Optimization of Emergency Care Pathway Beginning with Pre-admission Procedures for Patients with ST-elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention: Impact on First Medical Contact to Balloon Time and Prognosis Y Huang<sup>1,2</sup>, X-J Yang<sup>\*1</sup>, G Lin<sup>3</sup>, J-P Qiu<sup>2</sup>, J-J Zhang<sup>2</sup>, J Lin<sup>2</sup>

# ABSTRACT

**Objectives:** This study was conducted to compare the first medical contact to balloon time (FMC2B) and prognosis of patients with ST-elevation myocardial infarction (STEMI) receiving primary percutaneous coronary intervention (PCI) for two emergency care pathways, both beginning with a telephone call to the number 120 to reach Emergency Medical Services (EMS): 120 EMS -> Emergency Room -> Cardiac Catheterization Lab (optimized pathway); and 120 EMS -> Emergency Room -> Coronary Care Unit (CCU) -> Cardiac Catheterization Lab (conventional pathway).

**Methods:** A total of 183 patients with STEMI who were sent to the hospital by ambulance and received PCI within 12 hours after symptom onset was included in the study. These patients were divided into two groups: 100 were in the optimized pathway group and 83 were in the conventional pathway group. The primary endpoint was FMC2B time, and the secondary endpoints included the door-to-balloon (D2B) time, in-hospital mortality rate, recurrence rate for nonfatal myocardial infarction, cerebrovascular accident rate, heart failure rate, and rate of major cardiovascular events during the follow-up period. Multivariate regression analysis was performed to assess the risk factors for cardiovascular adverse events after the PCI procedure. **Results:** Both the FMC2B time (100.3 min vs. 145.6 min, P<0.05) and D2B time (77.1 min vs. 115.4 min, P<0.05) were significantly shorter in the optimized pathway group than in the conventional pathway group. The in-hospital mortality rate was significantly lower in the optimized pathway group than in the conventional pathway group than in the conventional pathway group than in the conventional pathway group (5.0% vs. 15.7%, P<0.05). The rates of rehospitalization due to cardiovascular disease, all-cause death and cardiovascular death during the follow-up period were also all significantly lower in the optimized pathway group.

group than in the conventional pathway group ( $\chi 2=5.17$ ,  $\chi 2=8.15$ ,  $\chi 2=4.55$ ; all P<0.05).

Multivariate regression analysis indicated that FMC2B time, D2B time and age were

significantly correlated with cardiovascular event rate during the follow-up period (OR= 0.91,

P=0.01; OR= 0.93, P=0.00; OR=0.74, P=0.02).

Conclusions: The optimized emergency care pathway, beginning with pre-admission

procedures, can significantly shorten the FMC2B time and D2B time, and will improve the

short- and long-term prognosis for STEMI patients.

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# **INTRODUCTION**

Studies have found that half of the deaths from acute myocardial infarction occur within 1 hour after symptom onset, and if earlier treatment can be given, the mortality is lowered and prognosis improved (1-3). Therefore, we can say that "time is myocardium; time is life."(4, 5) At present, percutaneous coronary intervention (PCI) is generally recognized as the best treatment available for ST-elevation myocardial infarction [STEMI] (2, 6). The efficacy of PCI depends on an effective emergency care system (7), so many hospitals have improved their emergency care pathways with regard to primary PCI treatment. The emergency care pathway related to primary PCI for patients with STEMI in our center was optimized in 2008. Since then, the pathway has been further improved based on the experience of other hospitals in China and our own experience. The optimized pathway is a kind of "green channel" connecting

**Keywords:** Door-to-balloon (D2B) time, emergency care pathway, first medical contact to balloon (FMC2B) time, myocardial infarction, percutaneous coronary intervention (PCI), prognosis

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pre-hospital procedures and in-hospital procedures for patients with STEMI, so as to shorten treatment delays. We looked at first medical contact to balloon (FMC2B) time and short- and long-term prognosis of patients with STEMI when treated with primary PCI for two emergency care pathways. Since first medical contact is generally when a telephone call is placed to 120 Emergency Medical Services (EMS), this study was conducted to compare an optimized treatment pathway, 120 EMS -> Emergency Room -> Cardiac Catheterization Lab, and a conventional treatment pathway, 120 EMS -> Emergency Room -> Coronary Care Unit (CCU) -> Cardiac Catheterization Lab.

### **Subjects and Treatments**

### Subjects

Inclusion criteria: patients aged between 35 and 85 years; (STEMI within 12 hours from symptom onset (183 cases). Definition of STEMI: chest pain less than 12 hours after onset;  $\geq 0.2 \text{ mV}$  of ST segment elevation in two contiguous precordial leads or  $\geq 0.1 \text{ mV}$  of ST segment elevation in limb leads; or, new left bundle branch block with or without an elevation in concentration of biomarkers of myocardial injury. Exclusion criteria: patients who were sent to the hospital, but not by 120 ambulance; patients with a myocardial infarction that occurred in the hospital; patients who were not suitable for primary PCI or who refused to receive PCI or who failed primary PCI; patients who had communication disabilities such as severe hearing loss, language disorders or cognitive impairment. Qualifying patients were divided into two groups: patients who were admitted to the hospital from January 2008 to December 2008 were in the optimized pathway group, and the patients who were admitted to the hospital from January 2007 to December 2007 were in the conventional pathway group. The optimized emergency care pathway included the following procedures: a patient with chest pain was picked up by the 120 EMS crew; the first electrocardiogram (ECG) was performed in the

ambulance; the ECG results were sent to the remote system of the emergency room; the emergency room staff called the on-duty cardiologist immediately after receiving the information from 120 EMS; the cardiologist arrived at the emergency room before the ambulance arrived; after the ambulance arrived, the cardiologist examined the patient and confirmed the diagnosis of STEMI; the primary PCI team was prepared and at the same time, informed consent was obtained; the patient was sent to the Cardiac Catheterization Lab directly (80 cases). Or, a patient with chest pain was picked up by the 120 EMS crew; the first ECG was performed in the ambulance; the EMS crew called the on-duty cardiologist directly; the primary PCI team was prepared; the patient was sent to the Cardiac Catheterization Lab and informed consent was obtained (20 patients). The conventional emergency care pathway included the following procedures: a patient was sent to the hospital by ambulance; the emergency room staff assessed the patient and transferred the patient to the CCU; the primary PCI team was prepared and the patient was moved to the Cardiac Catheterization Lab (83 patients).

#### **Treatments**

After giving informed consent for PCI, the patient was given aspirin enteric-coated tablets 300 mg (to be chewed and swallowed) and clopidogrel tablets 600 mg one hour before PCI, and was given aspirin 100 mg per day and clopidogrel 75 mg per day after PCI. Ordinary heparin (6000-8000 U) was injected intravenously during the procedure. Low molecular weight heparin (4000-6000 U every 12 hours) was given for 3 to 5 days. Intravenous infusion of Tirofiban (Wuhan Yuanda Pharmaceutical Company) at 10  $\mu$ g/kg was administered, followed by intravenous infusion of Tirofiban at 0.15  $\mu$ g/kg/min for 12-24 hours. For patients with inferior STEMI or patients who presented with bradyarrhythmia, temporary pacing electrodes were implanted. The Judkins technique of coronary angiography was used for the left and right coronary arteries to identify the infarct-related arteries (IRA). Balloon dilatation and stent

implantation or direct stenting was performed in the infarct-related coronary arteries. Definition of a successful PCI: angiography in at least two orthogonal projections displayed a <20% residual diameter stenosis (quantitative coronary angiography) and TIMI flow grade 2 to 3, and there were no major adverse cardiovascular events during PCI. Medical record collection and routine laboratory tests were carried out for both groups before the procedure. The following times were recorded: FMC2B time, D2B time, arterial puncture to balloon inflation time, and first medical contact to first ECG time.

All the patients were given aspirin enteric-coated tablets at 100 mg/d for a long period of time, and clopidogrel at 75 mg/d for at least 1 year. Other medications were added when necessary, which included statins, angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), or beta-blockers.

## **Observation and evaluation**

Definition of a successful PCI: see above. All the patients were followed up for one year or until death, whichever occurred first. Adverse reactions were recorded, if any. Adverse cardiovascular events were also documented, which included recurrence of angina, rehospitalization due to cardiovascular disease, recurrence of myocardial infarction, target vessel revascularization, serious arrhythmia, secondary heart failure, all-cause death and cardiovascular death. Cardiovascular death included death due to deterioration of heart failure, fatal myocardial infarction or sudden death.

### Statistical analysis

All measurement data were expressed as  $x\pm s$ . Intragroup comparisons were performed by t-test, and count data comparisons were carried out using a  $\chi^2$  test, likelihood ratio  $\chi^2$  test or Fisher's exact test. Kaplan-Meier survival curves were used to compare event-free survival rates between the two groups. Multivariate regression analysis was performed to determine the risk factors for cardiovascular events after the PCI procedure.

#### RESULTS

#### **Baseline characteristics of the patients**

A total of 183 patients, aged between 35 and 85 years ( $66.2\pm9.1$  years), were included in the study. No loss to follow-up occurred. There were no significant differences between the patients of the two groups in male/female ratio, age, causes of disease, risk factors for coronary heart disease, cardiac functional grading, liver and kidney function, or medications in use, which included ACEIs, ARBs, beta-blockers, aspirin, clopidogrel, ticlopidine, or statins (P>0.01). Therefore, the patients of the two groups were comparable. There were no significant differences between the two groups in social characteristics, including medical insurance, education background, living alone, or distance between the residence and the hospital (P>0.01). There were also no significant differences between the two groups in culprit vessel, number of occluded arteries, type of disease, proportion of cases with total occlusion, or type of implanted stent (P>0.01) (Table 1).

# Comparison of time to reperfusion between the two groups

The FMC2B time and D2B time were both significantly shorter in the optimized pathway group than in the conventional pathway group. The proportion of patients who underwent PCI within 120 minutes after first medical contact and the proportion of patients with D2B time less than 90 minutes were both significantly higher in the optimized pathway group than in the conventional pathway group (Table 2).

Comparison of cardiovascular events during hospitalization and follow-up period between the two groups

There were no significant differences in recurrence of nonfatal myocardial infarction, cerebrovascular accident or heart failure during hospitalization between the two groups (P>0.01). The cardiovascular death rate and all-cause death rate during hospitalization was significantly lower in the optimized pathway group than in the conventional pathway group (P<0.01). There were no significant differences in the rates of recurrence of angina, recurrence of nonfatal myocardial infarction, target vessel revascularization or serious arrhythmia during the follow-up period between the two groups (P>0.01). However, the rates of secondary heart failure, rehospitalization due to cardiovascular disease, all-cause death, and cardiovascular death during the follow-up period were significantly lower in the optimized pathway group than in the conventional pathway group (P<0.01) (Table 3). Figure 1 shows the event-free survival rates of the two groups.

Multivariate regression analysis of risk factors for cardiovascular events of the two groups. Multivariate regression analysis showed that FMC2B time (OR=0.93, P=0.00), D2B time (OR=0.91, P=0.01) and age (OR=0.74, P=0.02) were independent risk factors for cardiovascular events after PCI (Table 4).

### DISCUSSION

PCI has been confirmed as an effective treatment for acute STEMI and is recommended as the first choice for treatment of STEMI in various clinical practice guidelines throughout the world (6, 8-12). American STEMI guidelines suggest that the D2B time should be less than 90 minutes, which might be the time limit to make sure that the patient will benefit from the reperfusion strategy of PCI. Therefore, many previous studies have mainly focused on the D2B time. However, treatment delay in patients with STEMI includes pre-admission delay and post-admission delay (13, 14), and post-admission delay only accounts for about 25% of

treatment delay (15). Therefore, study of pre-admission delays is also very important. Pre-admission delay differs from area to area, so patient characteristics might differ in different areas. But our study was performed at a cardiovascular disease intervention treatment center, so the patient characteristics are comparable. The results of the study might be significant for improving STEMI treatment procedures and increasing the effectiveness of emergency care, and thus help save more lives.

The study center is one of the first few institutions providing a "green channel" 24/7 for patients with myocardial infarction in China. After a patient with STEMI is sent to the emergency room by ambulance, a physician will record the patient's ECG results for accurate diagnosis and call the on-duty cardiologist immediately. The PCI team is also expected to get a call and be ready in the Cardiac Catheterization Lab within 30 minutes. With this pathway, our median D2B time has been 86.5 minutes, which meets the requirements specified in the guidelines. In recent years, we have worked closely with 120 EMS and have noticed that improvement can be achieved in pre-admission procedures for patients with STEMI, so we optimized the treatment pathway in order to improve the survival of these patients(16).

This study showed that the FMC2B time and D2B time were significantly shorter in the optimized pathway group than in the conventional pathway group, which suggests that the optimized pathway has an advantage over the conventional pathway. This advantage is attributed to the time saved by immediate performance of the first ECG in the ambulance, in-time remote transfer of ECG results and medical information on the patient, and having an on-duty cardiologist waiting for the patient in the emergency room or the 120 EMS staff calling the PCI team directly. Multivariate regression analysis indicated that FMC2B time and D2B time are independent risk factors for cardiovascular events after PCI. Therefore, we can conclude that the optimized pathway not only can shorten the delay in reperfusion, but also plays a positive role in long-term prognosis of STEMI.

The optimized pathway can shorten the FMC2B time and D2B time so as to achieve earlier reperfusion of IRA, and also reduce the rates of cardiovascular death and all-cause death. This result is consistent with the results of other recent studies, confirming the advantage attributed to the patient being transferred from the emergency room to the Cardiac Catheterization Lab directly, instead of being admitted to CCU first(17-20). Furthermore, this advantage lasted until the end of a one-year follow-up period. The optimized pathway reduced the proportion of patients with secondary heart failure and the rate of rehospitalization due to cardiovascular disease during the follow-up period. Though the mechanism is not clear, it's presumed that this improvement could be attributable to early recovery of patency of IRA due to effective myocardial reperfusion, so complications like myocardial remodeling are reduced.

Unfortunately, this study is limited by its small size, short follow-up period, and retrospective and nonrandomized nature. Therefore, prospective, randomized controlled studies are needed to confirm the results of this study. However, this study indicates that it's essential to modify the conventional emergency care pathway into an optimized emergency care pathway, beginning with pre-admission procedures, in order to increase the effectiveness of STEMI treatment.

#### Conflict of Interest

All authors have no conflict of interest to declare.

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		Optimized pathway group	Conventional pathway group	$\chi^2$ value or <i>t</i> value	P value
Number of patients		100	83		
Male	(n, %)	75(75)	61(73.5)	0.05	0.82
Age	(years, x±s)	65.1±7.3	68.3±8.0	-0.39*	0.7
Smoking history	(n, 응)	65(65)	57(68.7)	0.28	0.61
LVEF	(%, x±s)	54.3±6.9	52.4±7.0	2.66*	0.34
Hypertension	(n, %)	50(50)	48(57.8)	0.28	0.6
Diabetes	(n, %)	24(24)	21(25.3)	0.04	0.84
Statins	(n, %)	90(90)	74(89.2)	0.04	0.85
ACEIS or ARBs	(n, %)	81(81)	65(78.3)	0.2	0.65
Beta blockers	(n, %)	82(82)	65(78.3)	0.2	0.65
Aspirin	(n, %)	91(91)	75(90.4)	0.2	0.88
Clopidogrel	(n, %)	91(91)	77(92.8)	0.19	0.66
With medical insurance	(n, %)	82(82)	63(75.9)	1.03	0.31
Middle school and higher	(n, %)	65(65)	52(62.7)	0.11	0.74
Not living alone	(n, %)	72(72)	63(75.9)	0.36	0.55
10 km from hospital	(n, %)	76(76)	66(79.5)	0.32	0.57
1 diseased vessel	(n, %)	50(50)	48(57.8)	1.12	0.29
2 diseased vessels	(n, %)	29(29)	22(26.5)	0.14	0.71
3 diseased vessels	(n, %)	21(21)	13(15.7)	0.85	0.36
<pre>IRA (left anterior descending artery)</pre>	(n, %)	40(40)	38(45.8)	0.62	0.43
IRA (left circumflex artery)	(n, %)	22(22)	20(24.1)	0.11	0.74
IRA (right coronary artery)	(n, %)	38(38)	38(30.1)	0.52	0.47

# Table 1: Basic characteristics of patients in the two groups

Note: Values with an asterisk (\*) are t values, others are  $\chi^2$  values. LVEF: left ventricular ejection fraction; ACEI: angiotensin converting enzyme inhibitors; ARB: angiotensin II receptor blockers.

Group	Number	of	FMC2	D2B	FMC2B <120	D2B <90		
	patients		В		min	min		
	-		(min)	(min)	(n=%)	(n=%)		
Optimized pathway	100		$100.3\pm$	77.1±2	79(79)	82(82)		
group	100		28.0	2.9	19(19)	02(02)		
Conventional	83		145.6±	115.4±	40(49.2)	37 (44.6)		
pathway group	83		25.0	21.2	40(48.2)			
$\chi^2$ value or <i>t</i> value			3.23*	-2.82*	18.90	27.90		
P value			0.02	0.03	0.00	0.00		

Table 2: Comparison of time to reperfusion between the two groups

Note: Values with an asterisk (\*) are *t* values, others are  $\chi^2$  values.

Hospitalization (n)							Follow-up period (n)									
Group	Num ber of patie nts	Recurr ence of non-fat al myoca rdial infarcti	Cerebrova scular accident	Hea rt fail ure	Cardiova scular death	All-ca use death	Ang ina	Recurr ence of non-fat al myoca rdial infarcti	Target vessel revasculari zation	Seriou s arrhyt hmia	Secon dary heart failure	Rehospitali zation due to cardiovasc ular diseases	All-ca use death	Cardiova scular death		
Optimiz	100	<u>on</u> 1	0	7	2	5	18	<u>on</u> 7	6	5	12	17	7	3		
ed pathway group							-									
Convent ional pathway	83	0	1	4	8	13	11	3	4	3	9	26	16	9		
group $\chi^2$ value		0.84	1.21	0.3 8	5.12	5.81	0.77	1.01	0.12	0.21	0.06	5.17	8.15	4.55		
P value		0.36	0.27	0.5 4	0.02	0.02	0.38	0.32	0.73	0.65	0.81	0.02	0.00	0.03		

Table 3: Comparison of cardiovascular events during hospitalization and the follow-up period between the two groups

	Ag e	Se x	Smoki ng history	Hyperten sion	Diabe tes	Hyperlipid emia	Time to sympto m onset	FMC 2B	D2 B	Malignan cy arrhythmi a	Killip gradin g 3-4	IR A	Numbe r of disease d vessels
OR value	0.7	1.0	0.88	1.18	1.12	2.03	0.68	0.93	0.9	0.33	1.16	2.1	0.15
P value	4 0.0 2	1 0.3 3	0.27	0. 55	0.59	0.72	0.32	0.00	1 0.0 1	0.62	0.82	/ 0.7 2	0.43

Table 4: Multivariate regression analysis of the risk factors for cardiovascular events of the two groups during the follow-up period

Note: Number of patients for optimized pathway group, 100 cases; for conventional pathway group, 83 cases.