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# **Original Research**

# Enhancing Coronary Intervention Outcomes Using Intravascular Ultrasound: Analysis of Long-Term Benefits in a Japanese Multicenter Registry



Toshiki Kuno, MD, PhD<sup>a,b,\*</sup>, Yoshihisa Miyamoto, MD, PhD<sup>c</sup>, Yohei Numasawa, MD, PhD<sup>d</sup>, Ikuko Ueda, PhD<sup>e</sup>, Masahiro Suzuki, MD<sup>f</sup>, Shigetaka Noma, MD<sup>g</sup>, Keichi Fukuda, MD<sup>e</sup>, Shun Kohsaka, MD<sup>e</sup>

<sup>a</sup> Division of Cardiology, Montefiore Medical Center, Albert Einstein College of Medicine, New York, New York; <sup>b</sup> Division of Cardiology, Jacobi Medical Center, Albert Einstein College of Medicine, New York; <sup>c</sup> Division of Nephrology and Endocrinology, The University of Tokyo Hospital, Tokyo, Japan; <sup>d</sup> Department of Cardiology, Japanese Red Cross Ashikaga Hospital, Ashikaga, Japan; <sup>e</sup> Department of Cardiology, Keio University School of Medicine, Tokyo, Japan; <sup>f</sup> Department of Cardiology, National Hospital Organization Saitama Hospital, Wako, Japan; <sup>g</sup> Department of Cardiology, Saiseikai Utsunomiya Hospital, Utsunomiya, Japan

## ABSTRACT

**Background:** Although the use of intravascular ultrasound (IVUS) during percutaneous coronary intervention (PCI) has been shown to improve clinical outcomes, its utilization remains inconsistent. We aimed to assess the association between IVUS-guided PCI and long-term outcomes in Japan, where a high proportion of patients undergo IVUS.

**Methods:** We analyzed 8721 consecutive patients in a multicenter PCI registry. The primary outcome was a composite of death, acute coronary syndrome, and heart failure requiring admission and coronary artery bypass grafting at 2 years after discharge. The secondary outcome was each component of the primary outcome. We used inverse probability-weighted analysis for adjustment. Subgroup analysis was conducted on patients with complex coronary anatomy (eg, those with bifurcation, chronic total occlusion, type C lesion, left main and those who underwent rotational atherectomy).

**Results:** Overall, 83.8% of patients underwent IVUS-guided PCI (mean age,  $68.3 \pm 11.3$  years). After adjustments, the IVUS group had significantly lower rates of death and coronary bypass compared to no IVUS group (hazard ratio [HR], 0.73; 95% CI, 0.55-0.96; and HR, 0.62; 95% CI, 0.39-0.98) at 2-year follow-up, although the primary outcome showed only marginal differences (HR, 0.85; 95% CI, 0.71-1.01). In the subgroup analysis of complex coronary anatomy, the use of IVUS was significantly associated with a reduced risk of the primary outcome (HR, 0.72; 95% CI, 0.55-0.93) as well as death, coronary bypass, and heart failure.

**Conclusions:** IVUS was frequently utilized in our registry and demonstrated potential benefit in reducing mortality and need for coronary bypass surgery, particularly in patients with complex coronary anatomy.

#### Introduction

Intravascular ultrasound (IVUS) guidance in percutaneous coronary intervention (PCI) provides detailed information on coronary lesion morphology, including plaque characteristics and calcification.<sup>1,2</sup> IVUS is known to aid in evaluating coronary dissection and the adequacy of stent expansion, which can aid in preventing postprocedural complications such as stent thrombosis and restensis.<sup>1–3</sup> In the past decade, several landmark randomized trials

and meta-analyses have demonstrated the additional benefits of IVUS-guided PCI in improving long-term outcomes, including reduced risk of death and myocardial infarction after PCI. These benefits are particularly evident in patients with high-risk features, such as acute myocardial infarction, chronic total occlusion, or left main disease.<sup>4–9</sup> However, the implementation of IVUS varies significantly by region and practice patterns.<sup>10</sup> Moreover, the recommendation for IVUS use professional guidelines in the United States has remained unchanged for over a decade, limited to class II

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Abbreviations: ACS, acute coronary syndrome; IVUS, intravascular ultrasound; JCD-KiCS, Japan Cardiovascular Database-Keio Interhospital Cardiovascular Studies; PCI, percutaneous coronary intervention.

Keywords: intravascular ultrasound; percutaneous coronary intervention.

<sup>\*</sup> Corresponding author: tkuno@montefiore.org (T. Kuno).

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#### Figure 1.

Trend of the proportions of IVUS use over the study period. IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention.

for its use during coronary stent implantation.<sup>11,12</sup> While expert consensus statements do recommend IVUS to lower the rates of clinical events,<sup>13,14</sup> real-world use in the US is mostly limited to evaluating left main lesions. Recent data from the US has shown IVUS usage of only 5%, while IVUS is used more frequently in East Asian countries, including Japan, where our previous data from an all-comers PCI registry showed over 80% of IVUS usage.<sup>15–17</sup>

To the best of our knowledge, no large-scale observational studies comprising consecutive all-comer patients have investigated the effectiveness of extensive utilization of IVUS guidance with long-term follow-up. Therefore, the objective of this study was to assess the relationship between IVUS use and long-term outcomes, during its widespread adoption.

#### Methods

## Database

This study was conducted as part of the Japan Cardiovascular Database-Keio Interhospital Cardiovascular Studies (JCD-KiCS) PCI registry, which is a multicenter, prospective registry including data of consecutive patients who underwent PCI since 2008 at 15 institutions within the Tokyo metropolitan area. The details of this registry have been published previously.<sup>18–23</sup> The participating hospitals were instructed to document and register patient data of consecutive hospital visits for PCI using an internet-based data collection system. Registered data were reviewed for completeness and internal consistency.

Quality assurance of the data was achieved through automatic system validation, reporting of data completeness, and education and training of clinical research coordinators who were specifically trained to use the present PCI registry. The senior study coordinator (I.U.) and exclusive on-site auditing by the investigator (S.K.) ensured appropriate registration of each patient. All participants provided written informed consent. Before the launch of the JCD-KiCS registry, information regarding the objective of this registry was provided for clinical trial registration in the University Hospital Medical Information Network of Japan (UMIN000004736). The study protocol was approved by the institutional review board of each participating hospital.

#### Studied patients

Of the 8792 consecutive patients registered between September 2008 and December 2017 with 2-year outcomes, we excluded 58 patients with missing sex information and 13 patients with missing long-term outcomes. The final cohort of our study was 8721 patients, divided by use of IVUS (n = 7308, 83.8%) and no use of IVUS (n = 1413, 16.2%).

#### Definition of outcomes and variables

The clinical variables and outcomes of the JCD-KiCS were aligned with the data of the National Cardiovascular Data Registry CathPCI Registry version 4.1. Acute coronary syndrome (ACS) was defined as ST-segment elevation myocardial infarction, non-ST-segment elevation myocardial infarction, and unstable angina. Stable coronary artery disease was defined as stable angina, previous myocardial infarction, and silent ischemia. The presence of heart failure was defined as left ventricular ejection fraction  $\leq$ 35% or documentation of heart failure by the attending physician, regardless of left ventricular ejection fraction. Multivessel disease was defined as 2 or more major coronary arteries with  $\geq$ 75% stenosis. The estimated glomerular filtration rate was calculated using the Modification of Diet in Renal Disease Equation for Japanese Patients proposed by the Japanese Society of Nephrology.<sup>24-26</sup>

EndEndlationPublicAge, yNo Kity (n - 143)Not's (n - 2008)Age, yNo Kity (n - 143)600 (60.0, 76.00).001Bady and kity (n')100 (73.0, 73.00)60.00 (60.0, 76.00).001Bady and kity (n')100 (73.0, 73.00)60.00 (60.0, 76.00).001Bady and kity (n')100 (73.0, 73.00)60.00 (60.0, 77.00).001Sinding40.003, 73.40).025 (191.0, 77.40).001Sinding40.003, 73.40).025 (191.0, 77.40).001Sinding40.003, 77.40.025 (191.0, 77.40).001Sinding40.003, 77.40.025 (191.0, 77.40).001Sinding100 (75.7).508 (75.0).001Cerebro angular disease119.6.40.021 (8.0, 10).001Chronic lung disease30.2.3.028 (75.0).021Chronic lung disease30.2.3.028 (75.0).021Chronic lung disease30.2.3.021.001Chronic lung disease100 (75.7).508 (75.0).001Chronic lung disease101.0,12.001.001Parket and companisa10.6.2,12.021.001Cardoguinoma yuratic an admission6.6.2,1.001.001Cardoguinoma yuratic an admission.02.6.6,8.001 (8.0,12.001Cardoguinoma yuratic an admission.02.6.6,8.001 (8.0,12.001Cardoguinoma yuratic and admission.02.6.6,8.001 (8.0,12.001Cardoguinoma yuratic admission.02.6.6,8.001 (8.0,12 </th <th colspan="6">Table 1. Baseline characteristics of all patients.</th>	Table 1. Baseline characteristics of all patients.					
Nu Ku S (n = 1413)         NUS (n = 7308)           Age, y         70.00 ( $\beta$ .200, 77.00)         6770 (75.0)         6770 (75.0)         6770 (75.0)         6770 (75.0)         602         6700 ( $\beta$ .200, 77.00)         602         6700 ( $\beta$ .200, 77.00)         602         6700 ( $\beta$ .200, 77.00)         6200 (10.0, 70.0)         602         602         1000 (12.0, 12.0)         1200 (10.0, 12.0)         1235 (12.7, 22.2)         633           Brody mass index, kg/m <sup>2</sup> 2388 (12.3, 32.40)         2558 (12.7, 72.3)         <001         607         670 (10.0, 72.3)         <001         670 (10.0, 72.3)         <001         670 (10.0, 72.3)         <001         670 (10.0, 72.3)         528 (12.7) (72.3)         600 (10.0, 72.3)         528 (12.6, 72.3)         628 (12.7, 72.3)         628 (12		Crude population		P value		
Age, y         70.00 (42.00, 77.00)         49.00 (100, 74.00)         0.017           Nake sex         104 (75.3)         5774 (79.0)         0.02           Body mass index, kg/m <sup>2</sup> 23.80 [21.33, 24.06]         23.95 [21.31, 21.37.0]         <.001           eGR, nL/min/12.3 m <sup>2</sup> 40.06 (46.03, 23.46]         42.28 (107, 74.73]         <.001           sendang         460 (32.3)         245.61 (35.1)         17.7           Previous heat falue         25.61 (35.2)         2003 (28.4)         5.67           Correbowscalcul disase         17.6 (4.0)         42.18 (8.5)         .697           Previous heat falue         25.63 (37.2)         203 (28.4)         .567           Correbowscalcul disase         17.6 (4.0)         42.18 (8.5)         .697           Peripheral artery disase         138 (7.6)         40.04 (8.8)         .188           Chonci Lung disase         32.6 (2.3)         .294         .697           Dispipis         63.64 (8.0)         24.63 (3.1)         .002           Dispipis disase         32.6 (2.3)         .494         .011           Previous PGL         353 (25.0)         .414 (4.7)         .001           Dispipis disase         .63 (4.8)         .246 (3.3)         .261         .262 </th <th></th> <th>No IVUS (n = 1413)</th> <th>IVUS (n = 7308)</th> <th></th>		No IVUS (n = 1413)	IVUS (n = 7308)			
Male sex         1044 (75.3)         577 (70)         .002           Backy mass index, kym <sup>1</sup> 2.88 [13.3 26.6]         22.395 [21.55, 26.2]         .031           Hemoglobin, gifd.         12.20 [10.80, 13.50]         22.395 [21.55, 26.2]         .031           Sinding         4.09 (84.03, 73.40]         22.58 [49.07, 74.73]         .001           Sinding         4.09 (84.03, 73.40]         22.58 [49.07, 74.73]         .002           Sinding         4.09 (82.3)         .001 (84.03, 73.40]         .022           Privous mycotroli Infection         22.61 (84.1)         .017         .017           Privous mycotroli Infection         126 (87.2)         .0203 (84.4)         .021           Datasets mellinus         154 (87.2)         .2033 (84.4)         .046           Centerionascular disease         1070 (75.7)         .540 (73.0)         .579           Opsipidentini         106 (44.9)         .446 (20.0)         .001           Previous PCI         235 (25.0)         144 (20.0)         .001           Previous PCI         235 (25.0)         144 (20.0)         .001           Previous PCI         235 (25.0)         .216 (1.1)         .016           Cardiopulnonany antert on admission         16 (4.8)         .226 (3.1)         .026 </td <td>Age, y</td> <td>70.00 [62.00, 77.00]</td> <td>69.00 [61.00, 76.00]</td> <td>.017</td>	Age, y	70.00 [62.00, 77.00]	69.00 [61.00, 76.00]	.017		
Body mass index, kg/m <sup>3</sup> 23.88 [21.53, 26.66]         23.98 [21.53, 26.66]         23.91 [25.95, 26.22]         .63           Hernoglobin, g/dit,         12.20 [11.12, 13.70]         <.001	Male sex	1064 (75.3)	5774 (79.0)	.002		
Hering John, gril.         12.20 [10.80, 13.50]         12.20 [10.80, 13.50]         12.20 [10.80, 13.50]         4.20 [81.90, 74.73]         <.001	Body mass index, kg/m <sup>2</sup>	23.88 [21.53, 26.06]	23.95 [21.95, 26.22]	.03		
eGFR_nUrmin/173 m <sup>2</sup> 60.96 (46.03, 73.46)         62.86 (49.07, 74.73)	Hemoglobin, g/dL	12.20 [10.80, 13.50]	12.50 [11.12, 13.70]	<.001		
Sinolog         449 (3.2)         25.6 (3.5)         177           Previous processial infraction         260 (18.4)         1181 (16.2)         .042           Previous heart failure         125 (6.8)         570 (7.8)         .202           Diabetes mellitus         556 (37.2)         2803 (8.4)         .557           Cerebrowscular disease         119 (8.4)         .421 (8.5)         .967           Previous groups disease         119 (8.4)         .421 (8.5)         .967           Previous groups disease         100 (7.6)         .430 (7.6)         .977           Dyalpidemia         716 (6.4)         .447 (14.40)         .557           Dyalpidemia         716 (6.4)         .446 (1.6)         .011           Previous corronary phages         .97 (6.9)         .341 (4.7)         .001           Cardiogunchangy approach         .64 (4.3)         .340 (7.4)         .018           Cardiogunchangy approach         .64 (2.7)         .222 (5.1)         .001	eGFR, mL/min/1.73 m <sup>2</sup>	60.96 [46.03, 73.46]	62.58 [49.07, 74.73]	<.001		
Previous invocandial infarction         260 (18.4)         111 (16.2)         0.42           Previous heart infaure         258 (8)         570 (7.8)         202           Diabetes mellina         554 (37.2)         280 (38.4)         567           Centbroxacular diasas         108 (7.6)         462 (8.5)         597           Peripheral atray diasas         108 (7.6)         464 (8.6)         188           Chronic lung diasas         1070 (75.7)         548 (07.50)         579           Diaplardiami         1016 (6.4.9)         464 (14.0)         545           Diapia         64 (4.8)         246 (3.4)         01           Previous Coronary bypass         97 (6.9)         444 (14.0)         001           Previous coronary bypass         97 (6.9)         848 (11.6)         001           Cardiopulmonay arrest on admission         51 (4.3)         228 (3.1)         026           Cardiopulmonay arrest on admission         51 (4.6,1)         101 (1.5)         101           Ferroral atray approach         446 (7.2)         323 (5.1)         404           Right coronary arrest on admission         52 (6.8)         354 (14.6.5)         <001	Smoking	469 (33.2)	2563 (35.1)	.177		
Previous heart failure         125 (8,8)         570 (7,8)         202           Diabetes mellius         554 (39.2)         2803 (36.4)         557           Cerebrowscular disease         119 (8.4)         640 (8.8)         188           Chronic lung disease         32 (2.3)         238 (3.3)         059           Peripheral arrey disease         32 (2.3)         540 (75.0)         557           Displayies         64 (4.9)         446 (4.0)         557           Displayies         64 (4.9)         246 (3.4)         01           Previous coronary bypass         97 (6.9)         341 (4.7)         001           Previous coronary bypass         97 (6.9)         341 (4.7)         002           Previous coronary bypass         97 (6.9)         341 (4.7)         003           Cardiopulnonary arres on admission         64 (2.2)         322 (5.1)         026           Bachal arrey approach         46 (1.1)         110 (1.5)         36 (2.5)         200 (1.5)         200 (1.5)	Previous myocardial infarction	260 (18.4)	1181 (16.2)	.042		
Dates mellina         554 (32.2)         203 (36.4)         557           Cerebrovscul diesse         119 (8.4)         621 (8.5)         947           Peripheral artery disease         108 (7.6)         440 (8.6)         138           Chronic lung disease         32 (2.3)         238 (3.3)         0.59           Hypertension         1070 (75.7)         5480 (75.0)         .579           Dialysis         66 (4.8)         246 (3.4)         .01           Previous coronary bypass         97 (6.9)         314 (4.7)         .001           Heart failure on admission         16 (4.3)         228 (3.1)         .026           Cardiogenic shock on admission         36 (2.5)         128 (1.8)         .056           Cardiogenic shock on admission         36 (2.5)         328 (1.6)         .001           Ferronal artery approach         948 (67.2)         372 (51.1)         .002           Ferronal artery approach         948 (67.2)         372 (51.1)         .001           Ferronal artery approach         948 (67.2)         372 (51.1)         .001           Ferronal artery approach         948 (67.2)         374 (48.5)         .001           Significant Leason	Previous heart failure	125 (8.8)	570 (7.8)	.202		
Carebrowscular disease         119 8.4)         421 8.5)         967           Peripherial artey disease         108 7.6)         420 8.5)         188           Pripherial artey disease         108 7.6)         420 8.8)         188           Pripherial artey disease         1070 (57)         5480 (75.0)         5.79           Dyspitedmia         106 (64.9)         4571 (44.0)         5.45           Dialysis         64 (4.8)         246 (3.4)         0.01           Previous CCI         333 (25.0)         1264 (2.0.0)         <.001	Diabetes mellitus	554 (39.2)	2803 (38.4)	.567		
Perpheral artery disease         108 7.6 /         440 8.9 ///         188           Chronic lung disease         32 (2.3)         238 (3.3)         0.579           Dylajticitumia         1070 75.7)         5480 (75.0)         5.579           Dylajticitumia         916 (4-9)         4540 (75.0)         5.579           Dylajticitumia         916 (4-9)         4540 (75.0)         5.579           Dylajticitumia         916 (4-9)         4540 (75.0)         .001           Previous coronary bypass         97 (6.7)         341 (4.7)         .001           Previous coronary bypass         97 (6.7)         344 (4.0)         .018           Cardiogenic bhock on admission         61 (4.3)         228 (3.1)         .026           Cardiogenic bhock on admission         61 (4.2)         .035 (5.1)         .026           Pencture ste	Cerebrovascular disease	119 (8 4)	621 (8 5)	967		
Interpretation and y datases         12 (2.3)         23 (2.3)         23 (2.3)           Hypertnamion         1070 (57)         5480 (7.50)         5.79           Paylinglemina         16 (64.9)         4671 (44.0)         543           Dialysis         66 (4.8)         244 (3.4)         0.11           Previous CCD         333 (25.0)         1464 (20.0)         <001	Peripheral arteny disease	108 (7.6)	640 (8.8)	188		
Chronic uning Canada	Chronic lung disease	32 (2 3)	238 (3.3)	.100		
Inplantation         100 (32)         440 (33)         4.37           Dialpisition         461 (4.4)         5.45           Dialysis         68 (4.8)         246 (3.4)         .01           Previous COO         333 (25.0)         144 (4.20.0)         <.001	Huppertension	1070 (75 7)	230 (3.3) E490 (7E 0)	.037		
Dyspinolitina         Pro Detrop         Prof (PAD)         Prof	Duelinidomia	014 (44 0)	5460 (7 5.0) 4471 (44 0)	.3/7		
Draysis         00 (H.0)         240 (S.4)         0.01           Previous CPCI         353 (25.0)         144 (4.7)         0.01           Previous coronay bypass         97 (6.7)         341 (4.7)         0.01           Cardiogulmonay arrest on admission         61 (4.3)         228 (3.1)         0.02           Cardiogulmonay arrest on admission         36 (2.5)         128 (1.8)         .056           Cardiogulmonay arrest on admission         36 (2.5)         323 (51.1)         .001           Redial arrey approach         446 (31.6)         3460 (47.4)         .001           Brachial arrey approach         16 (1.1)         110 (1.5)         .001           Significant lesions         .001         .001         .001           Right coronary arrey         802 (56.8)         3541 (48.5)         .001           Left raterior descending arrey         975 (70.4)         5402 (73.9)         .007           Left raterior descending arrey         975 (70.4)         5402 (73.9)         .005           Multivessel disease         332 (58.9)         4199 (57.5)         .336           Culprit lesions	Dishuis	(0, (4, 9))	4671 (04.0)	.545		
Trevious CV         353 (25.0)         1464 (200)         <.001		68 (4.8)	246 (3.4)	.01		
Previous coronary bypass         9/ (6.9)         44 (4.7)         .0.01           Heart failure on admission         19 (13.9)         448 (11.6)         .018           Cardiogunem admission         61 (4.3)         228 (3.1)         .026           Cardiogunemany arrest on admission         36 (2.5)         128 (1.8)         .056           Puncture site         -         <.001	Previous PCI	353 (25.0)	1464 (20.0)	<.001		
Heart failure on admission         199 (13.9)         848 (11.6)         .0.18           Cardiogenic bock on admission         36 (2.5)         228 (3.1)         .0.26           Cardiogenic bock on admission         36 (2.5)         3732 (51.1)         .0.26           Penoral atery approach         948 (67.2)         3732 (51.1)         .0.01           Radial atery approach         16 (1.1)         110 (1.5)         .0.01           Significant lesions	Previous coronary bypass	97 (6.9)	341 (4.7)	.001		
Cardiogunemay arrest on admission         61 (4.3)         228 (3.1)         .026           Cardiogunemay arrest on admission         36 (2.5)         128 (1.8)         .006           Femoral attery approach         446 (31.6)         3400 (47.4)         .001           Brachial attery approach         464 (31.6)         3400 (47.4)         .001           Brachial attery approach         16 (1.1)         110 (1.5)         .001           Significant lesions         .001         .001         .001           Right coronary artery         802 (56.8)         3541 (46.5)         .001           Left anterior descending artery         995 (70.4)         5402 (73.9)         .007           Left circumflex artery         676 (47.8)         3197 (43.7)         .005           Multivessel disease         823 (58.9)         4199 (57.5)         .336           Culpatit lesions	Heart failure on admission	196 (13.9)	848 (11.6)	.018		
Cardiopulmonary areast on admission         36 (2.5)         128 (1.8)         .056           Puncture site         <.001	Cardiogenic shock on admission	61 (4.3)	228 (3.1)	.026		
Puncture site         <.001	Cardiopulmonary arrest on admission	36 (2.5)	128 (1.8)	.056		
Fenoral artery approach         948 (67.2)         3732 (51.1)           Radial artery approach         46 (31.6)         3660 (67.4)           Brachial artery approach         16 (1.1)         110 (1.5)           Significant lesions         "         "           Right coronary artery         802 (56.8)         3541 (48.5)         <.001	Puncture site			<.001		
Racial artery approach         446 (31.6)         3460 (47.4)           Brachial artery approach         16 (1.1)         110 (1.5)           Significant lesions	Femoral artery approach	948 (67.2)	3732 (51.1)			
Brachial artey approach         16 (1.)         110 (1.5)           Significant lesions	Radial artery approach	446 (31.6)	3460 (47.4)			
Significant lesions         802 (56.8)         3541 (48.5)         <.001	Brachial artery approach	16 (1.1)	110 (1.5)			
Right coronary attry         802 (56.8)         3541 (48.5)         <.001           Left main         122 (8.6)         603 (8.3)         .671           Left attreir descending attry         995 (70.4)         5402 (73.9)         .007           Left attreir descending attry         676 (47.8)         3197 (43.7)         .005           Multivessel disease         632 (58.9)         4199 (57.5)         .336           Culpirt lesions	Significant lesions					
Left main         12 (8.6)         603 (8.3)         .671           Left anterior descending atery         995 (70.4)         5402 (73.9)         .007           Left circumflex atery         676 (47.8)         3197 (43.7)         .366           Culpirt lesions	Right coronary artery	802 (56.8)	3541 (48.5)	<.001		
Left anterior descending artery         995 (70.4)         5402 (73.9)         .007           Left circumflex artery         676 (47.8)         3197 (43.7)         .005           Multivessel disease         332 (58.9)         4199 (57.5)         .336           Culprit lesions	Left main	122 (8.6)	603 (8.3)	.671		
Left circumflex artery         676 (47.8)         3197 (43.7)         .005           Multivessel disease         832 (58.9)         4199 (57.5)         .336           Culprit lesions	Left anterior descending artery	995 (70.4)	5402 (73.9)	.007		
Multivessel disease       832 (58.9)       4199 (57.5)       .336         Culpit lesions	Left circumflex artery	676 (47.8)	3197 (43.7)	.005		
Culprit lesions	Multivessel disease	832 (58.9)	4199 (57.5)	.336		
Right coronary artery         523 (37.0)         2240 (30.7)         <.001           Left main         29 (2.1)         300 (4.1)         <.001	Culprit lesions					
Left main         29 (2.1)         300 (4.1)         <.001           Left anterior descending artery         662 (46.9)         3986 (54.5)         <.001	Right coronary artery	523 (37.0)	2240 (30.7)	<.001		
Left anterior descending artery         662 (46.9)         3986 (54.5)         <.001           Left circumflex artery         302 (21.4)         1433 (19.6)         .138           Use of intra-aortic balloon pump         83 (5.9)         405 (5.5)         .664           PCI indication	Left main	29 (2.1)	300 (4.1)	<.001		
Left circumflex artery         302 (21.4)         1433 (19.6)         .138           Use of intra-aortic balloon pump         83 (5.9)         405 (5.5)         .664           PCI indication          <.001	Left anterior descending artery	662 (46.9)	3986 (54.5)	<.001		
Use of intra-aortic balloon pump         63 (5.9)         405 (5.5)         .664           PCI indication	Left circumflex artery	302 (21.4)	1433 (19.6)	138		
BCI indication       (3.07)       (3.07)       (3.07)       (3.07)         ST-elevation myocardial infarction       452 (32.0)       1864 (25.5)       (3.07)         UA/NSTEMI       347 (24.6)       1903 (26.0)       (3.07)         Elective       604 (42.7)       3508 (48.0)       (3.07)         PCI urgency         (3.01)         Salvage       29 (2.1)       80 (1.1)       (3.01)         Emergent       444 (31.4)       1770 (24.2)       (3.01)         Urgent       280 (19.8)       1644 (22.5)       (4.42.25)         Elective       659 (46.7)       3811 (52.2)       (3.01)         Bifurcation lesion       108 (7.6)       308 (4.2)       <.001	Use of intra-aortic balloon pump	83 (5 9)	405 (5 5)	664		
ST-elevation myocardial infarction       452 (32.0)       1864 (25.5)         UA/NSTEMI       347 (24.6)       1903 (26.0)         Elective       604 (42.7)       3508 (48.0)         PCI urgency           salvage       29 (2.1)       80 (1.1)         Emergent       444 (31.4)       1770 (24.2)         Urgent       280 (19.8)       1644 (22.5)         Elective       659 (46.7)       3811 (52.2)         Chronic total occlusion       108 (7.6)       308 (4.2)       <.001	PCL indication		100 (0.0)	< 001		
Decendent information         Hore         Hore           UA/NSTEMI         347 (24, 6)         1903 (26.0)           Elective         604 (42.7)         3508 (48.0)           PCI urgency             Salvage         29 (2.1)         80 (1.1)           Emergent         444 (31.4)         1770 (24.2)           Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	ST-elevation myocardial infarction	152 (32 0)	1864 (25 5)	2.001		
Outvisition         347 (24.8)         1703 (26.0)           Elective         60 (22.0)         3508 (48.0)           PCI urgency             Salvage         29 (2.1)         80 (1.1)           Emergent         444 (31.4)         1770 (24.2)           Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001		432 (32.0)	1002 (24.0)			
PCI urgency         <.001           Salvage         29 (2.1)         80 (1.1)           Emergent         444 (31.4)         1770 (24.2)           Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	Elective	604 (42 7)	3508 (48 0)			
Salvage       29 (2.1)       80 (1.1)         Emergent       444 (31.4)       1770 (24.2)         Urgent       280 (19.8)       1644 (22.5)         Elective       659 (46.7)       3811 (52.2)         Chronic total occlusion       108 (7.6)       308 (4.2)       <.001	PCLurganav	004 (42.7)	3300 (40.0)	< 001		
Salvage         25 (2.1)         60 (1.1)           Emergent         444 (31.4)         1770 (24.2)           Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	Colugency Colugency	20 (2 1)	90 (1 1)	<.001		
Emergent         444 (31.4)         1770 (24.2)           Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	Salvage	29 (2.1)	80 (1.1)			
Urgent         280 (19.8)         1644 (22.5)           Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	Emergent	444 (31.4)	1770 (24.2)			
Elective         659 (46.7)         3811 (52.2)           Chronic total occlusion         108 (7.6)         308 (4.2)         <.001	Urgent	280 (19.8)	1644 (22.5)			
Chronic total occlusion         108 (7.6)         308 (4.2)         <.001           Bifurcation lesion         247 (17.5)         1891 (25.9)         <.001	Elective	659 (46.7)	3811 (52.2)			
Biturcation lesion         247 (17.5)         1891 (25.9)         <.001           Type C lesion         388 (27.5)         2049 (28.0)         .681           Use of rotational atherectomy         36 (2.5)         221 (3.0)         .377           Drug-eluting stent         765 (54.1)         5501 (75.3)         <.001	Chronic total occlusion	108 (7.6)	308 (4.2)	<.001		
Type C lesion         388 (27.5)         2049 (28.0)         .681           Use of rotational atherectomy         36 (2.5)         221 (3.0)         .377           Drug-eluting stent         765 (54.1)         5501 (75.3)         <.001	Biturcation lesion	247 (17.5)	1891 (25.9)	<.001		
Use of rotational atherectomy         36 (2.5)         221 (3.0)         .377           Drug-eluting stent         765 (54.1)         5501 (75.3)         <.001	Type C lesion	388 (27.5)	2049 (28.0)	.681		
Drug-eluting stent         765 (54.1)         5501 (75.3)         <.001           Bare metal stent         325 (23.0)         1283 (17.6)         <.001	Use of rotational atherectomy	36 (2.5)	221 (3.0)	.377		
Bare metal stent         325 (23.0)         1283 (17.6)         <.001           Left ventricular ejection fraction, %         60.00 [49.00, 67.00]         60.00 [50.00, 68.00]         .071	Drug-eluting stent	765 (54.1)	5501 (75.3)	<.001		
Left ventricular ejection fraction, %         60.00 [49.00, 67.00]         60.00 [50.00, 68.00]         .071	Bare metal stent	325 (23.0)	1283 (17.6)	<.001		
	Left ventricular ejection fraction, %	60.00 [49.00, 67.00]	60.00 [50.00, 68.00]	.071		

Data are presented as n (%), or median [IQR].

eGFR, estimated glomerular filtration rate; IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention; UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction.

All major procedural complications (eg, death, bleeding complications, and cardiac and cerebrovascular events) were defined by the clinical research coordinator and details were published previously.<sup>23</sup> Initially, the procedural complications were reviewed by a trained clinical research coordinator under the supervision of the project coordinator and categorized as those in need of adjudication and those exempt from it. A separate member of the event committee reviewed the abstracted record. A second or third adjudicator was asked for assistance in the event of disagreement between the opinions of the project coordinator and the first adjudicator.

We followed participants after hospital discharge to identify hospitalizations for cardiovascular or bleeding events and all-cause deaths via medical records, phone calls, or mail. All follow-up data were collected and recorded in a secure internet-based electronic data capture system by dedicated clinical research coordinators who were trained by the primary investigator and the project coordinators. The primary outcome for this study was a composite of ACS, heart failure, coronary artery bypass grafting events requiring readmissions, and all-cause death. The secondary outcome was each component of the primary outcome.

#### Statistical analyses

Continuous variables are presented as mean  $\pm$  SD or median (IQR), as appropriate, for data distribution. Categorical variables are expressed as percentages. The changes from baseline in continuous

Table 2.	In-hospital and	lona-term outc	omes of all p	atients.
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	Crude population		Р
	No IVUS	IVUS	value
	(n = 1413)	(n = 7308)	
In-hospital outcomes			
All complications	134 (9.5)	518 (7.1)	.002
Coronary dissection	12 (0.8)	56 (0.8)	.873
Coronary perforation	13 (0.9)	48 (0.7)	.362
Myocardial infarction	23 (1.6)	75 (1.0)	.068
Cardiogenic shock	20 (1.4)	79 (1.1)	.343
Heart failure	23 (1.6)	116 (1.6)	>.99
Cerebral infarction	6 (0.4)	16 (0.2)	.262
New induction of dialysis	7 (0.5)	46 (0.6)	.684
Cardiac tamponade	0 (0.0)	19 (0.3)	.108
Transfusion	29 (2.1)	125 (1.7)	.434
Bleeding (all types)	47 (3.3)	154 (2.1)	.007
Puncture site bleeding	12 (0.8)	43 (0.6)	.342
Puncture site hematoma	12 (0.8)	38 (0.5)	.191
Peritoneal bleeding	0 (0.0)	8 (0.1)	.445
Gastrointestinal bleeding	5 (0.4)	15 (0.2)	.444
Genitourinary bleeding	1 (0.1)	5 (0.1)	>.99
Intracranial hemorrhage	1 (0.1)	2 (0.0)	.983
Other bleeding	22 (1.6)	55 (0.8)	.005
Long-term outcomes requiring readmissions			
Acute coronary syndrome	56 (4.0)	253 (3.5)	.393
Heart failure	73 (5.2)	295 (4.0)	.063
Coronary artery bypass	27 (1.9)	81 (1.1)	.018
Death	84 (5.9)	287 (3.9)	.001
Composite of acute coronary syndrome,	194 (13.7)	780 (10.7)	.001
heart failure, coronary bypass, and death			
Bleeding	36 (2.5)	183 (2.5)	.997
Stroke	25 (1.8)	116 (1.6)	.703

Data are presented as n (%).

IVUS, intravascular ultrasound.

variables were evaluated using t-test or the Mann-Whitney U test. The  $\chi^2$  or Fisher exact test was used to analyze categorical variables.

We performed an inverse probability-weighted analysis with 5% truncated weight to adjust confounders.<sup>27</sup> The following variables were used to estimate propensity score: age, sex, body mass index, diabetes, dyslipidemia, hypertension, chronic lung disease, cerebrovascular disease, cancer, prior PCI, prior coronary artery bypass, prior myocardial infarction, prior heart failure, smoking, indication of PCI, urgency of PCI, heart failure symptoms, cardiogenic shock at presentation, cardiopulmonary arrest at presentation, diseased vessels, PCI lesions, lesion characteristics (bifurcation, type C lesion, chronic total occlusion), estimated glomerular filtration rate, hemoglobin, puncture site and early study period (through December 2012) versus late study period (from January 2013). Baseline characteristics were assessed as well balanced if the standardized mean difference was less than 0.1.<sup>28</sup> For long-term outcomes, we created Kaplan-Meier estimates and performed the Cox proportional hazard model among the crude and weighted data. Moreover, we imputed missing data with 10 data sets assuming missing at random.<sup>27</sup> In our study, no adjustments for multiplicity were performed for the prespecified exploratory secondary outcomes.<sup>29</sup> Using the imputed data, we conducted an inverse probability-weighted analysis with truncated weight and then pooled the estimates by Rubin's rule.

We also performed subgroup analyses of complex coronary artery disease, which was defined as bifurcation, chronic total occlusion, type C lesion, left main PCI, or use of rotational atherectomy (n = 4092) with truncated weighted analysis as well as noncomplex coronary artery disease (n = 4629). All statistical calculations and analyses were performed using R version 4.2.2 (R Foundation for Statistical Computing), and packages of "VGAM," and "mice" were used; P < .05 was considered statistically significant.

#### Results

In this cohort of 8721 patients, the mean age of the patients was  $68.3 \pm 11.3$  years, and 83.8% of patients underwent IVUS-guided PCI. The trend of the proportions of IVUS use is presented in Figure 1. The baseline characteristics and in-hospital and long-term outcomes of patients with IVUS versus no IVUS are displayed in Tables 1 and 2. Patients who underwent IVUS were younger and more likely to be male and had significantly lower proportions of comorbidities such as dialysis, prior myocardial infarction, prior coronary bypass, and PCI and heart failure (Table 1). On the other hand, patients without IVUS had significantly higher proportions of ACS and emergent PCI including cardiogenic shock. Procedural complications after PCI were overall similar in both groups, except for the total complications (Table 2). The Kaplan-Meier curve of the primary endpoint in Figure 2A showed significant differences between the 2 groups (hazard ratio [HR], 0.77; 95% CI, 0.65-0.89; P < .001) (Table 3). The long-term outcomes, such as the requirement for coronary bypass and death, were overall lower in the IVUS group (Tables 2 and 3, Figure 2B, C).

With inverse probability-weighted analysis with truncated weight, baseline characteristics were well balanced except for the puncture site (Figure 3). The long-term outcomes remained different between the 2 groups. The hazard ratios of the Cox proportional hazard model for each outcome are presented in Table 3, showing significant differences in coronary artery bypass grafting and death between the 2 groups, although the primary outcome showed only marginal differences (Figure 4A-C). ACS and heart failure requiring admissions were not significantly different between the 2 groups (Table 3). In addition, multiple imputations for missing values of truncated weight model analyses, the results remained similar for these outcomes, but the use of IVUS was associated with a decreased risk of the primary endpoint (Table 3).

In the subgroup analysis of complex coronary artery disease, the baseline characteristics, hospital complications, and long-term outcomes were compared between the 2 groups (Supplemental Tables S1 and S2). Notably, the use of IVUS was significantly associated with a reduced risk of the primary outcome as well as death, coronary bypass, and heart failure requiring admission after adjustment (Table 3). In another subgroup analysis of noncomplex coronary artery disease, the baseline characteristics, hospital complications, and long-term outcomes were compared between the 2 groups (Supplemental Tables 3-4). Long-term outcomes were not significantly different between the 2 groups (Table 3).

#### Discussion

The principal findings of our study are as follows (Central Illustration): First, IVUS has been frequently used in Japan for over a decade; second, the use of IVUS is associated with reduced risks of coronary artery bypass grafting and death; third, IVUS has demonstrated potential benefits in managing complex coronary artery disease and has provided evidence of its potential benefits in reducing death and the need for coronary bypass. Our study highlights the usefulness of IVUS guidance, even when used in a broader spectrum of patients, as a valuable tool to improve long-term outcomes in PCI patients, especially those with complex coronary artery disease.

To date, numerous randomized trials showed the benefit of intravascular imaging including IVUS.<sup>4,30</sup> The IVUS XPL study showed that IVUS was associated with reduced risks of major adverse cardiovascular outcomes, mainly due to ischemia-driven target vessel revascularization for patients with long coronary lesions.<sup>4</sup> More recently, large-scale multicenter randomized trials have shown that intravascular imaging-guided PCI decreased the risk of target vessel failure defined as cardiac death, target vessel myocardial infarction, and clinically





#### Figure 2.

Kaplan-Meier curve of the primary endpoint for the crude population. (A) the primary outcome, (B) all-cause death, (C) coronary artery bypass grafting. HR, hazard ratio; IVUS, intravascular ultrasound.

driven revascularization for patients with complex coronary anatomy.<sup>30</sup> Furthermore, a meta-analysis showed that IVUS was associated with reduced risks of cardiovascular death and myocardial infarction; however, the included patients were highly heterogeneous.<sup>31</sup> Despite these

data, the use of IVUS remains highly variable, with only 5% of all PCI cases in the US being performed with IVUS, while over 80% are performed with IVUS in Japan.<sup>16,17</sup> This all-comer analysis was conducted to clarify whether the long-term benefit of IVUS persists in countries

Table 3. The Cox proportional hazard model for each outcome, IVUS vs no IVUS.						
	The primary endpoint	Death	CABG	ACS admissions	HF admissions	
Crude cohort	0.77 (0.65-0.89)	0.65 (0.51-0.83)	0.57 (0.37-0.88)	0.86 (0.65-1.15)	0.77 (0.60-1.00)	
Truncated weight	0.85 (0.71-1.01)	0.73 (0.55-0.96)	0.62 (0.39-0.98)	1.06 (0.75-1.50)	0.78 (0.59-1.03)	
Truncated weight (imputation)	0.81 (0.68-0.95)	0.68 (0.53-0.88)	0.62 (0.39-0.99)	0.91 (0.67-1.23)	0.80 (0.61-1.04)	
Complex coronary with truncated weight	0.72 (0.55-0.93)	0.59 (0.40-0.88)	0.45 (0.25-0.83)	1.05 (0.62-1.80)	0.66 (0.44-0.98)	
Noncomplex coronary with truncated weight	0.96 (0.75-1.23)	0.91 (0.61-1.34)	0.71 (0.33-1.51)	1.00 (0.64-1.58)	0.93 (0.63-1.38)	

Values are hazard ratio (95% CI).

ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; HF, heart failure; IVUS, intravascular ultrasound.



#### Figure 3.

Standard mean difference of unadjusted, or adjusted population. AF, atrial fibrillation; BMI, body mass index; CABG, coronary artery bypass grafting; CPA, cardiopulmonary arrest; CS, cardiogenic shock; CTO, chronic total occlusion; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; HF, heart failure; LAD, left descending artery; LCX, left circumflex artery; LMT, left main trunk; MI, myocardial infarction; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; RCA, right coronary artery; SMD, standardized mean difference.

with higher IVUS usage, and we showed the beneficial effect of IVUS in reducing death and the need for coronary bypass. Furthermore, consistent with the results from randomized controlled trials, the benefit of IVUS was more prominent in patients with complex coronary artery disease, providing insight into the future of coronary interventions if IVUS is more widely used.

While the clinical benefit of IVUS-guided PCI was mostly confined to a reduced rate of target vessel revascularization, our data demonstrated that IVUS was associated with reduced risks of coronary bypass and death among the total cohort and heart failure admissions among patients with complex coronary artery disease.<sup>4,30</sup> These findings highlight the potential role of IVUS in reducing risk of flow-limiting severe coronary dissection, which may contribute to the decrease in adverse outcomes.<sup>16</sup> IVUS is also associated with the decreased risk of postprocedural flow-limiting severe coronary dissection, and this may explain why IVUS was more beneficial in complex coronary anatomy.

Despite the favorable data, IVUS use remains low in the US, with only 5% of PCI being IVUS-guided among Medicare patients.<sup>12,17</sup> It could be related to the difference in insurance and reimbursing systems in both countries, however, 1 potential barrier to adoption is the



#### Figure 4.

Kaplan-Meier curve of the primary endpoint for the adjusted population. (A) the primary outcome, (B) all-cause death, (C) coronary artery bypass grafting. HR, hazard ratio; IVUS, intravascular ultrasound.

difficulty in adapting to the use of imaging equipment and interpreting the results. However, recent cost analysis has demonstrated that IVUS is cost effective and Medicare will change the reimbursement, which may help increase adoption rates.<sup>32</sup> An additional issue is the difficulty of adapting IVUS-guided PCI for operators who are unfamiliar with imaging equipment and imaging interpretation.<sup>1,10</sup> Currently, more than 50% of institutions perform IVUS-guided PCI in less than 1% of cases, which may generate a negative cycle of low adaptation rates due to lack of exposure and experience with IVUS-guided PCI, potentially increasing procedure time as well.<sup>1,17</sup> A similar phenomenon occurred with transradial PCI; the procedure was already applied in Japan between 2008 and 2010, albeit only 4.2% of PCI were performed under transradial access during the same period in the US.<sup>26</sup> Given numerous favorable data on IVUS-guided PCI and our data from all-comers registry showing beneficial effect under extensive use of IVUS, we propose the guideline should be changed to class I recommendation since ACCF/AHA/SCAI recommended class IIb for IVUS-guided PCI but it has not been updated since 2011.<sup>29</sup> However, to achieve this, facilitation of lifelong training is essential, such as live demonstration for PCI operators or the mandate for IVUS-guided PCI training for fellows, to maintain high-level competency of catheterization laboratory in the US and facilitate greater adoption of IVUS-guided PCI.<sup>1</sup>

There are several limitations in our study. First, this is an observational study and unmeasured confounders could not be adjusted. However, we did a rigorous adjustment with an inverse probabilityNo large-scale studies comprising consecutive all-comer patients have investigated the effectiveness of extensive utilization of IVUS guidance



Overall, 83.8 % of patients underwent IVUS-guided PCI during the study period: The use of IVUS demonstrated potential benefit in reducing mortality and need for CABG, particularly in patients with complex coronary anatomy.

#### Central Illustration.

Forest plots of the adjusted hazard ratios of the primary outcome, all-cause death, and coronary artery bypass grafting among the total cohort and the subgroup of complex coronary artery disease. The bars show confidential intervals of hazard ratios. CABG, coronary artery bypass grafting; HR, hazard ratio; IVUS, intravascular ultrasound.

weighted analysis with 5% truncated weight in addition to multiple imputations of missing data. Despite that, high-risk profiles in patients without IVUS may contribute to the worse outcomes in the no IVUS group. Second, our data are derived from only the Japanese population, which may need attention to interpret our data since the East Asian population has relatively lower ischemic events than the Western population.<sup>33</sup> However, our data are crucial because extensive use of IVUS with more than 80% is quite remarkable and no other data with extensive IVUS use has not shown the beneficial effect of IVUS. Third, in our registry, the follow-up survey focused only on clinically driven events: death, ACS, heart failure, and coronary bypass. Therefore, a subsequent revascularization was retrospectively reviewed, and some revascularization events may not have been captured, especially, for cases transferred to institutions outside of the JCD-KiCS network. However, KiCS network hospitals typically serve as the central clinical centers in the region and we believe it is uncommon for events to go unnoticed within our study due to the diligence of our clinical research coordinators in monitoring and collecting data. Fourth, we did not adjust left ventricular ejection fraction since almost half of the patients did not have information on left ventricular ejection fraction; however, left ventricular ejection fractions were similar between IVUS and no IVUS groups. Finally, we did not have information on optical coherence tomography; but we consider most of the intravascular imaging-guided PCI were IVUS guided during the study period and the beneficial effects of IVUS are similar to optical coherence tomography.<sup>34</sup>

In conclusion, our study provides further evidence supporting the potential benefits of IVUS-guided PCI, particularly in patients with complex coronary anatomy. Wider adoption of IVUS-guided PCI may lead to improved outcomes for patients undergoing PCI.

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#### **Declaration of competing interest**

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## Ethics statement and patient consent

The present study was approved by the IRB committee of Keio University (Reference number: 20080073). The study protocol was approved by the institutional review board of each participating hospital. All participants provided written informed consent. Before the launch of the JCD-KiCS registry, information regarding the objective of this registry was provided for clinical trial registration in the University Hospital Medical Information Network of Japan (UMIN00004736).

#### Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular* Angiography & Interventions at 10.1016/j.jscai.2023.101190.

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