

## Modified STEMI protocol for PPCI during COVID-19 Pandemic: Does it prolong Door-To-Balloon performance?

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### Abstract

**Introduction:** COVID-19 has become a major health problem and has a heavy impact, especially on the healthcare system. Managing ST-Segment Elevation Myocardial Infarction (STEMI) patients before the COVID-19 pandemic was already challenging enough for Healthcare Professionals (HCPs) to pursue time-sensitive treatment. During the COVID-19 pandemic, the time-sensitive treatment of pursuing door-to-balloon (DTB) time put a lot more burden on HCP. In this study, we sought to analyze how a change in protocol of PPCI in STEMI patients before and during the pandemic influenced the performance of DTB in the hospital.

**Methods:** This is a single-centered retrospective observational study among STEMI patients which was treated by PPCI. Secondary data from the medical record were collected consecutively from April 2018 to January 2022 (46 months). We compared DTB performances before and during the pandemic.

**Results:** During 46 months period, the total population of this research was 880 patients. There were total 358 patients who underwent PPCI before the pandemic and 522 patients during the pandemic. Modified protocol with the additional step to prevent the spread of COVID-19 has been implemented since April 2020. DTB increased significantly during the pandemic (90 (70-124) minutes vs 97 (76-135) minutes,  $p$  0.002). The proportion of the patients who achieved DTB under 90 min was also significantly decreasing (56.4% vs 47.9%,  $p$  0.0013).

**Conclusion:** It is necessary for PPCI center to modify PPCI workflow during the pandemic. A decent workflow should consider practicality and simplicity without compromising HCP and patient safety. Implementing modified PPCI workflow during the pandemic significantly increased DTB time but it is still within the limit of being reasonable and acceptable for the benefit of the patients.

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## Introduction

Indonesia announced the first case of Coronavirus disease 2019 (COVID-19) in early March 2020.<sup>1</sup> COVID-19 became a main health problem and has a heavy impact, especially on healthcare system. Healthcare systems in various parts of the world have been put under pressure. At the heart of this unparalleled crisis, Healthcare Professionals (HCP), as well as hospital management, faced great challenges in treating patients. Limited resources exposed both parties to ethically difficult choices in determining the priority of providing health services to each patient. Sometimes, in giving extra effort in optimizing care for COVID-19 patients we tend to defer other emergency medical cases.<sup>2</sup>

Managing ST-Segment Elevation Myocardial Infarction (STEMI) patients before the COVID-19 pandemic was already challenging enough for HCPs to pursue time-sensitive treatment. During the COVID-19 pandemic, the time-sensitive treatment of pursuing door-to-balloon (DTB) time put a lot more burden on HCP. European countries showed a nearly 20% reduction in STEMI patients undergoing primary percutaneous coronary intervention (PPCI) during the COVID-19 pandemic.<sup>3</sup> Furthermore, the lockdown system in handling COVID-19 pandemic as observed in some specific countries was associated with increased door-to-balloon (DTB) time.<sup>4</sup> In Indonesia, data showed the number of patients with STEMI declined significantly. Moreover, the total number of PPCI procedures was reduced but the proportion of PPCI was not significantly reduced.<sup>1</sup> Indonesian Heart Association (PERKI) published a guideline for cardiovascular disease in COVID-19 pandemic based on the corresponding European Society of Cardiology (ESC) guideline. It explained that in the absence of previous SARS-CoV-2 testing, all STEMI patients undergoing PPCI should be managed as if they were COVID-19 positive. PPCI should be carried out in a specialized catheterization lab with appropriate Personal Protective Equipment (PPE) being used by HCP.<sup>5,6</sup> Despite all those recommendations, each hospital in Indonesia developed its own way to deal with STEMI patients during the pandemic.

Jakarta Heart Center (JHC) routinely provides PPCI in its respective regions before the pandemic. JHC had a solid protocol to ensure the time-sensitive treatment of

PPCI in STEMI cases was achieved in a good manner. However, there were changes in the protocol to facilitate better safety for HCPs during the pandemic. These changes might influence the performance of the hospital in managing STEMI patients.

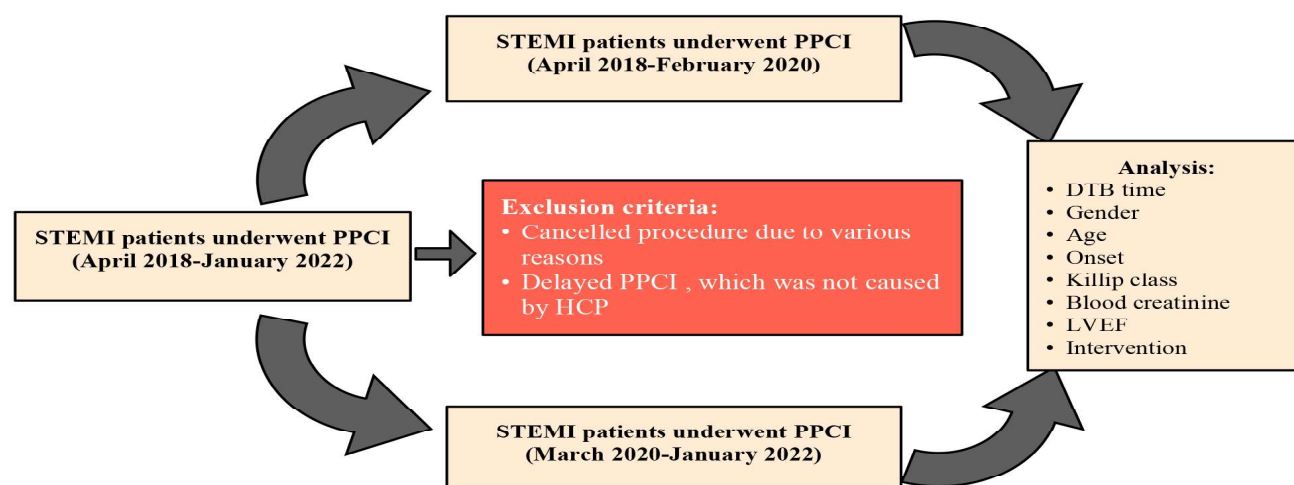
Analysis of PPCI performance is valuable to evaluate both regional and national policy. Previous publications in Indonesia regarding PPCI performance before and during COVID-19 pandemic were non-existent.<sup>5</sup> We sought to analyze how a change in protocol of PPCI in STEMI patients during the pandemic influenced the performance of DTB in the hospital.

## Methods

This is a single-centered (Jakarta Heart Center) retrospective observational study among STEMI patients which was treated by PPCI. Secondary data from the medical record were collected consecutively from April 2018 to January 2022 (46 months). Exclusion criteria were canceled procedures due to various reasons (the patient or the family refused the procedure, planned for emergent CABG without balloon dilatation intervention, or death prior to balloon dilatation procedure), and delayed PPCI which was not caused by HCP (hemodynamically critical patients who require stabilization first and patients whose family took too much time before agreeing to such procedure). There were finally 880 patients for the final analysis of this research. Patients' recruitment and the framework of this research are depicted in **Figure 1**.

All data was collected from the medical records of the patients. Diagnosis of STEMI was established by fulfilling the criteria based on ESC's universal definition of myocardial infarction.<sup>7,8</sup> DTB time is a phrase that denotes the time between the arrival of a patient with STEMI in the emergency room until the time that a balloon is inflated in the occluded of Primary PCI intervention.<sup>8</sup> DTB time was accounted manually by comparing first-time contact in the Emergency Room (ER) and the time log of initial balloon dilatation at the catheterization lab.

JHC has three operational catheterization labs. One of them merges with the ER on the ground floor which had been used for PPCI. Prior to the pandemic the workflow of STEMI patients was simple and could be initiated quickly (**figure 2**). However, it was revised



STEMI, ST-Segment Elevation Myocardial Infarction; PPCI, Primary Percutaneous Coronary Intervention; CABG, Coronary Artery Bypass Grafting; LVEF, Left Ventricular Ejection Fraction; and DTB, Door-To-Balloon

**Figure 1.** Patients recruitment and the framework of this research.

**Table 1.** Early Warning System (EWS) COVID-19 score<sup>12</sup>.

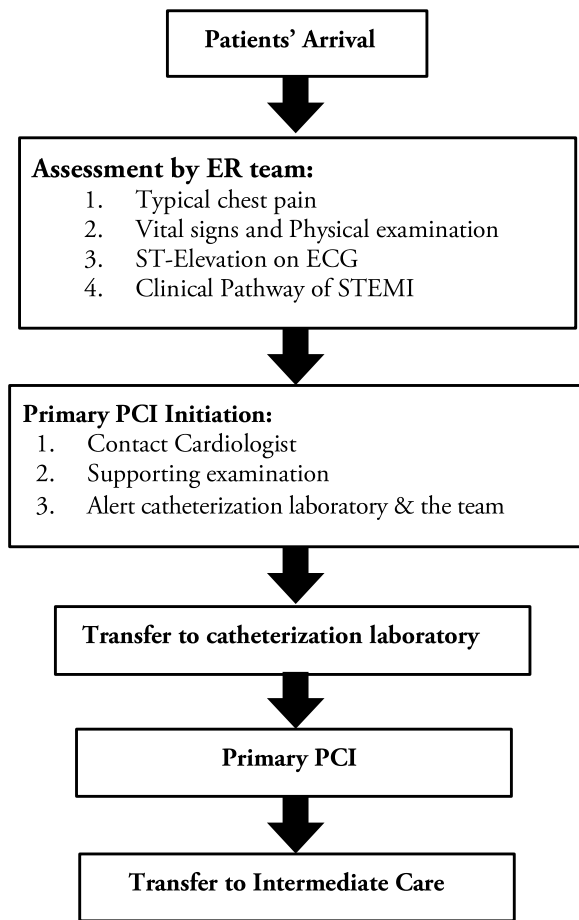
Parameters	Assessment	Score
Signs of pneumonia on CT	Yes	5
History of close contact with COVID-19 confirmed patient	Yes	5
Fever	Yes	3
Age	≥ 44 years old	1
Sex	Male	1
Tmax	≥ 37.8 C	1
Meaningful respiratory symptoms (including cough, expectoration and dyspnea)	≥ 1 symptoms	1
NLR	≥ 5.8	1

1. High probability COVID-19 (with lung CT Scan) >10
2. Moderate probability COVID-19 (without lung CT Scan) >5
3. Low probability COVID-19 (without lung CT Scan) <5

CT, Computerized Tomography; Tmax, Temperature Maximal; and NLR, Neutrophil-To-Lymphocyte Ratio.

and modified to adapt to changes that happened during the pandemic. The new workflow was more complex because it comprised additional steps in initiating PPCI and more effort to prevent the spread of COVID-19 within the hospital. Important additional step was the integration of Early Warning System (EWS) COVID-19 score throughout the assessment. All patients were

screened by COVID-19 swab test but PPCI was performed right away without the result of the swab test. All HCPs in both ER and catheterization lab used Level 3 PPE. The EWS COVID-19 scoring system can be observed from **Table 1**. The modified workflow is presented in **Figure 3**. This modified workflow has been used since April 2020.



ER, Emergency Room; ECG, Electrocardiogram; PCI, Percutaneous Coronary Intervention; and STEMI, ST-Segment Elevation Myocardial Infarction.

**Figure 2.** STEMI workflow for PPCI prior to the pandemic.

The data were divided into two groups: 23 months before the pandemic (April 2018-February 2020) and 23 months during the pandemic (March 2020-January 2022). Numerical data are presented as mean ± standard deviation if it was normally distributed and as median and Interquartile Range (IQR) if it was not. Categorical data are presented as frequencies and percentages. The difference between DTB median is analyzed using Mann-Whitney test. Furthermore, the patients were grouped based on the performance of DTB. DTB ≤ 90 minutes is considered better for the patients.<sup>8,9</sup> The proportion difference between better DTB performance before and during the pandemic was analyzed using

the X<sup>2</sup> test. All statistical analysis was performed using IBM SPSS statistics 25 (SPSS Inc, Chicago, Illinois). The p-value less than 0.05 was considered statistically significant.

## Result

During 46 months period, the total population of this research was 880 patients. There was total 358 patients who underwent PPCI before the pandemic and 522 patients during the pandemic. Detailed characteristics of the patients are listed in **Table 2**. It can be observed that the population was dominated by male (742 male vs 138 female patients). The median age of the population was 59 (49-63) years old. The majority of the patients came with onset < 12 hours (665 patients).

There was a significant increase in total STEMI patients undergoing PPCI for at least 164 during the pandemic. We also evaluate the proportion number of referral cases from other hospitals to undergo PPCI. The referral case ratio of STEMI patients to be treated with PPCI was generally increasing on a monthly basis. Before the pandemic, the total referral cases of STEMI to be treated with PPCI was 189 out of 352 patients (53.7%). During the pandemic, the total referral cases were 345 out of 522 patients (66.1%). Detailed data regarding this topic is depicted in **Figure 5**.

The highlighted result of our study is the difference in DTB performance before and during the pandemic (**table 2**). It can be observed from **Table 2** that our DTB increased significantly during the pandemic (90 (70-124) minutes vs 97 (76-135) minutes, p 0.002). The proportion of the patients who achieved DTB under 90 min was also significantly decreasing (56.4% vs 47.9%, p 0.0013). It is also worth mentioning in our result that there was a significant lowering of LVEF among STEMI patients who underwent PPCI during the pandemic (54 (44-60) % vs 51 (44-57) %, p 0.011).

## Discussion

COVID-19 has become a major health problem and has a heavy impact on healthcare system. COVID-19 adversely affects the revascularization procedure of STEMI patients around the world. A study in England demonstrated a 43% decrease in PCI activity following

**Table 2.** Differences of patient's profile before and during pandemic.

Variables	Value (n=880)	Before Pandemic (n=358)	During Pandemic (n=522)	P value
Gender				
Male, n(%)	742 (84.3)	297 (83)	445 (85.2)	0.359
Female, n(%)	138 (15.7)	61 (17)	77 (14.8)	
Age, years	56 (49-63)	56 (49-63)	55 (49-62)	0.332
Time of onset				
< 12 hour, n(%)	665 (75.6)	277 (77.4)	388 (74.3)	0.302
> 12 hour, n(%)	215 (24.4)	81 (22.6)	134 (25.7)	
Killip Class				
Killip Class I, n(%)	631 (71.7)	274 (52.3)	357 (68.4)	0.051
Killip Class II, n(%)	172 (19.5)	45 (8.6)	127 (24.3)	
Killip Class III, n(%)	17 (1.9)	3 (0.6)	14 (2.7)	
Killip Class IV, n(%)	60 (6.8)	36 (6.9)	24 (4.6)	
LVEF, %	52 (44-58)	54 (44-60)	51 (44-57)	0.011
Blood creatinine, mg/dL	1.0 (0.9-1.2)	1 (0.9-1.1)	1 (0.9-1.2)	0.444
Intervention				
Stent, n(%)	815 (92)	332 (63.6)	483 (92.5)	0.874
Balloon angioplasty, n(%)	17 (1.9)	9 (1.7)	8 (1.5)	
No intervention, n(%)	48 (5.4)	17 (3.3)	31 (5.9)	
Door to Balloon time, min		90 (70-124)	97 (76-135)	0.002
< 90 min, n(%)	452 (51.4)	202 (56.4)	250 (47.9)	0.013
> 90 min, n(%)	428 (48.6)	156 (43.6)	272 (52.1)	

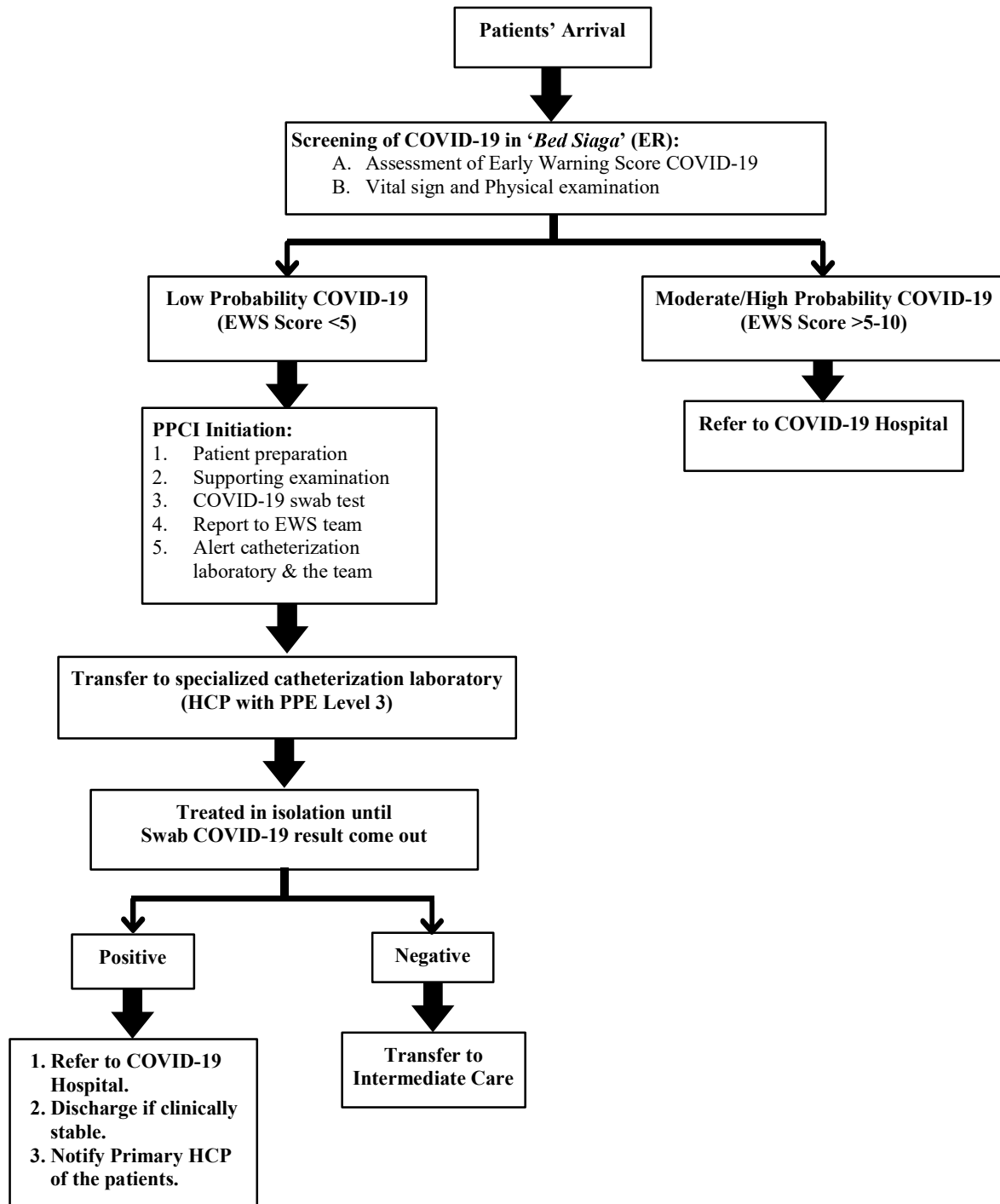
LVEF, Left Ventricular Ejection Fraction.

the COVID-19 pandemic.<sup>3,4</sup> This might be caused by both problems in patients and hospitals. It was reported that STEMI patients presented at a significantly longer time of onset during the pandemic. On the other hand, delayed reperfusion intervention was another adverse effect on the treatment of STEMI during the pandemic.<sup>10</sup> Fibrinolysis therapy should be considered as an alternative revascularization strategy during the pandemic. However, PPCI remains a standard treatment for patients with STEMI in PCI-capable hospitals.<sup>11</sup>

During the pandemic, hospitals needed to adopt a new protocol of PPCI by considering the spread of COVID-19. Our hospital implemented a new protocol regarding reperfusion strategy in STEMI patients in April 2020 which was based on PERKI guidelines. We modified the recommendation to suit our hospital in a good way. We formed the EWS COVID-19 team as

advisors for patient selections during the pandemic. All patients were screened by COVID-19 swab tests. Swab test results might have taken hours-days, hence, PPCI must be done without waiting for it. All HCPs in both ER and catheterization lab used Level 3 PPE. Based on the guidelines, it is necessary to do a lung Computerized Tomography (CT) Scan.<sup>5</sup> However, we skipped this examination because of the time-sensitive nature of PPCI to achieve a good DTB performance. We also changed it by providing an isolation room after PPCI to prevent cross-infection while waiting for the results of COVID-19 swab tests. Protocols were regularly evaluated and modified to adapt to changes that occurred during the pandemic.

Total number of STEMI patients has decreased significantly in Indonesia during the pandemic. Moreover, the total number of PPCI procedures was



ER, Emergency Room; STEMI, ST-Segment Elevation Myocardial Infarction; HCP Healthcare Professionals; PCI, Percutaneous Coronary Intervention; and PPE, Personnel Protective Equipment.

**Figure 3.** Modified STEMI workflow for PPCI in accordance with the pandemic in Jakarta Heart Center

also significantly reduced.<sup>5</sup> Many countries reported a reduction in STEMI patients undergoing PPCI compared to before COVID-19.<sup>7</sup> Our study resulted in a very different manner compared to those previous studies. In our study, we presented an increased total number of STEMI patients during the pandemic. It can be observed that this increase is greatly induced by the increased proportion of referral cases from other hospitals. This might imply that other hospitals in our region had difficulty in finding PCI centers to perform revascularization procedures in STEMI patients. This is very reasonable because other PCI centers were already overwhelmed in handling COVID-19 cases, unlike our hospital which did not treat COVID-19 cases. Our hospital with its modified PPCI protocol in this difficult time of the pandemic was able to provide and receive a large number of PPCI referral cases.

This study showed that DTB time increased significantly during the pandemic (90 (70-124) minutes vs 97 (76-135) minutes,  $p = 0.002$ ) after the implementation of the modified protocol of PPCI. This reduction in performance reflected changes in PPCI workflow during the pandemic because of some additional steps. Modified workflow obliged additional procedures which took time including the use of PPE, integration of EWS COVID-19 screening, COVID-19 swab tests, and integrated coordination with teams. This finding is in line with the results of previous studies. A study in Japan showed a significantly longer time to intervention during the pandemic than that before the pandemic at 83 minutes versus 153 minutes.<sup>8</sup> Five hospitals in Indonesia observed a significantly longer DTB time in the pandemic period than in 2019.<sup>1</sup> This is a common experience across different hospitals in Indonesia and also around the world.

In our study, the proportion of patients who achieved DTB under 90 minutes also significantly decreased during the pandemic (56.4% vs 47.9%,  $p = 0.0013$ ). This fits previous data from other research. According to a study in Singapore, fewer patients during the pandemic achieved DTB time  $\leq 90$  min compared with before the pandemic.<sup>13</sup> Workflow changes during the pandemic led to over 90 minutes of extra time on DTB. This delay in reperfusion strategy could not be prevented. However, this extended time of DTB is understandable and acceptable. This is in accordance with the new guidelines from PERKI which recommend

that STEMI patients be treated with PPCI within  $90 \pm 60$  minutes. The caveat of the additional 60 minutes was included as a compromise in response to the pandemic.<sup>5</sup> Despite decreasing the proportion of patients achieving good DTB, the effort of PPCI is still beneficial for the patient.

Our study has several limitations. First, we could not consider this research as a representation of regional or national performance because our data was derived from a single PPCI center only. In addition, our data were compiled from medical records, which could not fully record all clinical descriptions or other supporting examinations of the patients.

## Conclusion

It is necessary for PPCI center to modify PPCI workflow during the pandemic. A decent workflow should consider practicality and simplicity without compromising HCP and patient safety. Implementing modified PPCI workflow during the pandemic significantly increased DTB time but it is still within the limit of being reasonable and acceptable for the benefit of the patients.

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