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Appropriateness Ratings of Percutaneous Coronary Intervention in Japan and Its Association With the Trend of Noninvasive Testing

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate the appropriateness of percutaneous coronary intervention (PCI) in Japan and clarify the association between trends of pre-procedural noninvasive testing and changes in appropriateness ratings.

BACKGROUND Although PCI appropriateness criteria are widely used for quality-of-care improvement, they have not been validated internationally. Furthermore, the correlation of appropriateness ratings with implementation of newly developed noninvasive testing is unclear.

METHODS We assigned an appropriateness rating to 11,258 consecutive PCIs registered in the Japanese Cardiovascular Database according to appropriateness use criteria developed in 2009 (AUC/2009) and the 2012 revised version (AUC/2012). Trends of pre-procedural noninvasive testing and appropriateness ratings were plotted; logistic regression was performed to identify inappropriate PCI predictors.

RESULTS In nonacute settings, 15% of PCIs were rated inappropriate under AUC/2009, and this percent increased to 30.7% under AUC/2012 criteria. This was mostly because of the focused update of AUC, in which the patients were newly classified as inappropriate if they lacked proximal left anterior descending lesions and did not undergo pre-procedural noninvasive testing. However, these cases were simply not rated under AUC/2009. The amount of inappropriate PCIs increased over 5 years, proportional to the increase in coronary computed tomography angiography use. Use of coronary computed tomography angiography was independently associated with inappropriate PCIs (odds ratio: 1.33; $p = 0.027$).

CONCLUSIONS In a multicenter, Japanese PCI registry, approximately one-sixth of nonacute PCIs were rated as inappropriate under AUC/2009, increasing to approximately one-third under the revised AUC/2012. This significant gap may reflect a needed shift in appropriateness recognition of methods for noninvasive pre-procedural evaluation of coronary artery disease. (J Am Coll Cardiol Intv 2014;7:1000–9) © 2014 by the American College of Cardiology Foundation.

The advent of percutaneous coronary intervention (PCI) has significantly changed the treatment strategy for patients with coronary artery disease (CAD). However, although PCI has a significant benefit for reducing mortality and recurrent myocardial infarction among patients presenting

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with acute coronary syndrome (1), its survival benefit has not been clearly established for patients with stable CAD (2). Because the patients who undergo PCI are exposed to the risks of periprocedural complications such as bleeding or procedure-related myocardial infarction, the appropriate indications of PCI are of significant importance.

To promote the appropriate and judicious implementation of PCI, the American College of Cardiology Foundation and 6 other societies published joint appropriateness use criteria (AUC) for PCI in 2009 (AUC/2009) (3). These AUC have been applied to real-world clinical practice along with various registry data, and studies have demonstrated a strong possibility of PCI overuse in real-world practice in Western countries (4–6). However, reports on AUC application to patients outside of North America are sparse.

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In Japan, the number of PCI procedures has been increasing. More than 200,000 procedures in >800 hospitals were performed in 2012; this number is disproportionately large compared with the number of coronary artery bypass grafting (CABG) procedures. The number of PCI procedures is estimated to be >14 times greater than CABG procedures (7). Consequently, whereas the proportion of elective PCIs accounts for < 40% in the United States, as many as three-fourths of PCIs are performed in nonacute settings in Japan (7,8), and a greater number of patients with multivessel diseases are treated with PCI in Japan than in the United States (9). Furthermore, the pre-procedural evaluation is also quite different between the 2 countries: the performance of coronary CT angiography (CTA) is increasing remarkably in Japan, whereas the stress testing remains the main modality in the United States. These unique characteristics in Japan underscore the need for a proper evaluation of PCI appropriateness.

The purpose of our study was to evaluate the appropriateness of PCI indications in Japan on the basis of U.S. criteria and to compare the rate and characteristics of inappropriate PCIs between both countries. At present, 2 versions of AUC have been published in the United States. The original AUC/2009 was updated in 2012 (AUC/2012), emphasizing the importance of performing noninvasive stress testing before elective PCIs (10). The use of coronary CTA as a pre-procedural test is increasing in Japan and may have significantly altered appropriateness ratings. Although the risk of adverse cardiovascular events could be stratified by the extent of anatomic lesions on the basis of coronary CTA, computed tomography (CT)-based PCIs are rarely recognized as appropriate indications under current AUC. Therefore, in addition to reviewing the overall rating of PCI appropriateness, we sought to clarify its association with the trend in performing various noninvasive diagnostic tests.

METHODS

DATA SOURCE. The Japan Cardiovascular Database (JCD) is an ongoing, prospective multicenter registry designed to collect clinical background and outcome data on consecutive PCI patients (11). In this registry, 16 teaching hospitals within the metropolitan Tokyo area participated and registered all PCI procedures performed during the study period, including failure cases, using an Internet-based interface. Approximately 200 variables were collected for each patient; clinical variables and in-hospital outcomes for JCD were defined in accordance with the National Cardiovascular Data Registry version 4.1. This registry, sponsored by the American College of Cardiology (12,13), is the largest national clinical registry program for diagnostic cardiac catheterization and PCI, with >1,500 centers currently participating across the United States. Additionally, in the JCD-PCI registry, the subgroup of patients who underwent an intracoronary infusion of acetylcholine to induce coronary vasospasm was also registered because vasospastic angina accounts for a significant portion of patients with CAD and acute coronary syndromes in Japan (14). Clinical research coordinators specifically trained in registering PCI procedures confirmed the proper registration of each patient. In addition, data reported on the Internet-based system were checked, and investigators visited each hospital quarterly to audit the database for completeness and consistency.

STUDY POPULATION. A total of 11,258 consecutive patients who underwent PCI procedures between September 2008 and March 2013 for acute and nonacute indications were registered in the database. A total of 1,208 patients were excluded because they underwent serial PCIs during the same hospitalization, there were insufficient baseline data, or they only underwent the acetylcholine challenge test. The remaining 10,050 patients were included in our study (**Figure 1**).

DEVELOPMENT OF AUC/2009 AND ITS RATING ASSIGNMENTS. AUC/2009 was developed by a collaboration of 6 American professional organizations

ABBREVIATIONS AND ACRONYMS

AUC = appropriateness use criteria

CABG = coronary artery bypass grafting

CAD = coronary artery disease

CTA = computed tomography angiography

CT = computed tomography

FFR = fractional flow reserve

JCD = Japan Cardiovascular Database

PCI = percutaneous coronary intervention

PLAD = proximal left anterior descending artery

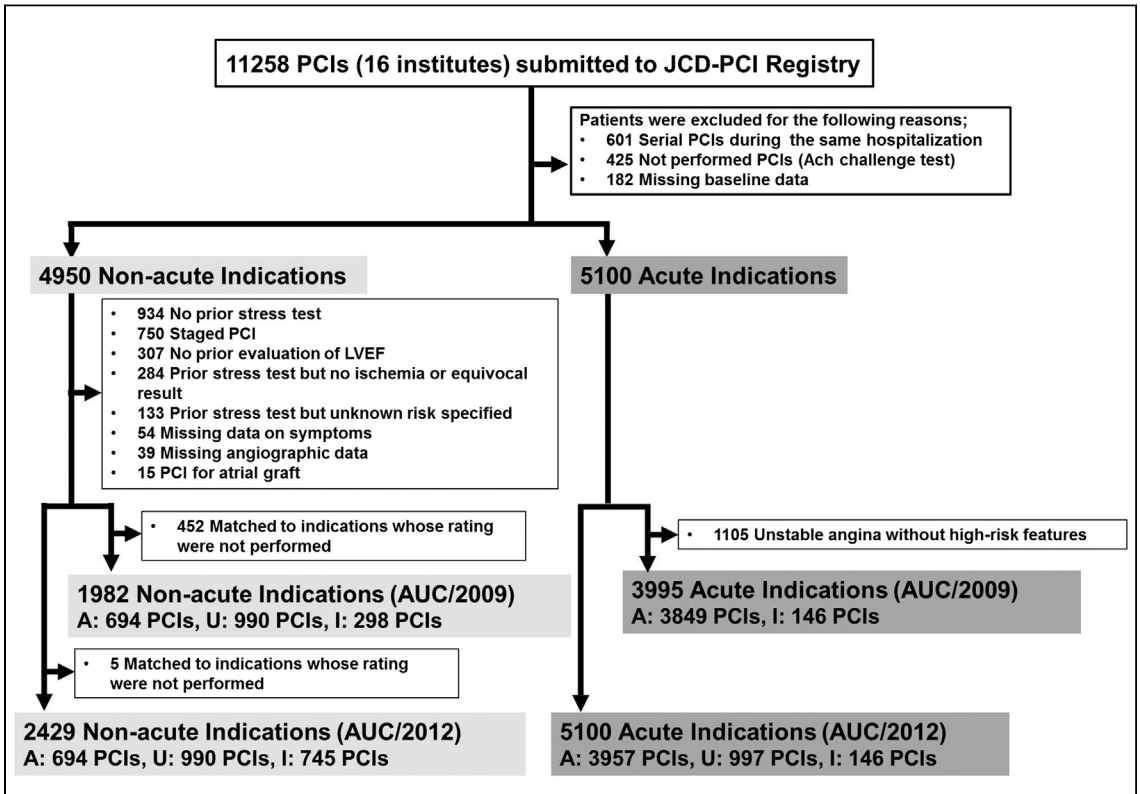

FIGURE 1 Study Cohort Creation

Patients registered in JCD-PCI Registry were divided into 2 groups (nonacute and acute indications). Each group was rated under AUC/2009 and AUC/2012. A = appropriate; Ach = acetylcholine; AUC = appropriateness use criteria; I = inappropriate; JCD-PCI = Japan Cardiovascular Database–Percutaneous Coronary Intervention; LVEF = left ventricular ejection fraction; U = uncertain.

(the American College of Cardiology Foundation, the Society for Cardiovascular Angiography and Intervention, the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, the American Heart Association, and the American Society of Nuclear Radiology) in 2009. The methodology to develop the AUC for coronary revascularization was previously described (3).

We used an algorithm to map PCIs in the JCD-PCI registry to AUC/2009 and rate the procedures as appropriate, uncertain, or inappropriate. This algorithm, which was validated in a previous study (6), enabled the mapping to be performed in an efficient manner. All the definitions in our study were identical to those in AUC/2009. We optimized our mapping algorithm to maximize the use of existing data and minimize the influence of missing data. For example, certain nonacute indications can be assigned the appropriateness rating independent of noninvasive risk results (e.g., 3-vessel CAD with abnormal left ventricular systolic function). In these scenarios, an appropriateness classification could be provided even when noninvasive risk testing was not performed or results were not available.

Among the 10,050 patients, a rating could not be determined for 2,968 nonacute and 1,105 acute PCIs, leaving a total of 1,982 nonacute and 3,995 acute PCIs that could be rated (Figure 1). Among the acute indications, unstable angina without high-risk features was the main cause of rating failure. In the nonacute settings, mapping failure was mainly due to one of the following: no previous stress test performed, staged PCI, previous stress test with no ischemia or equivocal result, previous evaluation of left ventricular systolic function, and matched to indications that were not rated.

REVISED AUC/2012 AND ITS RATING ASSIGNMENTS. AUC/2009 was updated in 2012 (AUC/2012) (10). In the revised AUC/2012 version, unstable angina without high-risk features, which was an excluded clinical scenario in AUC/2009, was successfully mapped and divided into 2 indications according to the Thrombolysis In Myocardial Infarction score. In AUC/2009,

the clinical scenario of an asymptomatic patient without previous bypass surgery and with 1- or 2-vessel disease not involving the proximal left anterior descending artery (PLAD) who underwent no noninvasive testing was not evaluated because it was thought to be uncommon. However, in the revised AUC/2012, this clinical scenario was determined to be inappropriate. Accordingly, successfully mapped procedures increased, and 2,429 nonacute and 5,100 acute PCIs were rated (Figure 1).

STATISTICAL ANALYSIS. The proportion of PCIs classified as appropriate, uncertain, or inappropriate was determined, after stratification by acute versus nonacute indications on the basis of AUC/2009 and AUC/2012. Baseline characteristics and clinical variables of patients were compared by appropriateness categories. Differences were evaluated using the chi-square or Fisher exact test for categorical variables and the Student unpaired *t* test for continuous variables. Cochran-Armitage analysis was used to evaluate the trends of the proportion of inappropriate PCIs and of the implementation of various tests. Multivariate logistic regression analysis was performed to examine the relationship between the implementation of coronary CTA and inappropriate PCI, adjusting for potential confounders. The covariates included in the model were symptomatic status (symptomatic vs. asymptomatic), extent of ischemic burden (low risk vs. intermediate or high risk), antianginal medication (optimal vs. suboptimal medication), angiographic characteristics (left main trunk, triple-vessel disease, chronic total occlusion, or PLAD), and the time period when the PCI was performed (divided into 8 categories: September 2008 to June 2009, July 2009 to December 2009, January 2010 to June 2010, July 2010 to December 2010, January 2011 to June 2011, July 2011 to December 2011, January 2012 to June 2012, and July 2012 to March 2013). Data were analyzed using SPSS, version 20 (SPSS Inc., Chicago, Illinois). All p values were 2-sided, and significance was defined as $p < 0.05$ for all analyses.

RESULTS

PATIENT CHARACTERISTICS. Table 1 summarizes the clinical characteristics of patients who underwent PCIs in acute and nonacute settings. The mean age was 67.9 ± 10.9 years; 79.4% were male. Coronary risk factors, including a history of myocardial infarction and PCI, hypertension, hypercholesterolemia, and diabetes mellitus, were common; however, the prevalence of a history of CABG was lower than that in previous reports (4).

TABLE 1 Baseline Characteristics of Acute and Nonacute PCIs

	Total (N = 10,050)	Acute (n = 5100)	Nonacute (n = 4950)
Demographics			
Male	7,978 (79.4)	3,972 (77.9)	4,006 (80.9)
Age, yrs	67.9 ± 10.9	67.5 ± 11.8	68.2 ± 9.7
Clinical factors			
Hypertension	7,462 (74.3)	3,588 (70.4)	3,874 (78.3)
Hypercholesterolemia	6,681 (66.6)	3,109 (61.1)	3,572 (72.2)
Diabetes mellitus	4,229 (42.1)	1,901 (37.4)	2,328 (47.0)
Current and past smoking	3,517 (35.1)	2,022 (39.8)	1,495 (30.3)
History of MI	2,501 (24.9)	799 (15.7)	1,702 (34.4)
Previous PCI	3,613 (36.0)	990 (19.4)	2,623 (53.0)
Previous CABG	532 (5.3)	195 (3.8)	337 (6.8)
Hemodialysis	430 (4.3)	181 (3.6)	249 (5.0)
Cerebrovascular disease	909 (9.1)	454 (8.9)	455 (9.2)
Peripheral arterial disease	817 (8.1)	292 (5.7)	525 (10.6)
Chronic lung disease	309 (3.1)	153 (3.0)	156 (3.2)

Values are n (%) or mean ± SD.

CABG = coronary artery bypass grafting; MI = myocardial infarction; PCI = percutaneous coronary intervention.

ACUTE INDICATIONS. Among the patients with acute indications for PCI, ST-segment elevation myocardial infarction was found in 49.3%, whereas cardiogenic shock was found in 16.9%. All clinical indications for appropriate and inappropriate PCIs in the acute settings are outlined in Table 2. Overall, most acute indications (96.3%) were categorized as appropriate under AUC/2009 (Figure 2, Online Table 1), whereas all inappropriate procedures were categorized as hemodynamic and electrically stable patients, with

TABLE 2 All the Clinical Scenarios in the Acute Setting

AUC/2009 Indication No.	Indication	n (%)
Appropriate PCI		
1	STEMI, ≤12 h from onset of symptoms Revascularization of the culprit artery	1,397 (35.0)
9	UA/NSTEMI and high-risk features of short-term risk if death or nonfatal MI Revascularization of the presumed culprit artery	1,361 (34.1)
11	Patients with acute myocardial infarction (STEMI or NSTEMI) Evidence of cardiogenic shock Revascularization of ≥1 coronary arteries	755 (18.9)
2	STEMI, onset of symptoms within the previous 12–24 h Severe HF, persistent ischemic symptoms, or hemodynamic or electrical instability present	336 (8.4)
Inappropriate PCI		
3	STEMI, >12 h from symptom onset Asymptomatic; no hemodynamic instability and no electrical instability	146 (3.7)

AUC = appropriateness use criteria; HF = heart failure; MI = myocardial infarction; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina.

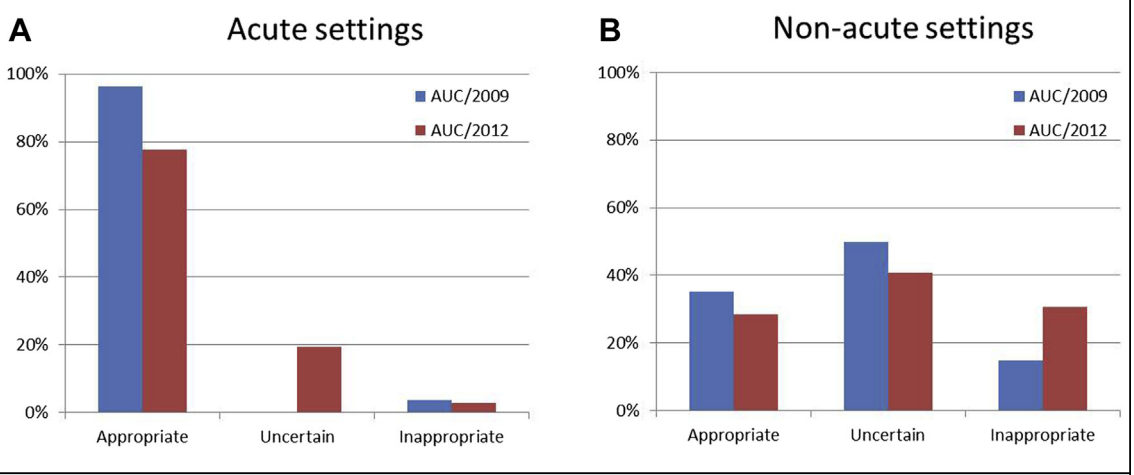

FIGURE 2 Appropriate Ratings Under Each Criterion

Appropriate ratings under each criterion in acute **(A)** settings and nonacute **(B)** settings. AUC = appropriateness use criteria.

PCI performed >12 h after symptom onset after ST-segment elevation myocardial infarction.

On the basis of AUC/2012, almost all cases of unstable angina without high-risk features (997 [90.2%]) were classified as uncertain, whereas 108 (9.8%) were considered appropriate. Overall, nearly 80% of acute procedures were categorized as appropriate (3,957 [77.6%]), whereas 997 (19.5%) were categorized uncertain and 146 (2.9%) were inappropriate (**Figure 2**, Online Table 1). All clinical indications for acute PCIs assessed by AUC/2012 are shown in Online Table 2.

NONACUTE INDICATIONS. In nonacute settings, 35.1% of PCIs were classified as appropriate, 49.9% as uncertain, and 15.0% as inappropriate under AUC/2009 (**Figure 2**, Online Table 1). Compared with procedures classified as appropriate or uncertain,

TABLE 3 Key Variables in Classifying Appropriateness for Nonacute PCIs in AUC/2009

		Procedural Appropriateness			
	Total (N = 1,982)	Appropriate (n = 694)	Uncertain (n = 990)	Inappropriate (n = 298)	p Value
Angina					<0.001
No symptoms	555 (32.2)	172 (24.8)	145 (14.6)	238 (79.9)	
CCS angina class					
I	377 (19.0)	67 (9.7)	283 (28.6)	27 (9.1)	
II	750 (37.8)	188 (27.1)	529 (53.4)	33 (11.1)	
III	239 (12.1)	214 (30.8)	25 (2.5)	0 (0)	
IV	38 (1.9)	30 (4.3)	8 (0.8)	0 (0)	
Unknown	23 (1.2)	23 (3.3)	0 (0)	0 (0)	
Noninvasive ischemia evaluation					<0.001
Low risk	228 (11.5)	19 (2.7)	82 (8.3)	127 (42.6)	
Intermediate risk	742 (37.4)	228 (32.9)	343 (34.6)	171 (57.4)	
High risk	195 (9.8)	156 (22.5)	39 (3.9)	0 (0)	
Maximal antianginal medications	117 (5.9)	70 (10.1)	45 (4.5)	2 (0.7)	<0.001
Angiographic characteristics					
Left main trunk	111 (5.6)	109 (15.7)	1 (0.1)	1 (0.3)	<0.001
3VD without left main trunk	345 (17.4)	290 (41.8)	46 (4.6)	9 (3.0)	<0.001
CTO without other coronary stenosis	77 (3.9)	15 (2.2)	44 (4.4)	18 (6.0)	0.007
Presence of proximal LAD stenosis	508 (25.6)	316 (45.5)	183 (18.5)	9 (3.0)	<0.001

Values are n (%).

CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; LAD = left anterior descending artery; 3VD = 3-vessel disease; all other abbreviations as in Table 2.

TABLE 4 Most Frequent Clinical Scenarios for Nonacute PCIs Classified as Inappropriate and Uncertain by AUC/2009

AUC/2009 Scenario No.	Indication					n (%)
	Anatomy	Previous CABG	Symptoms	Cardiac Risk (Noninvasive Tests)	Antianginal Medication	
Inappropriate PCIs						298
14a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	Intermediate	None or minimal	146 (7.4)
12a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	Low	None or minimal	60 (3.0)
12b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Low	None or minimal	57 (2.9)
56a	≥1 stenoses in non-CABG territory all bypass grafts patent	Yes	Asymptomatic	Intermediate	None or minimal	13 (0.7)
24a	CTO of 1 major coronary artery without other coronary stenoses	No	Asymptomatic	Intermediate	None or minimal	12 (0.6)
Uncertain PCIs						990
18b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Not available	Not available	524 (26.4)
14b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Intermediate	None or minimal	174 (8.8)
30b	1-vessel CAD involving the proximal LAD	No	CCS class I or II	Intermediate	None or minimal	49 (2.5)
36a	2-vessel CAD involving the proximal LAD	No	Asymptomatic	Intermediate	None or minimal	42 (2.1)
16a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	High	None or minimal	29 (1.5)

CAD = coronary artery disease; all other abbreviations as in Tables 1 to 3.

inappropriate PCIs were more likely to be performed for patients who had no symptoms (appropriate, 24.8%; uncertain, 14.6%; inappropriate, 78.9%; $p < 0.001$), low-risk results from noninvasive testing (appropriate, 2.7%; uncertain, 8.3%; inappropriate, 42.6%; $p < 0.001$), or chronic total occlusion (appropriate, 2.2%; uncertain, 4.4%; inappropriate, 6.0%; $p < 0.007$) (Table 3). Overall, almost all of the inappropriate PCIs were confined to 5 scenarios, as summarized in Table 4. Frequently encountered scenarios included PCIs with suboptimal antianginal medications or involvement of single or multiple epicardial vessels other than the left main trunk or PLAD.

Under AUC/2012, asymptomatic patients with 1- or 2-vessel CAD with no PLAD involvement and without previous noninvasive testing (indication 18a in AUC/2009, indication 20a in AUC/2012) were rated as inappropriate (n = 447). When these scenarios were added, the percent of inappropriate PCIs increased from 15.0% to 30.7% (Figure 2, Online Table 1). Of these cases, as many as 120 (26.8%) were evaluated using coronary CTA before the procedures, and the results were positive in almost all the cases (noninterpretable, 4 cases; negative, 1 case). The most frequent clinical scenarios for nonacute PCIs classified as inappropriate and uncertain by AUC/2012 are summarized in Table 5.

ASSOCIATION BETWEEN TEMPORAL TRENDS OF NONINVASIVE TESTING AND THE RATE OF INAPPROPRIATE RATINGS. Figure 3 summarizes the use of several noninvasive tests such as the stress myocardial perfusion imaging and coronary CTA and fractional flow reserve (FFR). FFR is a pressure wire-based ischemic evaluation during coronary angiography. Figure 3 also demonstrates the temporal trends of the proportion of inappropriate PCIs. Among patients who underwent PCI, the proportion of patients evaluated with coronary CTA and FFR substantially increased (p for trend < 0.001), which coincided with a decrease in use of the stress myocardial perfusion imaging over the course of 5 years (p for trend < 0.001). Contemporaneously, the proportion of inappropriate PCIs increased (p for trend $= 0.003$) in parallel with the increase in coronary CTA use. Implementation of coronary CTA was associated with the rating of inappropriate PCI (odds ratio: 1.33; 95% confidence interval: 1.03 to 1.70; $p = 0.027$). Further, the time variables were not independently associated with the rating of inappropriate PCI (Online Table 3).

Figure 4 presents the change in the proportion of PCIs rated as inappropriate. Although the proportion of inappropriate PCIs accounted for 30.7% of all the elective procedures when the CT-based procedures were classified as inappropriate, this proportion decreased substantially (from 5.0% to 25.7%) when the CT-based procedures were classified as appropriate. Although the proportion of inappropriate PCIs tended to increase even when the CT-based procedures were classified as appropriate, the trend was not statistically significant (p for trend = 0.09).

DISCUSSION

In this contemporary, multicenter Japanese PCI registry, almost all acute PCIs were acceptable regardless of the criteria applied. However, approximately one-sixth of nonacute PCIs were rated as inappropriate under the original criteria. Under the updated AUC/

TABLE 5 Most Frequent Clinical Scenarios for Nonacute PCIs Classified as Inappropriate and Uncertain by AUC/2012

AUC/2012 Scenario No.	Indication					n (%)
	Anatomy	Previous CABG	Symptoms	Cardiac Risk	Antianginal Medication	
Inappropriate PCIs						745
20a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	Not performed	Not available	447 (18.4)
16a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	Intermediate	None or minimal	146 (6.0)
14a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	Low	None or minimal	60 (2.5)
14b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Low	None or minimal	57 (2.3)
58a	≥1 stenoses in non-CABG territory, all bypass grafts patent	Yes	Asymptomatic	Intermediate	None or minimal	13 (0.6)
26a	CTO of 1 major coronary artery without other coronary stenoses	No	Asymptomatic	Intermediate	None or minimal	12 (0.5)
Uncertain PCIs						990
20b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Not available	Not available	524 (21.6)
16b	1- or 2-vessel CAD, no proximal LAD involvement	No	CCS class I or II	Intermediate	None or minimal	174 (7.2)
32b	1-vessel CAD involving the proximal LAD	No	CCS class I or II	Intermediate	None or minimal	49 (2.0)
38a	2-vessel CAD involving the proximal LAD	No	Asymptomatic	Intermediate	None or minimal	42 (1.7)
18a	1- or 2-vessel CAD, no proximal LAD involvement	No	Asymptomatic	High	None or minimal	29 (1.2)

Abbreviations as in Tables 1 to 4.

2012, the rate of inappropriate PCIs increased to nearly one-third because noninvasive stress testing was not performed before a large number of elective PCIs in Japan and was seemingly affected by the increasing trend of coronary CTA.

Under the original criteria (AUC/2009), the proportion of inappropriate procedures in our study was almost within the range reported in previous studies. Similar to our study, previous reports have shown that almost all coronary revascularization procedures performed in the acute setting were appropriate (4,6), whereas ratings in nonacute settings varied widely, from 11.6% to 17% depending on the study (4–6,15). Additionally, the characteristics of the nonacute procedures that we classified as inappropriate were also concordant with those reported in previous studies. Inappropriate PCIs were likely to be performed in patients who were either asymptomatic or mildly symptomatic (Canadian Cardiovascular Society class I or II), were receiving suboptimal antianginal medication, and had no PLAD coronary artery stenosis. In our study, the proportion and indications of inappropriate PCIs in Japan were similar to the results of previous studies from North America, which indicates that AUC/2009 may be useful for assessing the appropriateness of PCIs internationally. The same approach, including the education of physicians regarding procedural appropriateness, is needed to improve patient selection in nonacute settings globally.

Between the 2009 and 2012 criteria, the proportion of inappropriate procedures increased substantially from 15.0% to 30.7% in our registry, whereas Hannan et al. (5) reported that the percent of inappropriate PCIs using New York State's Cardiac Surgery Reporting System and the Percutaneous Coronary Interventions Reporting System would increase from 14.3% with AUC/2009 to 23.2% when AUC/2012 was applied. These increases were mainly explained by the following scenario: asymptomatic patients who did not undergo previous noninvasive testing, presence of 1- or 2-vessel CAD, and no PLAD involvement (indication 18a in AUC/2009, indication 20a in AUC/2012). In AUC/2009, this clinical scenario was not rated because the panel members thought that its likelihood was very low. However, these cases would appear to be particularly inappropriate for revascularization because there is no expectation of survival benefit and no possibility of improvement in quality of life. Accordingly, in the revised version AUC/2012, such cases were rated as inappropriate (10). Therefore, the greater increase in inappropriate procedures in our registry compared with the Hannan et al. (5) study is a reflection of the unwillingness to perform previous noninvasive stress testing in Japan.

Less frequent use of noninvasive stress testing may be due to the advent of coronary CTA, which has become recognized as a useful prognostic modality (16). In fact, approximately one-third of the patients in our registry who did not undergo noninvasive stress testing underwent coronary CTA. Furthermore, the proportion of inappropriate PCIs increased substantially in parallel with the increase in the use of coronary CTA. Because appropriateness criteria assign much value to functional information in reflection of a strong tilt toward physiological assessment of ischemia in the United States, coronary CTA, which

only provides anatomic information, is not recognized as one of the previous noninvasive tests under these criteria. In recent studies, the excellent negative predictive value and acceptable positive predictive value with diagnostic use of coronary CTA have been documented (17,18), and the analyses from the CONFIRM registry have demonstrated the prognostic value of coronary CTA. Those patients with nonobstructive or obstructive CAD detected by coronary CTA had an increased risk of long-term mortality compared with those without (16), which might indicate that the risk of adverse cardiovascular events could be stratified by the extent of anatomic lesions. Additionally, subanalysis of the COURAGE trial demonstrated that the anatomic burden of coronary disease, but not ischemic burden, predicted the risk of adverse cardiovascular events (19), which emphasized the importance of anatomic as well as ischemic assessment in patients with CAD. Because such a potential impact of anatomic assessment on adverse cardiovascular outcomes has been demonstrated, we can argue that CT-based procedures can be hypothetically graded as appropriate instead of inappropriate. In our analysis, the proportion of inappropriate PCI decreased by 5% when CT-based procedures were classified not as inappropriate but as appropriate. This proportion of inappropriate PCIs was similar to the findings of earlier reports assessed using revised 2012 criteria (5). This result might demonstrate that the appropriateness of PCIs in Japan was not properly assessed according to the current criteria because the recognition of CAD was totally different from that in the United States. Further studies are needed to evaluate the appropriateness of CT-guided PCIs, which may suggest that a revision of AUC is needed.

Although revascularization for patients who show no signs of functional ischemia is not the standard of care under current guidelines (20), ischemic evaluation is likely to be performed using FFR without a previous stress test, on the basis of the results of the FAME2 (Fractional Flow Reserve versus Angiography for Multi-vessel Evaluation II) study (21). Actually in our registry, the prevalence of PCIs using FFR substantially increased, which coincided with an increase in coronary CTA use. The number of inappropriate PCIs showed an increasing trend even when the CT-based procedures were excluded (or considered appropriate). This may due to the increase in the use of FFR. Because FFR enables the evaluation of the significance of CAD in the cardiac catheterization laboratory, pre-procedural tests might have been omitted in some of the patients. Among the patients mapped to scenario 20a under AUC/2012, almost one-tenth underwent FFR. This trend may indicate that methods for evaluating ischemia have been changing. However, in AUC/2009 or AUC/2012, ischemic evaluation by FFR is

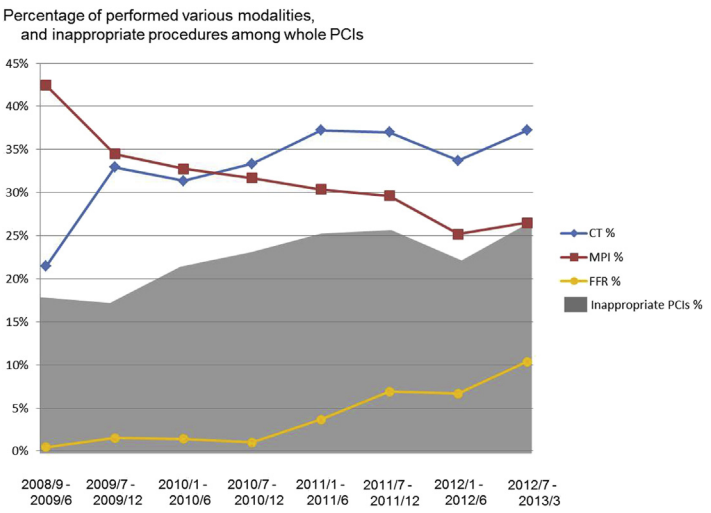

FIGURE 3 Association Between Temporal Trends of Noninvasive Testing and Frequency of Inappropriate Ratings

Gray area indicates the percentages of inappropriate procedures on the basis of original appropriateness criteria (AUC/2009). CT = computed tomography; FFR = functional flow reserve; MPI = myocardial perfusion imaging; PCI = percutaneous coronary intervention.

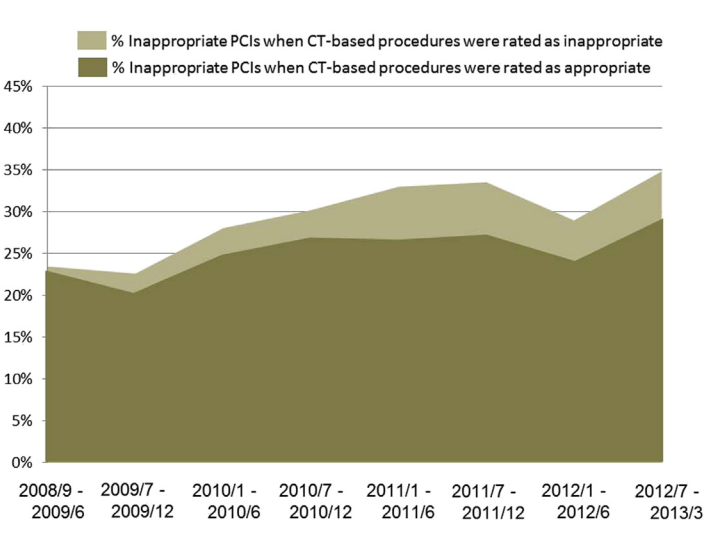

FIGURE 4 Change in the Proportion of PCIs Rated as Inappropriate When CT-Based Procedures Were Classified Not as Inappropriate but as Appropriate

Light brown indicates the trend of proportion of inappropriate PCIs when CT-based procedures were rated as inappropriate. **Dark brown** indicates the trend of proportion of inappropriate PCIs when CT-based procedures were rated as appropriate. Abbreviations as in Figure 3.

accepted only for 1- or 2-vessel CAD with borderline stenosis of 50% to 60%. The use of FFR in coronary artery stenosis >60% was not adjudicated, which was also mentioned in the previous study (4). In view of this, there is room for improvement in AUC/2009 or AUC/2012 to permit a more precise evaluation of appropriateness.

There are several reasons for the wide implementation of coronary CTA in Japan. First, high-technology medical equipment including CT and magnetic resonance imaging is widely available in Japan; the number of CT scanners per million people in Japan is estimated to be >7 times more than that in the United States (22). Second, there is universal health coverage in Japan, which makes it easier for patients to access medical resources. In 1961, Japan managed to extend social health insurance to the entire population and achieved universal health coverage (23). This health policy is equally applied to all healthcare facilities, and the provision of equal medical services is achieved across the entire nation. Further studies focused specifically on coronary CTA are needed to close this scientific gap in PCI indications.

STUDY LIMITATIONS. For a thorough understanding of our results, several limitations should be acknowledged. First, not all hospitals that perform PCI in Japan participate in our registry. Our registry, however, is multicenter and includes a relatively large number of procedures. We believe that this is one of the representative Japanese databases on PCI patients and that our results comprise the most complete assessment of practice patterns throughout Japan currently.

Second, the use of coronary CTA has become more widespread in Japan compared with the United States. In 2010, the percent of PCI patients evaluated with coronary CTA was >30% in Japan, whereas it was only 2.7% in the United States (8). Although there is a significant gap in the use of coronary CTA, the temporal trends of noninvasive testing, in which previous anatomic assessment has been increasing, are similar in both countries. This means that similar trends regarding appropriateness of PCIs will be highlighted in the near future in the United States.

CONCLUSIONS

In a multicenter Japanese PCI registry, approximately one-sixth of PCIs were rated as inappropriate under the AUC/2009 in nonacute settings, and the rate of inappropriate PCIs increased to approximately one-third on the basis of the revised AUC/2012. The significant changes in the inappropriate PCI rating between the 2009 and 2012 criteria may be due to the technological evolution of cardiovascular imaging, which continues to evolve in everyday cardiology practice. Further effort is needed to refine and correct the growing disconnection between the AUC and modern pre-PCI evaluation.

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APPENDIX For supplemental tables and information, please see the online version of this article.