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ORIGINAL ARTICLE

Real-world use of intravascular ultrasound in Japan: a report from contemporary multicenter PCI registry

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Abstract
Clinical trial data suggest that intravascular ultrasound (IVUS) may improve clinical outcomes after PCI. The aim of this study was to investigate the safety of IVUS in its broader use for percutaneous coronary intervention (PCI). A total of 11,570 consecutive patients undergoing PCI between 2008 and 2014 in Japan were analyzed. Associations between IVUS use, PCI-related complications were assessed with logistic regression and propensity score matching analyses. Subgroup analysis was performed in elective PCI patients. IVUS was used in 84.8% of patients ($N = 9814$; IVUS group); its use was almost universal in elective PCIs (90.8 vs. 81.7% in urgent/emergent PCIs, $P < 0.001$). The non-IVUS group were older (68.7 ± 11.4 vs. 67.9 ± 10.8 years, $P = 0.004$), with more comorbid conditions. The non-IVUS group had smaller stent lumens (2.97 ± 0.42 mm vs. 3.09 ± 0.45 mm, $P < 0.001$) and a higher proportion of plain old balloon angioplasty. After matching, a lower rate of flow-impairing coronary dissections was observed in the IVUS group, although this was limited only to elective PCIs, not among urgent/emergent PCIs (non-IVUS vs. IVUS; 2.7% vs. 1.0%, $P = 0.018$, 0.7% vs. 1.2%, $P = 0.32$, respectively). With a multivariate logistic regression analysis, IVUS use remained an independent predictor to reduce risk of flow impairing severe coronary dissection among elective PCIs (odds ratio 0.38, 95% confidence interval 0.22–0.66: $P = 0.001$). In this Japanese PCI registry, IVUS was used extensively during the study period, particularly in elective cases. Using IVUS was associated with a lower event rate of flow-impairing coronary dissections that was limited to elective PCIs, not among urgent/emergent PCIs, without increasing PCI-related complications.

Keywords Intravascular ultrasound · Percutaneous coronary intervention · Coronary dissection · Fluoroscopy time

Abbreviations

IVUS	Intravascular ultrasound
PCI	Percutaneous coronary intervention
MI	Myocardial infarction
JCD-KiCS	Japanese Cardiovascular Database-Keio inter-hospital Cardiovascular Studies
NCDR	National Cardiovascular Data Registry
PS	Propensity Score

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Introduction

Intravascular ultrasound (IVUS) guided percutaneous coronary intervention (PCI) provides detailed information on coronary lesion morphology and measurements. IVUS also aids in the evaluation of stent expansion adequacy and in the prevention of post-procedural stent thrombosis and restenosis [1–3]. Over the last few years, increasing data suggest that IVUS guidance provides additional benefits in long-term outcomes including death and myocardial infarction (MI) after PCI [4–8]. However, the implementation of IVUS varies by region and practice pattern. Furthermore, concerns remain in the broader use of IVUS in Western countries, since using IVUS can prolong overall procedure time and may increase intravascular complications [9]. The current indication of IVUS in the United States professional guidelines is limited to class IIb for its use during coronary stent implantation [10], and its real-world use is largely limited to evaluation of left main trunk lesions [11]. In contrast, IVUS has been used more frequently in East Asian countries including Japan [12]; its use is covered by national insurance, and PCI operators opt to evaluate lesion characteristics and stent apposition before and after interventions. There are also expert consensus statements that recommend the use of IVUS to lower rates of clinical events [13].

To date, no large-scale all-comers observational studies have investigated the safety of IVUS guidance under extensive use. In the present study, the aim was to evaluate the association between its use and PCI procedure-related complications for all patients, including elective patients. Demonstrating the safety of IVUS could support more global use of IVUS to improve PCI patients' outcomes. Particular attention was paid to the elective cases, as they more commonly use IVUS, and its use for acute coronary syndrome may not always be practical [14, 15].

Methods

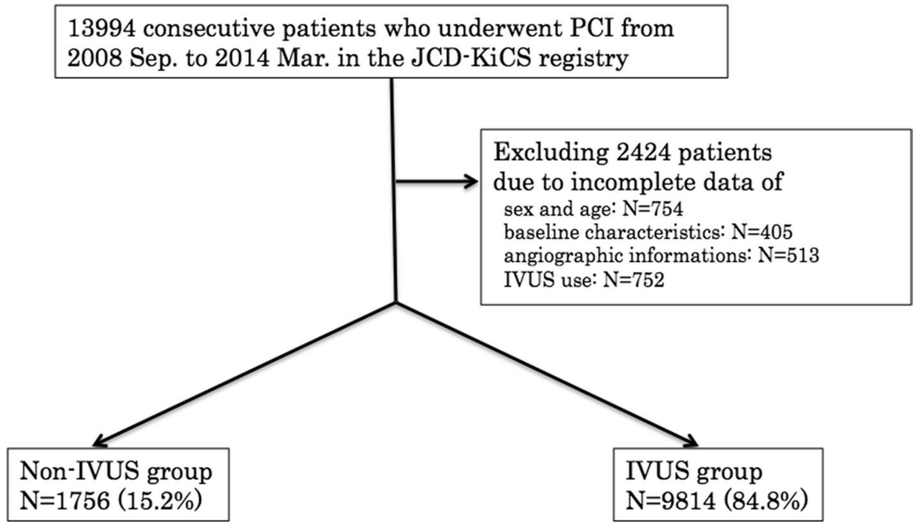
The Japanese Cardiovascular Database-Keio inter-hospital Cardiovascular Studies (JCD-KiCS) is an ongoing, multicenter prospective registry designed to collect clinical data on consecutive PCI patients. The JCD-KiCS started enrolling patients in September 2008, and participating hospitals collect patient data into an internet-based database system created by trained clinical research coordinators. Data from PCI procedures using any commercially available coronary devices are collected, including cases of failure, and consistency is routinely checked by the hospital catheterization reporting system. Quality assurance of the data is achieved through automatic system validation and reporting of data completeness, and education of the dedicated clinical research coordinators; the coordinators meet annually for their training. On-site auditing by the senior study coordinator (I. U.), along with the investigators (S. K. and H. M.) ensured proper registration at each site.

From September 2008 to March 2014, consecutive PCI patients from 14 hospitals in Kanto, Japan (Tokyo, Tochigi, Saitama, Chiba, and Kanagawa Prefectures) were registered. The database included patients with all acute coronary syndrome subtypes and elective PCIs. Data pertaining to approximately 150 variables are collected. The decision to perform PCI is made based on the attending physician's clinical assessments; the study does not mandate specific interventional or surgical techniques, such as vascular access, or use of a specific stent or closure device, or IVUS. The majority of the clinical variables in the JCD-KiCS were defined according to the National Cardiovascular Data Registry (NCDR), sponsored by the American College of Cardiology, to conduct comparative research and determine the factors that lead to disparities in PCI management [16, 17].

Before the launch of the JCD-KiCS, information on the objective of the present study, its social significance, and an abstract was provided for clinical trial registration to the University Hospital Medical Information Network (UMIN000004736). The JCD-KiCS Steering Committee was responsible for overall study guidance, including the study protocol, data analysis, and interpretation of the results. The study protocol was approved by the institutional review boards at each site and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each subject before the study.

In the present study, 11,570 consecutive PCI patients from September 2008 to March 2014 in 14 Japanese hospitals participating in the JCD-KiCS [18, 19] were included. The patients were divided into two groups, an IVUS group and a non-IVUS group, and the baseline characteristics and in-hospital mortality and complications after PCI were assessed (Fig. 1). In addition, fluoroscopy times ($N = 10{,}615$, 91.7%) were compared when the documentation was available in the catheterization report. The study endpoints included in-hospital mortality, heart failure, cardiogenic shock, and other complications. The safety profile of the PCI, including post-procedural complication rate (such as coronary artery dissection), was evaluated in the subgroup of 5936 patients with elective PCI (elective PCI group) and 5634 patients with urgent/emergent PCI. A composite endpoint for total complications was defined as occurrence of any of the following in-hospital events: coronary dissection, coronary perforation, post-procedural MI, new-onset cardiogenic shock, new-onset heart failure, cerebral bleeding or stroke, or any bleeding complication. Coronary dissection was defined as impairment of coronary flow causing

Fig. 1 Patients flow chart



ischemia irrespective of balloon pre-dilatation or post stent implantation in accordance with NCDR (Types C–F) [20]. Post-procedural MI was defined as the new occurrence of a biomarker positive MI after PCI. At least one determination of biomarkers obtained no sooner than 6 h after PCI, and preferably within 6–24 h post-PCI, was used. In addition, *Q* waves with absent, incomplete, or inconclusive biomarkers were considered evidence of MI [21]. Bleeding complications were defined as those requiring transfusion, prolonging hospital stay, and/or causing a decrease in hemoglobin of > 3.0 g/dl [22]. Further, bleeding complications were subdivided into puncture-site bleeding (external bleeding, or a hematoma > 10 cm for femoral, > 5 cm for brachial, or > 2 cm for radial access), retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or other bleeding. This bleeding definition is also consistent with Bleeding Academic Research Consortium grade 3A–C [23]. The definition of these complications was consistent with the NCDR CathPCI registry, and any additional data elements and definitions can be found at their web site (https://www.ncdr.com/webncdr/cathpci/).

Statistics

Continuous variables are expressed as means and standard deviations, and categorical variables are expressed as percentages. Continuous variables were compared using the Student's *t* test, and differences between categorical variables were examined using a χ^2 test. Univariate logistic regression analysis was performed, and factors with a *P* value < 0.25 were included in the multivariate analysis. A multivariate logistic regression analysis was performed to determine the independent predictors for coronary dissection for elective PCIs. Because IVUS use was non-random, a 1:1 matched analysis was performed, based on estimated propensity score (PS) for patients with or without use of IVUS. For PS matching, the model covariates included factors that could affect the operator's decision to use IVUS: sex, previous MI, previous heart failure, diabetes mellitus, dialysis, cerebrovascular disease, peripheral artery disease, chronic lung disease, hypertension, smoking, dyslipidemia, previous PCI, previous coronary bypass, congestive heart failure at admission, femoral artery approach, age > 80, intra-aortic balloon pump insertion, 3-vessels disease, bifurcation, type C lesion and proximal lesion for all patients, elective PCI group, and urgent/emergent PCI group, cardiogenic shock at admission, cardiopulmonary arrest at admission, ST-elevation MI, non-ST elevation MI, and unstable angina for all patients, and urgent/emergent PCI group, and interventions including left main and chronic total occlusion for the elective PCI group. The PS was developed using a logistic regression conditioned on these covariates. A 1:1 match was performed using a nearest neighbor match within a caliper of 1/5 of the standard deviation of the propensity model without replacement for elective patients (caliper = 0.01), however, the caliper was set to 0.001 for all patients and in patients with urgent/emergent PCI to create a stricter match [24]. All statistical calculations and analyses were performed using SPSS version 22 (SPSS, Chicago, IL, USA), and *P* values < 0.05 were considered statistically significant.

Results

Overall, IVUS was used in 9814 patients (84.8%) during the study period, with the percentage of IVUS use consistently being more than 80%. IVUS was used extensively in elective PCIs (90.8 vs. 81.7% in urgent/emergent PCIs,

Table 1 Baseline characteristics of all patients before and after propensity score matched analysis

	All patients			Propensity score matched patients		
	Non-IVUS group $n = 1756$ (%)	IVUS group $n = 9814$ (%)	P value	Non-IVUS group $n = 1591$ (%)	IVUS group $n = 1591$ (%)	P value
Female	428 (24.4%)	1951 (19.9%)	< 0.001	358 (22.5%)	365 (22.9%)	0.77
Previous MI	370 (21.1%)	2456 (25.0%)	< 0.001	338 (21.2%)	380 (23.9%)	0.075
Previous heart failure	156 (8.9%)	866 (8.8%)	0.935	131 (8.2%)	169 (10.6%)	0.021
Diabetes mellitus	737 (42.0%)	4137 (42.2%)	0.886	660 (41.5%)	688 (43.2%)	0.32
Diabetes mellitus with insulin	142 (8.1%)	820 (8.4%)	0.707	128 (8.0%)	146 (9.2%)	0.26
Dialysis	100 (5.7%)	421 (4.3%)	0.009	82 (5.2%)	98 (6.2%)	0.22
Cerebrovascular disease	163 (9.3%)	873 (8.9%)	0.601	138 (8.7%)	165 (10.4%)	0.10
Peripheral artery disease	125 (7.1%)	826 (8.4%)	0.068	111 (7.0%)	129 (8.1%)	0.23
Chronic lung disease	43 (2.4%)	311 (3.2%)	0.107	41 (2.6%)	52 (3.3%)	0.25
Hypertension	1337 (76.1%)	7425 (75.7%)	0.665	1206 (75.8%)	1193 (75.0%)	0.59
Smoking	607 (34.6%)	3357 (34.2%)	0.769	562 (35.3%)	407 (25.6%)	< 0.001
Dyslipidemia	1146 (65.3%)	6568 (66.9%)	0.173	1052 (66.1%)	1019 (64.0%)	0.22
Previous PCI	565 (32.2%)	3701 (37.7%)	< 0.001	525 (33.0%)	518 (32.6%)	0.79
Previous coronary bypass	108 (6.2%)	517 (5.3%)	0.132	89 (5.6%)	124 (7.8%)	0.013
Heart failure on admission	260 (14.8%)	1191 (12.1%)	0.002	195 (12.3%)	232 (14.6%)	0.054
Cardiogenic shock on admission	122 (6.9%)	339 (3.5%)	< 0.001	67 (4.2%)	65 (4.1%)	0.86
Cardiopulmonary arrest on admission	80 (4.6%)	192 (2.0%)	< 0.001	38 (2.4%)	42 (2.6%)	0.65
Puncture site			< 0.001			0.14
Femoral artery approach	1319 (75.1%)	5996 (61.1%)		1159 (72.8%)	1138 (71.5%)	
Radial artery approach	402 (22.9%)	3620 (36.9%)		403 (25.3%)	435 (27.3%)	
Brachial artery approach	30 (1.7%)	198 (2.0%)		29 (1.8%)	18 (1.1%)	
Intra-aortic balloon pump	169 (9.6%)	682 (6.9%)	< 0.001	125 (7.9%)	129 (8.1%)	0.79
Age > 80	310 (17.7%)	1323 (13.5%)	< 0.001	234 (14.7%)	232 (14.6%)	0.92
Age	68.7 ± 11.4	67.9 ± 10.8	0.004	68.1 ± 11.1	68.4 ± 10.8	0.48
PCI indications			< 0.001			0.97
ST-elevation MI	617 (35.1%)	2264 (23.1%)		513 (32.2%)	522 (32.8%)	
Non ST-elevation MI	141 (8.0%)	713 (7.3%)		120 (7.5%)	115 (7.2%)	
Unstable angina	271 (15.4%)	1628 (16.6%)		253 (15.9%)	247 (15.5%)	
Elective PCIs	727 (41.4%)	5209 (53.1%)		705 (44.3%)	707 (44.4%)	
Left main trunk stenosis	76 (4.3%)	407 (4.1%)	0.727	67 (4.2%)	49 (3.1%)	0.089
Intervention including left main trunk	41 (2.3%)	392 (4.0%)	0.001	36 (2.3%)	44 (2.8%)	0.37
Intervention including proximal lesion	681 (38.8%)	4477 (45.6%)	< 0.001	625 (39.3%)	618 (38.8%)	0.80
Vessels with disease			0.092			0.88
1 vessel disease	742 (42.3%)	4393 (44.8%)		696 (43.7%)	697 (43.8%)	
2 vessels disease	608 (34.6%)	3338 (34.0%)		559 (35.1%)	548 (34.4%)	
3 vessels disease	406 (23.1%)	2083 (21.2%)		336 (21.1%)	346 (21.7%)	
Type C lesion	487 (27.7%)	3167 (32.2%)	< 0.001	447 (28.1%)	456 (28.7%)	0.72
Bifurcation lesion	338 (19.2%)	3096 (31.5%)	< 0.001	328 (20.6%)	324 (20.4%)	0.86
Chronic total occlusion lesion	119 (6.8%)	603 (6.1%)	0.313	107 (6.7%)	99 (6.2%)	0.56
Balloon angioplasty	295 (16.8%)	826 (8.4%)	< 0.001	248 (15.6%)	160 (10.1%)	< 0.001
Bare metal stent	370 (21.1%)	1692 (17.2%)	< 0.001	322 (20.2%)	338 (21.2%)	0.48
Drug eluting stent	1044 (59.5%)	7188 (73.2%)	< 0.001	978 (61.5%)	1066 (67.0%)	0.001
Rotablator	30 (1.7%)	302 (3.1%)	0.002	30 (1.9%)	46 (2.9%)	0.063

IVUS intravascular ultrasound, *MI* myocardial infarction, *PCI* percutaneous coronary intervention

$P < 0.001$). Baseline characteristics in the two groups (non-IVUS vs. IVUS group) were quite different (Table 1).

The non-IVUS group was older, with a higher proportion of females, comorbidities, and severe presentation status at admission in comparison to the IVUS group. However, the non-IVUS group had fewer complex lesions in comparison to the IVUS group (type C lesion: 27.7% vs. 32.2%, $P < 0.001$; bifurcation lesion: 19.2% vs. 31.5%, $P < 0.001$) (Table 1). Furthermore, the non-IVUS group had smaller stent lumens (2.97 ± 0.42 mm vs. 3.09 ± 0.45 mm, $P < 0.001$), a higher proportion of plain old balloon angioplasty (not implanting stents), and fewer proximal lesions. Fluorescent times were similar between the two groups (non-IVUS vs. IVUS; 28.7 ± 25.2 min, 29.3 ± 21.1 min, $P = 0.376$). Unadjusted in-hospital mortality and complication rates are shown in Table 2. In-hospital mortality and complication rates including bleeding complications were consistently lower in the IVUS group compared to the non-IVUS group (Table 2).

A multivariate logistic regression analysis showed that IVUS use was not associated with a reduced risk of flow-impairing severe coronary dissections (odds ratio [OR] 0.75, 95% confidence interval [CI] 0.47–1.19, $P = 0.22$). However, both gender (female) and elective PCI were associated with an increased risk of flow-impairing severe coronary dissections (OR 2.17, 95% CI 1.47–3.21, $P < 0.001$; OR 1.61, 95% CI 1.08–2.43, $P = 0.019$, respectively).

In the subgroup of elective PCI patients (Table 3: 5936 patients [51.3%]), IVUS was almost universally implemented (90.8%). In this subgroup, baseline characteristics were similar, with the exceptions of lower proportions of female, diabetes mellitus, and dialysis in the IVUS group (Table 3). The non-IVUS group had higher rates of in-hospital mortality, post-PCI procedural complications including coronary dissection and perforation (Table 4). In this subgroup, fluoroscopy times were significantly different in the two groups (non-IVUS vs. IVUS; 33.3 ± 30.7 min vs. 30.8 ± 23.1 min, $P = 0.041$). With a multivariate logistic regression analysis, IVUS use was associated with reduced risk of flow impairing severe coronary dissection (OR 0.38, 95% CI 0.22–0.66: $P = 0.001$) and female gender was associated with increased risk of flow impairing severe coronary dissection (OR 1.81, 95% CI 1.07–3.05: $P = 0.026$).

In the subgroup of urgent/emergent PCI patients (Table 5: 5634 patients [48.7%]), IVUS was less universally implemented (81.7%). In this subgroup, the non-IVUS group had older patients, with a higher proportion of females, those on dialysis, and those with a severe presentation status at admission in comparison to the IVUS group (Table 5). The non-IVUS group had a higher proportion of plain old balloon

Table 2 In-hospital mortality and complications of all patients before and after propensity score matched analysis

	All patients			Propensity score matched patients		
	Non-IVUS group $n = 1756$ (%)	IVUS group $n = 9814$ (%)	P value	Non-IVUS group $n = 1591$ (%)	IVUS group $n = 1591$ (%)	P value
All complications	209 (11.9)	914 (9.3)	0.001	170 (10.7)	170 (10.7)	1.00
Coronary dissection	26 (1.5)	105 (1.1)	0.134	25 (1.6)	20 (1.3)	0.45
Coronary perforation	19 (1.1)	78 (0.8)	0.224	17 (1.1)	15 (0.9)	0.72
Myocardial infarction	28 (1.6)	180 (1.8)	0.486	25 (1.6)	28 (1.8)	0.68
Cardiogenic shock	58 (3.3)	186 (1.9)	< 0.001	49 (3.1)	36 (2.3)	0.15
Heart failure	30 (1.7)	184 (1.9)	0.634	28 (1.8)	32 (2.0)	0.60
Cerebral infarction	5 (0.3)	35 (0.4)	0.636	3 (0.2)	8 (0.5)	0.13
Intracranial hemorrhage	3 (0.2)	4 (0.04)	0.041	1 (0.06)	2 (0.1)	0.56
Cardiac tamponade	9 (0.5)	28 (0.3)	0.120	6 (0.4)	6 (0.4)	1.00
Hemodialysis	19 (1.1)	100 (1.0)	0.809	13 (0.8)	9 (0.6)	0.39
Transfusion	61 (3.5)	224 (2.3)	0.003	41 (2.6)	40 (2.5)	0.91
Bleeding all	66 (3.8)	275 (2.8)	0.029	50 (3.1)	48 (3.0)	0.84
Puncture site bleeding	13 (0.7)	86 (0.9)	0.569	12 (0.8)	14 (0.9)	0.69
Hematoma	13 (0.7)	74 (0.7)	0.951	11 (0.7)	15 (0.9)	0.43
Peritoneal bleeding	3 (0.2)	12 (0.1)	0.602	2 (0.1)	2 (0.1)	1.00
Gastrointestinal bleeding	9 (0.5)	34 (0.3)	0.292	5 (0.3)	7 (0.4)	0.56
Genitourinary bleeding	1 (0.06)	11 (0.1)	0.509	1 (0.06)	2 (0.1)	0.56
Other bleeding	32 (1.8)	99 (1.0)	0.003	24 (1.5)	14 (0.9)	0.10
In-hospital mortality	76 (4.3)	182 (1.9)	< 0.001	56 (3.5)	13 (0.8)	0.013

IVUS intravascular ultrasound

Table 3 Baseline characteristics of elective patients before and after propensity score matched analysis

	Elective patients			Propensity score matched patients		
	Non-IVUS group *n* = 727 (%)	IVUS group *n* = 5209 (%)	*P* value	Non-IVUS group *n* = 714 (%)	IVUS group *n* = 714 (%)	*P* value
Female	164 (22.6%)	982 (18.9%)	0.018	155 (21.7%)	177 (24.8%)	0.168
Previous MI	231 (31.9%)	1745 (33.5%)	0.355	228 (31.9%)	238 (33.3%)	0.572
Previous heart failure	89 (12.3%)	596 (11.4%)	0.527	84 (11.8%)	114 (16.0%)	0.022
Diabetes mellitus	375 (51.8%)	2433 (46.7%)	0.014	367 (51.4%)	390 (54.6%)	0.223
Diabetes mellitus with insulin	81 (11.2%)	528 (10.1%)	0.403	77 (10.8%)	108 (15.1%)	0.015
Dialysis	49 (6.8%)	258 (5.0%)	0.042	44 (6.2%)	66 (9.2%)	0.029
Cerebrovascular disease	70 (9.7%)	481 (9.2%)	0.731	67 (9.4%)	85 (11.9%)	0.122
Peripheral artery disease	84 (11.6%)	544 (10.4%)	0.454	77 (10.8%)	90 (12.6%)	0.284
Chronic lung disease	17 (2.3%)	171 (3.3%)	0.173	17 (2.4%)	21 (2.9%)	0.511
Hypertension	587 (81.1%)	4131 (79.3%)	0.369	576 (80.7%)	547 (76.6%)	0.061
Smoking	211 (29.1%)	1504 (28.9%)	0.933	209 (29.3%)	200 (28.0%)	0.598
Dyslipidemia	536 (74.0%)	3707 (71.2%)	0.154	527 (73.8%)	501 (70.2%)	0.125
Previous PCI	388 (53.6%)	2798 (53.7%)	0.861	381 (53.4%)	387 (54.2%)	0.750
Previous coronary bypass	63 (8.7%)	362 (6.9%)	0.093	59 (8.3%)	91 (12.7%)	0.006
Heart failure on admission	74 (10.2%)	473 (9.1%)	0.337	72 (10.1%)	112 (15.7%)	0.002
Puncture site			< 0.001			0.501
Femoral artery approach	465 (64.2%)	2761 (53.0%)		452 (63.3%)	463 (64.8%)	
Radial artery approach	244 (33.7%)	2321 (44.6%)		244 (34.2%)	236 (33.1%)	
Brachial artery approach	18 (2.5%)	127 (2.4%)		18 (2.5%)	15 (2.1%)	
Intra-aortic balloon pump	10 (1.4%)	81 (1.6%)	0.712	8 (1.1%)	14 (2.0%)	0.197
Age > 80	97 (13.4%)	593 (11.4%)	0.123	90 (12.6%)	102 (14.3%)	0.352
Age	69.0 ± 9.9	68.3 ± 9.8	0.113	68.8 ± 9.8	68.8 ± 10.2	0.960
Left main trunk stenosis	25 (3.5%)	228 (4.4%)	0.241	25 (3.5%)	24 (3.4%)	0.884
Intervention including left main trunk	9 (1.2%)	238 (4.6%)	< 0.001	9 (1.3%)	10 (1.4%)	0.817
Intervention including proximal lesion	236 (32.4%)	2369 (45.5%)	< 0.001	236 (33.1%)	246 (34.5%)	0.501
Vessels with disease			0.457			0.046
1 vessel disease	312 (42.9%)	2290 (44.0%)		308 (43.1%)	282 (39.5%)	
2 vessels disease	271 (37.4%)	1823 (35.0%)		263 (36.8%)	250 (35.0%)	
3 vessels disease	144 (19.9%)	1096 (21.0%)		143 (20.0%)	182 (25.5%)	
Type C lesion	226 (31.2%)	1877 (36.0%)	0.009	222 (31.1%)	264 (37.0%)	0.019
Bifurcation lesion	140 (19.3%)	1727 (33.2%)	< 0.001	140 (19.6%)	149 (20.9%)	0.553
Chronic total occlusion lesion	89 (12.3%)	493 (9.5%)	0.018	85 (11.9%)	103 (14.4%)	0.159
Balloon angioplasty	144 (19.9%)	445 (8.5%)	< 0.001	140 (19.6%)	84 (11.8%)	< 0.001
Bare metal stent	48 (6.6%)	454 (8.7%)	0.055	48 (6.7%)	45 (6.3%)	0.748
Drug eluting stent	528 (72.9%)	4303 (82.6%)	< 0.001	521 (73.0%)	583 (81.7%)	< 0.001
Rotablator	23 (3.2%)	245 (4.7%)	0.061	22 (3.1%)	32 (4.5%)	0.165

IVUS intravascular ultrasound, *MI* myocardial infarction, *PCI* percutaneous coronary intervention

angioplasty, and a lower proportion of bifurcation lesions. The non-IVUS group had a higher rate of in-hospital mortality; however, PCI-related complications including coronary dissection were not significantly different between groups (Table 6). In this subgroup, fluoroscopy times were significantly different between the two groups (non-IVUS vs. IVUS: 25.4 ± 19.7 min vs. 27.6 ± 18.3 min, $P = 0.041$).

After PS matching analysis, post-PCI procedural complications were almost similar; but notably, in the IVUS group, a lower rate of flow-impairing coronary dissections was observed, although this was limited only to patients with elective PCI, not among urgent/emergent PCIs (non-IVUS vs. IVUS; 2.7% vs. 1.0%, $P = 0.018$, 0.7% vs. 1.2%, $P = 0.32$, respectively) (Tables 1, 2, 3, 4, 5, 6).

Table 4 In-hospital mortality and complications of elective patients before and after propensity score matched analysis

	Elective patients			Propensity score matched patients		
	Non-IVUS group $n=727$ (%)	IVUS group $n=5209$ (%)	*P* value	Non-IVUS group $n=714$ (%)	IVUS group $n=714$ (%)	*P* value
All complications	58 (8.0)	295 (5.7)	0.013	54 (7.6)	55 (7.7)	0.921
Coronary Dissection	19 (2.6)	53 (1.0)	< 0.001	19 (2.7)	7 (1.0)	0.018
Coronary Perforation	15 (2.1)	45 (0.9)	0.002	13 (1.8)	9 (1.3)	0.390
Myocardial infarction	15 (2.1)	97 (1.8)	0.709	15 (2.1)	19 (2.7)	0.487
Cardiogenic shock	11 (1.5)	33 (0.6)	0.010	10 (1.4)	8 (1.1)	0.635
Heart failure	1 (0.1)	20 (0.4)	0.295	1 (0.1)	6 (1.1)	0.563
Cerebral infarction	0 (0)	8 (0.2)	0.29	10 (1.4)	2 (0.1)	0.157
Intracranial hemorrhage	1 (0.1)	0 (0)	0.007	0 (0)	0 (0)	
Cardiac tamponade	3 (0.4)	5 (0.1)	0.029	2 (0.3)	1 (0.1)	0.563
Hemodialysis	1 (0.1)	9 (0.2)	0.828	1 (0.1)	3 (0.4)	0.317
Transfusion	11 (1.5)	54 (1.0)	0.248	8 (1.1)	13 (1.8)	0.272
Bleeding all	14 (1.9)	81 (1.6)	0.456	12 (1.7)	12 (1.7)	1.000
Puncture site bleeding	2 (0.3)	34 (0.7)	0.219	2 (0.3)	5 (0.7)	0.256
Hematoma	5 (0.7)	38 (0.7)	0.901	5 (0.7)	5 (0.7)	1.000
Peritoneal bleeding	1 (0.1)	6 (0.1)	0.869	1 (0.1)	1 (0.1)	1.000
Gastrointestinal bleeding	1 (0.1)	4 (0.1)	0.597	0 (0)	0 (0)	
Genitourinary bleeding	0 (0)	0 (0)		0 (0)	0 (0)	
Other bleeding	4 (0.6)	14 (0.3)	0.196	33 (0.4)	33 (0.4)	1.000
In-hospital mortality	5 (0.7)	13 (0.2)	0.044	4 (0.6)	2 (0.3)	0.413

IVUS intravascular ultrasound

Discussion

The present data demonstrated the safety of IVUS use in the real-world PCI registry. Data from this registry showed that the use of IVUS was consistently high (> 80%), particularly in elective PCIs (> 90%). In the universal use of IVUS, the non-IVUS group had smaller stent lumens and a higher proportion of plain old balloon angioplasty. The use of IVUS was associated with a lower event rate of flow-impairing coronary dissections, limited to elective PCIs, not among urgent/emergent PCIs, without increasing PCI-related complications.

The use of IVUS guidance in this registry was much higher compared to previous studies, including the registry data from Korea (43–55%) [9, 25, 26] the United States (US)/the Netherlands (42%) [27], the US alone (42.2%) [14], and Italy (5.2%) [28]. Japanese PCI operators tend to use IVUS more often and this has been a trend for more than a decade [12]. This is supported by recent meta-analyses that showed reduced incidence of death, MI, stent thrombosis [5, 8]. And target lesion revascularization [8] among IVUS users compared to non-users. Higher rates of IVUS use in Japan might be a reason for reduced rates of mortality and stent thrombosis compared to European countries [12]. More optimal stent deployment, with a larger acute lumen gain, adequate stent apposition, and full lesion coverage with IVUS-guidance could all contribute to the improved outcomes. In accordance with this evidence, IVUS use could be supported since extensive use of IVUS was investigated, revealing lower complication rates. PCI registry data are heterogeneous populations in real-world practice. Demonstrating the safety of IVUS with all-comers registry data might promote IVUS use globally to improve PCI patients' outcomes.

Although another study was concerned about routine IVUS use increasing the risk of peri-procedural MI [9], our study's data assessed similar peri-procedural MI rates in the non-IVUS and IVUS group even after PS matching analysis. It was also analyzed whether IVUS would have protective effects for procedural complications in the elective PCI group. We revealed IVUS use was associated with reduced risk of flow impairing severe coronary dissection and female gender was associated with increased risk of coronary dissection. Previous study investigated proximal stent edge dissection was more common in female than in male [29], and stent oversizing and residual plaque were predictors for edge dissections [29, 30]. We might suspect IVUS could have a role to measure diameters of reference vessels correctly and avoid implanting oversized stents on the residual plaque. Reduction of the incidence of coronary dissection was crucial to reduce the event of stent thrombosis [31].

Table 5 Baseline characteristics of patients with urgent/emergent patients before and after propensity score matched analysis

	All patients			Propensity score matched patients		
	Non-IVUS group $n=1029$ (%)	IVUS group $n=4605$ (%)	*P* value	Non-IVUS group $n=810$ (%)	IVUS group $n=810$ (%)	*P* value
Female	264 (25.7%)	969 (21.0%)	0.001	184 (22.7%)	207 (25.6%)	0.18
Previous MI	139 (13.5%)	711 (15.4%)	0.12	98 (12.1%)	132 (16.3%)	0.016
Previous heart failure	67 (6.5%)	270 (5.9%)	0.43	43 (5.3%)	44 (5.4%)	0.91
Diabetes mellitus	362 (35.2%)	1704 (37.0%)	0.27	276 (34.1%)	337 (41.6%)	0.002
Diabetes mellitus with insulin	61 (5.9%)	292 (6.3%)	0.62	45 (5.6%)	62 (7.7%)	0.089
Dialysis	51 (5.0%)	163 (3.5%)	0.032	26 (3.2%)	29 (3.6%)	0.68
Cerebrovascular disease	93 (9.0%)	392 (8.5%)	0.58	57 (7.0%)	52 (6.4%)	0.62
Peripheral artery disease	41 (4.0%)	272 (5.9%)	0.015	32 (4.0%)	36 (4.4%)	0.62
Chronic lung disease	26 (2.5%)	140 (3.0%)	0.38	17 (2.1%)	25 (3.1%)	0.21
Hypertension	750 (72.9%)	3294 (71.5%)	0.38	581 (71.7%)	575 (71.0%)	0.74
Smoking	396 (38.5%)	1853 (40.2%)	0.30	348 (43.0%)	282 (34.8%)	0.001
Dyslipidemia	610 (59.3%)	2860 (62.1%)	0.092	494 (61.0%)	490 (60.5%)	0.84
Previous PCI	177 (17.2%)	903 (19.6%)	0.076	132 (16.3%)	163 (20.1%)	0.046
Previous coronary bypass	45 (4.4%)	155 (3.4%)	0.11	21 (2.6%)	22 (2.7%)	0.88
Heart failure on admission	186 (18.1%)	718 (15.6%)	0.050	106 (13.1%)	134 (16.5%)	0.050
Cardiogenic shock on admission	119 (11.6%)	334 (7.3%)	< 0.001	55 (6.8%)	54 (6.7%)	0.92
Cardiopulmonary arrest on admission	79 (7.7%)	189 (4.1%)	< 0.001	23 (2.8%)	33 (4.1%)	0.17
Puncture site			< 0.001			0.96
Femoral artery approach	854 (83.0%)	3235 (70.2%)		650 (80.2%)	648 (80.0%)	
Radial artery approach	163 (15.8%)	1299 (28.2%)		149 (18.4%)	152 (18.8%)	
Brachial artery approach	12 (1.2%)	71 (1.5%)		11 (1.4%)	10 (1.2%)	
Intra-aortic balloon pump	159 (15.5%)	601 (13.5%)	0.042	107 (13.2%)	100 (12.3%)	0.60
Age > 80	213 (20.7%)	730 (15.9%)	< 0.001	122 (15.1%)	135 (16.7%)	0.38
Age	68.5 ± 12.3	67.3 ± 11.9	0.003	67.0 ± 12.0	67.6 ± 11.7	0.31
PCI indications			< 0.001			0.82
ST-elevation MI	617 (60.0%)	2264 (49.2%)		467 (57.7%)	459 (56.7%)	
Non ST-elevation MI	141 (13.7%)	713 (15.5%)		117 (14.4%)	126 (15.6%)	
Unstable angina	271 (26.3%)	1628 (35.4%)		226 (27.9%)	225 (27.8%)	
Left main trunk stenosis	51 (5.0%)	179 (3.9%)	0.12	30 (3.7%)	25 (3.1%)	0.49
Intervention including left main trunk	32 (3.1%)	154 (3.3%)	0.70	22 (2.7%)	20 (2.5%)	0.76
Intervention including proximal lesion	447 (43.4%)	2125 (46.1%)	0.12	346 (42.7%)	331 (40.9%)	0.45
Vessels with disease			0.011			0.64
1 vessel disease	430 (41.8%)	1203 (26.1%)		357 (44.1%)	376 (46.4%)	
2 vessels disease	337 (32.8%)	1515 (32.9%)		276 (34.1%)	263 (32.5%)	
3 vessels disease	262 (25.5%)	987 (21.4%)		177 (21.9%)	171 (21.1%)	
Type C lesion	261 (25.4%)	1290 (28.0%)	0.085	207 (25.6%)	197 (24.3%)	0.57
Bifurcation lesion	198 (19.2%)	1369 (29.7%)	< 0.001	168 (20.7%)	175 (21.6%)	0.67
Balloon angioplasty	151 (15.0%)	381 (8.3%)	< 0.001	102 (12.6%)	75 (9.3%)	0.032
Bare metal stent	332 (32.3%)	1238 (26.9%)	0.004	256 (31.6%)	218 (26.9%)	0.038
Drug eluting stent	516 (50.1%)	2885 (62.6%)	< 0.001	422 (52.1%)	497 (61.4%)	< 0.001
Rotablator	7 (0.7%)	57 (1.2%)	0.13	5 (0.6%)	13 (1.6%)	0.058

IVUS intravascular ultrasound, *MI* myocardial infarction, *PCI* percutaneous coronary intervention

IVUS was used less frequently for females, those with diabetes mellitus, patients on dialysis, and with plain old balloon angioplasty; IVUS was used more frequently for proximal lesions and larger stents. Avoiding the use of IVUS may be related to decreased coronary vessel size; in general, females and patients with diabetes have smaller coronary vessel diameters [32, 33]. Additionally, in Japan, half of all patients on dialysis have been diagnosed with diabetes [34].

Table 6 In-hospital mortality and complications of urgent/emergent patients before and after propensity score matched analysis

	All patients			Propensity score matched patients		
	Non-IVUS group $n=1029$ (%)	IVUS group $n=4605$ (%)	*P* value	Non-IVUS group $n=810$ (%)	IVUS group $n=810$ (%)	*P* value
All complications	151 (14.7)	619 (13.4)	0.30	96 (11.9)	104 (12.8)	0.55
Coronary dissection	7 (0.7)	52 (1.1)	0.20	6 (0.7)	10 (1.2)	0.32
Coronary perforation	4 (0.4)	33 (0.7)	0.24	3 (0.4)	7 (0.9)	0.21
Myocardial infarction	13 (1.3)	83 (1.8)	0.23	7 (0.9)	11 (1.4)	0.34
Cardiogenic shock	47 (1.6)	153 (3.3)	0.051	29 (3.6)	20 (2.5)	0.19
Heart failure	29 (2.8)	164 (3.6)	0.24	19 (2.3)	35 (4.3)	0.027
Cerebral infarction	5 (0.5)	27 (0.6)	0.70	3 (0.4)	2 (0.2)	0.65
Intracranial hemorrhage	2 (0.2)	4 (0.09)	0.34	1 (0.1)	1 (0.1)	1.00
Cardiac tamponade	6 (0.6)	23 (0.5)	0.74	4 (0.5)	2 (0.2)	0.41
Hemodialysis	18 (1.8)	91 (2.0)	0.63	10 (1.2)	16 (2.0)	0.24
Transfusion	50 (4.9)	170 (3.7)	0.080	28 (3.5)	30 (3.7)	0.79
Bleeding all	52 (5.0)	194 (4.2)	0.23	34 (4.2)	35 (4.3)	0.90
Puncture site bleeding	11 (1.1)	52 (1.1)	0.87	9 (1.1)	9 (1.1)	1.00
Hematoma	8 (0.8)	36 (0.8)	0.99	6 (0.7)	6 (0.7)	1.00
Peritoneal bleeding	2 (0.2)	6 (0.1)	0.62	2 (0.2)	0 (0.0)	0.16
Gastrointestinal bleeding	8 (0.8)	30 (0.7)	0.66	5 (0.6)	7 (0.9)	0.56
Genitourinary bleeding	1 (0.1)	11 (0.2)	0.37	1 (0.1)	3 (0.4)	0.32
Other bleeding	28 (2.7)	85 (1.8)	0.070	17 (2.1)	15 (1.9)	0.72
In-hospital mortality	71 (6.9)	169 (3.7)	<0.001	37 (4.6)	24 (3.0)	0.090

IVUS intravascular ultrasound

Although angiographical reference diameter data were not available, it is suspected that IVUS is used universally in Japan, except in cases presenting with severe conditions and smaller vessels. Owing to the possibility of these selection biases, PS matching analysis was performed. PS matching analysis showed IVUS did not increase post-PCI procedural complications in all patients, elective PCI group, and urgent/emergent PCI group.

Not all hospitals that perform PCI in Japan participate in this registry; however, the registry consists of multiple centers and includes a relatively large number of procedures. Moreover, this registry was compared to the NCDR registry [35]. Patients in this registry were on average older, with higher proportions of diabetes, men, smoking, and more complex lesions, and the NCDR mortality risk model could be applied to this registry. Despite more complex lesions compared to NCDR, similar fluoroscopy time in the non-IVUS and IVUS groups was reported. Therefore, this can be considered one of the most representative Japanese PCI databases, and these results comprise the most complete assessment of current practice patterns throughout Japan and could be applied globally.

There are several limitations of this study. First, this was an observational, not randomized, study. IVUS use during PCI was dependent on the operator's decision. Inherent to the observational study, unmeasured confounders and selection biases may exist even after rigorous statistical adjustment. However, the safety data of IVUS use in actual practice is necessary, since randomized controlled trials may not reflect daily practice [36] and exclude severe cases such as STEMI [37]. Second, IVUS use was favored in hemodynamically stable patients and IVUS was used more frequently in less severe conditions in this registry. Owing to these selection biases, PS matching analysis was performed. Third, individual operator's skills could not be investigated. Skilled operators could potentially gauge optimal vessel size and optimal stent diameter without IVUS, especially for simple lesions, and this may skew results [38]. Fourth, cost-effectiveness of IVUS and its influence on national medical costs owing to its universal use need to be discussed. However, previous data revealed IVUS benefits for major adverse cardiac events and another study showed cost-effectiveness of IVUS due to these benefits [39]. Fifth, detailed IVUS parameters, such as stent under-expansion, malapposition, edge dissection, or plaque shift were not available in this study, and these quantitative assessments and clinical outcomes could not be assessed. Finally, we only evaluated in-hospital outcomes, not long-term outcomes.

In conclusion, in this Japanese contemporary PCI registry, IVUS was used extensively during the study period, particularly in elective cases. The use of IVUS was associated with a lower event rate of flow-impairing severe coronary dissections, limited to elective PCIs, not among urgent/emergent PCIs, without increasing PCI-related complications. These data might support the broader use of IVUS in the real world.

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Compliance with ethical standards

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