FULL LENGTH ARTICLE

The impact of introduction of Code-STEMI program on the reduction of door-to-balloon time in acute ST-elevation myocardial infarction patients undergoing primary percutaneous coronary intervention: A single-center study in Saudi Arabia

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Objectives: **This study was conducted to evaluate the effect of direct emergency department activation of the catheterization lab on door-to-balloon time (D2BT) and outcomes of acute ST-elevation myocardial infarction (STEMI) patients at a major tertiary care hospital in Riyadh, Saudi Arabia.**

Methods: **This was a retrospective cohort study that enrolled 100 consecutive patients with acute STEMI who underwent primary percutaneous coronary intervention between June 2010 and January 2015. The patients were divided into two groups of 50 patients each. The first group was treated prior to establishing the Code-STEMI protocol. The other group was treated according to the protocol, which was implemented in June 2013. The Code-STEMI protocol is a comprehensive program implementing direct activation of the catheterization lab team using a single call system, data monitoring and feedback, and standardized order forms.**

Results: **The mean age for both groups was 54 þ 12 years. Males represented 86% (43) and 94% (47) of the patients in the two groups, respectively. In both groups, 90% (90) of patients had one or more comorbidities. The Code-STEMI group had a significantly lower D2BT, with 70% of patients treated within the recommended 90 minutes (median, 76.5 minutes; interquartile range, 63–90 minutes). By contrast, only 26% of pre-Code-STEMI patients were**

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treated within this timeframe (median, 107 minutes; interquartile range, 74–149 minutes). In-hospital complications were lower in the Code-STEMI group; however, the only statistically significant reduction was in non-fatal re-infarction (8% vs. 0%, $p = 0.043$).

Conclusion: **Implementation of direct emergency department catheterization lab activation protocol was associated with a significant reduction in D2BT.**

Keywords: Door-to-balloon, Primary percutaneous coronary intervention, ST-elevation myocardial infarction

Introduction

Reperfusion strategies, such as thrombolytic (TL) therapy and primary percutaneous coronary intervention (PPCI), are the pillars of acute ST-elevation myocardial infarction (STEMI) treatment. There is overwhelming evidence that supports the use of PPCI over TL therapy due to evidently improved outcomes [1]. Compared with TL therapy, PPCI trials have shown a reduction in overall short-term death (7% vs. 9%), non-fatal reinfarction (3% vs. 8%), and stroke (1% vs. 2%) [2,3].

Time from hospital arrival to the first device that crosses the lesion in the PPCI procedure, called door-to-balloon time (D2BT), is an important factor that determines clinical outcomes of STEMI patients. Although the recommended cutoff D2BT by international guidelines is 90 minutes, PPCI programs should aim at reducing D2BT below this limit [4,5]. Indeed, it has been shown that if D2BT is 60–70 minutes greater than door-to-needle time (time to administer TL therapy), PPCI loses its mortality advantage over TL therapy [6–8].

International PPCI guidelines adoption in the Gulf region and Saudi Arabia remains a challenge [9]. The Gulf registry for coronary events (Gulf RACE) reported that only 46% of STEMI patients underwent PPCI, with 29.5% of them having a D2BT within the recommended range [10]. The number of hospitals with PCI capabilities, the number of hospitals with PPCI programs of 24 hours a day and 7 days a week, and the mean population served by a single PPCI center varies widely across the globe [11]. In Saudi Arabia, there are 30 hospitals with PCI capability, among which, only four hospitals offer fulltime PPCI service [11]. Moreover, the mean population served by a single PPCI center with round-the-clock service was 6,533,000 in Saudi Arabia, which is the worst among the 37 countries that participated in "Stent for Life Survey" [11]. Furthermore, the results of the Saudi Project for Assessment of Coronary Events (SPACE) showed that only 17.5% of STEMI patients in Saudi Arabia underwent PPCI [12].

Abbreviations

ACS	acute coronary syndrome
CAD	coronary artery disease
D2BT	door to balloon time
ED	emergency department
IQR	interquartile range
PPCI	primary percutaneous intervention
STEMI	ST elevation myocardial infarction
TL	thrombolytic

In June 2013, King Khalid University Hospital's (KKUH) cardiology and emergency teams established a standardized Code-STEMI program. The program's main aim was to develop a competent, highly efficient PPCI program to meet the demands and complexities of a regional program. Therefore, KKUH adopted the six D2BT reduction strategies [13], building a full protocol for PPCI activation and evaluation. This included a PPCI activation algorithm, care map, checklists, and prospective data collection sheets.

The aim of this study was to identify the impact of applying the Code-STEMI protocol on D2BT and patient outcome at KKUH in Riyadh, Saudi Arabia.

Materials and methods

This is a quantitative, observational, retrospective cohort study. Consecutive patients who presented to the emergency department (ED) of KKUH, with STEMI and who underwent PPCI before and after the establishment of Code-STEMI were enrolled in the study. The sampling technique process was planned to enroll all patients who underwent PPCI between June 2010 and January 2015. Patients were identified

Table 1. Code-STEMI protocol.

Time	Action	Notes	Team responsibilities
00.00	Upon arrival: • team at bedside • stopwatch on patient fileECG completed STEMI is confirmed by ED physician If non-STEMI → apply usual ED care and stopwatch is stopped If STEMI → ED physician reviews indication & contraindication for PPCI and discusses treatment with patient If he is not a candidate for PCI → discuss with CCU team other considerations If he is candidate for PCI → activate Code-STEMI and initiate primary PCI protocols	IF ECG shows definite evidence of STEMI with ST elevation of 1 mm or more in two contiguous leads (or a new LBBB) and **chest pain c/w acute MI**	1. ED Physician Verifies STEMI diagnosis Initiates Code-STEMI protocol Discusses case with cardiologist Considers treatment options 2. ED Nurse 1 and 2 Documentation (triage note, continuous care, fills checklist) Treatment of patient (monitoring, IV, labs, medication administration) Transfer of care to catheterization lab nurse ECG performance 3. ED Nurse assistant Page/phone to cardiologist, catheterization lab team Overhead page to all staff announcing ''Code-STEMI'' Enter orders 4. ED Pharmacist Assist with medication administration 5. Catheterization Lab nurse Receive verbal endorsement from ED nurse Assist with patient transfer from ED to the catheterization lab 6. Catheterization Lab staff Catheterization lab room set up Prepares patient for the procedure Assist with the procedure Checklist distribution post procedure
00.10	Call alternate cardiology back up number, if catheterization on call does not respond • Prepare patient for transfer to catheterization lab and consent • Catheterization lab team arrives • Verbal RN to RN report		
00.30	Patient is transferred to catheterization lab	AND Patient does not have any of the following conditions: • diagnosis of STEMI uncertain (? pericarditis, etc) • age above 80 y • onset of pain > **12 h** prior to presentation • resuscitated cardiac arrest with uncertain diagnosis • known to be DNR status • major trauma • severe comorbidities including the following: o renal failure (creatinine > 176 μmol/L) o severe COPD (patient on home oxygen, etc)	
00.45	Patient on catheterization lab table prepped and ready		

		o dementia, severe disorientation or inability to cooperate/provide consent o severe bleeding disorder
		THEN
00.50	Procedure is initiated	The ED physician should activate the catheterization lab without first waiting to consult cardiology • STEMI patients who meet the exclusion criteria can still go to the catheterization lab; however, an interventional cardiologist must be consulted before activating the catheterization lab • All ED activations must be done by the ED consultant directly, not by nursing staff or residents; clearly document activation on chart
00.60	Reperfusions achieved/stopwatch stopped	

CCU = critical care unit; COPD = chronic obstructive pulmonary disease; DNR = do not resuscitate; ECG = electrocardiogram; ED = emergency department; LBBB = left bundle branch block; MI = myocardial infarction; PPCI = primary percutaneous coronary intervention; RN = registered nurse; STEMI = ST-elevation myocardial infarction.

from the hospital's catheterization lab database. The total number of eligible patients was 100.

Patients were chosen based on the criteria of STEMI, which involves patients who presented to the ED with chest pain and ST-segment elevation on electrocardiogram (ECG) of >1 mm in two contiguous limb leads, or 2 mm in precordial leads, and/or presumably new-onset left bundle branch block [4]. Exclusion criteria for Code-STEMI program are shown in Table 1.

Before establishing the Code-STEMI program, the ED physician assessed patients presenting with STEMI and then consulted the on-call cardiology team who then reassessed the patients and subsequently activated the catheterization lab after STEMI status was confirmed. After introducing Code-STEMI, the attending ED physician would activate the catheterization lab directly without needing to contact the cardiology on-call team. The protocol follows specific, predetermined, documented steps aiming at reducing time from patient arrival at the ED to the time of opening his/her occluded artery. The program employs a parallel activation system where all Code-STEMI team members are contacted simultaneously. The program also introduced standardized order forms to ensure that all patients receive guideline-recommended therapies, along with other forms to direct and monitor care process. Details of Code-STEMI protocol are given in Table 1. Copies of the original proposal and all the related forms of the program can be obtained by contacting the corresponding author.

Moreover, the program collected prospective data of different time segments along the time continuum from D2BT, providing the PPCI team with continuous feedback. The catheterization lab manager, a member of STEMI quality improvement initiative (QII) committee, generated monthly reports on the Code-STEMI status that included the following performance indicators: 1, symptom onset-to-door time; 2, door-to-ECG time; 3, ECG-to-activation time; 4, activation-to-device time; 5, door-to-device time; 6, in-hospital major adverse cardiac events; and 7, percentage of false activation. The report was sent to the Director of the catheterization lab, Head of Adult Cardiology, Head of Department of Emergency Medicine, and the members of the STEMI QII committee that include the Director of the catheterization lab, physician representative from ED (co-director of the Code-STEMI program), catheterization lab and ED managers, nurses representative from the catheterization lab and ED, and a member from the hospital

Table 2. Baseline characteristics of the patients.

Variables	Pre-Code-STEMI (n = 50)	Post-Code-STEMI (n = 50)	p
Age, y	53.70 ± 11.87	54.18 ± 12.04	0.841
Sex			
Male	43 (86.0)	47 (94.0)	0.182
Female	7 (14.0)	3 (6.0)	
BMI	27.43 ± 7.30	27.31 ± 3.9	0.922
BMI class			
<18.5	0	1 (2.2)	0.774
18.6–24.9	16 (32)	15 (30)	
25–30	24 (48)	23 (50)	
30.1–35	4 (8)	3 (6.5)	
35.1–40	1 (2)	3 (6.5)	
>40	2 (4)	1 (2.2)	
Total missing	7 (14)		
Medical history			
Angina	3 (6)	3 (6)	0.980
MI	5 (10)	6 (12)	0.722
CHF	2 (4)	0	0.157
Coronary angiogram diagnostic for CAD	2 (4)	2 (4)	0.984
PCI	3 (6)	3 (6)	0.980
CABG	0	0	—
Family history of CAD	7 (14)	1 (2)	0.031
Diabetes mellitus	26 (52)	24 (48)	0.843
Hypertension	29 (59)	31 (62)	0.592
Dyslipidemia	6 (12)	12 (24)	0.107
Peripheral arterial disease	0	1 (2)	0.320
Atrial fibrillation	0	1 (2)	0.310
TIA/stroke	3 (6)	3 (6)	0.980
Current smoker	23 (46)	29 (58)	0.189
Renal insufficiency	1 (2)	0	0.320
Anemia	1 (2)	0	0.320

Data are presented as mean ± standard deviation.
BMI = body mass index; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; TIA = transient ischemic attack.

Table 3. In-hospital complications.

Variables	Pre-Code-STEMI (n = 50)	Post-Code-STEMI (n = 50)	p
Major in-hospital complications			
Heart failure	2 (4)	0 (0)	NS
Bleeding	9 (18)	8 (16)	NS
Recurrent MI	4 (8)	0 (0)	0.043
Stroke	1 (2)	1 (2)	NS
Death	1 (2)	1 (2)	NS

Data are presented as mean ± standard deviation.
MI = myocardial infarction; NS = not significant; STEMI = ST-elevation myocardial infarction.

quality department. Compiled data was shared with the catheterization lab and ED staff through bulletin boards and regular staff meetings. The intention of the feedback was to ensure that the ED and catheterization lab teams are aware of their performance, to identify any factors contributing to longer D2BT, and to introduce the necessary interventions to resolve these issues.

A detailed case report form was used to gather all pertinent clinical and angiographic data, such as age, gender, weight, height, risk factors, comorbidities, pre-hospitalization medications, PPCI angiographic data, laboratory results, in-hospital therapies, complications, and mortality. Data were collected from patients' medical records and added to an Excel-based database.

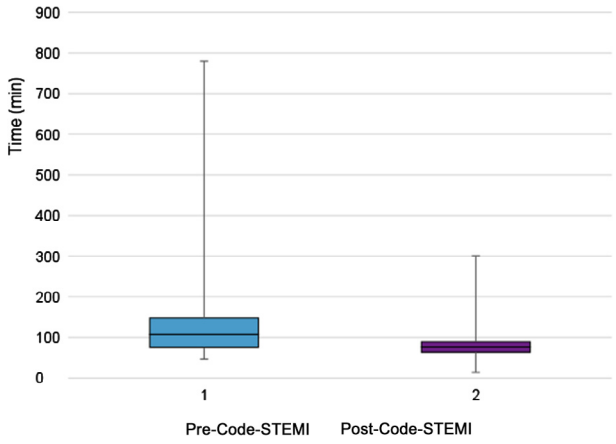

Figure 1. Summary of door-to-balloon time. Median and interquartile range in the two groups. STEMI = ST-elevation myocardial infarction.

Data were treated according to international guidelines, and all the individual patient-related data were kept strictly confidential. The study complied with the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of KKUH.

A pilot study involving 20 patients was conducted to assess the quality of data and identify any issues regarding data collection or the entry process. Statistical analyses were performed using SPSS version 20.0 (IBM SPSS Statistics, Armonk, NY IBM Corp, USA).

Continuous data were presented as mean and standard deviation. D2BT was presented as median and interquartile range, and categorical data were analyzed with the Chi-square test. The p value was set at 0.05.

Results

Patient characteristics

A total of 100 patients who presented with STEMI and underwent PPCI between June 2010 and January 2015 were studied retrospectively. The cohort was divided into two groups. The first group consisted of 50 patients who were treated before establishing the Code-STEMI protocol (mean age, 54 ± 12 years; 86% were men). The second group consisted of 50 patients treated according to the Code-STEMI protocol that was initiated in June 2013 (mean age, 54 ± 12 years; 94% were men).

The baseline characteristics and medical history in both groups were similar, except for a family history of coronary artery diseases, which was significantly lower in the Code-STEMI patients (14% vs. 2%, $p = 0.031$; Table 2). Noticeably, the majority of patients in both groups were overweight (66% and 67.4%), with a high prevalence of smoking (46% and 59%) and diabetes (52% and 48%).

D2BT

The primary aim of this study was to compare D2BT in the two groups. The Code-STEMI group had a significantly lower D2BT, with a median of 76.5 minutes and an inter-quartile range (IQR) of 63–90 minutes, compared with a median of 107 minutes and IQR of 74–149 minutes in pre-Code-STEMI patients (Fig. 1). In addition, 70% of Code-STEMI patients had a D2BT within the recommended 90 minutes compared with only 26% of pre-Code-STEMI patients.

In-hospital complications

Although the study was designed to examine the effect of Code-STEMI program on D2BT, we noticed a trend in the reduction of major in-hospital complications in Code-STEMI patients (Table 3). However, reduction in recurrent myocardial infarction was the only complication that was statistically significant (8% vs. 0%, $p = 0.043$). In-hospital mortality was low in both groups and showed no difference.

Discussion

In this study, we found that the implementation of Code-STEMI protocol for patients presenting to the ED of KKUH with STEMI improved D2BT and reduced in-hospital complications. These results are similar to previously published studies from Western countries [14,15]. For example, four studies with sample sizes of 44, 97, 88, and 470 patients showed statistically significant reduction in the D2BT [15–18]. A 5-year population study that included STEMI patients from the Centers for Medicare and Medicaid Services in the United States showed improved D2BT over this time period [19].

In our study, the mean age of presentation was 54 ± 12 years, which is almost a decade earlier than that reported in developed countries [20]. This observation was similar to the findings of the Saudi Registry (SPACE) [12] and the Third Gulf Registry of Acute Coronary Syndrome Events (Gulf RACE-3Ps) [10]. Furthermore, our patients have a high prevalence of risk factors for coronary artery diseases, especially diabetes mellitus, smoking, hypertension, and obesity, which is similar to the observations of larger registries from the region [10,12]. This emphasizes the need for the introduction of well-designed

programs to deal with this epidemic of increased incidence of metabolic syndrome in our region.

The D2BT of less than 90 minutes has been shown to be associated with a reduction in major in-hospital complications [10,21]. Although we did not detect any reduction in the overall occurrence of in-hospital complications in the Code-STEMI group, we observed a decrease in three of the five main in-hospital complications (heart failure: 4% vs. 0%, $p = 0.157$; bleeding: 18% vs. 16%, $p = 0.825$; and re-infarction: 8% vs. 0%, $p = 0.043$). However, we believe that our study's sample size is not large enough to detect statistically significant differences in the in-hospital complications between the two groups.

The success of the Code-STEMI protocol is likely related to the strategies it employs. The first strategy aimed to reduce the steps required for the activation of the catheterization lab. This was accomplished by authorizing ED physicians to directly activate the catheterization lab without cardiac team consultation. The second strategy was enabling the ED physicians to simultaneously contact the interventional cardiologist and the catheterization lab staff. These two strategies have been shown to significantly shorten the catheterization lab team arrival time [13].

PPCI is considered as the first-line reperfusion therapy for STEMI patients if it is performed in a timely fashion. Recent guidelines recommend the transfer of patients who present with STEMI from non-PPCI-capable hospitals to PPCI-capable hospitals if the first medical contact-to-device time will be reserved to less than 120 minutes. However, when PPCI is unavailable, as in many areas across Saudi Arabia and the Gulf countries, a pharmacoinvasive strategy is recommended. This includes early fibrinolysis followed by transfer of the patient to a PCI center for immediate or non-urgent coronary angiography to determine the need of PCI within 3–24 hours [22].

Our study had several limitations: a retrospective design, non-randomized sample, small sample size, and samples from a single center. Additionally, our cohort represented a highly selected STEMI population; the post-cardiac arrest and cardiogenic shock patients were excluded because they did not qualify for direct catheterization lab activation and likely accounted for the reported very low event rate. These limitations threatened the study's generalizability to the rest of the country and the region. Further limitations include lack of adequate assessment of time intervals within D2BT in the pre-Code-STEMI group. We were also unable to determine the number of other STEMI patients who did not undergo primary PCI, whether they did or did not receive any reperfusion therapy and their outcomes because our institution did not have a database for acute coronary syndrome patients.

There are only a few PPCI centers in Saudi Arabia with a round-the-clock service or with Code-STEMI protocol. If more Saudi hospitals implement such programs, more data can be generated to conduct larger studies with enough power to examine the full effect of these programs on STEMI outcomes.

Conclusion

The Code-STEMI protocol implementation was associated with a significant reduction in D2BT.

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