Furui M, et al., Cardiol Cardiovasc Med 2023
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door time, mechanical complications, and hospital mortality between patients before and after the COVID-19 emergency declaration in Japan. Mechanical complications, including cardiac rupture, ventricular septal perforation, and papillary muscle rupture, were assessed using echocardiography [20-22].

Statistical analysis

Categorical variables are expressed as numbers and proportions, whereas continuous variables are presented as means ± standard deviations. The Student's t-test, chi-squared test, and Mann–Whitney U test were used for other statistical analyses. Multivariate logistic regression analysis was performed for risk factors associated with hospital mortality and mechanical complications in STEMI patients. This analysis considered age, walk-ins, referrals, out-of-hospital cardiac arrest (OHCA), LVEF, intra-aortic balloon pump (IABP) use, mechanical complications, and the time period post-declaration, including known factors [7,22,23]. The odds ratios (OR) and 95% confidence intervals (CI) were calculated. The number of patients who underwent venoarterial extracorporeal membrane oxygenation (VA-ECMO) was few; therefore, it was not entered because we could not effectively analyze it. Moreover, NSTEMI analysis was not valid due to the small number. All statistical analyses were performed using JMP® version 9.0 (SAS Institute Inc., Cary, NC), and differences were considered statistically significant at a P-value <0.05.

Results

We extracted the data of 796 patients who required emergency PCI for ACS from medical records. Of these, 503 AMI patients were identified as participants in this study (Figure 1), of whom 426 and 77 patients were categorized into the STEMI and NSTEMI groups, respectively. Table 1 summarizes their basic characteristics, including the patients'

Table 1: Basic characteristics of AMI patients before and after the COVID-19 declaration

Demographics n (%) or mean±SD		STEMI (n=426)			NSTEMI (n=77)		
		Before declaration (n=349)	**After declaration (n=77)**	**P- value**	**Before declaration (n=62)**	**After declaration (n=15)**	**P- value**
Age (year)		67.7±12.6	68.7±11.9	0.514	67.3±12.7	71.6±11.4	0.152
Sex (male)		268 (76.8%)	55 (71.4%)	0.139	46 (74.2%)	7 (46.7%)	0.842
Body mass index (kg/m2)		24.0±4.0	23.7±4.0	0.642	23.7±3.9	22.3±3.5	0.703
Comorbidities							
Hypertension		189 (54.2%)	45 (58.4%)	0.494	35 (56.5%)	8 (53.3%)	0.075
Diabetes mellitus		100 (28.7%)	24 (31.2%)	0.66	15 (24.2%)	3 (20.0%)	0.737
Dyslipidemia		121 (34.7%)	30 (39.5%)	0.428	20 (32.3%)	7 (46.7%)	0.063
Renal dysfunction		163 (46.7%)	30 (39.0%)	0.217	25 (40.3%)	4 (26.7%)	0.327
Dialysis		4 (1.1%)	2 (2.6%)	0.328	1 (1.6%)	0 (0%)	0.621
Cerebral infarction		22 (6.3%)	5 (6.5%)	0.951	5 (8.1%)	3 (20.0%)	0.102
COPD		3 (0.9%)	0 (0%)	0.414	0 (0%)	10 (66.7%)	0.041*
Prior PCI		36 (10.3%)	7 (9.1%)	0.747	9 (14.5%)	2 (13.3%)	0.187
Clinical presentation							
Killip classification†	I–II	307 (88.0%)	59 (78.7%)	0.010*	58 (93.5%)	10 (100%)	0.312
	III–IV	42 (12.0%)	16 (21.3%)		4 (6.5%)	0 (0%)	
OHCA		8 (2.3%)	5 (6.5%)	0.052	1 (1.6%)	1 (6.7%)	0.27
LVEF (%)		47±12	47±13	0.618	48±14	50±15	0.374
Laboratory data							
CPK‡ (U/L)		453±771	398±622	0.562	529±881	255±234	0.256
Peak CPK (U/L)		3198±2808	3428±3038	0.528	2073±2380	799±730	0.156
CK-MB‡ (U/L)		49±84	39±52	0.377	69±122	30±34	0.262
Peak CK-MB (U/L)		297±302	274±216	0.531	189±199	80±75	0.248
Troponin I‡ (pg/mL)		9378±36961	5491±18821	0.406	7905±28590	5855±1041	0.702

MI, acute myocardial infarction; CK-MB, creatine kinase-myocardial band; COPD, chronic obstructive pulmonary disease; CPK, creatine phosphokinase; LVEF, left ventricular ejection fraction; NSTEMI, non- ST-segment elevation myocardial infarction; OHCA, out-of-hospital cardiac arrest; PCI, percutaneous coronary intervention; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction.

*P<0.05.
†Killip classification after the declaration has a defect value of 2 in STEMI and 5 in NSTEMI.
‡Value at admission.

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Furui M, et al., Cardiol Cardiovasc Med 2023
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Table 2: Consultation type, time course, and outcomes in AMI patients before and after the declaration

Demographics n (%) or mean±SD	STEMI (n=426)			NSTEMI (n=77)		
	Before declaration (n=349)	After declaration (n=77)	P- value	Before declaration (n=62)	After declaration (n=15)	P- value
Consultation type						
Walk-in	50 (14.3%)	12 (16.0%)	0.733	9 (14.5%)	3 (20%)	0.599
EMS	296 (85.3%)	64 (83.1%)	0.71	52 (83.9%)	12 (80.0%)	0.72
In-hospital patients	2 (0.6%)	1 (1.3%)	0.491	1 (1.6%)	0 (0%)	0.621
Referral	94 (27.0%)	11 (14.3%)	0.019*	19 (30.7%)	2 (13.3%)	0.177
Time course						
Onset-to-door (min)	124±134	180±144	0.001*	126±134	186±158	0.327
Door-to-balloon (min)	109±129	96±54	0.42	120±60	117±54	0.609
Culprit						
LMT	6 (1.7%)	1 (1.3%)	0.785	6 (9.7%)	0 (0%)	0.096
LAD	160 (45.9%)	34 (44.2%)		19 (30.7%)	6 (40%)	
pLAD	67 (19.2%)	15 (19.5%)		7 (11.3%)	3 (20.0%)	
mLAD	86 (24.6%)	17 (22.1%)		12 (19.4%)	3 (20.0%)	
dLAD	7 (2.0%)	2 (2.6%)		0 (0%)	0 (0%)	
LCX	34 (9.7%)	9 (11.7%)		16 (25.8%)	8 (53.3%)	
RCA	148 (42.4%)	32 (41.6%)		19 (30.7%)	1 (6.7%)	
Diagonal branch	1 (0.3%)	1 (1.3%)		2 (3.2%)	0 (0%)	
Culprit in proximal part of LCA; LMT + pLAD	73 (20.9)	16 (20.8)	0.979	13 (21.0%)	3 (20.0%)	0.934
Mechanical Circulatory Support						
IABP	22 (6.3%)	7 (9.1%)	0.383	7 (11.3%)	0 (0%)	0.172
VA-ECMO	11 (3.2%)	4 (5.2%)	0.382	2 (3.2%)	0 (0%)	0.481
Outcomes						
Mechanical complications	9 (2.6%)	6 (7.8%)	0.025*	1 (1.6%)	1 (6.7%)	0.27
Cardiac rupture	6 (1.7%)	3 (4.0%)	0.231	1 (1.6%)	0 (0%)	0.621
VSP	2 (0.6%)	2 (2.7%)	0.1	0 (0%)	0 (0%)	-†
PMR	1 (0.3%)	1 (1.3%)	0.241	0 (0%)	1 (6.7%)	0.041*
Operative mortality rate for mechanical complications	1/5[a] (20.0%)	0/4[b] (0%)	0.343	-[c]	0/1 (0%)	-†
30-day mortality	34 (9.7%)	10 (13.0%)	0.397	5 (8.1%)	1 (6.7%)	0.856
In-hospital mortality	36 (10.3%)	11 (14.3%)	0.299	5 (8.1%)	1 (6.7%)	0.856

AMI, acute myocardial infarction; EMS, emergency medical service; IABP, intra-aortic balloon pump; LAD, left anterior descending coronary artery; LCA, left coronary artery; LCX, left circumflex coronary artery; LMT, left main trunk; NSTEMI, non-ST-segment elevation myocardial infarction; dLAD, distal LAD; mLAD, mid LAD; pLAD, proximal LAD; PMR, papillary muscle rupture; RCA, right coronary artery; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction; and VA-ECMO, venoarterial extracorporeal membrane oxygenation; VSP, ventricular septal perforation.

*P<0.05.

†The value is not valid.

[a]Four, [b]two, and [c]one case with cardiac rupture could not undergo surgery.

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Furui M, et al., Cardiol Cardiovasc Med 2023
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background and pre-PCI examination findings before and after the COVID-19 declaration in each group. In the STEMI group, the number of patients with Killip classes III–IV was significantly higher after the declaration than it was before the declaration (12.0% [42/349] vs. 21.3% [16/77], P=0.010). Although the prevalence of OHCA was not significantly different, it tended to be higher after the declaration (2.3% [8/349] vs. 6.5% [5/77], P=0.052). There were no significant differences in comorbidities, clinical presentation, and laboratory data before and after the declaration, except for Killip III–IV classification in the STEMI group, as previously described.

Table 2 shows consultation forms, such as walk-ins, arrival by EMS, and referrals; time course; and outcomes before and after the declaration in each group. In the STEMI group, there were fewer referred patients after the declaration than there were before the declaration. However, there was no significant difference in the door-to-balloon time before and after the declaration (109±129 vs. 96±54 min, P=0.420). Onset-to-door time (a primary outcome) in STEMI patients was significantly longer after the declaration than it was before the declaration (124±134 vs. 180±144 min, P=0.001). Hospital mortality, another primary outcome, occurred in 11.0% (47/426) of STEMI patients and 7.8% (6/77) of NSTEMI patients. Contrarily, mechanical complications, a secondary outcome, occurred in 3.5% (15/426) of STEMI patients and 2.6% (2/77) of NSTEMI patients. The mechanical complication rate was significantly higher after the declaration than it was before the declaration (2.6% [9/349] vs. 7.8% [6/77], P=0.025) in the STEMI group; however, there was no significant difference in hospital mortality (10.3% [36/349] vs. 14.3% [11/77], P=0.299). In the post-intervention course of all patients, ten patients with four cases of ventricular septal perforation, three of cardiac rupture and three of papillary muscle rupture needed urgent surgery for mechanical complications, although seven patients could not undergo surgery in time because of cardiac rupture in the general ward. Operative mortality for mechanical complications was 10.0% (1/10); only one cardiac rupture needed VA-ECMO after a sudden change in ward out of a total of ten surgical cases, died after surgery.

Table 3 presents the results of the multivariate analysis for the primary outcomes. Age (1-year increase: OR 1.087, 95% CI 1.045–1.135, P≤0.0001), OHCA (OR 61.883, 95% CI 9.726–595.506, P<0.0001), LVEF (1% increase: OR 0.943, 95% CI 0.911–0.975, P=0.0004), and mechanical complications (OR 10.724, 95% CI 2.233–57.236, P=0.003) were established as independent predictors of hospital mortality. Table 4 presents the results of the multivariate analysis for the secondary outcome. Age (1-year increase: OR 1.115, 95% CI 1.037–1.221, P=0.0019), walk-in visits (OR 14.695, 95% CI 3.265–80.468, P=0.0005), referral visits (OR

Table 3: Multivariate logistic regression analysis of risk factors for STEMI

Dependent variable: hospital mortality			
	Odds ratio	**95% CI**	**P-value**
Age (per year)	1.087	1.045–1.135	<0.0001*
Walk-in	2	0.527–10.829	0.332
Referral	0.744	0.289–1.999	0.55
OHCA	61.883	9.726–595.506	<0.0004*
LVEF (1% increase)	0.943	0.911–0.975	0.0019*
Mechanical complications	10.724	2.233–57.236	0.0030*
Post-declaration (vs. pre-declaration)	1.03	0.293–3.129	0.9603

CI, confidence interval; LVEF: left ventricular ejection fraction; OHCA, out-of-hospital cardiac arrest; and STEMI, ST-segment elevation myocardial infarction.

*P<0.05.

Table 4: Multivariate logistic regression analysis of risk factors for STEMI

Dependent variable: mechanical complications			
	Odds ratio	**95% CI**	**P-value**
Age (per year)	1.115	1.037–1.221	0.0019*
Walk-in	14.695	3.265–80.468	0.0005*
Referral	4.854	1.050–25.003	0.0432*
LVEF (1% increase)	0.971	0.915–1.030	0.276
Post-declaration (vs. pre-declaration)	5.006	1.131–22.443	0.035*

CI, confidence interval; LVEF, left ventricular ejection fraction; STEMI, ST-segment elevation myocardial infarction.

*P<0.05.

Furui M, et al., Cardiol Cardiovasc Med 2023
DOI:10.26502/fccm.92920327

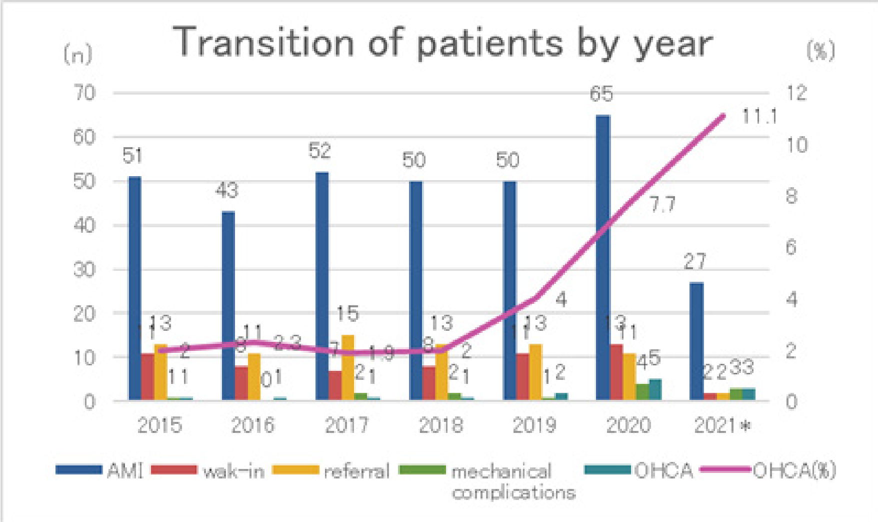

Figure 2: Transition of patients with total AMI, walk-in, referral, mechanical complications, OHCA and OHCA rates (%), the last seven year

* 2021only includes from April to December, other years include from April to next March.

Abbreviations: AMI, acute myocardial infarction; OHCA, out-of-hospital cardiac arrest

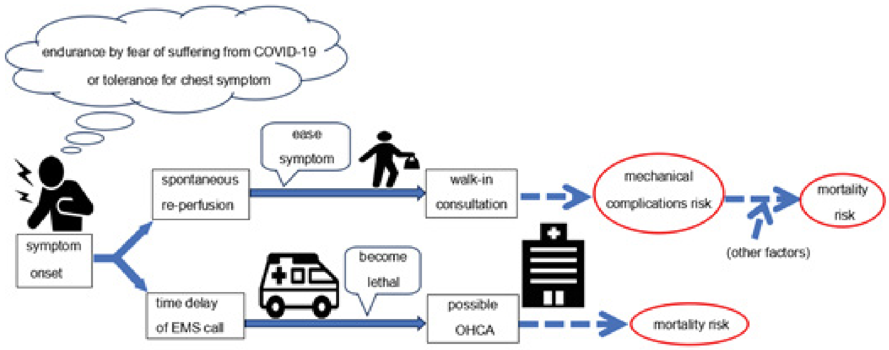

Figure 3: Polarization tendency of potential risks occurring from the patients' psychology and possible time course after the COVID-19 pandemic

Abbreviations: EMS, emergency medical service; OHCA, out-of-hospital cardiac arrest.

4.854, 95% CI 1.050–25.003, P=0.043), and post-declaration (OR 5.006, 95% CI 1.131–22.443, P=0.035) were identified as independent predictors of mechanical complications.

Figure 2 shows transition of patients with total AMI, walk-in, referral, mechanical complications, OHCA and OHCA rates (%) the last seven years. Total AMI counts in 2020 and 2021 (the post-COVID-19) varied, however, remained relatively stable except for OHCA and OHCA ratio.

Discussion

Several studies have reported the impact of the COVID-19 pandemic on AMI in Tokyo [3,7]. However, our hospital's secondary medical service area in South Osaka is distinct from that in Tokyo and has an unevenly distributed population, similar to hospitals, especially PCI-capable facilities [12,24,25]. Moreover, arrival by walk-in or referral as risk factors for AMI have rarely been discussed following the COVID-19 pandemic. We established that onset-to-door time was prolonged and mechanical complications developed more frequently in STEMI patients after the declaration. These findings suggest that, in addition to post-declaration, walk-ins and referrals were risk factors for mechanical complications. To the best our knowledge, this is the first study that pointed out the risk factor of walk-in and referral visits, discussed after the COVID-19 pandemic. Regarding risk factors for hospital mortality, it was reported that patients with lower LVEF have higher mortality rates and develop heart failure easily [26,27]. Once mechanical complications occur, they can fatally affect patients' hemodynamics. Although various operative procedures and strategies in surgery timing have been devised, operative mortality remains high [20,21,28]. Therefore, investigating the risk factors and preventing subsequent complications may be important in reducing associated mortality. Several risk factors for mechanical complications are known; previous studies have shown that established mechanical complication risk factors include age,

Furui M, et al., Cardiol Cardiovasc Med 2023
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female sex, anterior MI, de novo MI, and single-vessel disease [21,22]. Once mechanical complications occur, patients often experience cardiogenic shock, thus requiring IABP use, which may naturally become a risk factor. Considering previous findings, the identification of walk-ins and referrals as risk factors for mechanical complications are unique points in the present study. Walk-in patients often have mild symptoms, making this seem contradictory. However, in some cases with mild symptom presentation, walk-in patients are unrestricted in their activities or mobility until AMI diagnosis. That is, patients' hearts can suffer from unnoticed load until AMI diagnosis, even after visiting the hospital. Failure to limit this activity may become a mechanical complication risk. Thus, the time course for walk-in patients is distinct from that for patients transported by ambulance. Actual onset-to-door time in walk-in patients was over 50 minutes longer than that in non-walk-in patients. Patients who notify the EMS are likely to immediately undergo consultation and check-ups by emergency doctors who begin monitoring as soon as the patient arrives at the hospital. Useful information by rescue crews generally aids in smooth AMI diagnosis. Conversely, walk-in patients have to wait longer for consultation or check-ups. Our hospital aggressively receives EMS patients from the surrounding area; however, only one or two doctors and a few emergency department nurses deal with EMS patients and out-of-hours walk-in patients, in that order. Although minimal triage is performed, walk-in patients may have waiting times because EMS patients are prioritized. Therefore, there may be a pronounced time lag from their arrival to diagnosis or PCI, compared with that in patients who notify EMS. Referred patients were reported to have a prolonged onset-to-door time because they came from a nearby clinic or were transferred from non-PCI-capable facilities [13,18]. Previous studies reported that the time interval from an AMI onset to ventricular septal perforation manifestation had a bimodal distribution [23]. Therefore, a longer ischemic time can become a risk factor for mechanical complications due to interactions with unknown factors. In any case, because a referral is indispensable due to the surrounding non-PCI-capable facilities, we suggest that an effective EMS system and crew education on carrying suspected patients to PCI-capable facilities is important [10,12,13]. In the future, telemedicine will also have an important role in AMI treatment [29]. In the STEMI group, OHCA rates tended to be higher after the declaration than they were before, although this failed to reach statistical significance. In the NSTEMI group in Table 2, the rate of lesions at left main was lower after the COVID-19 declaration. However, the lower rate may reflect milder AMI patients, after exclusion of AMI patients with severe left main who did not reach hospital. Accordingly, we cannot tell if this reduced number indicates real or pretending decrease. A previous study stated that 32% of patients with AMI at a left main lesion who were only medically treated medically died [30]. That is, AMI at left main may easily lead to death and hesitation to visiting hospital can be deadly. The OHCA may be just the tip of the iceberg. Given the potential for a higher OHCA rate and the risk factors for mechanical complications such as walk-ins and referrals shown in Table 4, AMI risk polarization may have emerged on the clinical scene during the COVID-19 pandemic. Although rare, spontaneous reperfusion can occur in 7–30% of STEMI patients, as stated in previous studies [31,32]. In addition, patients who follow stay-at-home orders and initially tolerate or adapt to their symptoms may likely experience spontaneous reperfusion. Walk-in patients with apparently mild symptoms or referral STEMI patients may be at risk of mechanical complications after the COVID-19 pandemic. The mechanical complications were identified in the present study as a mortality risk in STEMI. Therefore, care should be taken regarding walk-in or referral patients suspected of STEMI. Conversely, more severe symptoms can result in patients notifying EMS; however, their situation can become critical due to delays that may lead to OHCA during transport to PCI-capable facilities. The fear of contracting COVID-19 may have led to patient hesitation to visit hospitals, resulting in risk polarization (Figure 3). Although we can not just blame it on walk-in and referral, referral and walk-in which can lead treatment delay may contribute to increased OHCA rates as shown in Figure 2, in our medical area. We believe that the upward trend in OHCA rates means that more patients tend to endure until the last minute. Timely arrival to PCI-capable facilities without hesitation is necessary for patients at risk of AMI.

The first limitation of this study is its retrospective observational design coupled with limited sample size and performance at a single center. Our hospital covers only one of the areas in South Osaka. Thus, our data may not accurately represent Osaka as a whole because of emergency care or PCI volume disparity [10–12]. Second, additional data, encompassing EMS calls, transfer-to-door time, or COVID-19 examination waiting time, may be desirable in future studies to support the initial findings outlined in this study. Finally, the number of patients who died at home or during transport to our hospital was unknown. They were excluded, and AMI patients who were COVID positive were not included in the study population. Therefore, OHCA and AMI prevalence rates may have been underestimated. Future research including these data will be required to further evaluate AMI-related mortality risk or mechanical complications during the COVID-19 pandemic.

Conclusion

The onset-to-door time was prolonged and mechanical complications developed more frequently in STEMI patients after the COVID-19 pandemic declaration than they were before. Age, low LVEF, OHCA, and mechanical complications were established as independent risk factors for hospital mortality in STEMI patients. Additionally,

Furui M, et al., Cardiol Cardiovasc Med 2023
DOI:10.26502/fccm.92920327

age, walk-ins, and referrals were identified as independent predictors of mechanical complications in those with STEMI. Arrival by walk-in or referral, chosen by patients with seemingly mild disease may also carry risks and may need to be handled with caution. Therefore, longitudinal studies are needed as the risks posed by the COVID-19 pandemic may be changing.

Author Contributions:

Conceptualization, M.F., K.K. and T.Y.; methodology, M.F.; validation, M.F. and H.W.; formal analysis, M.F. and H.N.; investigation, B.K., N.O. and M.A.; data curation, M.F.; writing—original draft preparation, M.F.; writing—review and editing, M.F. and H.W.; supervision, H.W. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement:

The study protocol conformed to the ethical guidelines of the Declaration of Helsinki and was approved by the Ethics Committee of the Matsubara Tokushukai Hospital (approval number: 22-01).

Informed Consent Statement:

The informed consent requirement from patients was waived due to the retrospective nature of this study.

Data Availability Statement:

The original contributions presented in this study are included in the article, further inquiries can be directed to the corresponding author.

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Conflicts of Interest:

The authors declare no conflict of interest.

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