

Comparison of a 6-hour and 9-hour Protocol for Evaluation of Moderate-to-Low Risk Chest Pain Patients in an Emergency Department Diagnostic Unit

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ABSTRACT

Objective: To compare the 30-day outcomes of patients enrolled in a 6-hour and 9-hour emergency department (ED)-based chest pain centre (CPC) protocol.

Methods: All patients with the chief complaint of chest pain, who were older than 25 years, or with cocaine usage within 96 hours of initial presentation, were eligible for enrolment. Exclusion criteria included acute ST-segment elevation or depression >1 mm in 2 contiguous leads, history of coronary artery disease (CAD), haemodynamic instability or clinical syndromes consistent with unstable angina. Outcomes included ED disposition and cardiac events at 30 days (defined as acute myocardial infarction (AMI), percutaneous trans-luminal coronary angiography (PTCA), coronary artery bypass graft surgery (CABG), ventricular tachycardia or fibrillation (VT/VF) arrest, congestive heart failure (CHF) admission or cardiac-related death).

The 9-hour protocol consisted of ST-segment monitoring, serial CK-MB draws at 0, 3, 6 and 9 hours as well as a graded exercise test (GXT) prior to ED disposition. The 6-hour protocol eliminated the 9-hour serum marker determination, included cardiac Troponin-I (cTn-I) and allowed a GXT, 3 hours earlier. Follow-up was obtained by medical record review, phone contact, letter and also review of national and state death registries.

Results: The 9-hour protocol (October 1991-December 1997) included 2,133 patients and the 6-hour protocol (January 1998-August 1998) had 184 patients enrolled. The 6-hour protocol was not different from the 9-hour one in terms of percentage admissions (9-hour: 310, 14.5%; 6-hour: 33, 17.9%; $p=0.213$), Coronary Care Unit admission (9-hour: 59, 2.8%; 6-hour: 5, 2.7%; $p=0.303$) or 30-day cardiac events (9-hour: 38, 1.9%; 6-hour: 2, 1.3%; $p=0.605$).

Conclusion: The 6-hour CPC strategy is an effective and safe evaluation method for patients at low to moderate risk for acute coronary syndromes.

Keywords: Chest pain centre, acute coronary syndrome

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INTRODUCTION

Each year over 6 million patients in the United States of America present to the Emergency Departments (ED) with chest pain⁽¹⁾. More than half of these patients are subsequently admitted for further evaluation and treatment⁽²⁻⁴⁾. Despite the propensity to admit all 'suspicious' patients with chest pain, approximately 2 to 10 % are still inadvertently released home and suffer an acute myocardial infarction (AMI)⁽⁵⁻⁸⁾. Approximately 20 percent of the total malpractice dollars in Emergency Medicine (EM) are awarded for patients discharged from the ED who subsequently have a cardiac event^(8,9). As a result of this, emergency physicians (EP) tend to use a liberal admission policy which contributes to the high cost of acute coronary evaluation.

Chest Pain Center (CPC) protocols have been developed to evaluate and observe patients at low-to-moderate risk of acute coronary syndromes (ACS) in the ED⁽¹⁰⁻¹⁵⁾. This assessment has been shown to be cost-effective and safe⁽¹⁶⁻²⁵⁾. Today, CPCs and the broader practice of ED observation, represent one of the fastest growing additions to the health-care delivery system⁽¹⁹⁻²⁵⁾.

The minimum length of evaluation for safe and effective CPC care is affected by the available diagnostic tests and characteristics of the patient population enrolled. Shorter evaluation periods have been encouraged by routine use of serial cardiac markers, continuous ST-segment trend monitoring and ED graded exercise stress testing (GXT). In addition, managed care issues have driven the desire for shorter evaluation periods. The traditional in-hospital, 3-day 'rule-out' MI admission has, with time, been shortened to 24 hours and 12 hours⁽²⁶⁻²⁸⁾. With more sophisticated and state-of-the-art diagnostics, this time may continue to be further reduced⁽²⁹⁻³²⁾. ED CPC evaluations have now been reported for the use of immediate GXT testing up to 72 hours from presentation⁽³³⁻³⁴⁾. While

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ED evaluations for chest pain have been reported to utilize immediate GXT in the appropriate population, the more traditional CPCs have included an evaluation for necrosis, prior to provocative testing.

OBJECTIVES

The University of Cincinnati established and reported the results of a 9-hour CPC-based protocol to rule-out infarction and rest ischaemia⁽¹⁹⁾. This was followed by a GXT to rule-out exercise-induced ischemia. Based on a 1998 review of 30-day cardiac events, a 6-hour CPC protocol was implemented as the standard of care. It was hypothesized that the use of a 6-hour protocol would not increase the 30-day complication rate compared to the 9-hour protocol. We thus compared these two protocols with the primary outcomes of ED disposition and 30-day cardiac events.

METHODOLOGY

This is a retrospective follow-up study of consecutive patients admitted to an urban university CPC from October 1991 through December 1997 (9-hour protocol) and January 1998 through August 1998 (6-hour protocol). Both these protocols were developed as the standard of care in the Center for Emergency Care at the University of Cincinnati, thus informed consent was not required.

Patients were eligible for enrolment if they were older than 25 years, presented to the ED with non-traumatic chest pain, suspicious of acute coronary syndrome (ACS), and an initial 12-lead ECG non-diagnostic for ischaemia or myocardial infarction (MI). The initial ECG was considered diagnostic for MI if there was ST-segment elevation or depression > 1 mm in 2 contiguous leads. These patients, as well as those with history consistent with unstable angina pectoris or hypotension with systolic blood pressure < 90 mmHg were excluded.

The 9-hour protocol consisted of continuous ST-segment monitoring and serial CK-MB testing at presentation, 3, 6 and 9 hours. A graded exercise stress test (GXT) was performed upon successful completion of the protocol. The 6-hour protocol was similar, but included cardiac troponin-I (cTnI) levels and omitted the 9-hour marker determination.

Any patient with elevated CK-MB or cTnI levels, new ST-segment elevation or depression of 1 mm in electrically contiguous leads, chest pain unresolved by standard treatment, abnormal GXT results or haemodynamic instability, were admitted for further inpatient management. A comprehensive database for the CPC was maintained in the ED and updated continuously for patients' results and outcome. Patient demographic data, risk factors and initial ED data were recorded at the time of presentation on a

Table 1. Comparison of the 6-hour and 9-hour CPETU strategies.

Factor	6-Hours		9-Hours		
	N	%	N	%	
Age group					
<30	17	9.2	170	8.0	p=0.599
30-39	65	35.3	644	30.2	
40-49	71	38.6	685	32.1	
50-59	20	10.9	357	16.7	
60-69	10	5.4	202	9.5	
≥70	1	0.6	75	3.5	
Sex					
Male	93	50.5	995	46.6	p=0.309
Female	91	49.5	1138	53.4	
Race					
Non-white	112	60.9	1302	61.0	p=0.964
White	72	39.1	831	39.0	
GXT					
Normal	163	88.6	1579	74.0	p=0.582
Indeterminate	17	9.2	509	23.9	
Ischemic	4	2.2	45	2.1	
CK-MB					
Negative	177	96.2	2077	97.4	p=0.311
Positive	7	3.8	56	2.6	
Admission					
	34	18.5	307	14.4	p=0.182
Discharged					
	150	81.5	1826	85.6	
CCU Admissions					
	5	2.7	59	2.7	p=0.303
30-day Complication					
	2	1.1	38	1.9	p=0.936

* Mean difference between the 2 groups is not significant at p values of <0.05

standardized form by the treating physician. The patients were followed-up for 30 days, for death or first cardiac event, which represented the primary end-point of the study⁽³⁵⁻³⁷⁾. Cardiac event was defined as AMI, ventricular fibrillation/ventricular tachycardia arrest, congestive heart failure, PTCA, CABG or any cardiac-related deaths. Follow-up information was obtained by review of the ED and hospital medical records, telephone contact, written communication in the form of a letter as well as review of the state and national death registry records.

Chi-squared test was utilized for significance testing. Microsoft ACCESS was used for data management and SAS programs for descriptive and comparative analyses⁽³⁸⁾.

RESULTS

From October 1991 to December 1997 (9-hour protocol), a total of 2,133 patients were enrolled. From January to August 1998 (6-hour protocol), 184 patients were enrolled. There were no statistically significant difference between the 2 groups of patients, after correction for age (p=0.599), sex (p=0.309) and race (p=0.964) (Table I). The median age was 44.7 and 49.3 years for the 9-hour and 6-hour groups respectively. The risk factors for coronary artery disease (CAD) were also

Table II. Comparison of Risk Factors in the 6 and 9-hour groups.

Factor	6-Hours		9-Hours		p
	N	%	N	%	
Hypertension	57	31.0	738	34.6	p=0.309
Diabetes	15	8.2	230	10.8	p=0.343
Cigarette Smoking	100	54.3	1224	57.4	p=0.209
Family History	79	42.9	767	38.0	p=0.139
Lipids	21	11.4	176	8.3	p=0.383
Illegal drug usage	10	5.4	187	8.8	p=0.120

* Mean difference between the 2 groups is not significant at p values of <0.05

compared for the 2 groups of patients. The differences in prevalence of hypertension (34.6% vs 31.0%), diabetes mellitus (10.8% vs 8.2%), family history of CAD (38.0% vs 42.9%), cigarette smoking (57.4% vs 54.3%) and elevated lipids (8.3% vs 11.4%) were not statistically significant between the 9-hour and 6-hour groups (Table II).

Fifty-six (2.6%) and 7 (3.8%) patients had elevated CK-MB levels in the 9-hour and 6-hour groups respectively, but the difference in this CK-MB positive rate was not statistically significant (p=0.311) (Table 1). No significant difference was noted for the GXT test results (p=0.582). Those with positive results for ischemia (2.1 % in the 9-hour and 2.2% in the 6-hour group) were also admitted for inpatient management.

The 6-hour protocol was not different from the 9-hour one in terms of percentage admissions (9-hour: 307, 14.4%; 6-hour: 34, 18.5%; p=0.182), coronary care unit (CCU) admissions (9-hour: 59, 2.8%; 6-hour: 5, 2.7%; p=0.303) or 30-day cardiac-event rates (9-hour: 38, 1.9%; 6-hour: 2, 1.1%; p=0.936) (Table 1). One hundred and thirty eight (6.5%) and 7 (3.8%) patients were lost to follow-up at 30 days in the 9-hour and 6-hour groups respectively.

DISCUSSION

The diagnosis of ACS in patients presenting to the ED is challenging. Over the last 15 years, the evaluation and treatment of these patients with possible myocardial ischemia or infarction has evolved significantly. Interventions for AMI such as fibrinolytic therapy and PTCA have intensified the interest of clinicians in earlier diagnosis and treatment^(39,40).

Patients at low to moderate risk of ACS are particularly challenging due to their non-diagnostic initial ED, as well as the high cost of eventually negative cardiac work-ups. While some authors have suggested that serial marker evaluation alone⁽⁴¹⁾ or immediate GXT^(33,34) may allow rapid and cost-effective ED discharge, practitioners appropriately remain concerned about discharging a patient from the ED with unstable angina pectoris. We believe a CPC protocol should

address necrosis, rest ischemia and exercise-induced ischemia prior to consideration for ED discharge. Evidence-based and protocol-driven medicine is being applied for the management of patients with chest pain and possible ACS in CPCs located in the ED. A protocol providing intensive diagnostic testing over a period of time can provide a rapid assessment method for detecting patients with ACS. The length of evaluation is a critical factor, considering the available diagnostic tools and cost-effectiveness implications^(17,18,24,25).

The traditional practice of admitting patients to the hospital for 2 to 3 days to 'rule-out' AMI has largely been reduced to 24-36 hours⁽²⁶⁾. Protocols for ED based CPCs have utilized time periods of 9-24 hours^(27,28). A 6-hour protocol has thus far not been formally evaluated. Our reduction from 9 to 6 hours was based on improvement in diagnostics, increased familiarity with the CPC concept, critical evaluation of the literature and review of the first six years of our CPC patient outcomes.

Measurements of CK-MB and its isoforms by high-voltage electrophoresis is now an effective method for the rapid diagnosis of myocardial ischemia, within 3 hours of presentation, with the isoform enhancing sensitivity⁽⁴⁵⁻⁵⁰⁾. There are also modern automated and sophisticated systems and analysers readily available⁽⁵¹⁾. Single Troponin-T levels have now been shown to have a sensitivity, at presentation, of 85%, with false negative results, if taken earlier than 3 hours or after 10 days of symptoms. It also effectively identifies non-Q AMI earlier than CK-MB. Qamar et al, concluded that with this, a patient with serious coronary ischemia can be identified by 3.5 hours after symptom onset⁽⁵²⁾.

Also readily available now is real-time continuous 12-lead ST-segment trend monitoring. Frequent serial ECGs are also commonly included in the CPC protocols⁽⁵³⁾. This form of monitoring can provide the earliest evidence of coronary occlusion or painless/ silent ischemia. Transient ST-segment elevation or depression may also identify high-risk patients, who otherwise would have been released from the ED⁽⁵⁴⁻⁵⁸⁾.

Graded exercise testing too has been brought to the front-line. Several studies done in the ED/ CPC have shown favourable results⁽⁵⁹⁻⁶²⁾. Single-Photon Emission Computerized Tomography (SPECT) is now available for these patients as a risk stratification tool in the ED/ CPC. Resting SPECT has the highest sensitivity when the tracer is injected during active chest pain. Injection after resolution of chest pain lowers sensitivity but the time course for this reduction is not clearly defined^(63,64).

The ED-based CPC concept has been pioneered and in operation for more than 8 years now. The recent change from the 9-hour to the 6-hour protocol at the University of Cincinnati is timely comparison of two approaches, as there continues to be development and

improvement, with the expansion of the CPC practice, which will enhance quality of care and patient satisfaction.

Some of the limitations in the study included the possible variation expected in the completion of the forms by the treating physicians, even though a standardized format was used. The addition of cTnI to the 6-hour protocol may have an effect on the sensitivity and specificity. There was also the possibility of missing out on some events, if patients had presented to another hospital, although our population generally utilized the University of Cincinnati as their sole source of care.

We conclude that the 6-hour CPC strategy is as effective and safe as the 9-hour protocol for patients at low-to-moderate risk for acute coronary syndrome.

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