

Off-hours admission does not impact outcomes in patients undergoing primary percutaneous coronary intervention and with a first medical contact-to-device time within 90 min

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Abstract

Background: It remains unclear whether the outcomes of ST-elevation myocardial infarction (STEMI) patients treated with primary percutaneous coronary intervention (PPCI) during off-hours are as favorable as those treated during on-hours, especially those with a first medical contact-to-device (FMC-to-device) time within 90 min. We aimed to determine whether off-hours admission impacted late outcomes in patients undergoing PPCI and with an FMC-to-device time ≤ 90 min.

Methods: This multicenter retrospective study included 670 STEMI patients who underwent successful PPCI and had an FMC-to-device time ≤ 90 min from 19 chest pain centers in Beijing from January 2018 to December 2018. Patients were divided into on-hours group and off-hours group based on their arrival time. Baseline characteristics, clinical data, and key time intervals during treatment were collected from the Quality Control & Improvement Center of Cardiovascular Intervention of Beijing by the “Heart and Brain Green Channel” app.

Results: Overall, the median age of the patients was 58.8 years and 19.9% (133/670) were female. Of these, 296 (44.2%) patients underwent PPCI during on-hours and 374 (55.8%) patients underwent PPCI during off-hours. Compared with the on-hours group, the off-hours group had a longer FMC-to-device time and fewer patients with FMC-to-device time ≤ 60 min ($P < 0.05$). During the mean follow-up period of 24 months, a total of 64 (9.6%) participants experienced a major adverse cardiovascular event (MACE), with 28 (9.1%) in the on-hours group and 36 (9.6%) in the off-hours group ($P > 0.05$). According to the Cox regression analyses, off-hours admission was not a predictor of 2-year MACEs ($P = 0.788$). Similarly, the Kaplan-Meier curves showed that the risks of a MACE, all-cause death, reinfarction, and target vessel revascularization were not significantly different between the two groups ($P > 0.05$).

Conclusions: This real-world, multicenter retrospective study demonstrated that for STEMI patients who underwent PPCI within 90 min, off-hours admission was safe, with no difference in the risk of 2-year MACEs compared with those with on-hours admission.

Keywords: First medical contact-to-device time; ST-segment elevation myocardial infarction; Primary percutaneous coronary intervention; Major adverse cardiovascular events; Off-hours

Introduction

Primary percutaneous coronary intervention (PPCI) is the main recommended reperfusion method for the occluded coronary arteries in patients with ST-elevation myocardial infarction (STEMI).^[1] First medical contact-to-device (FMC-to-device) time has been a key factor in the treatment of PPCI in recent years. Accordingly, multiple studies have focused on finding strategies to decrease the FMC-to-device time to reduce the total ischemic time.

Recently, the American College of Cardiology/American Heart Association and the European Society of Cardiology recommended an FMC-to-device time ≤ 90 min^[1,2] for patients presenting to a PCI-capable hospital.

Off-hours arrival^[3-5] was found to be independently associated with prolonged FMC-to-device time and

Access this article online

Quick Response Code:



Website:
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DOI:
10.1097/CM9.0000000000001621

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Chinese Medical Journal 2021;134(15)

Received: 08-11-2020 Edited by: Yan-Jie Yin and Xiu-Yuan Hao

increased mortality rates in some studies because invasive revascularization procedures been delayed inappropriately. Nevertheless, other research showed negative results and there were no differences in outcomes related to the time of admission.^[6-9] Furthermore, studies analyzing the late outcomes associated with different admission times for PPCI-treated STEMI patients with an FMC-to-device time ≤ 90 min are sparse. Hence, this study aimed to identify whether “off-hours” presentation affected outcomes in patients who were treated with PPCI in Beijing and achieved the guidelines recommended an FMC-to-device time ≤ 90 min.

Methods

Ethical approval

This multicenter retrospective study was approved by the Ethics Committees of each hospital that used the app and was conducted in accordance with the *Declaration of Helsinki*. Informed consent was waived because of the retrospective nature of the study.

Study population

A multicenter retrospective study was performed in Beijing and 1713 patients who underwent PPCI for STEMI between January 2018 and December 2018 in 19 hospitals were enrolled. The following patients were excluded: (1)

patients with an FMC-to-device time >90 min ($n = 702$); (2) patients with a symptom onset-to-FMC time >12 h ($n = 93$); (3) patients who died before the PPCI procedure or who had a normal coronary angiogram ($n = 11$); (4) patients who developed STEMI during hospitalization instead of presenting with STEMI at admission or who were transferred from another hospital ($n = 31$); (5) patients who had incomplete or incorrect data ($n = 117$); and (6) patients who were lost to follow-up ($n = 89$). As a result, 670 patients were included in the final analysis. Patients were divided into on-hours group and off-hours group based on their arrival time [Figure 1].

Baseline characteristics, clinical data, and treatment times were collected from the Quality Control & Improvement Center of Cardiovascular Intervention of Beijing by the “Heart and Brain Green Channel” app, which is available for a variety of smartphone devices and personal computers (ANMED Beijing Medical Technology Ltd., Beijing, China). In addition, we collected the exact time, day, and date of symptom onset; FMC time, electrocardiogram (ECG) acquisition time; catheter lab activation time; emergency room and catheter lab admission times; and first balloon inflation or thrombus aspiration time during PCI.

Definitions

STEMI was diagnosed in accordance with published guidelines^[10] and was defined as clinically suggestive

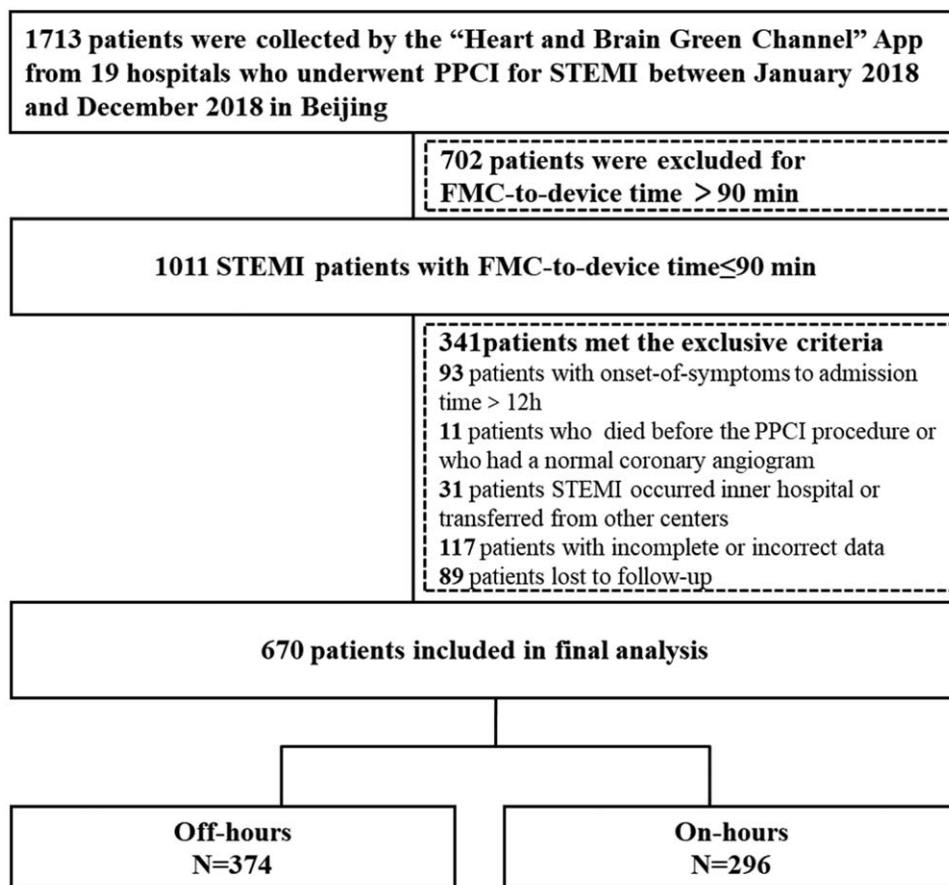


Figure 1: Flowchart of the patients selection process. FMC: First medical contact; PPCI: Primary percutaneous coronary intervention; STEMI: ST-elevation myocardial infarction.

symptoms associated with ST-segment elevation ≥ 0.1 mV in at least two contiguous precordial and/or adjacent limb leads (≥ 0.2 mV in leads V2–V3) or a new left bundle branch block. FMC-to-device time was defined as the interval between FMC and the time of first balloon dilatation or thrombus aspiration. Symptom-to-device time was defined as the time from the symptom onset to first balloon dilatation or thrombus aspiration. Symptom-to-FMC (STFMC) time was defined as the time interval between symptom onset and FMC.

We defined patients as emergency medical services (EMS) transport if they were transported to the hospital by EMS. Self-transported patients were those who arrived at the hospital by private transportation, public transportation, taxis, or on foot. Off-hours were defined as arrival at any time on a weekend or a Chinese holiday or arrival between 18:00 and 08:00 on a weekday.

We divided the FMC-to-device time into four component-based segments: (1) FMC-to-ECG time: the interval from FMC to ECG acquisition; (2) ECG-to-activation time: the time interval from the end of the ECG to activation of the catheter lab; (3) activation-to-catheter lab time: the time interval from catheter lab activation to arrival at the catheter lab; and (4) catheter lab-to-device time: the time interval from catheter lab arrival to balloon dilatation or thrombus aspiration [Figure 2].

Major adverse cardiovascular events (MACEs) were defined as a composite of all-cause death, non-fatal myocardial reinfarction, and target vessel revascularization (TVR). Data on mortality were obtained from hospital records or phone contact with patients' relatives. Non-fatal myocardial reinfarction was defined as recurrence of acute myocardial infarction (AMI) regardless of whether the reinfarction area was located at the original site or not; AMI was diagnosed by clinical symptoms, an increase in cardiac enzymes, and typical changes in electrocardiography. TVR was defined as any repeat PCI or bypass surgery in the target vessel during follow-up. Follow-up information was obtained through outpatient, inpatient, and telephonic interviews. In all time-to-event analyses, for each type of event, patient data were censored at the time of the first event that occurred in that patient.

Statistical analysis

Statistical analyses were performed using SPSS software, version 26.0 (IBM Corp, Armonk, NY, USA). The

normality of the data distribution was determined using the Kolmogorov-Smirnov test. Normally and non-normally distributed variables are expressed as mean \pm standard deviation and median (interquartile range), respectively. The baseline data, key time intervals, and (MACE rates) were compared between the two groups. The *t*-test, Mann-Whitney *U* test, Chi-square test, and Fisher exact test were used for intergroup comparisons when appropriate.

Univariate and multivariate cox analysis was performed to analyze variables associated with 2-year MACEs. We included demographic factors (gender, age, and body mass index), baseline variables that were significantly different between the two groups with *P* value < 0.10 , and variables that were associated with MACE based on the literature and our clinical knowledge, in the regression model. Each correlation between the variables is expressed as a hazard ratio (HR) with a 95% confidence interval (CI).

Kaplan-Meier curves were constructed to compare MACEs, all-cause death, TVR, and reinfarction between the two groups, and the differences between curves were statistically assessed by the log-rank test. *P* values < 0.05 were considered to indicate statistically significant.

Results

Baseline characteristics of the study population

We enrolled 1713 STEMI patients; 1043 met the exclusion criteria and 670 patients were included in this study [Figure 1]. Overall, the median FMC-to-device time was 69 min in all patients (quartile 1–quartile 3, 56–80 min); 34.2% had an FMC-to-device time within 60 min. The median age of the patients was 58.8 years and 19.9% (133/670) were female. Of these, 296 (44.2%) patients underwent PPCI on a weekday between 08:00 and 18:00 (on-hours group) and 374 (55.8%) patients underwent PPCI on a weekday between 18:00 and 08:00 or on a weekend (off-hours group) [Table 1]. The distributions of the numbers of patients in the two groups according to different FMC-to-device times are shown in Figure 3.

Key time intervals between the on-hours group and off-hours group

Compared with the on-hours group, the off-hours group had a longer FMC-to-device time (71 *vs.* 65 min, *P* < 0.001) and activation-to-catheter lab time (22 *vs.*

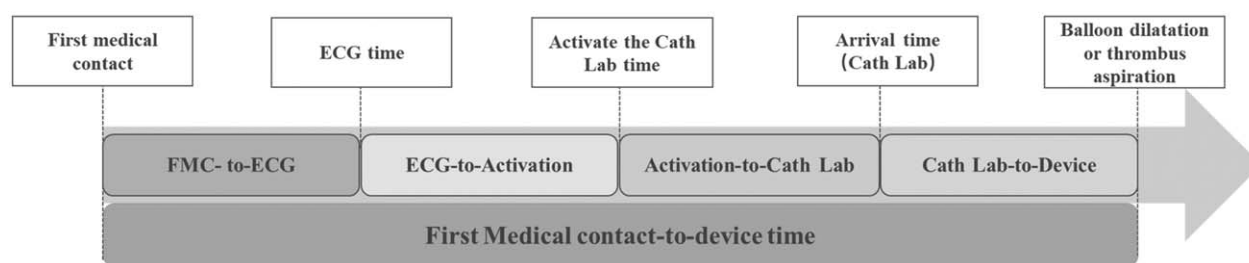


Figure 2: The component segments of the first medical contact-to-device time during the process. Cath Lab: Catheter lab; ECG: Electrocardiogram; FMC: First medical contact.

Table 1: Baseline demographic characteristics, clinical characteristics, and risk factors of STEMI patients who underwent PPCI within 90 min in two groups.

Variables	Overall N = 670	On-hours N = 296	Off-hours N = 374	P
Age (years)	58.8 ± 12.4	59.2 ± 12.2	58.5 ± 12.5	0.499
Female	133 (19.9)	64 (21.7)	69 (18.4)	0.296
BMI (kg/m ²)	25 (23, 27)	25 (23, 27)	25 (23, 27)	0.949
Past history				
Prior CHD	126 (18.8)	49 (16.6)	77 (20.6)	0.191
Prior atrial fibrillation	4 (0.6)	1 (0.3)	3 (0.8)	0.440
Prior diabetes mellitus	177 (26.4)	79 (26.8)	98 (25.9)	0.806
Prior hyperlipemia	113 (16.9)	51 (17.3)	62 (16.6)	0.808
Prior hypertension	352 (52.5)	156 (52.9)	196 (52.1)	0.849
Prior stroke	40 (6.0)	17 (5.8)	23 (6.1)	0.834
Admission status				
Heart rate (beats/min)	74 (63, 83)	72 (63, 82)	75 (63, 84)	0.284
SBP (mmHg)	129 (110, 144)	128 (110, 145)	130 (110, 143)	0.607
DBP (mmHg)	80 (70, 91)	80 (70, 91)	80 (70, 91)	0.941
SPO ₂	98 (97, 99)	98 (98, 99)	98 (97, 99)	0.236
Typical chest pain	431 (64.3)	198 (66.8)	233 (62.3)	0.230
Troponin-I (ng/mL)	4.7 ± 1.3	4.9 ± 1.1	4.6 ± 1.3	0.157
Ejection fraction (%)	51.9 ± 12.2	52.8 ± 12.8	51.1 ± 13.4	0.606
Killip class				
1	503 (75.1)	216 (73.0)	287 (76.7)	0.263
2	84 (12.5)	43 (14.5)	41 (11.0)	0.166
3	37 (5.5)	18 (6.1)	19 (5.1)	0.573
4	46 (6.9)	19 (6.4)	27 (7.2)	0.684
Culprit vessel				
LM	13 (1.9)	5 (1.7)	8 (2.1)	0.675
LAD	327 (48.8)	141 (47.6)	186 (49.7)	0.590
LCX	58 (8.7)	22 (7.4)	36 (9.7)	0.316
RCA	272 (40.6)	128 (43.3)	144 (38.5)	0.215
Pre-PCI TIMI flow				0.438
≥2	138 (20.6)	65 (22.0)	73 (19.5)	
≤1	532 (79.4)	231 (78.0)	301 (80.5)	
Post-PCI TIMI flow				0.844
≥2	655 (97.8)	289 (97.6)	366 (97.9)	
≤1	15 (2.2)	7 (2.4)	8 (2.1)	
Key time intervals				
FMC-to-device (min)	69 (56, 80)	65 (51, 78)	71 (58, 82)	<0.001
FMC-to-device ≤ 60 min	229 (34.2)	120 (40.7)	109 (29.1)	0.002
STB (min)	166 (124, 254)	174 (125, 255)	163 (123, 252)	0.466
STFMC (min)	103 (59.0, 188.0)	110 (60.0, 193.8)	95 (55.0, 185.5)	0.097
FMC-to-ECG (min)	2 (0, 5)	2 (0, 5)	2 (1, 4)	0.962
ECG-to-activation (min)	19 (11, 30)	18 (11, 30)	20 (11, 29)	0.636
Activation-to-catheter lab (min)	20 (10, 29)	16 (9, 23)	22 (12, 32)	<0.001
Catheter lab-to-device (min)	20 (15, 26)	20 (16, 26)	20 (15, 25)	0.627
Transportation				
EMS-transported	271 (40.4)	118 (39.9)	153 (40.9)	0.692
Self-transported	399 (59.5)	178 (60.1)	221 (59.1)	0.692
Follow up time (months)	24 (22, 26)	24 (22, 26)	24 (22, 25)	0.553
In-hospital mortality	14 (2.1)	7 (2.4)	7 (1.9)	0.653

Data are presented as *n* (%), mean ± standard deviation and median (interquartile range). BMI: Body mass index; CHD: Coronary heart disease; DBP: Diastolic blood pressure; ECG: Electrocardiogram; EMS: Emergency medical services; FMC: First medical contact; FMC-to-device: First medical contact-to-device time; HR: Heart rate; LAD: Left anterior descending artery; LCX: Left circumflex artery; LM: Left main artery; MACEs: Major adverse cardiovascular events; PCI: Percutaneous coronary intervention; PPCI: Primary percutaneous coronary intervention; RCA: Right coronary artery; SBP: Systolic blood pressure; SPO₂: Oxyhemoglobin saturation; STB: Symptom to balloon time; STFMC: Symptom to first medical contact time; STEMI: ST-elevation myocardial infarction; TVR: Target vessel revascularization.

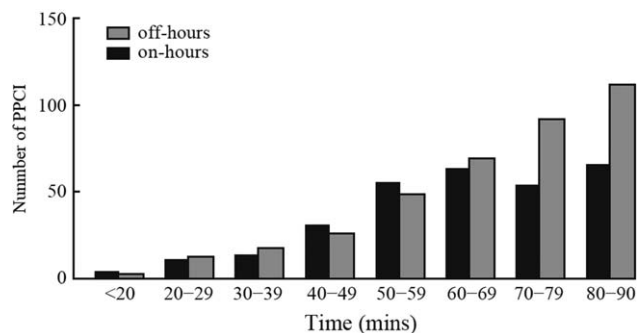


Figure 3: Distribution of the number of patients in different first medical contact-to-device time groups. PPCI: Primary percutaneous coronary intervention.

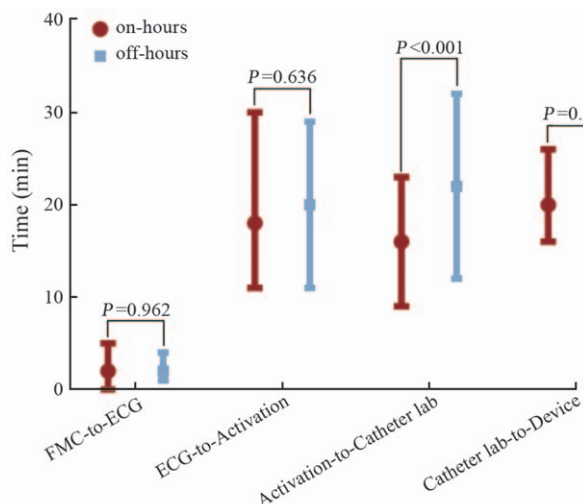


Figure 4: Component segments of first medical contact-to-device time in patients who presented during on-hours and off-hours. ACT2CL: Activation-to-catheter lab time; CL2D: Catheter lab-to-device time; ECG2ACT: Electrocardiogram-to-activation time; FMC-to-ECG: First medical contact to electrocardiogram time.

16 min, $P < 0.001$), and fewer patients had an FMC-to-device time ≤ 60 min (29.1% vs. 40.7%, $P = 0.002$). However, there were no differences in STB, STFMC, FMC-to-ECG, ECG-to-activation, or catheter lab-to-device time between the two groups ($P > 0.05$) [Table 1 and Figure 4].

Clinical outcomes according to off-hours admission

The in-hospital mortality rate was non-significantly higher in the off-hours group than that in the on-hours group (1.9% vs. 2.4%; $P = 0.653$). Similarly, over an average follow-up period of 24 months (quartile 1–quartile 3, 22–26 months), 6.1% (41/670) patients died from all causes, including 5.0% (18/296) patients in the on-hours group and 6.1% (23/374) patients in the off-hours group (Kaplan-Meier estimates of mortality, 6.5% vs. 6.3%, respectively; log-rank test P value = 0.970). Reinfarctions occurred in 2.2% (15/670) patients, including 2.0% (6/296) patients in the on-hours group and 2.4% (9/374) patients in the off-hours group (Kaplan-Meier estimates of percentage, 2.1% vs. 2.5%, respectively; log-rank test P value = 0.502). Totally, 1.1% (8/670) patients

Table 2: Clinical outcomes at 2-year follow-up of STEMI patients who underwent PPCI within 90 min in two groups.

Outcome	On-hours N = 296	Off-hours N = 374	P
MACEs	28 (9.1)	36 (9.6)	0.838
All cause death	18 (6.5)	23 (6.3)	0.970
Reinfarction	6 (2.1)	9 (2.5)	0.502
TVR	4 (1.4)	4 (1.1)	0.734

Data are presented as n (%). Data are number of events with Kaplan-Meier estimates. MACEs: Major adverse cardiovascular events; PPCI: Primary percutaneous coronary intervention; STEMI: ST-elevation myocardial infarction; TVR: Target vessel revascularization.

underwent TVR during the follow-up period, including 1.4% (4/296) patients in the on-hours group and 1.0% (4/374) patients in the off-hours group (Kaplan-Meier estimates of percentage, 1.4% vs. 1.1%, respectively; log-rank test P value = 0.734). Kaplan-Meier curves were constructed to compare the rates of MACEs, all-cause death, reinfarction, and TVR between the two groups. The risks were not significantly different between the two groups ($P > 0.05$) [Table 2 and Figure 5].

The Cox regression results in Figure 6 indicated that higher ages and heart rates were associated with higher 2-year MACEs risks ([HR = 1.052; 95% CI: 1.027–1.078, $P < 0.001$] and [HR = 1.019; 95% CI: 1.005–1.033, $P < 0.001$]). However, off-hours arrival was not a predictor of 2-year MACEs in the univariate (HR = 1.016; 95% CI 0.620–1.665, $P = 0.949$) and multivariate (HR = 1.071; 95% CI 0.649–1.767, $P = 0.788$) Cox regression analyses.

Discussion

The present study found that patients presenting with STEMI during off-hours and treated with PPCI within 90 min had a longer FMC-to-device time than those presenting during on-hours. Moreover, the late outcomes were similar between admission times. In line with previous studies,^[11-13] we found that age and heart rate were independently associated with 2-year MACEs. Advanced age has been reported to be associated with reduced physical function, atypical symptoms,^[14] and multiple comorbidities in the elderly. An increased heart rate has been linked to increased myocardial oxygen consumption, accelerated atherothrombosis, and exacerbation of heart failure in some patients.

Some previous studies^[15-17] reported an average delay in FMC-to-device time of 11 to 17 min when patients presented during off-hours. The main possible explanation for this result is that the catheterization lab could not be activated immediately because of a lack of on-duty nurses, technicians, or interventional cardiologists at the hospital during this period of time. This is supported by the significantly longer activation-to-catheter lab time in the off-hours group than that in the on-hours group (22 vs. 16 min, $P < 0.001$) in our study. Some studies also reported that fewer cardiologists were available during off-hours and off-hours staff had a lower level of expertise.^[18,19] Consequently, patients with borderline

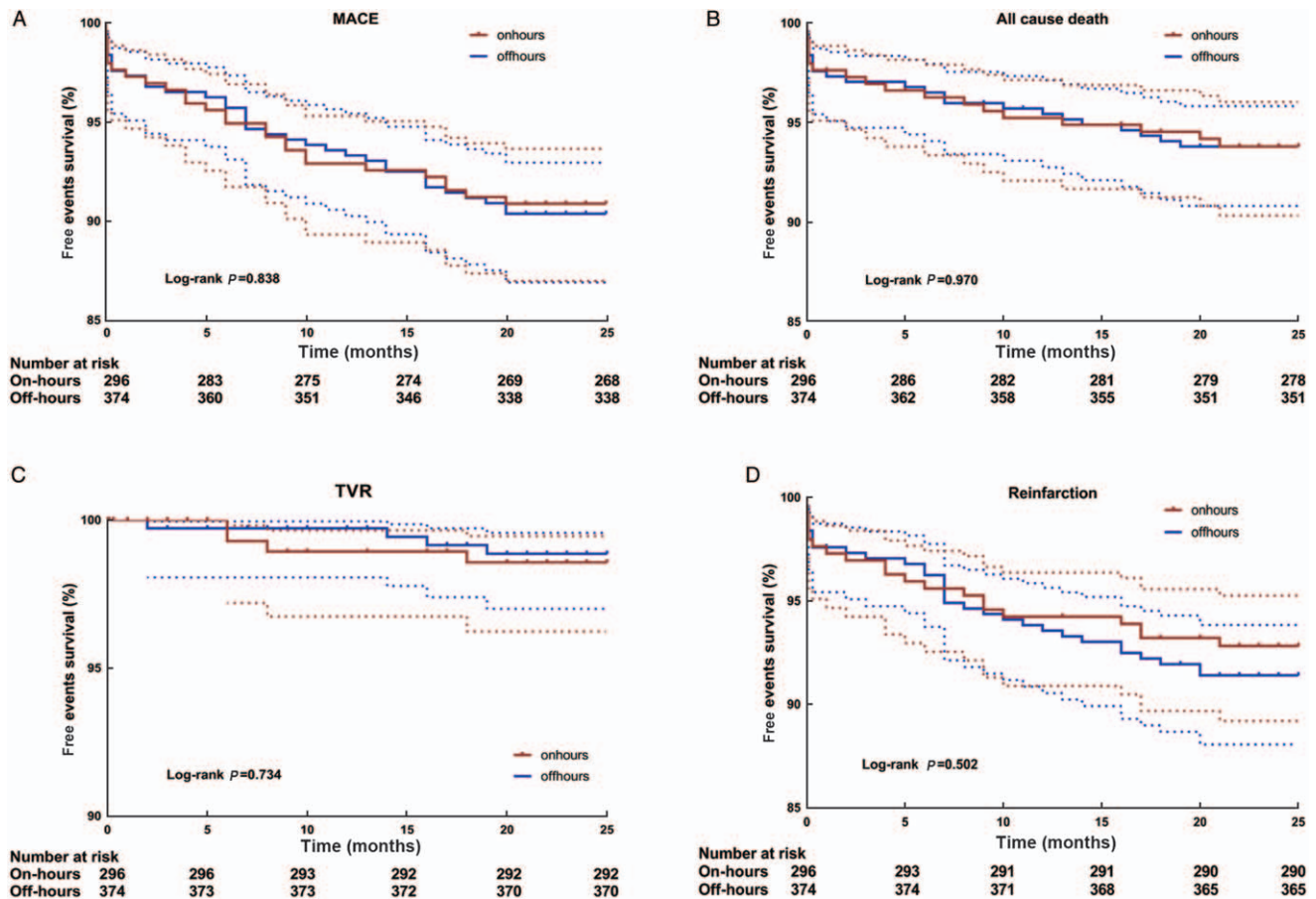


Figure 5: Kaplan-Meier curves for 2-year MACE, all-cause death, reinfarction, and TVR. FMC-to-device: First medical contact-to-device time; MACE: Major adverse cardiovascular event; TVR: Target vessel revascularization.

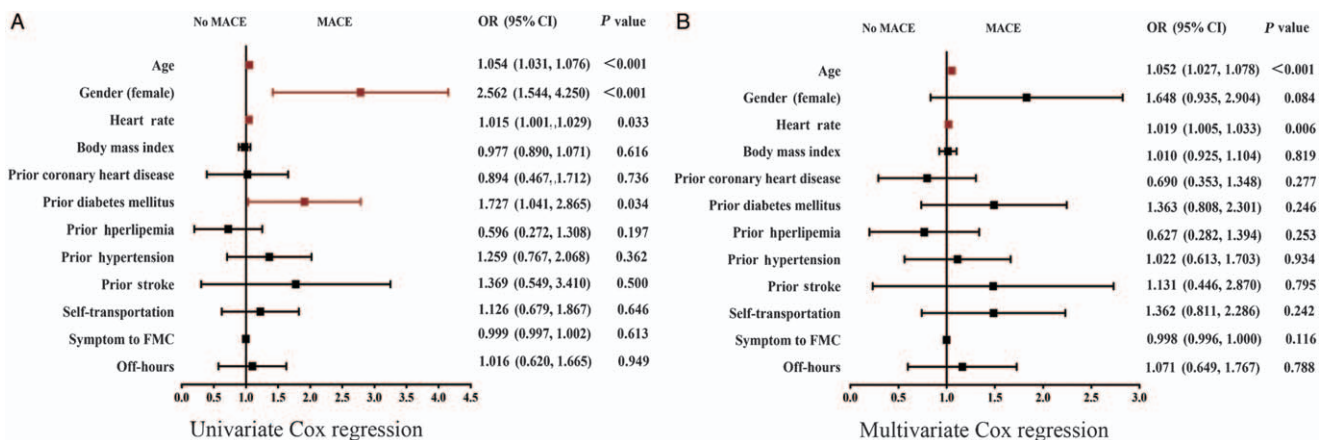


Figure 6: Univariate and multivariate Cox regression analyses about long time MACEs. FMC: First medical contact; MACE: Major adverse cardiovascular event.

ECG changes and atypical symptoms were not diagnosed in a timely manner. However, in the current study, no differences were observed in ECG-to-activation time between the off-hours group and the on-hours group. This was probably because of the increase in the number of chest pain centers in China over the past few years, which has resulted in an increased proportion of patients undergoing primary PCI^[20] and improved the STEMI

diagnosis time. Thus, the strategy of a 24-h-per-day, 7-day-per-week (24/7) in-house interventional cardiology team has been proposed to diminish the “off-hours phenomenon.”^[21,22]

Interestingly, we found that the off-hours group had a longer FMC-to-device time than the on-hours group; however, the incidence of 2-year outcomes in the off-hours

group was not increased. In our opinion, the main reason may be the non-significant difference in the total ischemic time (symptom to device time) between the two groups. In contrast to pre-hospital time delays, in-hospital time delays were significantly prolonged in the off-hours group. Although the interval from symptoms onset to FMC was shorter, the FMC-to-device time was longer in the off-hours group than that in the on-hours group. Future efforts should focus on optimizing the in-hospital PPCI processes in an attempt to decrease the FMC-to-device time in patients treated during off-hours. The impact of off-hours arrival on MACEs has been reported previously. Tang *et al.*^[23] reported that patients who underwent PPCI during off-hours had longer delays to revascularization and a higher incidence of short-term MACEs than those who underwent PPCI during on-hours in Hunan, China. A meta-analysis of 30 studies with 33 cohorts including 192,658 STEMI patients found that off-hours presentation was associated with increased short-term mortality but not long-term mortality in STEMI patients.^[24] Some studies have argued that increased mortality during off-hours reflects an increased severity of illness^[25,26]; however, our study revealed no significant difference between the two groups. Additional reasons for the non-significant difference in 2-year MACE rate might be as follows. First, previous studies included patients with an FMC-to-device time >90 min, and the incidence of MACE was already low in patients with an FMC-to-device time <90 min. Second, the current study had a small sample size and a low single adverse event rate; thus, the difference did not reach significance. Third, MACEs associated with STEMI have declined dramatically over the past several years because of the improvements of healthcare delivery models in Beijing. Fourth, our inclusion criteria excluded patients who died before the PPCI procedure. This could lead to an artificial decrease in case fatality and reduce the number of patients who might have a poor prognosis. Finally, the increased utilization of PPCI during off-hours and the widespread adoption of guidelines regarding the FMC-to-device time contribute greatly to the absence of “off-hours” presentation among STEMI patients in Beijing.

Our study has several limitations. First, as a representative of developed regions in China, Beijing has a high concentration of high-quality medical resources, and the findings are not generalizable to most regions in China. Second, the retrospective design of this study may have led to selection bias. Additionally, there might be other unknown factors that were not analyzed that may contribute to bias in our study. Third, stent thrombosis data were missing or lacking. Fourth, our study had a small sample size and a retrospective study design; thus, a randomized controlled trial with a larger sample size needs to be conducted to validate the results of this research.

There was no statistically significant difference in the 2-year outcome of patients undergoing PPCI who had an FMC-to-device time within 90 min between the two presentation times. Our findings support the safety of PPCI performed during off-hours, which followed the guideline-recommended target FMC-to-device time.

Acknowledgements

The authors appreciate the help of all members from the Quality Control & Improvement Center of Cardiovascular Intervention of Beijing.

Funding

This study was supported by a grant from the National Natural Science Foundation of China (No. 81670415).

Conflicts of interest

None.

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How to cite this article: Ma WJ, Gao SD, Huang SZ, Lin XZ, Yang YJ, Yu MY, the Quality Control & Improvement Center of Cardiovascular Intervention of Beijing. Off-hours admission does not impact outcomes in patients undergoing primary percutaneous coronary intervention and with a first medical contact-to-device time within 90 min. *Chin Med J* 2021;134:1795–1802. doi: 10.1097/CM9.0000000000001621