ORIGINAL ARTICLE

The impact of a dedicated coronavirus disease 2019 primary angioplasty protocol on time components related to ST-segment elevation myocardial infarction management in a 24/7 primary percutaneous coronary intervention–capable hospital

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KEY WORDS
coronavirus disease 2019 outbreak, primary angioplasty, ST-segment elevation myocardial infarction

ABSTRACT

BACKGROUND Primary percutaneous coronary intervention (PPCI) as the treatment of choice for ST-segment elevation myocardial infarction (STEMI) should be rapidly performed. It is necessary to use preventive strategies during the coronavirus disease 2019 (COVID-19) outbreak, which is an ongoing global concern. However, critical times in STEMI management may be influenced by the implementation of infection control protocols.

AIMS We aimed to investigate the impact of our dedicated COVID-19 PPCI protocol on time components related to STEMI care and catheterization laboratory personnel safety. A subendpoint analysis to compare patient outcomes at a median time of 70 days during the pandemic with those of patients treated in the preceding year was another objective of our study.

METHODS Patients with STEMI who underwent PPCI were included in this study. Chest computed tomography (CT) and real-time reverse transcriptase–polymerase chain reaction (rRT-PCR) tests were performed in patients suspected of having COVID-19. A total of 178 patients admitted between February 29 and April 30, 2020 were compared with 146 patients admitted between March 1 and April 30, 2019.

RESULTS Severe acute respiratory syndrome coronavirus 2 infection was confirmed by rRT-PCR in 7 cases. In 6 out of 7 patients, CT was indicative of COVID-19. There were no differences between the study groups regarding critical time intervals for reperfusion in STEMI. The 70-day mortality rate before and during the pandemic was 2.73% and 4.49%, respectively (P = 0.4).

CONCLUSIONS The implementation of the dedicated COVID-19 PPCI protocol in patients with STEMI allowed us to achieve similar target times for reperfusion, short-term clinical outcomes, and staff safety as in the prepandemic era.

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INTRODUCTION Coronavirus disease 2019 (COVID-19) was first reported in Wuhan, China, in December 2019 and, since then, it has spread rapidly around the world. Currently, almost the entire world is affected by the ongoing COVID-19 pandemic.[1,2] It has been confirmed

WHAT'S NEW?

One of the major questions asked by cardiologists is "What is the preferred treatment in the management of acute ST-segment elevation myocardial infarction (STEMI) during the coronavirus disease 2019 (COVID-19) outbreak? Primary angioplasty or fibrinolytic therapy." It is necessary to implement infection prevention protocols in hospitals. However, using full personal protective equipment by the medical staff may lead to STEMI-related time interval prolongation and affect patient outcomes. This study in Tehran Heart Center demonstrated unexpected trends towards reduced target times in the in-hospital pathway during 2 months amid the COVID-19 pandemic compared with the prepandemic era. It seems that limited elective invasive procedures during the disease outbreak resulted in reduced waiting time for the preparation of routinely occupied catheterization laboratories and diminishing the staff workload. Meanwhile, the 70-day outcomes including mortality and nonfatal major adverse cardiac event rates did not significantly differ as compared with the preceding year. Thus, we did not find it necessary to change the current STEMI protocols.

that coronavirus disease 2019 spreads by human-to-human transmission, even from an asymptomatic carrier, with a basic reproductive number best estimated at 2.2,[2] which suggests that, on average, every case of COVID-19 will generate 2 new cases. Since the disease is highly contagious and there is no specific treatment for it, prevention through infection control protocols is necessary and inevitable.[2-4] Hospitals and other medical centers are responsible for adapting their inpatient and outpatient healthcare services for this critical condition.[5]

Acute ST-segment elevation myocardial infarction (STEMI) is the most severe presentation of coronary artery disease and results in considerable morbidity and mortality. In order to minimize the myocardial infarct size and preserve the viability of the ischemic region, it is crucial to expedite treatment with early diagnosis and quick patient transfer to the catheterization laboratory for primary percutaneous coronary intervention (PPCI), which is a definitive treatment method.[6-8] However, there have been limited data regarding the impact of the COVID-19 outbreak on the management and outcomes of patients undergoing PPCI.[4,5,9]

Scarce data available have shown that the COVID-19 outbreak might result in prolonging ischemic time in patients with acute STEMI, probably due to: 1) the implementation of infection control protocols such as using full personal protective equipment (PPE) by the PPCI staff during the procedure; 2) asking about the history of travelling to affected regions and contact with persons with suspected or confirmed COVID-19 as well as evaluating the symptoms of respiratory infection before transferring the patient to the catheterization laboratory; and 3) patients' disinclination to go to the hospital during the COVID-19 pandemic.[4,5] Given that reperfusion delay decreases the survival of patients with STEMI, the current pandemic may have a negative impact on clinical outcomes.[4,10] However, to the best of our knowledge, no study has reported the impact of the COVID-19 pandemic on the outcomes of patients undergoing PPCI.

It is well known that PPCI for acute STEMI is a more effective revascularization method than thrombolytic therapy, if it can be swiftly performed (within 90 minutes) in capable centers.[10] However, concerns regarding infection transmission from infected patients to the PPCI team have resulted in challenging recommendations for choosing the reperfusion strategy in patients with acute STEMI.

The Tehran Heart Center (THC), as the major academic tertiary hospital specialized in cardiovascular disorders in Iran, has been providing PPCI services 24 hours a day, 7 days a week since 2015. On average, 960 PPCI procedures are performed in THC every year. Infection control protocols against COVID-19 have been implemented in this center since February 19, 2020.

In this study, we aimed to investigate the impact of the COVID-19 outbreak on time components related to STEMI management and assess the outcomes of the study patients at a median time of 70 days as a secondary endpoint.

METHODS

Study participants All eligible patients who presented to the THC emergency department with acute STEMI between February 29 to April 30, 2020 and underwent PPCI were enrolled in the study. Patients whose diagnosis were not compatible with STEMI on coronary angiography were excluded from further analysis. In addition, patients who refused to undergo the procedure or in whom cardiac arrest occurred before PPCI (n = 0) were not eligible. Other exclusion criteria pertained to patients with an unclear onset time of angina symptoms (n = 0) and inpatient candidates (n = 5). The ethics committee of THC and the institutional review board approved the study protocol (IR.TUMS.VCR.REC.1399.023).

Protocol In the THC emergency department, acute STEMI is diagnosed by a cardiology resident, based on the patient's electrocardiogram. Then, an on-site interventional cardiologist is informed about the case by an immediate telephone call. Then, the Heart Team including a cardiology resident and an on-site interventional cardiologist evaluate the patient's eligibility for PPCI; the assessment includes but is not limited to severe comorbidities. If the patient is considered eligible for PPCI, the 24/7 code is activated without any further ado and the patient is being prepared for transfer to the catheterization laboratory after obtaining their informed consent. If necessary, the loading dose of aspirin, P2Y12 receptor inhibitors, statins,

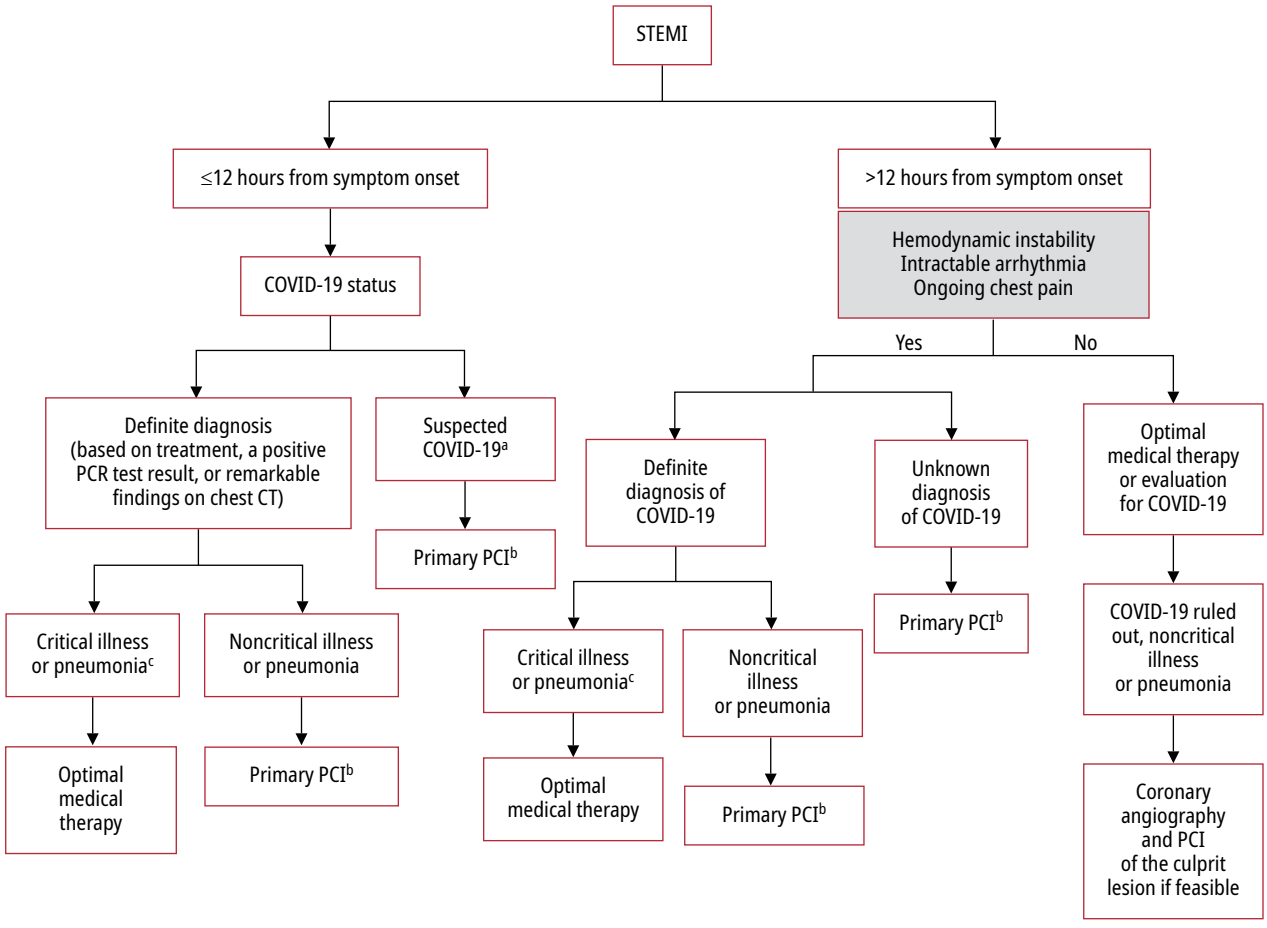

FIGURE 1 The Tehran Heart Center protocol for the management of ST-segment elevation myocardial infarction during the coronavirus disease 2019 pandemic

a Any of the following: fever, dry cough, sore throat, myalgia, chills, oxygen saturation <93%, lymphopenia, thrombocytopenia

b All patients should be transferred to the catheterization laboratory with an oxygen mask on.

c Respiratory failure due to coronavirus disease 2019, septic shock, and poor lung prognosis

Abbreviations: COVID-19, coronavirus disease 2019; CT, computed tomography; PCI, percutaneous coronary intervention; PCR, polymerase chain reaction; STEMI, ST-segment elevation myocardial infarction

and other drugs are administered in the emergency department. The PPCI procedure is performed if it is indicated according to the international guidelines.[7,8] In line with the 2017 European Society of Cardiology (ESC) guidelines,[7] all patients receive a maintenance dose of aspirin and a P2Y12 receptor inhibitor (as dual antiplatelet therapy) and lipid-lowering agents (high-dose statins) during the early phase of STEMI. Angiotensin-converting enzyme inhibitors are administered on admission in patients with reduced left ventricular systolic function (left ventricular ejection fraction <40%), anterior STEMI, hypertension, and diabetes. Angiotensin II receptor blockers are considered as an alternative in patients who are intolerant to angiotensin-converting enzyme inhibitors. All patients are treated with oral β-blockers, unless contraindicated.

The STEMI management strategy during the COVID-19 outbreak in THC as a 24/7 referral center is presented in FIGURE 1. All patients are evaluated for signs and symptoms of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection using a predefined checklist (TABLE 1). In patients suspected of having COVID-19, spiral chest computed tomography is performed after PPCI as well as nasal and oropharyngeal swab samples are collected for nucleic acid testing by real-time reverse transcriptase–polymerase chain reaction (rRT-PCR) using the (2019-nCoV) Triplex RT-qPCR Detection Kit (CE-IVD) (Nanjing Vazyme Medical Technology Co., Ltd., Nanjing, China). Unfortunately, due to shortage of RT-PCR kits, the "test-all" strategy was not followed in all admitted patients.

Given that patients may be asymptomatic carriers of SARS-CoV-2, the entire catheterization laboratory staff who comes in close contact with the patient should wear appropriate PPE regardless of the patient's signs and symptoms of respiratory infection. Personal protective equipment

TABLE 1 Coronavirus disease 2019 screening checklist

Fever (>37.3 °C)	Headache
History of direct contact with a COVID-19–positive person within the last 2 weeks	Diarrhea
Sore throat	Chills
Dry cough	Dyspnea
Myalgia	Anosmia
Rhinorrhea or sneezing	Ageusia

Abbreviations: see FIGURE 1

includes an isolated gown, disposable gloves, a face shield or goggles, and an N95 mask for each procedure. The healthcare personnel is evaluated daily and asked about their symptoms. Body temperature is routinely checked.

To determine the impact of the COVID-19 outbreak on STEMI care–related time frames and 70-day outcomes in this patient population, we compared patients treated with PPCI for acute STEMI during the pandemic with those treated between March 1 and April 30, 2019 (n = 146) using the THC 24/7 registry. The same inclusion and exclusion criteria were applied in all patients. Due to the possibility of patients' fear of leaving home during the pandemic era, antiplatelets, statins, and antihypertensive agents were prescribed for at least 3 months at discharge. Both during and before the COVID-19 outbreak, oral anticoagulation was not indicated in any of the patients. To follow up the patients during the pandemic, trained nurses contacted them by phone at 1 month, 3 months, and 6 months after discharge, recorded their current symptoms, drug compliance, adherence to treatment, living status, and major adverse cardiac event (MACE) components, and informed cardiologists about any findings. Our follow-up clinics were also available for patients willing to visit their doctors in person.

Definitions We evaluated target times related to STEMI care according to the 2017 ESC recommendations[7] including time intervals from symptom onset to first medical contact (FMC), from FMC to STEMI diagnosis, from STEMI diagnosis to wire crossing, and from FMC to wire crossing.

First medical contact denoted the initial examination of the patient by a physician, a nurse, a paramedic, or another trained emergency medical service staff member who could perform electrocardiography and interpret its results. The timepoint at which ST-segment elevation or equivalent was present on the electrocardiogram of a patient with ischemic symptoms was defined as the time of STEMI diagnosis.[7]

A 70-day MACE rate was evaluated as the outcomes of patients with STEMI and defined as all-cause mortality, nonfatal MI, repeated revascularization (PCI or coronary artery bypass grafting), cerebrovascular accidents, and rehospitalization.

Statistical analysis We reported categorical variables as number (percentage), and continuous variables, as mean (SD) and median (interquartile range) for those with and without normal distribution, respectively. The Kolmogorov–Smirnov test was used to assess the normality of distribution.

Differences between the study groups were analyzed using the independent *t* test, the Mann–Whitney test, and the χ^2 test for continuous (normally or non-normally distributed) and categorical variables, respectively. Statistical analysis was performed using the SPSS software, version 26 (IBM Corporation, Armonk, New York, United States). A *P* value less than 0.05 was considered significant.

RESULTS A total of 178 patients with STEMI who underwent PPCI between February 29 and April 30, 2020 were compared with 146 patients with STEMI treated during the same time period in 2019. The demographic and clinical characteristics of the study patients are presented in TABLE 2. There were no differences between the 2 groups except for a significantly higher prevalence of hypertension among patients treated during the COVID-19 outbreak (52.24% vs 40.41%; *P* = 0.04). Chest CT and rRT-PCR nucleic acid testing were performed in 33 patients who were suspected of having COVID-19, based on the checklist. Out of 21 cases with chest CT indicative of COVID-19, the diagnosis was confirmed by rRT-PCR testing in 6 patients. Serial chest CT scans in a single patient with suspicious symptoms were unremarkable, but rRT-PCR testing confirmed the infection.

Although no differences were observed between the 2 study groups in terms of STEMI-related target times, a trend towards a prolonged time from symptom onset to FMC (*P* = 0.84) and shorter time intervals from FMC to STEMI diagnosis (*P* = 0.16), from STEMI diagnosis to

TABLE 2 Demographic and clinical characteristics of the study patients with acute ST-segment elevation myocardial infarction who underwent primary coronary angioplasty during (February 29 to April 30, 2020) and before (March 1 to April 30, 2019) the coronavirus disease 2019 pandemic

Characteristics		During the COVID-19 outbreak (n = 178)	Before the COVID-19 outbreak (n = 146)	*P* value
Age, y, mean (SD)		58.80 (12.18)	59.82 (11.03)	0.43
Sex	Female	41 (23.03)	32 (21.91)	0.81
	Male	137 (76.97)	114 (78.09)	
Diabetes		81 (45.5)	65 (44.52)	0.89
Hypertension		93 (52.24)	59 (40.41)	0.04
Dyslipidemia		95 (53.37)	80 (54.79)	0.83
Cigarette smoker	Current	64 (35.95)	56 (38.35)	0.47
	Former	10 (5.61)	12 (8.21)	
Opium consumption	Current	18 (10.11)	16 (10.95)	0.87
	Former	6 (3.37)	7 (4.79)	
Family history of PCAD		45 (25.28)	35 (23.97)	0.81

Data are presented as number (percentage) of patients unless otherwise indicated.

Abbreviations: PCAD, premature coronary artery disease; others, see FIGURE 1

TABLE 3 Critical time intervals for reperfusion in the study patients with acute ST-segment elevation myocardial infarction during and before the coronavirus disease 2019 pandemic

Time interval, min	During the COVID-19 outbreak (n = 178)	Before the COVID-19 outbreak (n = 146)	*P* value
Symptom onset to FMC	365.5 (144.75–928.75)	363 (135.75–930)	0.84
FMC to STEMI diagnosis	5 (5–6)	5 (5–10.25)	0.16
STEMI diagnosis to wire crossing	49.5 (35–78.5)	50 (30.75–85)	0.95
FMC to wire crossing	61 (42–94.25)	67.5 (44.5–134.25)	0.12

Data are presented as median (interquartile range).

Abbreviations: FMC, first medical contact; others, see FIGURE 1

wire crossing (P = 0.95), and from FMC to wire crossing (P = 0.12) were reported during the COVID-19 outbreak compared with the same period in the preceding year (TABLE 3).

There was no significant difference between patients treated during the COVID-19 outbreak (8 patients [4.49%]) and those treated during the same period in the preceding year (4 patients [2.73%]) with respect to 70-day all-cause mortality (P = 0.4). Single cases of nonfatal MI, repeated revascularization with coronary artery bypass grafting, and rehospitalization in the cardiac care unit were reported at a median follow-up of 70 days in patients who were admitted in 2019. A single case of nonfatal MI and 2 readmissions to the cardiac care unit occurred at follow-up of the same duration in patients with STEMI during the COVID-19 outbreak. There was no difference between the 2 study groups in terms of 70-day occurrence of nonfatal MACEs (P = 0.8) (TABLE 4). None of the catheterization laboratory personnel members presented with COVID-19–related symptoms until the end of the study period.

All patients with STEMI during the prepandemic era received and tolerated dual antiplatelet therapy for 12 months. Follow-up showed that patients had no problems with access and adherence to medications during the pandemic.

One out of 7 patients with COVID-19 confirmed by rRT-PCR died during hospitalization. The patient was a 48-year-old man with a history of diabetes, hypertension, and kidney transplant performed 9 years earlier. He also received immunosuppressive drugs, smoked cigarettes, and abused opium. The patient presented with sore throat and weakness accompanied by typical chest pain. The time intervals from symptom

TABLE 4 Major adverse cardiac events at 70 days in the study patients with ST-segment elevation myocardial infarction who underwent primary coronary angioplasty before and during the coronavirus disease 2019 outbreak

MACE		During the COVID-19 outbreak (n = 178)	Before the COVID-19 outbreak (n = 146)	*P* value
All-cause mortality		8 (4.49)	4 (2.73)	0.4
Repeated revascularization	PCI	0	0	0.8
	CABG	0	1 (0.68)	
Nonfatal myocardial infarction		1 (0.56)	1 (0.68)	
Cerebrovascular accidents		0	0	
Rehospitalization		2 (1.12)	1 (0.68)	

Data are presented as number (percentage) of patients.

Abbreviations: CABG, coronary artery bypass grafting; MACE, major adverse cardiac event; others, see FIGURE 1

onset to FMC and from STEMI diagnosis to successful wire crossing were 149 minutes and 30 minutes, respectively. His coronary angiography showed left anterior descending artery occlusion at the mid part, normal diagonal arteries, a normal left circumflex artery, 60% stenosis in the obtuse marginal artery, and 60% stenosis in the proximal part of the right coronary artery with good distal run-off. Successful PPCI of the left anterior descending artery was performed, and the catheterization laboratory personnel wore full PPE during the procedure. Coronavirus disease 2019 was confirmed by spiral chest CT (FIGURE 2) and rRT-PCR nucleic acid testing on the day of admission. Supportive care including ventilation and routine empiric treatment (hydroxychloroquine and lopinavir / ritonavir) was started. On the day following the procedure, the patient complained of dyspnea. Echocardiography was immediately performed; left ventricular ejection fraction was 40% and no significant valvular disease or pericardial effusion were noted. The patient's oxygen saturation decreased to 93%. However, his condition rapidly deteriorated and ventricular fibrillation occurred. Unfortunately, cardiopulmonary resuscitation was unsuccessful. Long QT intervals were not detected during the patient's hospitalization. The creatinine level was 265.2 µmol/l, and electrolyte levels were within the reference range. Severe hypoxia and acute respiratory disease in the context of COVID-19 may be the causes of his death.

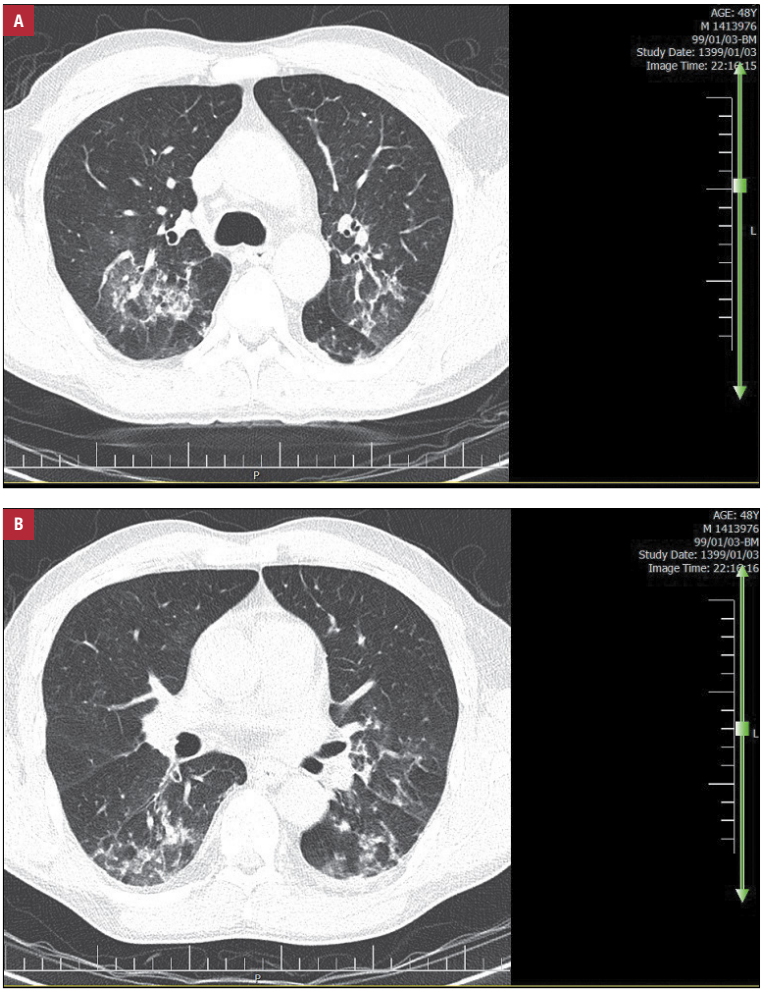

FIGURE 2 Spiral chest computed tomography findings in a patient with confirmed coronavirus disease 2019 who died during hospitalization: ground-glass opacities suggestive of coronavirus disease 2019 in upper (**A**) and middle lung lobes (**B**)

DISCUSSION Our study demonstrated that the critical times for reperfusion in patients with STEMI undergoing PPCI (except the time from symptom onset to FMC) did not increase during the COVID-19 outbreak. Also, a trend towards shorter FMC-to-wire crossing time and its subintervals was observed. Moreover, the outcomes of patients in terms of the 70-day occurrence of mortality and nonfatal MACEs during the COVID-19 outbreak did not differ from those in the corresponding time period in 2019. Considering the vast dimensions of the COVID-19 pandemic, the impact of the disease on emergency management such as in acute MI is largely obscure.

Our findings regarding STEMI-related time components are in contrast to a recent study by Tam et al.[4] The authors compared STEMI-related

time components between 7 patients with STEMI who underwent PPCI within 15 days during the COVID-19 outbreak and 108 patients in a similar condition in the preceding year and observed the prolongation of all time intervals during the pandemic, especially the time from symptom onset to FMC. Tam et al[4] stated that those differences were related to patients' unwillingness to go to the hospital during the COVID-19 outbreak and the time needed to implement infection prevention protocols. In our study, we also observed a prolonged time interval from symptom onset to FMC. This finding may be related to patients' disinclination to present to the emergency department during the pandemic. However, it seems that a lower number of elective invasive procedures during the COVID-19 outbreak resulted in a shorter waiting time for the preparation of routinely occupied catheterization laboratories and reduced staff workload, subsequently showing improved performance. This was observed even though infection control protocols and PPE were routinely used in all patients.

Concerns regarding the spread of the disease prompted some recommendations and adaptations in the standard management of patients with STEMI. A Chinese protocol[11] suggested fast nucleic acid testing to detect suspected or confirmed cases of infection prior to deciding about the reperfusion strategy. Thrombolytic therapy was recommended in patients with suspected or confirmed COVID-19 with mild or moderate pneumonia who present to the emergency department within 12 hours from symptom onset. However, this approach has been challenged in other communities, eg, in the United States where PPCI is a routine revascularization method. Additionally, rapid nucleic acid testing is not easily available for all patients. The American College of Cardiology's Interventional Council and the Society of Cardiovascular Angiography and Interventions recommended fibrinolytic therapy as an option in relatively stable patients with STEMI and confirmed active COVID-19. The use of appropriate PPE is advised if PPCI is to be performed in those cases.[5] Another study recommended a single-bolus administration of fibrinolytics as the preferred method in early presenting stable patients with limited infarct size, when time delays due to catheterization laboratory staff preparation, lack of beds, scarce PPE, and considerable absence rates of the hospital personnel may increase the use of thrombolytic therapy.[12] However, routine coronary angiography and/or rescue angioplasty usually performed following thrombolytic therapy negate the possible advantage of fibrinolysis with regard to limiting the staff exposure and PPE consumption.[13] Furthermore, lytic therapy is challenging in patients with COVID-19–related myopericarditis with symptoms mimicking STEMI, in whom not only reperfusion is likely to be ineffective but also routine cardiac catheterization after fibrinolytic therapy may be associated with unfavorable outcomes, possibly due to increasing the risk of bleeding. Moreover, the efficacy of thrombolytic therapy for the treatment of systemic microthrombus formation associated with COVID-19 has not been proven yet.[12,13] In addition, total ischemic time prolongation is mostly attributable to the prehospital pathway (time from symptom onset to FMC), which is not affected by the reperfusion method.[13]

According to the ESC guidance for the diagnosis and management of cardiovascular diseases during the COVID-19 pandemic,[14] if the STEMI diagnosis-to-wire crossing time frame is feasible within up to 120 minutes and the implementation of the approved COVID-19–dedicated protocol for patients and healthcare providers is accessible, PPCI remains the reperfusion method of choice. As shown in TABLE 3, the median time from STEMI diagnosis to wire crossing in our study was 49.5 minutes during the pandemic.

In this study, we demonstrated that the outcomes of patients undergoing PPCI during the COVID-19 outbreak were the same as in the past. Meanwhile, using PPE, none of the catheterization laboratory personnel members was infected despite performing PPCI in 21 patients with chest CT scans suggestive of COVID-19 and 7 patients with COVID-19 confirmed by a rRT-PCR test.

To conclude, if full PPE can be provided for the PPCI team, using the THC protocol for the management of patients with STEMI (FIGURE 1) might be a more efficient, practical, and evidence-based approach compared with recommendations to use thrombolytic therapy in patients with suspected or confirmed COVID-19. However, further studies of larger patient samples and with longer follow-up are needed to determine a standard protocol for the management of patients with acute STEMI during the COVID-19 pandemic.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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