitals were stratified into three strata by region and grade. At each stratum, a simple random sampling process was used to select participating sites. Finally, 22 sites were randomly selected. One site refused to participate, and one site dropped out during the implementation. The coordinating centre was included in the study without participating in the sampling process. Hence, a total of 21 EDs contributed to the enrolment (online supplemental figure 1). Each participating site consecutively enrolled targeted patients for at least 12 months from August 2015 to September 2017.

The management of acute chest pain patients in China primarily occurs in EDs. However, a proportion of patients with low-to-moderate risk may seek care directly at specialist outpatient clinics due to their routine daytime availability and appointment convenience. Additionally, influenced by the reimbursement system and inpatient bed availability, some chest pain patients who initially present to the ED are admitted directly to inpatient wards for further evaluation rather than completing their assessment in the emergency setting. These practices vary depending on regional factors and hospital levels.

Participants

Patients presenting to the participating EDs with acute chest pain or other symptoms suggestive of ACS were eligible for enrolment if they met the following criteria: 18 years and older, symptoms occurring within 24 hours, written informed consent from the patient or next of kin. We excluded traumatic chest pain, persisting or recurrent chest pain caused by rheumatic diseases or cancers and patients transferred from another secondary or tertiary hospital within the province. In the cases of multiple visits by the same patient, only the first visit within 30 days was counted.

Data collection

Information was collected using patient or family interviews and medical record abstraction by trained investigators, including patient characteristics, history, initial evaluation, diagnostic tests and treatment in the ED. A follow-up was conducted through telephone interview 30 days after the date of enrolment to acquire information about clinical outcomes, representation to ED and rehospitalisation during the 30 days following the initial presentation.

Information was recorded on paper case report forms, entered into an electronic system and monitored in real-time. Quality control included algorithmic checks, investigator reviews and daily online monitoring by the coordinating centre.

Adjudication of outcomes and diagnoses

Outcomes refer to the major adverse cardiac events (MACE), a composite of all-cause death, non-fatal subsequent acute myocardial infarction (AMI), urgent revascularisation, stroke, cardiac arrest and cardiogenic shock. The MACE and final diagnoses of index chest pains were adjudicated by two independent cardiologists. All available medical records and follow-up information were used for adjudication. In case of disagreement, a third senior adjudicator was set to give a final judgement. The diagnosis of ST-elevation myocardial infarction (STEMI) and non-ST-elevation myocardial infarction (NSTEMI) were defined according to the Third Universal Definition of Myocardial Infarction.[13] Unstable angina (UA) was defined according to the 2013 ACCF/AHA guideline.[14] The diagnosis of UA was incorporated with NSTEMI as non-ST-elevation acute coronary syndrome (NSTE-ACS).

Statistical analysis

The annual incidence and key variables were weighted by the reciprocals of hospital selection probabilities according to the sampling procedure and the enrolment period divided by 12 months to produce annual estimates of provincial representativeness. In calculating the annual incidence rate, the population aged 18 years or

older in Shandong based on the 2010 China Census was used as the denominator.[15] Age-specific incidence rates with 95% CI were calculated assuming a Poisson distribution. The Cochran-Armitage test was used to test for linear trends in age-specific incidence rates. Categorical variables are reported for unweighted frequency and weighted percentages. Continuous variables are reported as weighted mean and SD, or if not normally distributed, as weighted median and IQR. Since a certain proportion of patients were admitted to the inpatient ward soon after the presentation and prescribed medication in the ward, we randomly sampled 100 patients from each subgroup of adjudicated ACS and verified their medical use. We used the t-test to compare the means, the χ^2 test or Fisher exact test to compare percentages and the Wilcoxon signed-rank test to compare the medians. We employed a random-effects multivariable Cox regression model to explore the predictors of adverse outcomes, incorporating the participating site as a random factor. Age, gender, body mass index, hypertension, diabetes mellitus, prior myocardial infarction, chronic heart failure, chronic kidney disease, ST-segment elevation on ECG, heart rate, systolic blood pressure, symptom-to-door time and ambulance transport were included in the model.

A two-sided p value <0.05 is considered statistically significant in the analysis. All analyses were conducted with R (V.3.6.3).

Ethics and dissemination

This study was conducted in accordance with the Declaration of Helsinki and approved by the Central Ethics Committee at Qilu Hospital of Shandong University ((Scientific Research) Ethics Approval No. (2015) 058). All participating hospitals accepted the central ethics approval, except the Affiliated Hospital of Jining Medical University, which obtained local approval from its internal ethics committee ((2015) JYFY – Scientific Research Ethics Approval No. 4). Written informed consent was required from each patient to participate in the study.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Incidence

A total of 13918 patients were screened in 21 participating EDs during the study period. Out of these, 5024 patients were excluded for various reasons. Consequently, 8894 patients were deemed eligible, with 545 declining consent. Ultimately, 8349 patients were included (figure 1). The estimated annual incidence rate of ED-assessed acute chest pain in the population aged 18 years or older was 96.6 (95% CI 95.9 to 97.3) per 100 000, and the rate increased with age (p for trend <0.0001; figure 2).

Patient characteristics

Baseline characteristics of the study population are summarised in table 1. The mean age was 63.8±13.6 years, with 57.9% being males. Cardiovascular risk factors included hypertension (52.6%), current smoking (25.3%), diabetes mellitus (20.4%) and dyslipidaemia (7.9%). Medical histories revealed instances of angina (44.1%), myocardial infarction (14.6%), stroke (12.7%)

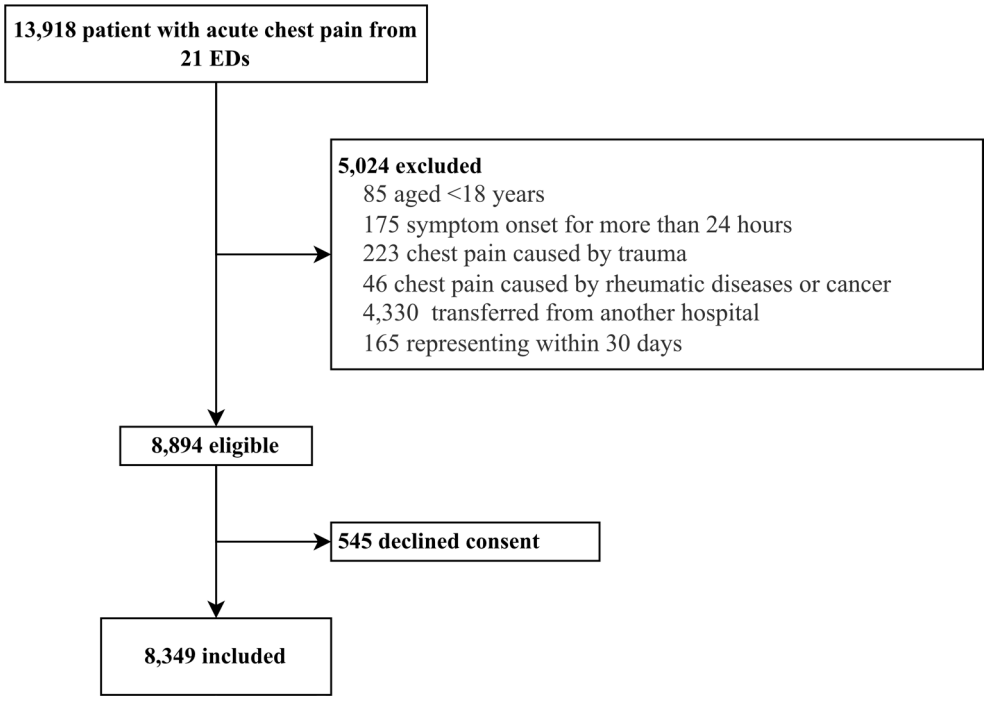

Figure 1 Flowchart of included patients in the EMPACT registry. ED, emergency departments; EMPACT, Evaluation and Management of Patients with Acute ChesT pain.

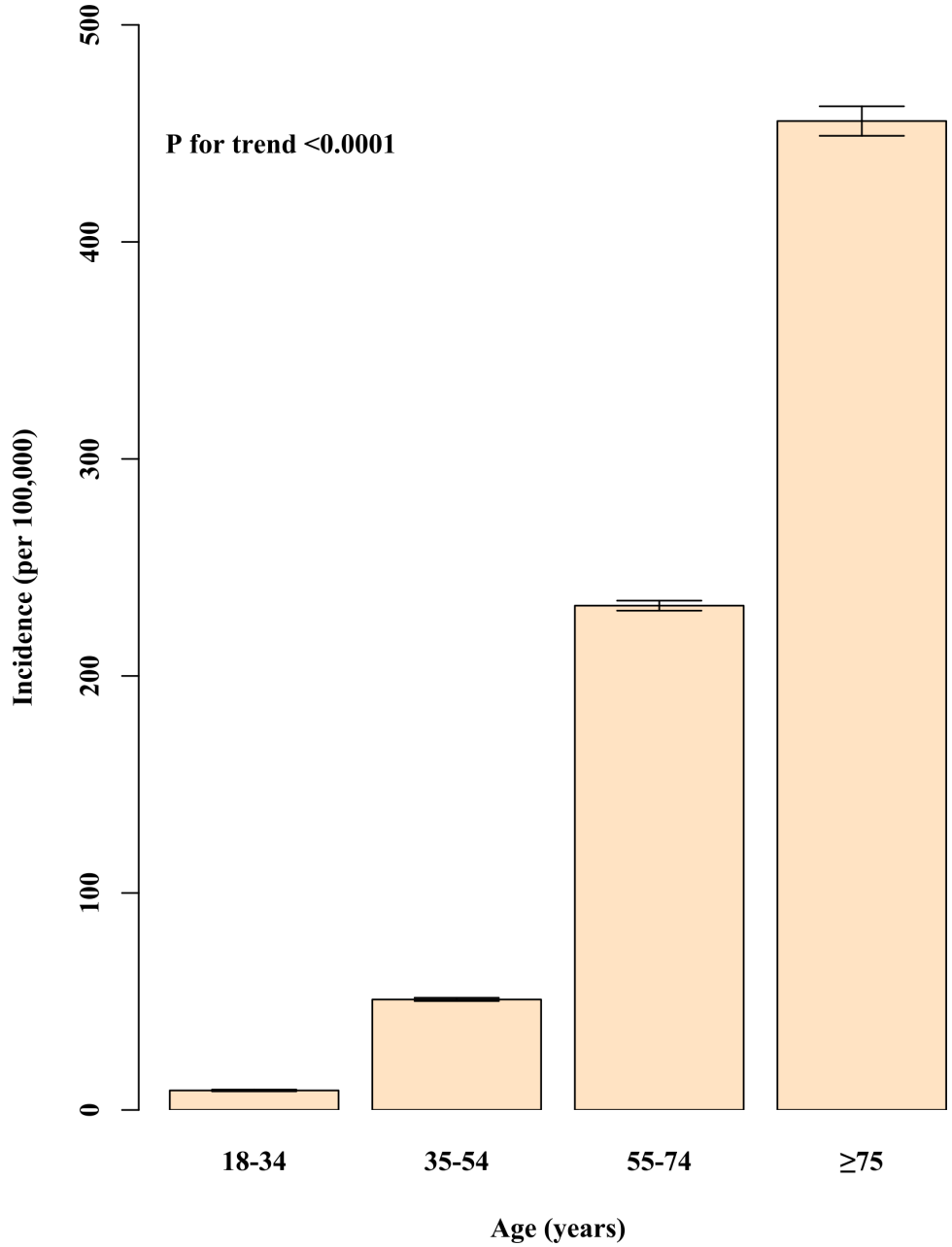

Figure 2 Age-specific incidences of acute chest pain in the EMPACT registry. EMPACT, Evaluation and Management of Patients with Acute ChesT pain.

and percutaneous coronary intervention (13.0%). Prehospital delay was a median of 2.8 (IQR, 1.2–10.3) hours, with 17.9% transported by ambulance. Vital signs at presentation included a mean heart rate of 79.4±19.6 bpm and mean systolic blood pressure of 143.7±28.6 mm Hg.

Evaluation and disposition

Initial and diagnostic tests during the ED stay are presented in table 2. About 94.1% of the patients underwent ECG testing, with a median time to first ECG of 4.0 (IQR, 1.0–9.0) min. About 75.6% of patients received their first ECG within 10 min. Cardiac troponin was tested in 54.2% of patients, with high-sensitivity cardiac troponin in 24.5% and serial troponins in 5.1%. Few patients received stress tests, chest X-rays (3.1%), echocardiography (2.9%) and CT angiography (CTA) (1.0%) in ED. Disposition indicated that 74.0% were admitted to the inpatient ward, 24.3% were discharged home, and 1.2% were transferred to other hospitals. The median length of stay in the ED was 65.0 min (IQR, 27.0–385.0).

Outcomes and diagnoses

At 30 days postpresentation, 548 (6.8%) patients experienced MACE out of 8349 participants (table 2). All-cause death occurred in 300 (3.8%) patients, subsequent AMI in 55 (0.6%) and revascularisation in 12 (0.1%). Cardiac shock and cardiac arrest both resulted in 225 cases (2.8% each), while stroke affected 44 (0.5%) patients. Additionally, 356 (4.2%) patients had representations.

Table 1 Baseline characteristics of patients with acute chest pain in the EMPACT registry

	n=8349
Demographics	
Age (years)*	63.8 (13.6)
Males	4776 (57.9)
Cardiovascular risk factors	
Body mass index (kg/m^2)*	24.8 (3.4)
Current smoker	2049 (25.3)
Hypertension	4468 (52.6)
Diabetes mellitus	1752 (20.4)
Dyslipidaemia	666 (7.9)
Medical history	
Angina	3721 (44.1)
Myocardial infarction	1282 (14.6)
Percutaneous coronary intervention	1148 (13.0)
Coronary artery bypass grafting	169 (1.9)
Stroke	1085 (12.7)
Chronic heart failure	245 (2.9)
Peripheral artery disease	45 (0.5)
Renal insufficiency	151 (1.8)
Chronic lung disease	428 (5.2)
Prehospital delay and ambulance use	
Prehospital delay (hours)†	2.8 (1.2–10.3)
Transported by ambulance	1463 (17.9)
Vital signs at presentation	
Heart rate (bpm)*	79.4 (19.6)
Systolic blood pressure (mm Hg)*	143.7 (28.6)
Oxygen saturation (%)*	97.8 (4.0)

Values are n (%) unless otherwise indicated.
Percentages, means and medians were weighted according to the site sampling ratio and enrolment duration. Categorical variables are reported for unweighted frequency and weighted percentages.
*Data presented as mean±SD deviation.
†Data presented as median (IQR).
EMPACT, Evaluation and Management of Patients with Acute ChesT pain.

Table 2 Management and outcomes of patients with acute chest pain in the EMPACT registry

	n=8349
Initial and diagnostic tests	
ECG	7867 (94.1)
Time to first ECG (min)*	4.0 (1.0–9.0)
First ECG within 10 min	5826 (75.6)
Serial ECGs	932 (11.1)
Cardiac troponin	4792 (54.2)
High-sensitivity cardiac troponin	2346 (24.5)
Conventional cardiac troponin	2428 (29.5)
Serial cardiac troponin	487 (5.1)
Stress test	1 (0.0)
Chest X-ray	239 (3.1)
Ultrasound cardiogram	233 (2.9)
CT angiography	88 (1.0)
ED disposition	
Admitted to the inpatient ward	5982 (74.0)
Discharge to home	2224 (24.3)
Transferred to other hospitals	99 (1.2)
Died in ED	44 (0.5)
Length of stay (min)*	65.0 (27.0–385.0)
Outcomes at 30 days	
MACE	548 (6.8)
All-cause death	300 (3.8)
Subsequent AMI	55 (0.6)
Revascularisation	12 (0.1)
Cardiac shock	225 (2.8)
Cardiac arrest	225 (2.8)
Stroke	44 (0.5)
Representation	356 (4.2)

Values are n (%) unless otherwise indicated.
*Data presented as median (IQR). Percentages and medians were weighted according to the site sampling ratio and enrolment duration. Categorical variables are reported for unweighted frequency and weighted percentages.
AMI, acute myocardial infarction; ED, emergency department; MACE, major adverse cardiovascular events.

Among 8349 included patients, 5135 (62.9%) were adjudicated with ACS (figure 3). The incidence of ED-assessed STEMI was 22.3 (95% CI 22 to 22.6) per 100 000.

Management of patients with adjudicated ACS

In patients with adjudicated ACS, patients with ST-segment elevation were more likely to receive antiplatelet therapy than those without ST-segment elevation (online supplemental table 1). Almost (99.0%) of the STEMI cases and 80.5% of the NSTE-ACS cases received dual-antiplatelet therapy 24 hours after presentation (online supplemental table 2). Among patients with STEMI, 57.3% received reperfusion therapy, with 51.3% receiving primary percutaneous coronary intervention (PCI) and 6.3% receiving fibrinolysis (online supplemental table 3).

Predictors of clinical outcomes

In the random-effects multivariable Cox analysis (table 3), older age, hypertension, diabetes mellitus, previous infarction, chronic heart failure, renal insufficiency, ST-segment elevation, higher heart rate, longer symptom-to-door time and ambulance use were associated with a higher risk of 30-day MACE. While higher body mass index and systolic blood pressure were associated with a lower risk of 30-day MACE.

DISCUSSION

To our knowledge, this is the first regionally representative registry of acute chest pain in China. We report for the first time the annual incidence of adult ED-assessed

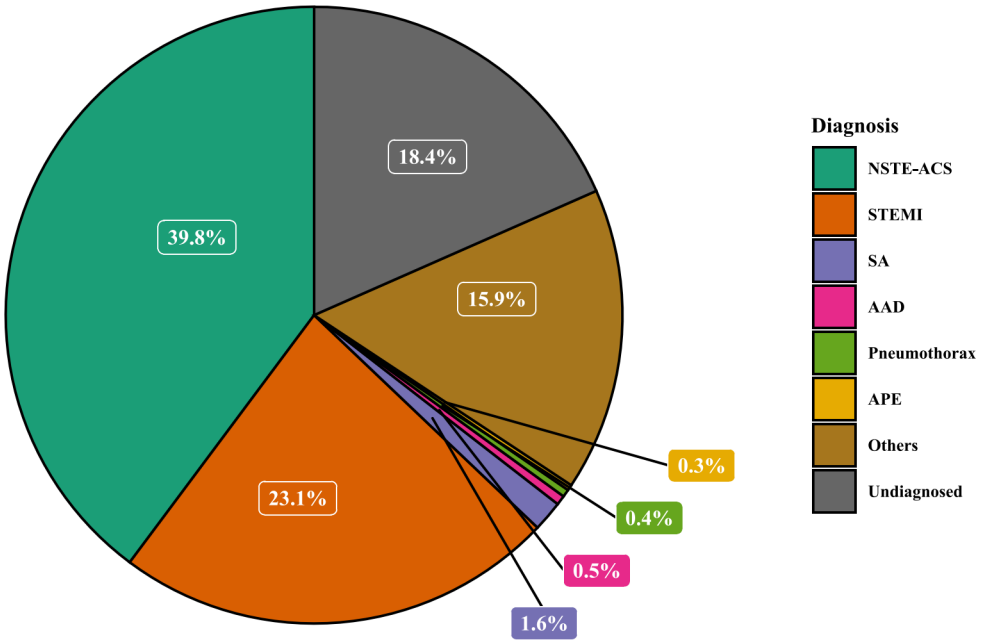

Figure 3 Distribution of primary aetiologies of acute chest pain in the EMPACT registry. AAD, acute aortic dissection; APE, acute pulmonary embolism; EMPACT, Evaluation and Management of Patients with Acute ChesT pain; NSTE-ACS, non-ST-elevation acute coronary syndrome; SA, stable angina; STEMI, ST-elevation myocardial infarction.

acute chest pain in China, which was 96.6 per 100 000. The 30-day MACE rate was 6.8%. Gaps in the early evaluation and treatment were observed.

Lower incidence and higher proportion of ACS

Our study reports a lower incidence when compared with previous studies in high-income countries (HICs). In a cohort study based on the UK electronic health record database, the estimated annual incidence of acute chest pain was 1500 per 100 000 adults.[16] Both in the USA and Australia, the crude incidence was around 2000 per 100 000 persons.[17 18] An explanation for the large difference was that our data were derived from a sample of ED visits. In China, scheduling and attending specialist outpatient consultations is a straightforward process for patients. Therefore, many patients with low-to-moderate risk chest pain opt to visit cardiology or respiratory outpatient clinics instead of going to the ED due to long waiting times. As a result, a large number of chest pain patients are effectively managed through daytime specialist outpatient clinics. This possible explanation is supported by the

Table 3 Random-effects multivariable Cox regression analysis for the predictors of 30-day MACE in patients with acute chest pain in the EMPACT registry

Characteristics	HR (95% CI)	P value
Age (per year)	1.04 (1.03 to 1.04)	<0.001
Male	0.99 (0.93 to 1.06)	0.817
Body mass index (per kg/m²)	0.97 (0.96 to 0.98)	<0.001
Hypertension	1.41 (1.32 to 1.50)	<0.001
Diabetes mellitus	1.18 (1.10 to 1.28)	<0.001
Prior myocardial infarction	1.31 (1.21 to 1.42)	<0.001
Chronic heart failure	1.50 (1.30 to 1.74)	<0.001
Chronic kidney disease	1.56 (1.29 to 1.89)	<0.001
ST-segment elevation	4.10 (3.82 to 4.40)	<0.001
Heart rate (per bpm)	1.01 (1.01 to 1.01)	<0.001
Systolic blood pressure (per mm Hg)	0.98 (0.98 to 0.98)	<0.001
Symptom to door > 6 vs < 6 hour	1.12 (1.05 to 1.21)	0.001
Ambulance transport	1.48 (1.38 to 1.58)	<0.001

EMPACT, Evaluation and Management of Patients with Acute ChesT pain; MACE, major adverse cardiovascular events.

ratio of physician office visits and ED visits, which is 29 times the number of ED visits in China.[10] While in the USA, it was only six times as many.[17 19]

This also explains why the proportion of ACS in our ED-assessed chest pain cohort (60%) is significantly higher than in other studies (15–40%).[18 20] For high-risk patients who have to visit the ED, such as STEMI, the incidence rate was in line with that in HICs.[21 22] When compared with that in a previous Chinese national study, the incidence showed an increasing trend, from 3.7 in 2001, to 8.1 in 2006, to 15.8 in 2011 and to 22.3 in 2016–2017 in our study.[23]

Gaps in evaluation and management

An ambulance with professional staff, equipment and emergency medications is the recommended way to transfer high-risk chest pain.[24] Patients may receive initial evaluations and sometimes essential medications during the ambulance transfer. In the ACS guideline, the role of the ambulance is no longer limited to transport but expands to early intervention.[24] For those diagnosed with STEMI, timely prehospital fibrinolysis has been proven to reduce early mortality.[25] In our study, although over 60% of the patients were diagnosed with ACS, less than 20% of the patients used ambulance service. This suggested that the role of the pre-hospital system was underestimated in China.

Evaluation in the ED is critical for patients' subsequent treatment and disposition. Rather than clinical judgement alone, guidelines have recommended some initial and diagnostic tests for the evaluation of chest pain.[26] In the study, the proportion of patients receiving an ECG within 10 min of arrival was comparable to that in the USA.[27] However, over 40% of the patients did not receive any cardiac biomarker test, and few patients received serial ECG or serial cardiac biomarkers during ED stay. CTA was not widely used despite the growing evidence for its benefits in the evaluation of chest pain.[5 28] In Chinese hospitals, admission refers to the hospitalisation of patients to inpatient general wards or intensive care unit wards, which are charged and reimbursed differently from the outpatient system. The consulting room, observation unit and rescue unit of the ED belong to the outpatient system rather than the admission system. It is worth noting that a significant proportion of patients were admitted to hospitalisation directly and received an assessment in the ward in this study, especially in rural hospitals, owing to the relative availability of ward beds, the fact that many tests and treatment costs are reimbursed only after admission and the lack of emergency assessment and triage capacity of ED. Therefore, it is not difficult to speculate that many patients did not undergo risk stratification or diagnosis at the time of departure.

Once the diagnosis of ACS is made, early antiplatelet treatment is recommended regardless of whether ST-elevation is observed. The study revealed that on departure from the ED, only half of ACS patients and 70% of patients with STEMI had received antiplatelet therapy. Nevertheless, within 24 hours of arrival, these rates had risen to be comparable with those recorded in nationwide registries in both China and the USA.[27 29 30] In the study, only 60% of patients diagnosed with STEMI received reperfusion therapy, which is similar to the results of a previous Chinese study, but significantly lower than the rates observed in the USA and Europe.[27 29 31] Although fibrinolytic therapy is recommended in cases where primary PCI cannot be performed promptly, it was uncommonly used even in patients within the time window. Overall, huge gaps exist in the medication and reperfusion therapy in comparison with HICs. In addition to the uncertainty of diagnosis resulting from insufficient evaluation, some other factors may have contributed to this, including poor compliance with guidelines among emergency physicians.

Underlying causes of guideline discordance

Both medical provider and patient factors could have contributed to guideline discordance. Similar to many other countries, China faces a shortage of emergency physicians.[9] Some EDs are staffed by physicians who are not specialised in emergency medicine. Moreover, in some hospitals with sufficient beds, patients are admitted to the inpatient ward soon after arrival at the ED. Therefore, some of the ED functions are deferred to wards. On the other hand, patient adherence can be limited by socioeconomic factors and health education in LMICs. Although social health insurance has covered more than 97% of residents in China,[32] expenses incurred in the ED cannot be reimbursed in some circumstances. Therefore, some patients may require hospitalisation for further evaluation and treatment covered by reimbursement. In our additional analysis, the proportion of antiplatelet therapy at 24 hours of arrival was significantly higher compared with departure from the ED. The proportion of patients with STEMI receiving dual-antiplatelet therapy was close to that of the CCC-ACS project. For these reasons, enhancing cardiovascular specialised training for emergency physicians, conducting quality improvement programmes in the ED, enhancing health education to patients and health insurance policy support may be helpful to improve guideline adherence.

Strengths and limitations

Using stratified cluster sampling and weighted analysis, the study revealed the current incidence, emergency care and outcomes of acute chest pain in China. However, the study has several limitations. First, we only enrolled patients presenting to the ED. Patients presenting to community or township health centres or hospital specialist clinics were not included. This may have led to an underestimation of the incidence and under-representativeness of low-risk chest pain, and hence limit the generalisability of the study results. Second, although we did collect essential materials for the adjudication of final diagnoses, the full information on evaluation and treatment after hospitalisation, which could have contributed to the differences

in prognosis, was not collected. Third, the EMPACT study included only those who provided written informed consent, which may have introduced potential selection bias. However, since only 6.1% of eligible individuals did not provide informed consent, the degree of selection bias is considered minimal and acceptable.

CONCLUSIONS

In the first regionally representative registry of chest pain in China, the incidence of ED-assessed acute chest pain was relatively lower than previous reports from other countries. However, the high-risk group accounted for a relatively higher proportion. Gaps still existed between the emergency management and the guideline recommendation. Further programmes and policies are required to improve the quality of care for acute chest pain in China.

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Contributors FX and YC contributed to the initiation, planning and conduction of the study. WZ, JW, JZ, WS, JM, JP, CP and GW conducted the study supervision. KC and WZ contributed to the manuscript writing. YW advised on the study design and performed a critical revision of the manuscript. KC, WZ and SW performed the analysis and interpretation of data. YC is responsible for the overall content as the guarantor.

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Competing interests YW serves as a member of the Editorial Advisory Board for BMJ Open.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was conducted in accordance with the Declaration of Helsinki and approved by the Central Ethics Committee at Qilu Hospital of Shandong University ((Scientific Research) Ethics Approval No. (2015) 058). All participating hospitals accepted the central ethics approval, except the Affiliated Hospital of Jining Medical University, which obtained local approval from its internal ethics committee ((2015) JYFY – Scientific Research Ethics Approval No. 4). Participants gave informed consent to participate in the study before taking part.

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