



Improving Door-to-Balloon Time for Patients With Acute ST-Elevation Myocardial Infarction: A Controlled Clinical Trial

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Abstract: According to the latest guidelines, the best intervention to restore blood flow through occluded coronary arteries is angioplasty at a time less than 90 minutes. Thereby, the present study was conducted to determine the impact of implementing ST-elevation myocardial infarction (STEMI) code on door-to-balloon time in patients with ST-segment elevation myocardial infarction. This clinical trial was conducted in 2019 at Boali Sina heart center hospital in Qazvin, Iran, in 2019. Fifty-eight patients with STEMI were purposively and consecutively enrolled in the study. Patients were then divided into control and intervention groups, based on their referral period. In both groups, patients were observed since their Arrived by emergency medical services to emergency department until inflating the balloon in the occluded coronary artery, and the intended times were recorded by the researchers. For Participants in the intervention group

Ethics approval and consent to participate: This study is the result of a master's thesis approved by the research committee of Qazvin University of Medical Sciences that was conducted after obtaining the approval of the Ethics Committee (ethics code: IR.QUMS.REC.1396.65) as well as Iranian Registry of Clinical Trials (Clinical Trials code: IRCT20171210037814N1). Before conducting the study, the researchers explained the study and its aims to the participants and a written informed consent was obtained from all the participants.

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the “STEMI code” was designed and activated by an emergency physician once there is a patient experiencing a chest pain and early confirmed as a myocardial infarction. The SPSS program (v. 16) was used for data analysis at a significance level of less than 0.05. The difference in the door-to-balloon mean time in both control (113.5 ± 43.6 minutes) and intervention (79.3 ± 27.4 minutes) groups, was statistically significant ($P=0.001$). Regarding other parameters, the reduction in the mean between Cath lab time (26.2 ± 18.2 minutes) and balloon time (15.5 ± 7.8 minutes) was also statistically significant ($P=0.008$). In this study, implementation of the “STEMI code” could greatly prevent parallel work and squandering time while treating patients with acute myocardial infarction. As the door-to-balloon time gets shorter, the bed occupancy rate in the emergency department had reduced which in turn allowed more patients to be admitted. (Curr Probl Cardiol 2021;46:100674.)

Introduction

ST-Elevation Myocardial Infarction (STEMI) is a clinical case takes place when myocardial infarction (MI) occurs together with ST-segment elevation in the electrocardiogram (ECG). STEMI can be attributed to complete thrombotic occlusion of the main coronary artery.¹⁻³ It is noteworthy that any delay in the diagnosis and prompt treatment of MI-affected patient will increase the likelihood of severe complications including heart failure, cardiogenic shock, life-threatening arrhythmias, pericarditis, ventricular aneurysms, tamponade, and myocardial rupture.^{4,5} Restoring blood flow in patients with STEMI is possible by injecting a fibrinolytic agent or performing Primary Percutaneous Coronary Intervention (PPCI).^{6,7} These interventions in patients suspected with clinical ischemic heart disease and ST-segment elevation should embark as soon as possible.^{8,9} Nowadays, recanalization of the occluded coronary artery is the best known intervention which is able to mitigate the infarction by angioplasty and stent placement.^{10,11} Importantly, the availability of required equipment for primary angioplasty might mostly lead to relinquishing the utilization of thrombolytic drugs.^{7,12,13} The prompt administration of coronary reperfusion therapy in patients with an evolving acute myocardial infarction (AMI) is crucial in reducing mortality and lowering

the risk of serious clinical complications in those patients.^{14,15} The optimal treatment for AMI is angioplasty that should be undertaken within a time less than 90-120 minutes after the patient's arrival at the hospital.^{8,15,16} The time needed for restoring blood flow is usually determined by measuring the door-to-balloon time (D2B),¹⁶ which stands for the time interval between the patient's arrival at the hospital and the first balloon inflation inside the coronary artery.^{17,18} Accordingly, it is clear that reducing such time will result in diminishing the degree of myocardial injury and enhancing the outcomes.¹⁹ Guidelines in this regard recommend that D2B time should be 90 minutes or less,^{15,20,21} and this time can be divided into the following clinically relevant intervals: door-to-ECG time, ECG-to-STEMI diagnosis and confirmation of MI time, confirmation of MI to Cath lab time, and Cath lab to balloon time.²² Previous studies have shown that there is a strong relationship between the initiation of PPCI at the right time and lowering mortality rate.²³⁻²⁶ The American College of Cardiology, the American Heart Association, the Centers for Medicare and Medicaid Services, and the Joint Commission on Accreditation of Healthcare Organizations have all addressed D2B time as one of the main measures that should be reported.^{27,28}

Every 30 minutes delay in the early coronary intervention from the onset of symptoms of AMI raises the potential of mortality by 8% over the next year.²⁹ Therefore, even in the centers where the early coronary intervention is carried out within 90 minutes, the D2B time should be shortened as much as possible,³⁰ for which, the management of STEMI, including diagnosis and treatment, begins at the first contact between the medical staff and the patient.^{8,31} To achieve the greatest impact of treatment, it is recommended to adopt a regional strategy which can be adapted nationally.⁸

Assessment and treatment of STEMI cases can be facilitated by various strategies once they arrive to the emergency department. These strategies encompass early ECG, rapid ECG interpretation, early activation of catheterization lab, an expedited response to activation, and fast reperfusion.³² The first step in diagnosing STEMI is early ECG for all patients who are referred to the hospital, and experiencing symptoms similar to those of STEMI. This procedure should take not more than 10 minutes after the first medical contact according to the clinical recommendations.³³

The availability of professional, qualified, and well-trained medical staff can play a key role in the successful treatment of patients with MI.^{30,34} It is suggested that the ideal medical team in these cases to comprise of an emergency physician, a cardiologist, an interventional cardiologist, Cath lab professionals, nurses, pharmacists, and laboratory and services staff who prepare the patient to be transferred to the Cath lab sooner.²⁹

According to the recent surveys in Iran, most Iranian hospitals are currently using serial and person-to-person activation process in order to provide care to patients with AMI. In this process, the patient suspected of having MI is initially examined by a triage nurse, and an ECG is carried out, then interpreted by an emergency physician. In case of possible AMI, the cardiac assistant will be informed for patient's checkup and further investigation. Afterward, the results will be reported to the cardiologist who is going to do more assessment to ascertain the diagnosis. Cath lab has to be engaged for being activated as well. In the meantime, some other procedures should be addressed such as obtaining the informed consent from the patient and the family, securing blood bags, shaving and changing the patient's clothes, and eventually getting the patient into the Cath lab. Special attention should be paid to the considerable time required for these procedures and also repetition which is highly probable. Furthermore, these procedures may encounter several challenges outside the normal working hours and during holidays, for example, the few number of personnel as well as the absence of specialists in the Cath lab. Hence, it is expected that implementation of STEMI code alongside with involvement of team members as well as better management of time and staff would improve the care provided to this group of patients through identifying tasks and responsibilities and avoiding redundancy during working and non-working hours.

Based on our searches, the establishment of such teams has not been seriously pursued in many Iranian treatment centers. Besides, to the best of our knowledge, no previous studies have been conducted in Iran to investigate the effect of the STEMI code, in addition, similar studies performed in other countries have some limitations including the absence of a control group, different inclusion and exclusion criteria, multiple structures in the STEMI teams, and heterogeneous strategies that can lead to inconsistent results and outcomes in diverse regions and cultures. Thereby, the present study was designed and conducted to determine the impact of implementing STEMI code on D2B time in patients with STEMI.

Materials and Methods

Study Design

This study was a clinical trial aimed at determining the impact implementing STEMI code on D2B time in patients with STEMI referred to the hospital by emergency medical services (EMS), in 2019.

Sampling Method

The study sample embraced all the patients with AMI, referred to the hospital to the hospital by EMS, and confirmedly diagnosed with STEMI by a cardiologist .patients with STEMI were purposively and consecutively enrolled in the study. Patients were then divided into, control and intervention groups, based on their referral period.

Inclusion/Exclusion Criteria

We have included all patients with acute and typical angina who Arrived by EMS to emergency departments and those confirmedly diagnosed with acute STEMI by a cardiologist. While, we have excluded those patient who were referred to the hospital more than 12 hours after the chest pain onset, patients referred from other medical hospitals, patients who were admitted to other departments while experiencing STEMI, unwilling patients to perform primary angioplasty, patients referred to the hospital during the in-process-time of a previous patient (ie, incomplete procedure), and also patients who were unable to undergo angioplasty due to any reason.

Sample Size

The sample size was calculated using epi info software. Considering 20% as a drop out percentage, 70 patients have been recruited to the study, nonetheless, 12 were excluded based on exclusion criteria. Consequently, the total number of participants was 58, 29 in each group. Participants were distributed to control and intervention groups based on their referral period (pre or post the implementation of STEMI code; [Fig](#)).

Procedures

Control Group. For the control group, the researchers were present in the emergency department for 24 hours and write down the demographic data of the patients in addition to the D2B time and the relevant intervals including door-to-ECG time, ECG to diagnosis of AMI time, diagnosis of AMI to Cath lab time, Cath lab to balloon time. Data related to the control group was firstly collected and recorded.

Intervention Group. Aimed at explaining the study objectives, brief meetings were held separately with the chancellor, administrative, and Metron of the hospital, emergency physicians and cardiologists, head nurse of emergency department, triage officer, telephone and services

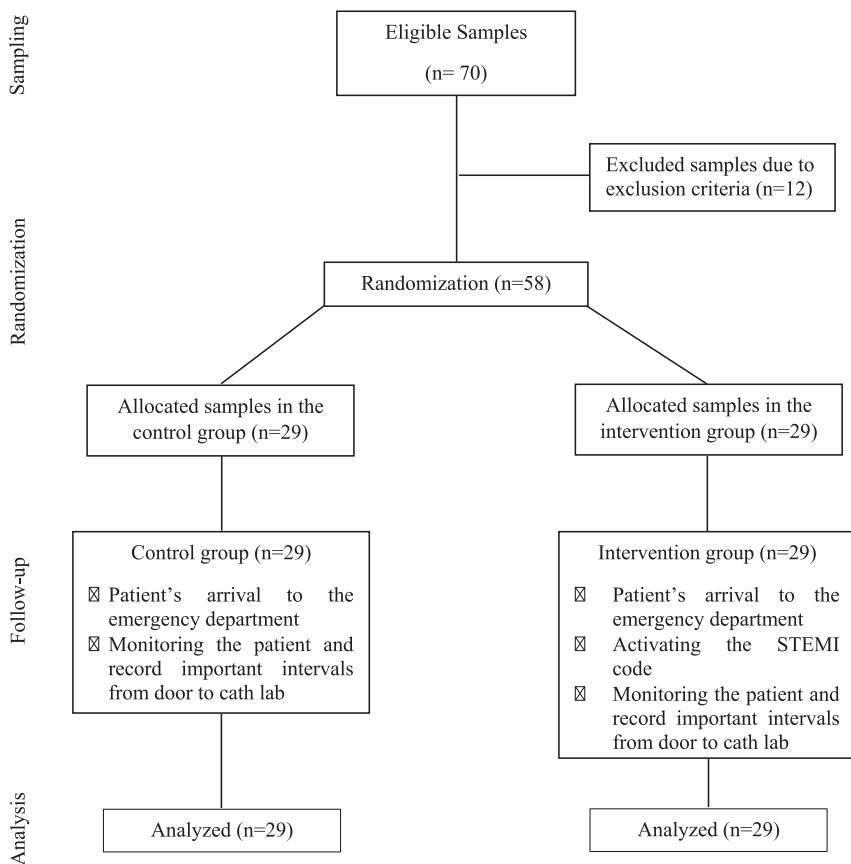


FIG. The study plan.

officer. Thereafter, the STEMI code team members selected from among those well-trained and skillful staff, were assigned in the monthly schedule in the morning, evening and night shifts and hired to the emergency department. The team in each shift has been consisting of an emergency physician for early diagnosis, a cardiologist to confirm the diagnosis of STEMI and activate the Cath lab, 2 nurses (1 from the triage unit, and the other from the emergency department) to do ECG, fix an intravenous line, send the early diagnostic tests, explain the situation to the patient and caregivers, obtain the written consent to embark the necessary interventions, inform the Cath lab unit, and complete the STEMI form, and 2 servants (1 female and 1 male) to prepare the patient, deliver the samples to the laboratory and transfer the patient to the Cath lab.

The researchers, along with one of the well-trained nurses for this study, were present in the emergency department for 24 hours. At this time, once there is a patient suffering from chest pain and referred to the hospital by EMS, the telephone unit has been announcing the STEMI code through the Central information system. The members of this code then have been gathering at the patient's bedside, and the necessary arrangements have been initiating to transfer the patient to the Cath lab as soon as possible. During sampling, the D2B time and the relevant intervals for each patient were measured and recorded by the researchers.

Instruments

Data were collected using 2 checklists developed by the researchers and endorsed by the faculty members. The checklists comprised of 2 parts including the demographic characteristics and the relevant time intervals through direct observation. The relevant time intervals in this study were door-to-ECG time, ECG to AMI diagnosis time, diagnosis of AMI to Cath lab time, and Cath lab to balloon time.

Data Analysis

After data collection, data were analyzed using SPSS version 16. For this purpose, descriptive statistics (mean, standard deviation, and frequency) were applied to describe the descriptive variables. Moreover, Mann-Whitney test was applied to compare between the control and intervention groups in terms of the D2B time. All the results were reported based on their significance considering P value <0.05 .

Results

Fifty-eight patients experienced STEMI were enrolled in the study divided and into 2 groups, 29 per each. The means of participants' ages in the intervention and control groups were 57.4 ± 11.7 , and 59 ± 13.3 years, respectively. Patients' demographic characteristics are illustrated in [Table 1](#). Information on the occluded arteries among patients are shown in [Table 2](#).

The mean D2B time in the control and intervention groups were 113.5 ± 43.6 minutes and 79.3 ± 27.4 , respectively, indicating a statistically significant reduction between the time interval among the 2 groups ($P = 0.001$; [Table 3](#)).

At all phases of setting and implementing STEMI code, a reduction was observed between the time intervals among the 2 groups. However,

TABLE 1. Patients' demographic characteristics in the control and intervention groups

Variables		Control		Intervention	
		No. (%)	Total (%)	No. (%)	Total
Sex	Female	4 (13.9)	29 (100)	7 (24.2)	29 (100)
	Male	25 (86.1)		22 (75.8)	
Marital Status	Married	28 (96.5)	29 (100)	29 (100)	29 (100)
	Single	1 (3.5)		0 (0.0)	
Hypertension	Yes	10 (34.4)	29 (100)	15 (51.7)	29 (100)
	No	19 (65.6)		14 (48.3)	
Diabetes	Yes	11 (37.9)	29 (100)	6 (20.8)	29 (100)
	No	18 (62.1)		23 (79.2)	
Dyslipidemia	Yes	0 (0.0)	29 (100)	2 (6.9)	29 (100)
	No	29 (100)		27 (93.1)	
BMI	Normal	15 (51.7)	29 (100)	3 (10.3)	29 (100)
	Overweight	8 (27.5)		22 (75.8)	
	Obese	6 (20.8)		4 (13.9)	
Smoking	Yes	1 (37.9)	29 (100)	15 (51.7)	29 (100)
	No	18 (62.1)		14 (48.3)	
Opium	Yes	5 (17.3)	29 (100)	17 (58.6)	29 (100)
	No	24 (82.7)		12 (41.4)	
Alcohol	Yes	3 (10.3)	29 (100)	0 (0.0)	29 (100)
	No	26 (89.7)		29 (100)	
History of Angiography	Yes	9 (31.0)	29 (100)	11 (37.9)	29 (100)
	No	20 (69.0)		18 (62.1)	
History of PCI	Yes	6 (20.8)	29 (100)	11 (37.9)	29 (100)
	No	23 (79.2)		18 (62.1)	
CPR	Yes	0 (0.0)	29 (100)	3 (10.3)	29 (100)
	No	29 (100)		26 (89.7)	
Death	Yes	0 (0.0)	29 (100)	1 (3.5)	29 (100)
	No	29 (100)		28 (96.5)	
Type of MI	Anterior MI	9 (31.0)	29 (100)	10 (34.5)	29 (100)
	Inferior MI	13 (44.8)		14 (48.3)	
	Anteroseptal MI	5 (17.3)		2 (6.9)	
	Other	2 (6.9)		3 (10.3)	

TABLE 2. Patients' blocked arteries in the control and intervention groups*

Artery	Control		Intervention	
	Total No. of blocked arteries	No. of PCI	Total o. of blocked arteries	No. of PCI
LAD	17	13	13	11
RCA	12	8	13	7
LCX	6	1	6	2
PLV	0	0	3	2
Diagonal	4	1	0	0
OM	6	6	8	3
Total*	45	29	43	25

* In some patients, more than 1 artery was blocked.

TABLE 3. Comparing the mean D2B time between the 2 groups of control and intervention

Time	Group	Mean (minutes)	SD (minutes)	P value
D2B time	control	113.5	43.6	0.001
	intervention	79.3	27.4	

this reduction was only significant in the Cath lab to balloon time, and the D2B time ($P < 0.05$; [Table 4](#)).

Discussion

The present study was conducted with the aim of determining the impact of implementing STEMI code on D2B time in patients with STEMI. In the management of AMI cases, restoring blood flow is one of the key procedures, according to the latest guidelines, should be completed at a time less than 90 - 120 minutes. In this study, we found that adopting a good time-management strategy and preparing a qualified medical team can be effective in reducing the patient's waiting time for receiving treatment.

The results showed that the implementation of STEMI code decreased the D2B time in the intervention group by 34.2 minutes, and this reduction was statistically significant ($P = 0.001$).

Albugami et al aimed to measure the D2B time in an improvement project among 37 patients with acute STEMI, and determined the causes of delay in their PPCI. For this purpose, they established a multidisciplinary team out of the emergency personnel to minimize D2B time. The results revealed that "late identifications of STEMI-patients" had the major contribution in elongation D2B time. Consistent with the current study results, it should be noted that the aforementioned study has succeeded in ameliorating the overall situation by decreasing the D2B time significantly. However, they failed to measure the time improvement.⁶

TABLE 4. Comparing the mean of the partial times from the to-balloon by the 2 groups

Time	Group	Mean (minutes)	SD (minutes)	P value
door to ECG time	control	9.4	13	0.5
	intervention	8.1	6.9	
ECG to diagnosis of AMI time	control	21.5	27	0.56
	intervention	13.3	8.3	
diagnosis of AMI to Cath lab time	control	44.1	25.7	0.3
	intervention	39.5	25.9	
Cath lab to balloon time	control	26.2	18.2	0.008
	intervention	15.5	7.8	

In accordance to the latest guidelines, the time interval between transferring the patient to emergency nurse by EMS until the first ECG, is expected to be done within less than 10 minutes.⁸ The results of the present study were in line with guidelines as they also showed that the mean door to ECG time was less than 10 minutes in both the control and intervention groups, (9.4 ± 13 minutes) and (8.1 ± 6.9 minutes), respectively. Nevertheless, this difference in this time between the 2 groups was not statistically significant ($P = 0.5$). In the same vein, Pournorouz et al studied the time intervals between the patients calling EMS to the inflation of the balloon in the coronary artery in 121 patients with AMI, in Tehran. The mean door to ECG time in that study was 16.33 ± 15.43 minutes, which is higher than recommended.³⁵ In another study undertaken by Coyne et al, this time to be decreased by 13 minutes, after setting a Cardiac Triage Unit at the emergency department.³² When compared with similar studies, it can be deduced that relevant clinical practices at the emergency department in Boali Sina hospital are relatively sound, in addition, the emergency nurses were ready at the time of AMI-patients admission and demonstrated a good commitment either before or after implementing the STEMI code, and this accounts for taking ECG at a proper time. However, what is notable here is the similarity to the other 2 studies regarding door-to-ECG time in the intervention group and post-intervention, which was close to the time recommended by the latest guidelines. Based on these guidelines, ECG is expected to be carried out within less than 10 minutes after the patient's arrival,⁸ therefore, further decrease in this time should be considered. Personnel commitment alone is not enough to meet this goal, rather, it is necessary to adopt some other strategies including taking ECG in the ambulance, installing at least one bed, provided with ECG device, specific to MI-patients.

In the present study, the ECG-to-AMI diagnosis time was 21.5 ± 27 minutes in the control group and 13.3 ± 3.8 in the intervention group. Although this time in the intervention group was decreased by 8.2 minutes, this difference in time was not statistically significant ($P = 0.56$). In this regard, the latest guidelines recommend that obtaining a 12-lead ECG and its interpretation should be done quickly in a maximum time up to ten minutes after the first medical contact with the patient.⁸ It is well-noted that this time longer than recommended in both groups. Eskandari et al studied the effect of human resource management team so-called "the Rapid Response Team" on care outcomes among patients admitted to the emergency department of a medical center. Their effort in establishing a specialized and trained team able to take care patients was similar to the present study. The results of their study also confirmed the

positive effects such specialized team on the outcomes of patient care in the emergency department as well as the goals of the medical center.³³

Concerning the diagnosis of AMI to Cath lab time, various studies have shown that this interval can contribute to the major delay in performing primary angioplasty. In fact, this duration is related to the time of preparing the patient and the Cath lab for admission. Obtaining the consent of patients and their families, waiting for the arrival of Cath lab personnel and the specialist, especially during the night hours and official holidays, waiting for a bed in the Cath lab during peak hours, doing the regular works such as shaving and wearing the special dresses, the absence of a male servant to transfer the patient, the lack of an empty stretcher, the long distance between the emergency department and Cath lab unit, a likely defect in the elevator and such things are some of the possible issues that can elongate this time interval. In the current study, issues such as lack of services staff, were resolved by simultaneous coordination with the Cath lab and keeping the services staff existent in the emergency department after announcing the code, thereby, the personnel and physicians of Cath lab have a sufficient time to arrive and prepare the laboratory. Also, having a bed during the peak hours for an AMI-patient in the emergency department was highly available. Finally, this mean time interval in the control group was 44.1 ± 25.7 minutes which had been reduced to 39.5 ± 25.9 minutes in the intervention group, this difference was not statistically significant ($P = 0.3$). In this study, this time was the longest among the relevant time intervals to D2B time. This finding corresponds the results of previous studies nationally or internationally.

In our study, Cath lab to balloon mean time in the control group was 26.2 ± 18.2 minutes which was decreased by 10.7 minutes in the intervention group as it became 15.5 ± 7.8 minutes. This difference between the 2 groups was statistically significant in accordance to Mann-Whitney test ($P = 0.008$). In this regard, Albugami et al recommended 15 minutes as an intended goal for this time interval. However, Pournorouz et al reported 27.98 ± 17.88 minutes as a Cath lab to balloon time based on measuring the time intervals from the first call of an AMI-patient to pre-hospital emergency departments up to the end of primary angioplasty. The results of Bajaj et al study also indicated that establishing a STEMI team can reduce this time interval by 5 minutes.^{6,35} Therefore, it can be concluded that a STEMI team along with notifying the Cath lab unit, prioritizing patients with AMI over elective patients, and the on-time attendance of the relevant specialist in the unit have the ability to contribute in the desirable effect in reducing this time interval.

In some former studies, reducing the D2B time was addressed as the main goal of minimizing the side effects of MI. For instance, Camp-Rogers et al undertook a study entitled "Hospital-based strategies contributing to PCI time reduction in the patients with STEMI" and aimed to evaluate the contribution of hospital-based strategies to reducing PCI time in STEMI-patients. Arised of the study results, 2 of the 8 strategies have substantial evidence to support their implementation encompassing the role of emergency physician in Cath lab activation, in addition to the role of alert process in pre-hospital activation. Another 2 strategies have moderate evidence reinforcing their implementation including real-time data feedback to team members and team-based approach to STEMI management. What was dedicated by that review was the effective strategies needed in reducing the time of the treatment of STEMI-patients to get adequate space, well-disciplined work schedules in the medical centers for nursing as well as medical staff, managers, emergency and heart department personnel as well as EMS.³⁴ In line with Camp-Rogers et al study, our results manifested that forming a team for reducing this time can be deemed as a golden measure; as the activation of STEMI code, diagnostic, decision-making, and patient transfers will be done in a coordinated and rapid manner, and the patients will receive better care and suffer less. Furthermore, the mortality rate is anticipated to be declined. On the other hand, this situation would increase the satisfaction of patients, their families, and even the providers at the emergency department.

This study has several limitations, one of which is the study setting as it was conducted in only one hospital on a small sample size. Therefore, further future research is suggested to assess the effect of setting and implementing STEMI code on the performance of emergency personnel dealing with STEMI-patients in other specialized centers over more participants such as outpatient cardiac patients.

Conclusions

Based on the results of our study, the implementation of the STEMI code could greatly prevent parallel work and waste of time in the treatment of AMI-patients. Also, alerting the personnel to initiate the treatment process of this group of patients was done by earlier notification which leads to more coherent and purposeful work. As the D2B time gets shorter, the emergency beds occupancy rate gets reduced, and more patients will be able to be admitted and receive care. Well-planned work can result in lowering waiting time for the patients and their anxious

companions, and raising the status of their calmness. These factors can potentially enhance the satisfaction of both patients and providers. Drawing on the literature, mortality rate among these patients, the number of admissions to the hospital per year, and the disability rate among them will be minimized. It is necessary to mention implementing the STEMI code does not have an extra charge and it does not impose a new charge on the system.

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