

Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction: Direct Transportation to Catheterization Laboratory by Emergency Teams Reduces Door-to-Balloon Time

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Summary

Background: Primary percutaneous coronary intervention (PCI) is the recommended revascularization strategy for patients presenting with acute ST-elevation myocardial infarction (STEMI). In most hospitals, transfer of patients with STEMI is organized from the emergency site via emergency room (medical and cardiologic evaluation) and then to the catheterization laboratory.

Hypothesis: In this prospective study, we sought to evaluate the effect of a logistic modification in this treatment process.

Methods: Local emergency ambulance teams were instructed to identify and evaluate patients with STEMI eligible for direct PCI and to transport them directly to the cardiac catheterization laboratory for immediate percutaneous coronary intervention (“ER bypass”). This study prospectively included 74 consecutive patients with acute coronary syndromes (STEMI) and compared them with a matched historic control group (“ER evaluation”). Primary endpoint was the reduction in door-to-balloon time; secondary endpoint was quality of preclinical emergency diagnosis.

Results: Median door-to-balloon time was reduced by 27 min. Primary interventional success was achieved in 92% of patients. Preclinical emergency diagnoses were correct in 95% of patients.

Conclusion: The preclinical emergency diagnosis of STEMI was reliable. Direct transport of patients with STEMI to the cardiac catheterization laboratory and early preclinical alert by the interventional PCI team significantly reduces door-to-balloon-times compared with established standard processes-of-care for patients considered for primary PCI.

Key words: primary coronary angioplasty, ST-elevation myocardial infarction, 12-channel surface electrocardiogram, logistic, emergency care

Introduction

In patients with acute ST-segment elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI) is the preferred therapeutic strategy to achieve reperfusion.^{1, 2} Mortality and morbidity in patients with STEMI correlate directly with a longer time interval between onset of symptoms and complete restoration of coronary reperfusion.^{3, 4} Recently published European guidelines recommend primary PCI over thrombolytic therapy in all patients who can be transported to interventional facilities within a period of 90 min after first qualified medical contact.⁵ Door-to-balloon time is influenced by various factors such as delays in triage, evaluation and diagnosis, and limited specialized competence during off-hours. It is therefore important to focus on improving the logistic details of this complex process-of-care. Early PCI team activation and direct transfer from the emergency team to the catheterization laboratory have recently been advocated strategies.^{6, 7} This study prospectively evaluated such a strategy of accelerated logistics in patients with acute STEMI.

Methods

Out-of-hospital emergency ambulance teams consisting of qualified physicians (anesthesiologists or fellows in internal medicine), trained in emergency medicine, were instructed by two interventional cardiologists to make precise diagnoses of the acute coronary syndrome. A series of systematically planned teaching sessions focusing on typical and atypical presentation of angina and coronary heart disease preceded

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the initiation of the program. The correct interpretation of pre-clinically recorded electrocardiogram (ECG) was the second focus in the training schedule for emergency ambulance teams. After an initial systematic review of ischemic ECG alterations, a case-focused feedback session was scheduled 3 and 6 months after initiation of the study. Interventional cardiologists presented emergency diagnoses, initial ECG, and coronary angiograms, and individual aspects of single cases were discussed.

Ambulant 12-lead surface ECG recorders (Responder 3000, GE Healthcare, Milwaukee, Wisc., USA) were placed on all ambulances as recommended by current guidelines.⁸ Crews were trained to record a 12-lead ECG in each patient suspect of acute coronary syndrome.

In presence of predefined criteria (Table I), the team initiated medical therapy according to current guidelines and was encouraged to alert the local university hospital's intensive care unit and the PCI team by telecommunication. The emergency team then transported the patient directly to the catheterization laboratory to meet the PCI team. A PCI team, consisting of one of five experienced interventional cardiologists and a nurse, was on call on a 24-h-a-day, 7 days-a-week basis. Coronary interventions were carried out according to current guidelines.⁹ Adjunctive therapies such as the use of glycoprotein-IIb/IIIa- inhibitors or intra-aortic balloon counterpulsation were left to the discretion of the investigator. All coronary culprit lesions were stented. Close internal monitoring of angiograms and individual interventional procedures was required in each patient.

The following information from the study group patients was collected: baseline patient data (obesity was defined as body mass index > 26, hypercholesterolemia was defined as low-density lipoprotein cholesterol > 140 mg/dl), time of alert, treatment and transportation interval, time of arrival at the catheterization laboratory, door-to-balloon-time, surface ECG, coronary angiogram, interventional outcome, relevant complications, concomitant medication, and left ventricular ejection fraction at discharge.

The data were compared with those of a group of consecutively included patients who had been treated by direct PCI for STEMI during the year before the start of this study.

TABLE I Criteria for direct alert of percutaneous coronary intervention (PCI) team and transportation to catheterization laboratory

Anginal chest pain and typical ST-segment elevation in 12-lead surface electrocardiogram (ECG)
Anginal chest pain and presumably new left bundle-branch block
Anginal chest pain and typical ST-segment elevation in 12-lead surface ECG and clinical signs of cardiogenic shock
Cardiac arrest and successful preclinical resuscitation
Patients informed consent to immediate PCI
Absence of other severe life threatening conditions (i.e., extensive malignant disease)

All 12-lead surface ECGs recorded by the emergency team were read by two independent cardiologists to evaluate the diagnostic competence of the emergency doctor.

Statistical Analysis

Numbers are given as mean and median values where indicated with their standard deviation. The median was calculated for time intervals. Statistical differences between groups were calculated by Student's *t*-test for unpaired samples where appropriate. We used Microsoft (Redmond, Wash., USA) XP Excel standard software.

Results

Patients

In all, 137 patients with STEMI as diagnosed by the emergency ambulance team were included in this study. Table II displays baseline characteristics of the group that was transferred directly to the catheterization laboratory (emergency room bypass; "ER bypass") and the control group ("ER evaluation"). No significant difference in baseline data was found between the two groups.

Quality of Emergency Diagnosis

We found that in 70 of 74 (94.6%) cases the emergency ambulance team's preclinical evaluation was shared post hoc by two independent cardiologists in the ER bypass group. Two of these ECGs showed insignificant ST alterations; two other ECGs had ST-segment depression. All but one patient directly referred to interventional therapy (ER bypass) underwent im-

TABLE II Baseline characteristics of patients included in both groups

Patient characteristics	ER bypass (n = 74)	ER evaluation (n = 63)	p Value
Age (MW \pm SD)	64 \pm (range 35–94)	66 \pm (range 36–92)	NS
Women (%)	25	36	NS
Hypertension (%)	39	42	NS
Diabetes (%)	16	14	NS
Known CAD (%)	14	8	NS
Prior MI (%)	11	7	NS
Obesity (%)	34	39	NS
Hypercholesterolemia (%)	19	29	NS
Smoker (%)	22	24	NS

ER bypass = direct transportation to catheterization after out-of-hospital diagnosis of ST-elevation myocardial infarction bypassing the interventional center's emergency room; ER evaluation = control group of patients referred for evaluation to the emergency room.

Abbreviations: M = mean, SD = standard deviation, NS = not significant, CAD = coronary artery disease, MI = myocardial infarction.

TABLE III Relevant interventional time intervals

Patient characteristics	ER bypass (MW ± SD, range)	ER evaluation (MW ± SD, range)	p Value
Symptom to alert (min)	245 ± 640(1–3600) Median 65	128 ± 197(1–1217) Median 54	NS
Arrival of medic team (min)	7 ± 3 (1–20)	7 ± 2 (3–15)	NS
Time at emergency site (min)	24 ± 9 (8–69)	23 ± 11 (4–62)	NS
Transport (min)	9 ± 4 (3–20)	12 ± 5 (4–62)	NS
Door-to-start of procedure (min)	22 ± 18 (1–89) Median 18	60 ± 47 (1–205) Median 44	<0.001
Door-to-balloon (min)	62 ± 27 (29–164) Median 56	96 ± 55 (14–269) Median 83	<0.001
Complete intervention (min)	62 ± 33 (17–212) Median 55	66 ± 32 (17–163) Median 61	NS
First medical contact-to-balloon (min)	95 ± 26 Median 89	131 ± 59 Median 118	<0.001

Abbreviations as in Table II.

mediate coronary angiography. This patient had no angina but did have orthostatic syncope, and at the age of 94 she would not consent to urgent coronary angiography. Coronary heart disease was ruled out in one patient and the final diagnosis was massive pulmonary embolism. One patient had aortic dissection and was sent to cardiac surgery from the catheterization laboratory. In one further patient, the diagnosis of hemodynamically relevant aortic stenosis was overlooked during rapid execution of primary coronary intervention.

Reduction in Percutaneous Coronary Intervention Intervals

Table III represents the time intervals measured for both groups. Patients in the ER evaluation group had a shorter interval between onset of anginal symptoms and alert of the emergency team. This study's most relevant result is the reduction in median door-to-balloon-time by 27 min, that is, from 1h 23 min to 56 min (median). The interval between first qualified medical contact and balloon inflation of was similarly reduced by a mean of 29 min.

Clinical Course

Interventional information is displayed in Table IV. All patients eligible for PCI underwent balloon dilatation and obligatory coronary stenting; 91% in the ER bypass group versus 92% in the ER evaluation group were successfully treated. Adjuvant therapy such as treatment with glycoprotein IIb/IIIa inhibitors was used at the interventional cardiologists' discretion in comparable proportions in both groups. Relevant variables in clinical outcome are shown in Table V. There is a trend toward shorter in-hospital treatment for patients directly referred to PCI of 9.5 ± 7.9 versus 12.5 ± 10.9 days. Patients in the ER bypass group had a better ejection fraction at the time of discharge as determined echocardiographically. In-hospital mortality did not differ significantly in both groups.

Discussion

Quality of Emergency Diagnosis

One essential condition for implementing this logistic approach to improving interventional times in primary PCI—a cost-intensive procedure—is the high quality of primary diag-

TABLE IV Interventional data

Variable	ER bypass (n = 74)	ER evaluation (n = 63)
No detectable CAD (%)	7 (9.4)	0
Coronary artery		
LAD (%)	52 (40.7)	43 (50.4)
LCx (%)	14 (13.6)	8 (9.5)
RCA (%)	46 (44.7)	34 (40.1)
LM (%)	1 (0.9)	0 (0)
Triple-vessel disease	16 (21.6)	18 (28.6)
Procedure		
Medical	7	0
ACB	2	0
PCI/stent (%)	61 (91)	58 (92)
GP IIB/IIIa inhibitor		
Abciximab (%)	23 (42.6)	29 (56.9)
Tirofiban (%)	14 (25.9)	6 (11.8)
Integrilin (%)	17 (31.5)	16 (31.4)
TIMI 3 after intervention (%)	53 (86)	56 (96)

ER bypass and evaluation defined in Table II.

Abbreviations: CAD = coronary artery disease, LAD = left anterior descending, LCx = left circumflex, RCA = right coronary artery, LM = left main stem, ACB = aorto-coronary bypass, PCI = percutaneous coronary intervention, GP = glycoprotein, TIMI = Thrombolysis In Myocardial Infarction (TIMI 3 relates to good flow of contrast medium after PCI and stenting).

TABLE V Clinical outcome

Variables	ER bypass (n = 74)	ER evaluation (n = 63)	p Value
Peak CK max			
< 12 h (%)	45 (61)	38 (60)	
Use of IABP (%)	3 (4.0)	2 (3.0)	NS
VF arrest (%)	3	5	NS
EF at discharge			
≤ 25 % (%)	5 (8.4)	5 (11.6)	>0.05
25–50 % (%)	16 (37.4)	21 (43.7)	>0.05
> 50 % (%)	22 (51.1)	22 (45.8)	>0.05
Day of discharge	Median 7	Median 10	
	Mean 9.5 ± 7.9	Mean 12.5 ± 10.9	
	Range 1–50	Range 1–25	NS
Died in hospital (%)	6 (8.1)	3 (4.8)	>0.05

Abbreviations: CK = creatine kinase, IABP = intra-aortic balloon pump, VF = ventricular fibrillation, EF = ejection fraction.

nosis. Preclinical diagnosis of acute coronary syndrome and STEMI is made by the presence of typical anginal chest pain and a 12-lead resting ECG. Modern emergency vehicles are equipped with transportable ECG recorders, as recommended by the European Society of Cardiology (ESC)⁵ and the German Cardiac Society.⁸ The doctor on call is specialized in emergency medicine but not a cardiologist. After repeated briefings and case-focused feedback sessions between the interventional cardiologist and emergency teams, all doctors on the teams were familiar with frequent ECG variations and their interpretation before the start of this study. Our post hoc analysis shows that from the interventional cardiologist's point of view 95% of the patients directly referred had been correctly managed preclinically. The ambulant 12-lead surface ECG interpreted by a doctor is an essential and reliable tool in this setting.

Reduction of Percutaneous Coronary Intervention Intervals

The direct correlation between duration of cardiac ischemia and mortality is established clinical knowledge that primarily originates from meta-analyses of thrombolytic reperfusion studies.¹⁰ In an evaluation of 27,080 patients undergoing primary PCI for STEMI, Cannon *et al.* observed a significant correlation between in-hospital mortality and duration of door-to-balloon time. They concluded that physicians and health care organizations should work toward effective reduction of this decisive interval.¹¹ For 1,791 patients undergoing primary PCI for STEMI, De Luca *et al.* recently analyzed the correlation between ischemic time and 1-year mortality. After adjustment for known risk factors, they found that each delay of 30 min between start of symptoms and reperfusion was associated with a relative risk of 1.075 ($p = 0.041$).¹² Authors of recently published U.S. studies evaluating whether transfer to direct PCI is a profitable strategy for patients with STEMI advocate the improvement of logistic details in the process of care for these patients.^{6, 13}

In this study, we demonstrate that direct transportation of patients with STEMI to the cardiac catheterization laboratory (ER bypass), compared with prior evaluation in the emergency department, effectively reduces door-to-balloon time by a median of 27 min. In an urban situation with a baseline door-to-balloon time of nearly 90 min, an optimized logistic approach can reduce this relevant time interval by one third. A door-to-balloon time of 60 min for primary PCI under standard conditions was reported by Zahn *et al.*¹⁴ in an analysis involving 1,063 patients with primary PCI in a metropolitan area. During the first 3 h following onset of symptoms in patients with STEMI, this is a highly relevant reduction resulting in less ischemia-induced myocardial damage.

Clinical Implications

It is important to note that in some patients, instant coronary angiography would not have been the first diagnostic measure in retrospective analysis. Acute pulmonary embolism and aortic dissection were diagnosed after ruling out myocardial infarction. In one patient, severe aortic stenosis was found after percutaneous revascularization. The acute therapeutic strategy would not have been modified. Mortality and left ventricular function were not predefined endpoints in this study. However, ejection fraction determined before discharge shows a trend to better left ventricular function in the ER bypass group referred directly to primary PCI, although this fails to reach statistical significance.

Study Limitations

The number of patients included is too small to prove a relevant clinical benefit from the described improvement in logistics at this stage. However, the dynamic cooperation between interventional center and preclinical emergency medicine resulting from this concept highly motivates providers of modern therapy for acute coronary syndrome. This cooperative aspect will be highly relevant as specialized high-volume centers for primary PCI develop, as advocated by Smalling and Giesler.¹⁵

Conclusion

The preclinical diagnosis of STEMI can be made precisely by well-trained emergency ambulance teams consisting of paramedics and physicians. Direct transport to the catheterization laboratory, bypassing the emergency room, is a safe, attractive strategy for reducing time to successful coronary intervention.

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