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Transfer of Patients with ST Elevation Myocardial Infarction for Primary Percutaneous Coronary Intervention During Ordinary & Pandemic Times Position statement of the Saudi Arabian Cardiac Intervention Society

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Abstract

Primary percutaneous coronary intervention is the most effective therapy in the management of acute ST Elevation Myocardial Infarction. Evidence recommends keeping the period from symptom onset to reperfusion to a minimum in order to preserve left ventricular function, improve outcome and reduce mortality. This position statement describes the recommendations of the Saudi Arabian Cardiac Intervention Society for optimal conditions and timing for the acute management of patients presenting with ST Elevation Myocardial Infarction during ordinary and pandemic times.

Keywords: STEMI, PCI, ACS, Transfer, Pandemic

1. Introduction

Primary percutaneous coronary intervention (PPCI) is the most effective therapy in the management of acute ST Elevation Myocardial Infarction (STEMI) [1]. Evidence recommends keeping the period from symptom onset to reperfusion to a minimum in order to preserve left ventricular function, improve outcome, and reduce mortality [2,3,4].

Currently, many hospitals offer PPCI services in Saudi Arabia. Data from the first Saudi Acute

Myocardial Infarction Registry Program showed that STEMI was the most frequent presentation of acute myocardial infarction (AMI) and that 29% of patients received thrombolytic therapy, 45% had PPCI, 3% had pharmaco-invasive approach while 29% received neither thrombolytic therapy nor PPCI. Among patients who had PPCI, 65% of men had a door-to-balloon time (D2BT) of less than 90 minutes whilst only 42% of women were treated in a timely manner. Additionally, just 5.2% of all acute coronary syndrome (ACS) patients utilized an ambulance service to reach a hospital [5].

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During a Pandemic situation, practice is modified to limit the spread and contain the infection. Transporting a patient with droplet and or airborne transmitted infection may constitute unacceptable risk for the team responsible for the transfer without appropriate personal protective equipment. In addition implementing appropriate personal protective equipment may cause unacceptable delays that may result in loss of the expected benefit for the transfer if this cannot be achieved within the recommended time window [6,7,8,9].

These recommendations have been made following the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Working Group. This system was developed and refined to assess the certainty of evidence of effects and strength of recommendations [10,11,12]. The GRADE system classifies the quality of evidence as high, moderate or low and offers two grades for the recommendations: Either strong where the desirable effects clearly outweigh the undesirable effects or weak where the tradeoffs between desirable effects and the undesirable effects are less certain. Some recommendations are based on expert consensus. In some situations, performing further studies is either not possible or unlikely to be clinically worthwhile, thus some recommendations are based on low or very low-quality evidence. Some of these recommendations are still given strong status because of overwhelming consensus among practicing physicians that this is what should be done. Where there are randomized clinical trials showing clear benefit from certain treatments or actions these have been given strong recommendations status based on high quality evidence.

The recommendations were made in order to set an acceptable and desirable standard of care for patients presenting with STEMI. These recommendations should be used by practicing physicians as well as policy makers, hospital administrators as well as payers for healthcare to inform on the expected safe standards supported by best available evidence and that are applicable to practice conditions in Saudi Arabia. We relied on full text and abstract publications in English language in Pub Med. We also searched abstracts from the Saudi Heart Association meetings including the terms; STEMI transfer, PPCI, STEMI network and thrombolysis for STEMI.

2. Patient transfer for primary PCI versus on-site thrombolytic therapy

The Prospective Codi IAM network multi-center STEMI registry collected data from non- PCI

Abbreviations

AMI	acute myocardial infarction
ACS	acute coronary syndrome
ACLS	advanced cardiac life support
D2BT	door to balloon time
D2NT	door to needle time
ECG	electrocardiogram
ER	emergency room
FMC	first medical contact
GRADE	Grading of Recommendations Assessment, Development and Evaluation
PPCI	primary percutaneous coronary intervention
STEMI	ST Elevation Myocardial Infarction

capable centers. Thirty-day mortality of patients who had thrombolysis among those whose symptom onset to first medical contact (FMC) was less than 120 minutes was worse compared to those who were transferred to a PCI capable center with symptom onset to FMC less than 140 minutes. Although door to needle time (D2NT) was relatively long in the study, the mortality rate was 2% amongst patients treated in less than 99 minutes by PPCI in comparison to 7.7% in patients who received thrombolytic therapy [13].

In the Acute Coronary Treatment and Intervention Outcomes Network Registry-Get with The Guidelines (ACTION-GWTG), 33,901 STEMI patients who were transferred for PPCI were studied. 26510 patients (78.2%) were transferred directly to a catheterization laboratory while 7,391 (21.8%) were transferred first to a hospital's emergency department. Compared with patients transferred to an emergency department, STEMI patients who were transferred to a cardiac catheterization unit had significantly lower first D2BT (median 191 versus 116 minutes, $P < 0.0001$). This was associated with lower mortality with a hazard ratio of 0.58 [14].

Current guidelines and practice are based on non-pandemic situations. During the current COVID-19 pandemic there is overwhelming concern for the potential for spreading infection from areas where the infection is prevalent to other areas. In addition, the risk for the transfer team may be quite high without strict adherence for wearing personal protective equipment according to infection control recommendations. What has been observed in cardiac catheterization units is that implementing appropriate personal protective equipment results in delays of patients reaching the unit in a timely manner. Under these circumstances many have advocated using thrombolytic therapy unless there are contraindications [6,7,8,9].

Performing polymerase chain reaction testing for the SARS-CoV-2 virus before transfer of patients from one hospital to another is not practical for PPCI because of the time it takes to take the swab and to perform and obtain the result. However testing, where available, is advisable for patients who are treated by thrombolytic therapy in order to give patients with negative polymerase chain reaction result the benefit of transferring them within the first 24 hours for subsequent PCI.

3. Evidence on the safety of transfer

Transferring patients up to 120 km from a non PCI hospital to a PCI center was found to be safe, resulting in lower 30-day mortality in comparison to thrombolytic therapy particularly if symptom onset was more than 3 hours [15]. In the Trial of Routine Angioplasty and Stenting after Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction (TRANSFER-AMI) pilot study, no complications occurred during transfer to PCI centers [16].

One very high risk subgroup is patients with STEMI and cardiogenic shock. This group accounts for significant in-hospital and post discharge mortality in STEMI patients. Every effort should be made to improve the survival of these patients, as the number needed to treat to save one additional life is low. [17].

The German prospective multicenter feedback intervention and treatment times in STEMI trial (FITT-STEMI) analyzed raw time data to calculate the interval between FMC and balloon inflation. [17] Categorical outcomes were compared between four groups. 12,675 STEMI patients received emergency medical services transportation (EMS) and treated with primary PCI, whereas 10,776 patients (85%) had no pre-hospital resuscitation and reached a PCI hospital in stable condition. A total of 1,200 patients (9.5%) had out of hospital cardiac arrest, 369 patients had stable condition and 831 patients had cardiogenic shock at the PCI hospital. 699 patients had cardiogenic shock without out of hospital cardiac arrest. This latter group derived maximum benefit from early primary PCI with a number needed to treat of 5 to save one life. A particular high risk of death was observed in patients with contact to balloon time from 150 to 180 min, with 20% mortality after PCI. For contact to balloon time ranging from 60 to 180 min, they found a nearly linear relationship between treatment time and mortality in all the groups. Every 10-min treatment delay resulted in 3.31 additional deaths in 100 PCI treated cardiogenic shock patients with no out of hospital cardiac arrest. The most recent European Society of Cardiology Guidelines recommend the

maximum expected delay between FMC and primary PCI should be considered as the essential time target for clinical decision and the quality metric for care delivery, and not just the in-hospital D2BT. [2] The D2BT has been extensively used as a quality measure of in-hospital processes. The FITT-STEMI trial indicated strong impact of contact to balloon time on in-hospital mortality in patients with cardiogenic shock and or out of hospital cardiac arrest and shows that 90 minutes should be the target [17].

A strategy of bundled care including direct transfer of STEMI patients for PPCI was implemented in Makkah during the Hajj season and was found to significantly reduce cardiovascular disease specific mortality from 53.2% in 2008 to 16.7% in 2011. Pharmacologic-invasive strategy was the primary re-perfusion approach when primary PCI could not be offered in a timely manner [18].

4. Transfer back to local hospital

In the Transfer AMI pilot study, patients were returned back to their community hospital without any clinical event of note [16]. In a study in Oslo on patients with ACS, a fast-track approach was compared to ordinary care and found that up to 95% could be returned safely the same day after PCI to their referring hospital [19].

In a study at Prince Sultan Cardiac Center Qassim, stable patients without complications during PCI procedure were returned to the referring hospital immediately following the PPCI. The transfer back was with the agreement of the local hospitals. The local hospital could provide adequate care for patients with acute myocardial infarction following revascularization. In a series of 124 patients returned following primary PCI, one patient had AV block and one patient developed a right arm hematoma and was managed conservatively. No other adverse events were encountered during the ambulance journey or up to 30 days [20].

5. SACIS recommendations

5.1. General recommendations

Programs to improve public health awareness regarding when to seek medical advice (Strong Recommendation, Low-Quality Evidence) [5,21].

Improve healthcare workers awareness of importance of timely evaluation, therapy and urgent transportation for patients with symptoms of acute coronary syndrome (Strong Recommendation, Moderate-Quality Evidence) [22].

Establish formal protocols and communication networks between all clinics and hospitals with no PCI capability with primary PCI facilities. A champion is required for each facility participating in a primary PCI network (Strong Recommendation, Moderate-Quality Evidence) [2,3,4,23].

The impact of early primary PCI is greatest in patients with cardiogenic shock with or without out-of-hospital cardiac arrest (Strong Recommendation, Moderate-Quality Evidence) [17].

Hospitals with PCI capability should facilitate accepting transferred patients with STEMI from non-PCI capable hospitals with direct transfer to the cardiac catheterization unit following a non-refusal principle (Strong Recommendation, Moderate-Quality Evidence) [14].

Referring hospitals with cardiology service should take back patients after primary PCI when required upon interventional cardiologist recommendation (Strong Recommendation, Moderate-Quality Evidence) [19,20].

5.2. Recommendations for hospitals without PCI facilities (Fig. 1)

The diagnosis of STEMI is clinically confirmed with an ECG within 10 minutes from presentation (Strong Recommendation, Low-Quality Evidence) [2,3,4].

The decision for transfer should be made by the first medical contact (Strong Recommendation, Moderate-Quality Evidence) [13,14].

Patients should be loaded with 162-325 mg Aspirin, P2Y12 inhibitors (preferably Ticagrelor 180 mg or clopidogrel 600 mg when the former is not available or contraindicated and 60 units per kilogram (maximum dose 4000 units) intravenous un-fractionated heparin in the referring hospital or clinic within the first 10 to 15 minutes from presentation (Strong Recommendation, High-Quality Evidence) [2,3,4].

During Pandemic situation thrombolytic therapy should be administered in the emergency room within the first 30 minutes of arrival if no contraindications exist. PPCI may be considered if thrombolytic therapy is contraindicated, not available or patient presents beyond the 12-hour window. Rescue PCI may be considered for those that do not show evidence of re-perfusion. The greatest concern associated with transfer is infection to healthcare workers and other patients. Because of this, transfer of patients' needs to be limited. If transfer is deemed necessary then adequate protection of staff must be ensured. Transfer should be considered for patients with cardiogenic shock without out of hospital cardiac arrest and to those with contraindications for thrombolytic therapy. If polymerase chain reaction testing is available then routine testing and obtaining

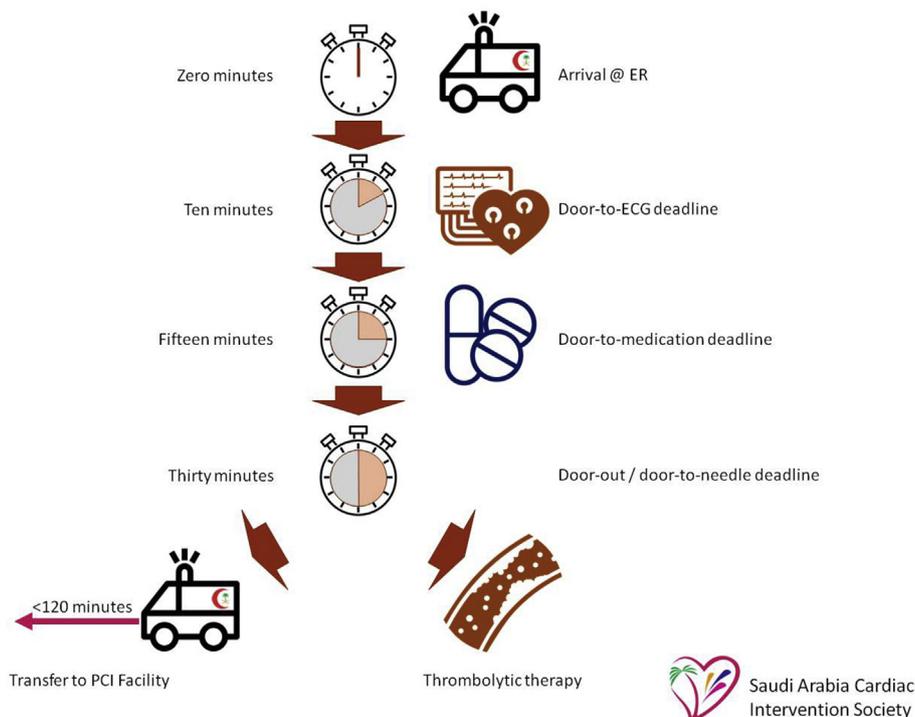


Fig. 1. Arrival to Non-PCI Facility.

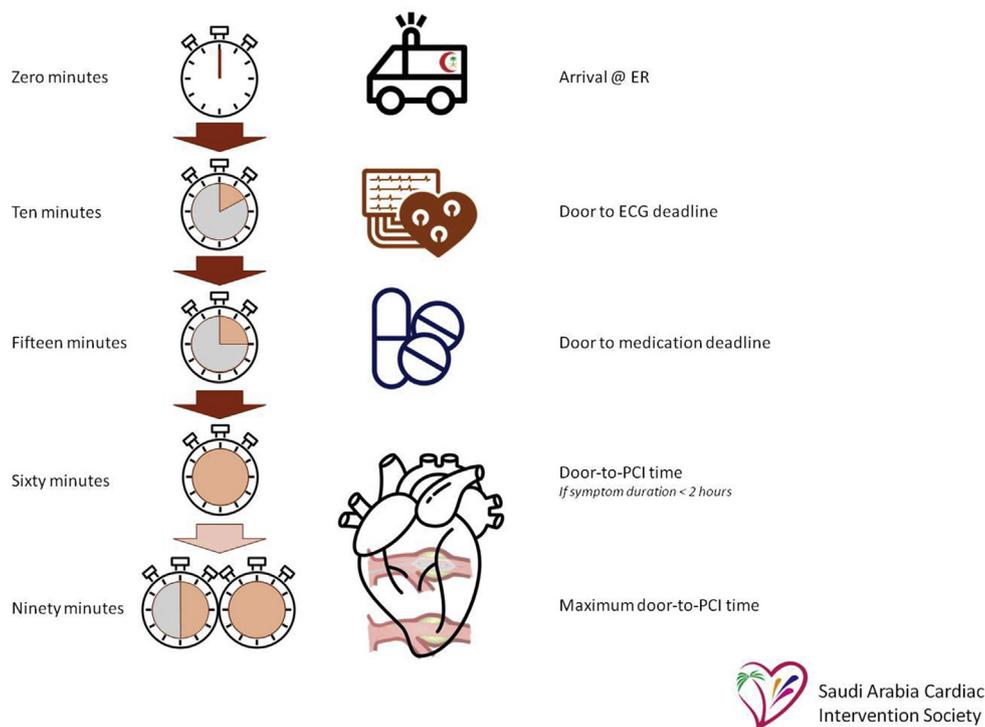


Fig. 2. Arrival to PCI Facility.

the result urgently is appropriate for patients who are given thrombolytic therapy (Strong Recommendation, Moderate-Quality Evidence) [6,7,8,9].

Patients must be continuously monitored once STEMI is confirmed with a functioning defibrillator attached (Strong Recommendation, Low-Quality Evidence) [2,3,4].

All staff attending the patient must be ACLS certified (Strong Recommendation, Low-Quality Evidence) [2,3,4].

The process of transfer between facilities must include ACLS certified staff (physicians, paramedics or nurses) and a monitor defibrillator (Strong Recommendation, Low-Quality Evidence) [2,3,4].

The door-in-door-out time must not exceed 30 minutes (Strong Recommendation, Low-Quality Evidence) [13,14,15,16,17].

Transfer of patients should be directly to the catheterization lab in the receiving hospital bypassing the emergency room (Strong Recommendation, Moderate-Quality Evidence) [14].

The benchmark from first medical contact to device time should not exceed 120 minutes (Strong Recommendation, Moderate-Quality Evidence) [13,17].

The benchmark from arrival to the primary PCI facility to device time should not exceed 60 minutes (Strong Recommendation, Moderate-Quality Evidence) [24].

If patients cannot be transferred within first medical contact to device time of less than 120 minutes, these patients must receive thrombolytic therapy (if no contraindications) at the non-PCI facility with door-to-needle time of less than 30 minutes (Strong Recommendation, Moderate -Quality Evidence) [2,3,4,13].

5.3. Recommendations for hospitals with PCI facilities (Fig. 2)

The diagnosis of STEMI is clinically confirmed with an ECG within 10 minutes from presentation (Strong Recommendation, Low-Quality Evidence) [2, 3,4].

The cardiac catheterization unit should be activated by the ER physician (Strong Recommendation, Low-Quality Evidence) [2,3,4,22].

Patients should be loaded with 162-325 mg Aspirin, P2Y12 inhibitors (preferably Ticagrelor 180 mg or clopidogrel 600 mg when the former is not available or contraindicated and 60 units per kilogram bodyweight (maximum dose 4000units) intravenous un-fractionated heparin within the first 10 to 15 minutes from presentation (Strong Recommendation, High Quality Evidence) [2,3,4].

Patients must be continuously monitored once STEMI is confirmed with a functioning defibrillator

attached (Strong Recommendation, Low Quality Evidence) [2,3,4].

All staff attending the patient must be ACLS certified (Strong Recommendation, Low Quality Evidence) [2,3,4].

Transfer to the catheterization lab by an ACLS certified physician and nurses and a monitor defibrillator and with adequate personal protective equipment protection for the transfer team during pandemic times. The transfer as well as the transfer route must comply with relevant local infection control recommendations to ensure safety of patients as well as all healthcare workers (Strong Recommendation, Low Quality Evidence) [2,3,4,6,7,8,9].

The benchmark from first medical contact to device time should not exceed 90 minutes, unless symptom onset was less than two hours. In this case, first medical contact to device time should not exceed 60 minutes (Strong Recommendation, Moderate Quality Evidence) [2,3,4,24].

Author contribution

Conception and design of Study; Literature review; Acquisition of data; Drafting of manuscript; Revising and editing the manuscript critically for important intellectual contents; Data preparation and presentation: Shukri Al Saif, Owayed Alshammeri, Abdullah Alkhashail, Ramzi Almohammadi, Mohamed Kurdi. Supervision of the research: Shukri Al Saif. Research coordination and management: Shukri Al Saif. Funding for the research: Mohamed Kurdi.

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Conflict of interest

None of the authors has any conflict of interest to declare in relation to this manuscript.

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