



ORIGINAL STUDY

Reduction of door-to-balloon time in patients with ST-elevation myocardial infarction by single-catheter primary percutaneous coronary intervention method

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Abstract

Objectives: The objectives of this study is to confirm reduction of door-to-balloon (D2B) time with single-catheter percutaneous coronary intervention (SC-PCI) method.

Background: Reduction of total ischemic time is important in the emergency treatment of ST-elevation myocardial infarction (STEMI). There have been no established methods in primary percutaneous coronary intervention (PCI) to shorten ischemic time via radial access. Ikari left curve was reported as a universal guiding catheter for left and right coronary arteries. Several procedure steps can be skipped by SC-PCI method as the advantage of a universal catheter.

Methods: This study is a retrospective analysis of a total of 1,275 consecutive STEMI cases treated with primary PCI in 14 hospitals. Patients were divided into two groups, SC-PCI method ($n = 298$) and conventional PCI method ($n = 977$). Primary endpoints were door-to-balloon (D2B) time and radiation exposure dose.

Results: The mean age was 68 ± 13 years old. Radial access was used in 85% of participants. PCI success was achieved in 99.5% of participants and the SC-PCI method was successfully performed in 92.6%. The D2B time was shorter (68 ± 46 vs. 74 ± 50 min, respectively; $p = .02$), and the radiation exposure dose was lower ($1,664 \pm 970$ vs. $2,008 \pm 1,605$ mGy, respectively; $p < .0001$) in the SC-PCI group than in the conventional group.

Conclusion: Primary PCI with SC-PCI method for patients with STEMI demonstrated shorter D2B time and lower radiation exposure dose.

KEYWORDS

Ikari catheter, radial access, radiation exposure

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1 | INTRODUCTION

A primary percutaneous coronary intervention (PCI) strategy is recommended for all ST-elevation myocardial infarction (STEMI) patients.^{1,2} Although STEMI-related mortality has declined with the widespread use of primary PCI, recent mortality rates have not changed.³⁻⁶ The radial artery approach reportedly reduced total mortality in acute coronary syndrome despite its low implementation rate.⁷

Total ischemic time reduction is considered important since time delays to reperfusion are reportedly an independent predictor of both in-hospital and one-year mortality rates.⁸⁻¹⁰ Several evaluated strategies, such as an improved emergency medical system,¹¹⁻¹⁵ in-hospital announcement, and professional team training,¹⁶⁻¹⁸ reduce the total ischemic time and transport time from onset to catheterization laboratory. The PCI procedure time is an important part of the total ischemic time, even though no systematic attempt was made when radial access was recommended.

In our prior report, we demonstrated significantly lower door-to-balloon (D2B) time using a single universal guiding catheter, the Ikari left curve, which enables an operator to perform both angiography and primary PCI for both left and right coronary arteries.¹⁹ However, that study had certain limitations: a single-center retrospective analysis and a small sample size. Therefore, the current study aims to evaluate the technique's efficacy in a multicenter registry with a larger size.

2 | MATERIALS AND METHODS

2.1 | Subjects

The study enrolled 1,316 consecutive STEMI patients undergoing primary PCI from January 2014 to January 2018 in 14 hospitals. The inclusion criteria for the registry were as follows:

- chest pain for which the patient consulted a physician within 12 h after symptom onset, and
- lasted more than 20 min with ST-segment elevation at the J point in at least two contiguous leads of over 2 mm (0.2 mV) in men or over 1.5 mm (0.15 mV) in women in leads V2-V3, and/or
- of over 1 mm (0.1 mV) in other contiguous chest leads or the limb leads more than 1 mm in at least two contiguous leads or new left bundle branch block.¹

On the other hand, the exclusion criteria included patients with missing treatment strategy data. The patients were then divided into two treatment groups: the single-catheter percutaneous coronary intervention group (SC-PCI group, $n = 298$) and the conventional method group ($n = 977$) (Supplement 1).

This study complied with the Declaration of Helsinki on the investigation in humans, and the institutional ethics committee of the Tokai University Hospital approved the study protocol.

2.2 | The SC-PCI method and the conventional method

In the conventional method, initial diagnostic angiography was performed using diagnostic catheters. These can be done in several ways: (1) using the Judkins R and Judkins L diagnostic catheters, (2) using a diagnostic catheter to contrast the contralateral side of the culprit artery and a guiding catheter to contrast the culprit artery, or (3) using a universal diagnostic catheter (TIG, Mitsudo, etc.) to contrast both sides and then change to a guiding catheter (Figure 1).

Ikari left catheter reportedly had a high success rate as a universal guiding catheter for both left and right coronary arteries.²⁰ In the SC-PCI method, the Ikari left guiding catheter is used not only for diagnostic coronary angiography of both left and right coronary arteries but also for the guiding catheter of primary PCI. First, the non-culprit coronary artery's angiography, which was predicted with electrocardiogram and another non-invasive diagnostic method, was performed. Afterward, the guiding catheter was disengaged from the non-culprit coronary artery and directly engaged to the culprit. Then, the PCI procedure could begin immediately after diagnostic angiography (Figure 1). The SC-PCI method using the Ikari left guiding catheter allowed operators to skip five steps, two steps or three steps compared with conventional method #1, #2 or #3. In this study, conventional method #1 was mostly used.

2.3 | PCI procedure

All STEMI patients were treated with dual antiplatelet therapy (DAPT). If the patients had not taken any antiplatelet drugs, they were treated with a loading dose of 200 mg to 300 mg aspirin and a P2Y12 inhibitor. The patients achieved procedural anticoagulation with preliminary administration of an unfractionated heparin bolus. They received a supplemental bolus during the procedure to maintain >250 s activated clotting time. The approach site, sheath size, type of diagnostic and guiding catheter in the conventional group, usage of intracoronary imaging devices, and duration of DAPT after primary PCI were at the operators' discretion.

2.4 | Study endpoints

The primary endpoints were D2B time, defined as the time between the patient's arrival in the emergency department and first device activation such as a balloon, aspiration catheter, excimer laser catheter, and radiation exposure dose. Secondary endpoints were sheath-to-balloon (S2B) time, defined as the time between sheath insertion and first device activation, fluorescent time, contrast volume, and adverse events such as major bleeding, cardiac death, and all-cause death. Cardiac death was any procedure-related death, such as cardiac cause, including major bleeding as per the Bleeding Academic Research Consortium Definition (BARC) 3 or 5.²¹

2.5 | Statistical analysis

Continuous normally-distributed variables were expressed as mean \pm SD and analyzed using Student's *t* tests. Categorical variables were expressed as percentages, analyzed using the chi-square test. The analysis for predictors of D2B time and sheath-to-balloon time in each institute used the general linear model. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina).

3 | RESULTS

Both groups had similar baseline clinical characteristics except for age and history of old myocardial infarction (Table 1). Radial access was used in 85% of cases, higher in the SC-PCI group (91% vs. 83%) than in the conventional method group. The occurrence of culprit lesions in the left anterior descending artery was higher in the SC-PCI group

(55% vs. 49%) than in the conventional method group. There were no significant differences in other factors.

Table 2 shows that overall, PCI was successful in 99.5% of cases. The SC-PCI method was successful in 92.6% of cases for left and right coronary diagnostic angiography plus coronary intervention using a single guiding catheter without using other diagnostic or guiding catheters.

In the case of SC-PCI method failure, the catheter was changed, and the procedure continued, with an eventual PCI success rate of 100%. D2B time, the primary endpoint of this study, was significantly shorter in the SC-PCI group (68 ± 46 min vs. 74 ± 50 min, $p = .02$) than in the conventional method group. This result was due to the significantly shorter sheath-to-balloon time in the SC-PCI group (Figure 2). There was no significant difference in the door-to-sheath time.

The radiation exposure dose was significantly lower in the SC-PCI group (Figure 3). Fluorescent time was also shorter, and the number

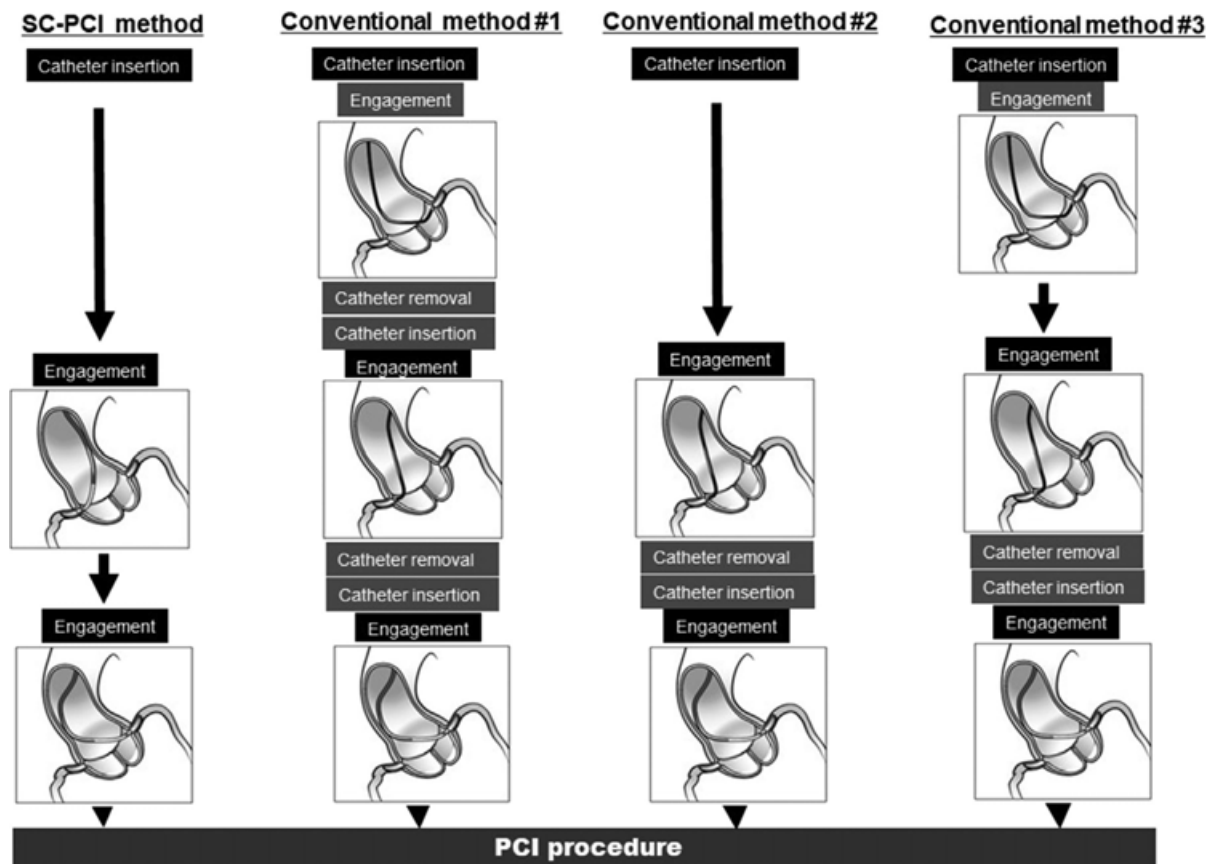


FIGURE 1 Single-catheter primary percutaneous coronary intervention (SC-PCI) method and conventional methods. In primary percutaneous coronary intervention (PCI), coronary angiography is performed first. In SC-PCI method, an Ikari left curve is used as a diagnostic catheter both for left and right coronary arteries and a guiding catheter to perform PCI. In the conventional methods, initial diagnostic angiography was performed using diagnostic catheters. These can be done in several ways; Conventional method #1) using the Judkins R and Judkins L diagnostic catheters, Conventional method #2) using a diagnostic catheter to contrast the contralateral side of the culprit artery and a guiding catheter to contrast the culprit artery, or Conventional method #3) using a universal diagnostic catheter (TIG, Mitsudo etc.) to contrast both sides and then change to a guiding catheter. The SC-PCI method can skip several steps; five steps compared with the conventional method #1 as two catheter insertions, two catheter removals, and one engagement to the coronary artery, two steps compared with conventional method #2, or three steps compared with conventional method #3

TABLE 1 Patient baseline characteristics

	Total (n = 1,275)	SI-PCI group (n = 298)	Conventional group (n = 977)	p value
Patient characteristics				
Male sex, %	75	78	74	.2
Age, years	68 ± 13	67 ± 13	68 ± 13	.04
BMI, kg/m ²	24 ± 3.9	24 ± 3.9	24 ± 4	.1
Smoking never/past/current smoker, %	42/25/33	40/23/38	43/26/31	.1
Diabetic mellitus, %	30	26	31	.1
Dyslipidemia, %	55	55	55	.9
Hypertension, %	65	62	66	.2
Old myocardial infarction, %	9	5	10	.01
Clinical status				
Killip classification I/II/III/IV, %	71/12/7/10	76/8/6/10	70/13/8/10	.07
Temporary pacemaker, %	10	12	9	.07
Circulatory support device, % ^a	11	9	11	.3
Cardiac arrest before primary PCI, %	3	2	3	.6
Systolic blood pressure, mmHg	131 ± 40	131 ± 40	131 ± 40	.9
Diastolic blood pressure, mmHg	79 ± 24	80 ± 24	78 ± 24	.2
Heart rate, /min	76 ± 25	76 ± 25	75 ± 25	.8
eGFR ^b , ml/min./1.73 m ²	63 ± 29	64 ± 23	62 ± 31	.4
Creatinine, mg/dl	1.07 ± 1.15	1.00 ± 0.85	1.09 ± 1.22	.2
Grace score	164 ± 43	160 ± 43	165 ± 44	.1
Access site radial/femoral/other, %	85/13/2	91/8/1	83/15/2	.004
Culprit LAD/LCX/RX/LM/graft, % ^c	51/10/38/2/0	55/4/38/2/0	49/11/37/2/0	.01
Number of vessel disease 1/2/3, %	61/26/13	62/26/12	61/26/14	.8

^aCirculatory support device included intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO), and Impella.

^beGFR, estimated glomerular filtration rate.

^cLAD, left anterior descending artery; LCX, left circumflex artery; RCX, right circumflex artery; LM, left main artery; Graft, graft vein.

of diagnostic catheters was lower in the SC-PCI group. There were no significant differences in clinical endpoints such as cardiac death, all-cause death, major bleeding, or duration of intensive care unit (ICU) stay, except for shorter admission days in the SC-PCI group.

Table 3 shows D2B time predictors. The SC-PCI method and high estimated glomerular filtration rate were significant predictors of shorter D2B time.

Since the shorter D2B time in the SC-PCI group was due to a shorter sheath-to-balloon time, as shown in Figure 2, further analysis of sheath-to-balloon time was performed by dividing into each institute (Figure 4). For this analysis, we used data from 10 institutes, where at least five cases of the SC-PCI method were enrolled. Nine institutes (90%) had a shorter sheath-to-balloon time, and the difference was statistically significant in eight institutes (80%).

4 | DISCUSSION

The SC-PCI method using the lkari left guiding catheter demonstrated shorter D2B time in primary PCI for patients with STEMI. It also reduced the radiation dose, the fluorescent time, and the number of

diagnostic catheters. The percentage of radial access is as high as 85% in this study.

Figure 1 shows several steps of the SC-PCI procedural method that could be skipped to save time. The average sheath-to-balloon time significantly decreased by 4 min, and the fluoroscopy time significantly decreased by 4 min compared to the conventional method group. However, when the guiding catheter does not fit the patients' anatomy, it requires another catheter exchange, resulting in the loss of its time-saving performance. This study showed a 92.6% success rate of the SC-PCI method, even in emergencies, indicating a sufficient success rate to make a difference. Youssef et al. reported that lkari left is an ideal universal guiding catheter in radial access with a 99% success rate for the left coronary artery and a 98% success rate for the right coronary artery in elective PCI cases.²⁰ At that time, a universal guiding catheter was expected to reduce the costs of diagnostic catheters. The increasing demand for radial access and reduced total ischemic time in the emergency treatment of STEMI makes the universal guiding catheter's performance an answer to this demand.

Reduced total ischemic time in STEMI has been reported using several methods such as pre-hospital electrocardiogram system,^{11,15}

TABLE 2 PCI procedure and clinical outcomes

	Total (n = 1,275)	SC-PCI group (n = 298)	Conventional group (n = 977)	p value
PCI success (%)	99.5	100	99.3	.14
SC-PCI method success (%)	-	92.6	-	
Contrast volume (ml)	135 ± 60	135 ± 50	136 ± 63	.8
Peak CK(IU/L)	2,733 ± 2,625	3,194 ± 2,918	2,592 ± 2,514	.0014
ICU stay days (days)	3 ± 4	3 ± 4	3 ± 4	.9
Admission days (days)	16 ± 17	13 ± 12	17 ± 18	.002
Mortality at 30 days cardiac/noncardiac (%)	3.8/0.7	5.3/0.7	3.3/0.7	.3
Hemorrhage (%)	1	0.7	1	.5
Number of guiding catheters	1.1 ± 0.3	1.0 ± 0.3	1.1 ± 0.3	.07
Number of diagnostic catheters	1.2 ± 0.8	0.1 ± 0.3	1.6 ± 0.6	<.0001

Abbreviations: CK, creatine kinase; ICU, intensive care unit; PCI, percutaneous coronary intervention; SC-PCI, single-catheter primary percutaneous coronary intervention.

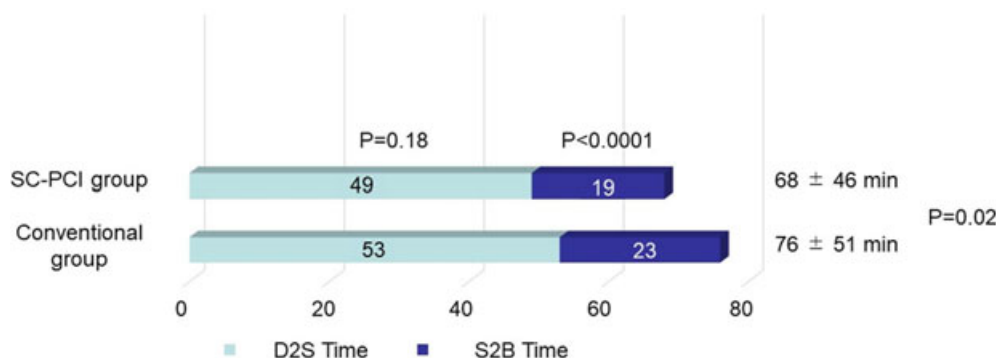


FIGURE 2 Door-to-balloon time (D2B). The D2B time was significantly shorter in the single catheter primary percutaneous coronary intervention (SC-PCI) method group (68 ± 46 vs. 76 ± 51 min, respectively; $p = .02$) than in the conventional method group. When the D2B time is divided into door-to-sheath (D2S) time and sheath-to-balloon (S2B) time, the S2B time was significantly different (19 ± 14 vs. 23 ± 14 min, respectively; $p < .0001$), but the D2S time was not significantly different (49 ± 42 vs. 53 ± 46 min, respectively; $p = .18$) [Color figure can be viewed at wileyonlinelibrary.com]

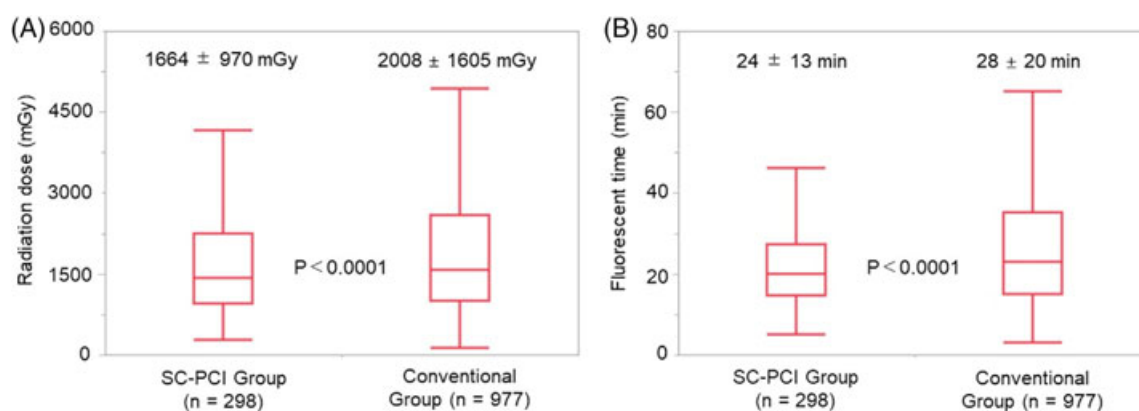


FIGURE 3 Radiation exposure dose and fluorescent time. (A) Radiation exposure dose and (B) fluorescent time [Color figure can be viewed at wileyonlinelibrary.com]

emergency medicine physicians activating the catheterization laboratory,^{22,23} or an attending cardiologist always on site.^{24,25} These successful reports were based on pre-hospital and in-hospital transport. On the other hand, only a few reported attempts reduced PCI

procedural times; for example, primary PCI without diagnostic angiography. However, it has not been widely performed, probably because of the lack of information on the contralateral coronary artery may be a potential source of trouble.

TABLE 3 D2B time predictors

Variable	Univariate analysis		
	Estimate	95% CI	p value
SC-PCI method	-7.47	(-14.0 ~ -0.92)	.02
Institute with radial rate > 80%	-1.51	(-1.10 ~ 7.97)	.75
Sex	1.02	(-5.41 ~ 7.44)	.76
Age	0.08	(-0.13 ~ 0.29)	.44
Body mass index	-0.12	(-0.84 ~ 0.59)	.74
Smoking	.304	(-3.44 ~ 9.52)	.36
Diabetic mellitus	-1.63	(-7.70 ~ 4.44)	.60
Dyslipidemia	0.53	(-5.07 ~ 6.13)	.85
Hypertension	-3.52	(-9.35 ~ 2.30)	.23
Old myocardial infarction	-4.19	(-14.0 ~ 5.62)	.40
Cardiogenic shock	-1.14	(-10.4 ~ 8.09)	.81
Temporary pacemaker	4.81	(-4.64 ~ 14.20)	.32
Circulatory support device	-1.35	(-10.30 ~ 7.60)	.77
Cardiac arrest before PCI	-13.5	(-30.5 ~ 3.51)	.12
Systolic blood pressure	-0.004	(-0.07 ~ 0.07)	.91
Diastolic blood pressure	-0.02	(-0.14 ~ 0.10)	.77
Heart rate	0.01	(-0.11 ~ 0.12)	.92
eGFR ^a	-0.24	(-0.36 ~ -0.12)	< .0001
Grace score	0.03	(-0.04 ~ 0.09)	.42
Culprit LCA vs. RCA ^{b,c}	-4.8	(-10.5 ~ 0.93)	.10
Access site change	16.9	(-2.47 ~ 36.30)	.09

^aeGFR, estimated glomerular filtration rate.

^bLCA, left coronary artery.

^cRCA, right coronary artery.

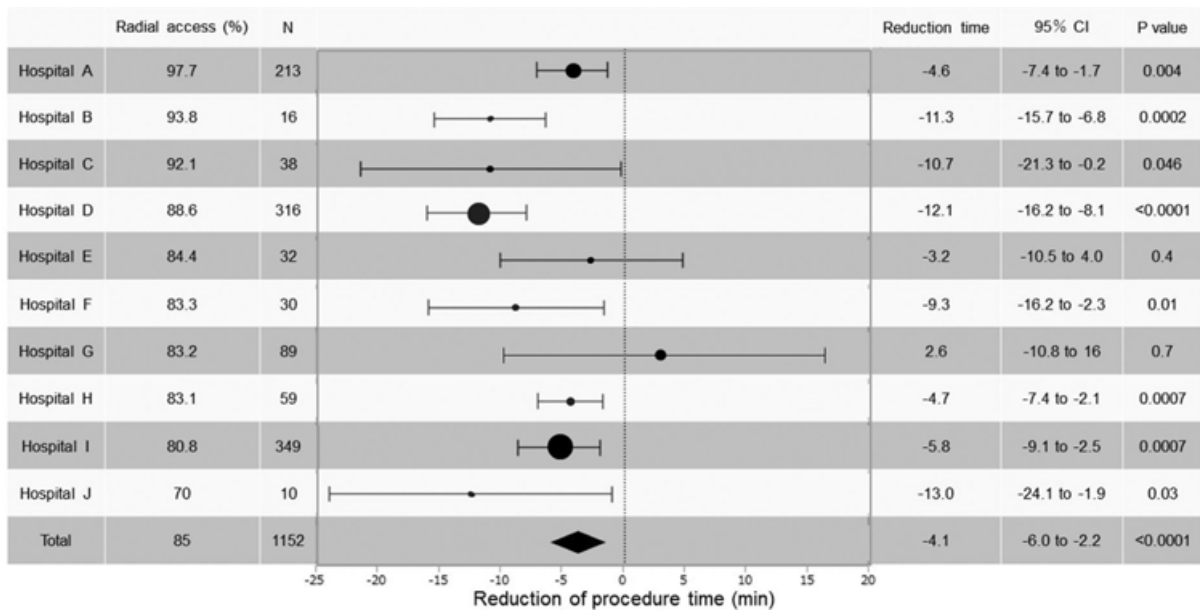


FIGURE 4 Analysis of sheath-to-balloon time by institute. Reduced sheath-to-balloon time with the single catheter primary percutaneous coronary intervention (SC-PCI) method was analyzed separately for each institution. For this analysis, we used data from ten institutes, where at least five cases of the SC-PCI method were enrolled. The sheath-to-balloon time in the SC-PCI method was shorter in 90% of institutes, and the difference was statistically significant in 80%

This study demonstrated that the SC-PCI method reduced D2B time and radiation dose. Other than that, the SC-PCI method might have the advantage of increasing safety by skipping potentially hazardous procedural steps. The catheter insertions and catheter removals that were no longer necessary under the SC-PCI method are not always safe. Guidewires were developed to prevent vascular damage associated with catheter insertion, but bleeding complications due to small vessel damage caused by stray guidewires have been reported. Also, there have been reports of complications during catheter removal, such as removal difficulty due to catheter bending. Thus, guidewire insertion is also suggested during catheter removal. Skipping potentially hazardous procedural steps could increase primary PCI safety under the SC-PCI method.

In this study, there was a negative correlation between eGFR and D2B time. In other words, D2B time was prolonged in chronic kidney disease (CKD) patients. In detail, both door-to-sheath and sheath-to-balloon time were prolonged. This is presumably due to the fact that it takes longer to diagnose CKD patients because their symptoms are more non-specific and the procedure is more complicated due to coronary calcification and aortic tortuosity.

Radial access is recommended since it can reduce mortality and bleeding complications.⁷ In this study, radial access was used in a total of 85% (91% in SC-PCI vs. 83% in conventional groups) of cases, and 11 institutes (79%) had a radial access rate of >80%. Since this study was performed under conditions with a high rate of radial access, it indicates that the SC-PCI method may become one of the primary PCI styles in the future.

This study had several limitations. It used non-randomized, relatively limited, retrospective data from 14 hospitals. Potential biases cannot be ignored. The primary endpoints were the D2B time and radiation dose, but not clinical endpoints. A lower mortality rate may result from the reduced D2B time, which could be a surrogate marker for mortality in patients with STEMI. However, it cannot be analyzed since it lacks statistical power in this study. Further prospective randomized controlled trials with longer follow-up durations are required.

5 | CONCLUSION

The primary PCI with the SC-PCI method demonstrated a shorter D2B time and a lower radiation dose for patients with STEMI via radial access.

6 | IMPACT ON DAILY PRACTICE

SC-PCI method could be reduce the ischemic time in STEMI

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CONFLICT OF INTEREST

Sho Torii received institutional research support from Boston Scientific Japan, honoraria from Boston Scientific Japan, Abbott vascular Japan, and Medtronic Japan. Yuji Ikari received a research grant from Boston Scientific and an inventor of the Ikari curve. The other authors have no conflicting interests to disclose.

DATA AVAILABILITY STATEMENT

Since the extent of patient consent is the conduct of this study, it is difficult to disclose the data.

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