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The Current Status of Percutaneous Coronary Intervention in Korea –Based on Year 2014 Cohort of Korean Percutaneous Coronary Intervention (K-PCI) Registry–

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Background and Objectives: Although several multicenter registries have evaluated percutaneous coronary intervention (PCI) procedures in Korea, those databases have been limited by non-standardized data collection and lack of uniform reporting methods. We aimed to collect and report data from a standardized database to analyze PCI procedures throughout the country.

Materials and Methods: Both clinical and procedural data, as well as clinical outcomes data during hospital stay, were collected based on case report forms that used a standard set of 54 data elements. This report is based on 2014 Korean PCI registry cohort data.

Results: A total of 92 hospitals offered data on 44967 PCI procedures. The median age was 66.0 interquartile range 57.0-74.0 years, and 70.3% were men. Thirty-eight percent of patients presented with acute myocardial infarction and one-third of all PCI procedures were performed in an urgent or emergency setting. Non-invasive stress tests were performed in 13.9% of cases, while coronary computed tomography angiography was used in 13.7% of cases prior to PCI. Radial artery access was used in 56.1% of all PCI procedures. Devices that used PCI included drug-eluting stent, plain old balloon angioplasty, drug-eluting balloon, and bare-metal stent (around 91%, 19%, 6%, and 1% of all procedures, respectively). The incidences of in-hospital death, non-fatal myocardial infarction, and stroke were 2.3%, 1.6%, and 0.2%, respectively.

Conclusion: These data may provide an overview of the current PCI practices and in-hospital outcomes in Korea and could be used as a foundation for developing treatment guidelines and nationwide clinical research. **(Korean Circ J 2017;47(3):328-340)**

KEY WORDS: Percutaneous coronary intervention; Registry.

Introduction

Percutaneous coronary intervention (PCI) has emerged as an important modality to treat coronary artery disease (CAD). As research improves pharmacology and clinical approaches for patient treatment, more complex CADs are being successfully treated with PCI and clinical outcomes are consistently improving. PCI can now be performed in most patients that require revascularization and it is also offered to subjects that have a high operative risk.[1]

Guideline-based strategies and monitoring of PCI procedures are strongly recommended to improve in-hospital and long-term clinical outcomes of patients that undergo PCI.[2-5] Specifically, performance
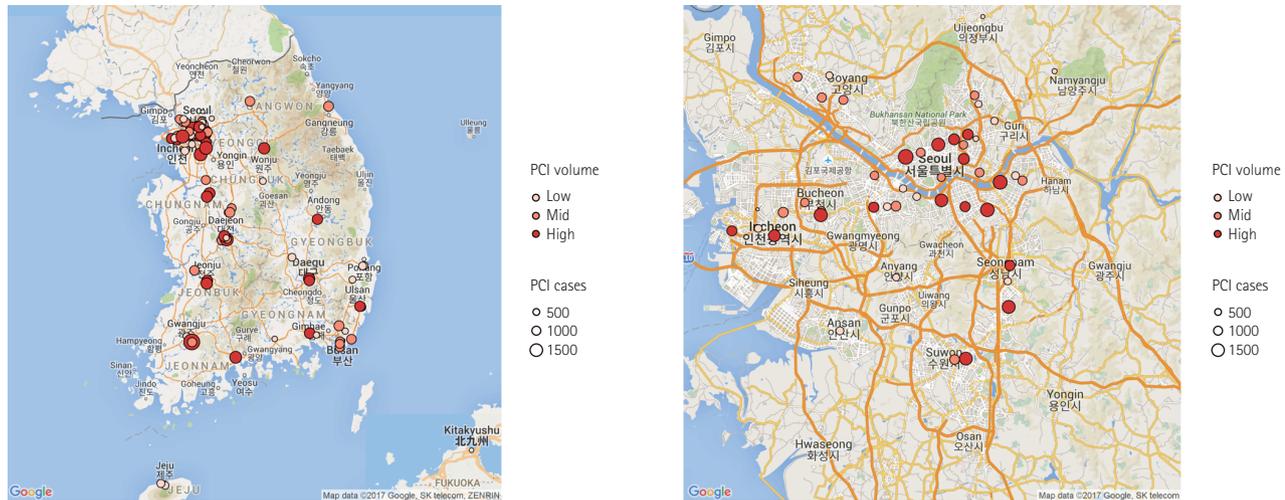
Fig. 1. Geographic distribution of PCI facilities participating in the K-PCI registry. Ninety-two hospitals submitted data for 44967 PCI cases. High-volume facilities were concentrated in Seoul and metropolitan areas. PCI: percutaneous coronary intervention, K-PCI: Korean percutaneous coronary intervention.

measures for PCI and ST-elevation myocardial infarction (STEMI)/non-ST-elevation myocardial infarction (NSTEMI) were established to guide physicians with approaches for these interventions.[6-8]

Although several multicenter registries have evaluated PCI procedures in Korea,[9-13] no nationwide contemporary PCI registries have been collected with standardized collection forms and unified reporting methods. The Korean Society of Cardiology (KSC) and Korean Society of Interventional Cardiology (KSIC) established the Korean percutaneous coronary intervention (K-PCI) registry to collect and report results in a standardized database for PCI case analysis throughout the country. The purpose of this study was to construct baseline data standards to set-up treatment guidelines that reflect relevant clinical situations and to facilitate clinical research for cardiologists that treat CAD in Korea.

Materials and Methods

Participation and data definitions

The K-PCI registry final protocol was created in the task force team meeting and the K-PCI registry governing committee conference, it was designed for enrolling participants with respect to clinical diagnosis information, procedural data, and by considering major complications after PCI procedures performed to treat ischemic heart disease. The hospitals that could perform PCI were asked to participate and 92 hospitals voluntarily took part in this registry. Demographic characteristics, clinical history, procedural information and PCI complications that occurred before hospital discharge were collected retrospectively using case report forms (CRFs) comprised of a standard set of 54 data elements. When multiple interventions were performed

in a subject, individual procedures were considered as single cases and were entered in the database. All variables corresponded with written definitions in the CRF dictionary (K-PCI registry 2014 CRF v1.4., Supplementary Table 1 in the online-only Data Supplement) to standardize the data, and were provided by using common specifications with question and answer cases for participants.

This study was approved by the local institutional review board (IRB) at each participating site. The written consent document was waived in participating centers, because of the retrospective nature of the study, with no clinical follow-up. Data were collected using a web-based reporting system.

Data collection and management

This report represents PCI data of the participating hospitals from January 1, 2014, through December 31, 2014. The K-PCI registry governing committee centrally managed the web-based registered study data. After the K-PCI registry was approved by the IRBs, demographic, procedural, and in-hospital outcomes data for 44967 PCI cases from 92 hospitals were collected. About half (45.7%) of the PCI centers were located in the capital area and high-volume facilities that performed more than 781 PCI procedures annually were concentrated in metropolitan areas, including Seoul (Fig. 1).

The K-PCI data management and inspection program determined whether collected data were accurate and complete and the CRF variables were refined based on the program results. The K-PCI registry governing committee periodically monitored the enrollment status and shared the results with participating hospitals via newsletters, the committee also performed data management quality verification through the query process.
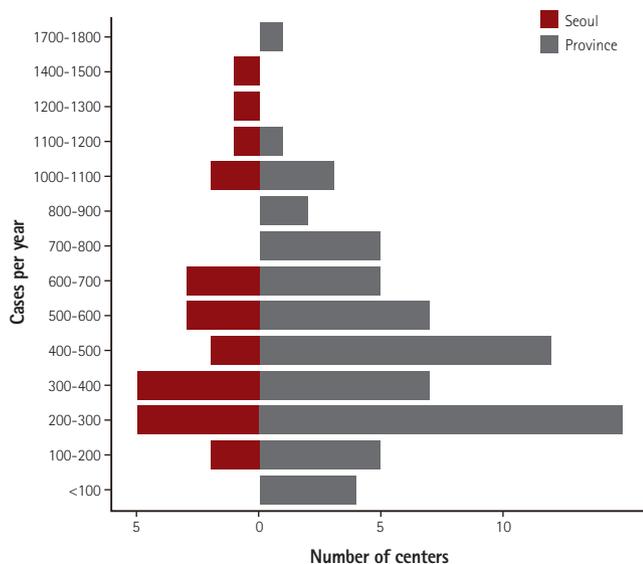
Fig. 2. Distribution of facilities with different PCI volume. Sixty-two percent of the included hospitals performed 500 or fewer PCI procedures and 11% performed more than 1000 PCIs during the collection period. PCI: percutaneous coronary intervention.
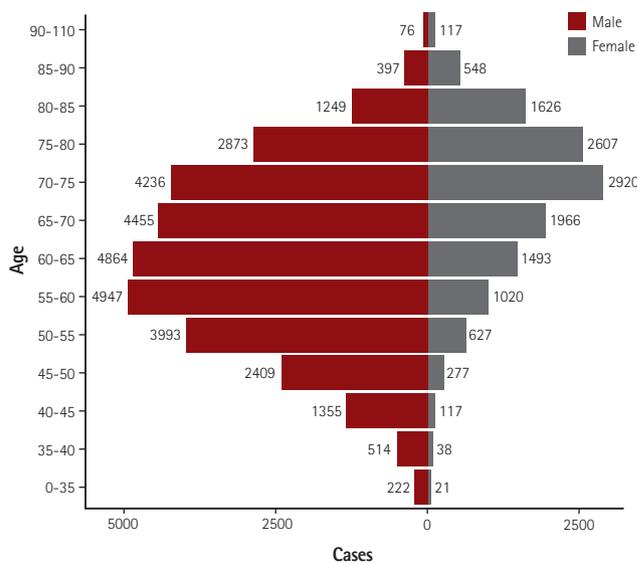

Fig. 3. Age and gender distribution. Median age was 66 years and the proportion of male patients was 70.3%.
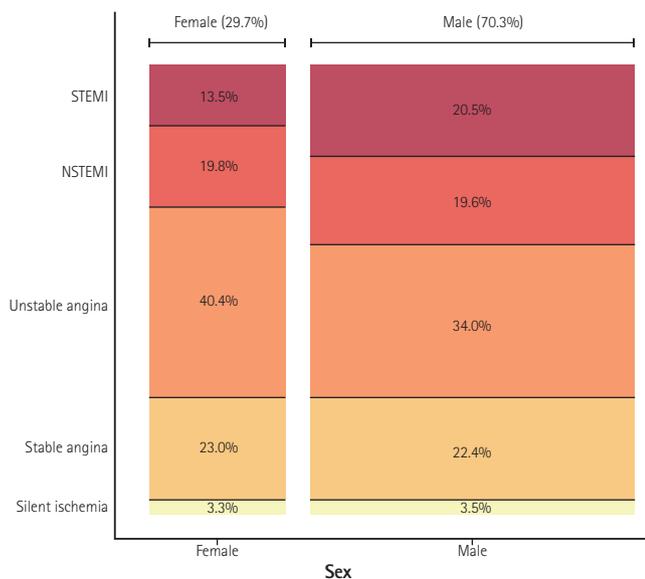

Fig. 4. Gender-specific clinical indications for PCI. The width of the bars in the histogram indicates the number of patients. NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, PCI: percutaneous coronary intervention.

Statistical analysis

Discrete data for demographic, clinical, procedural and outcome variables were presented as numbers and percentages and compared using Chi-square tests. Continuous variables are presented as medians

with interquartile ranges (IQRs) unless otherwise specified, and were compared using the Student's t-test, analysis of variance (ANOVA) or the Wilcoxon rank-sum test, where applicable. All p values were 2-tailed, and a p value<0.05 was considered statistically significant. All analyses were conducted using R version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Study populations

A total of 92 hospitals submitted data on 44967 PCI procedures performed from January through December 2014. The data presented in this report provide a contemporary assessment of PCI, as performed in Korea during the collection period, and represent important aspects of coronary interventions, including use of diagnostic support tools and procedural devices, as well as clinical outcomes before hospital discharge. Among the hospitals included in the K-PCI registry, 62% performed 500 or fewer PCI procedures and 11% performed more than 1000 PCIs during the collection period. Twelve hospitals (13%) performed 200 or fewer PCIs for one year and these hospitals accounted for 3.2% of all PCI procedures (Fig. 2).

Clinical characteristics and presentation

Baseline demographic and clinical characteristics of included patients are presented in Table 1. Median age was 66.0 [IQR 57.0-74.0]
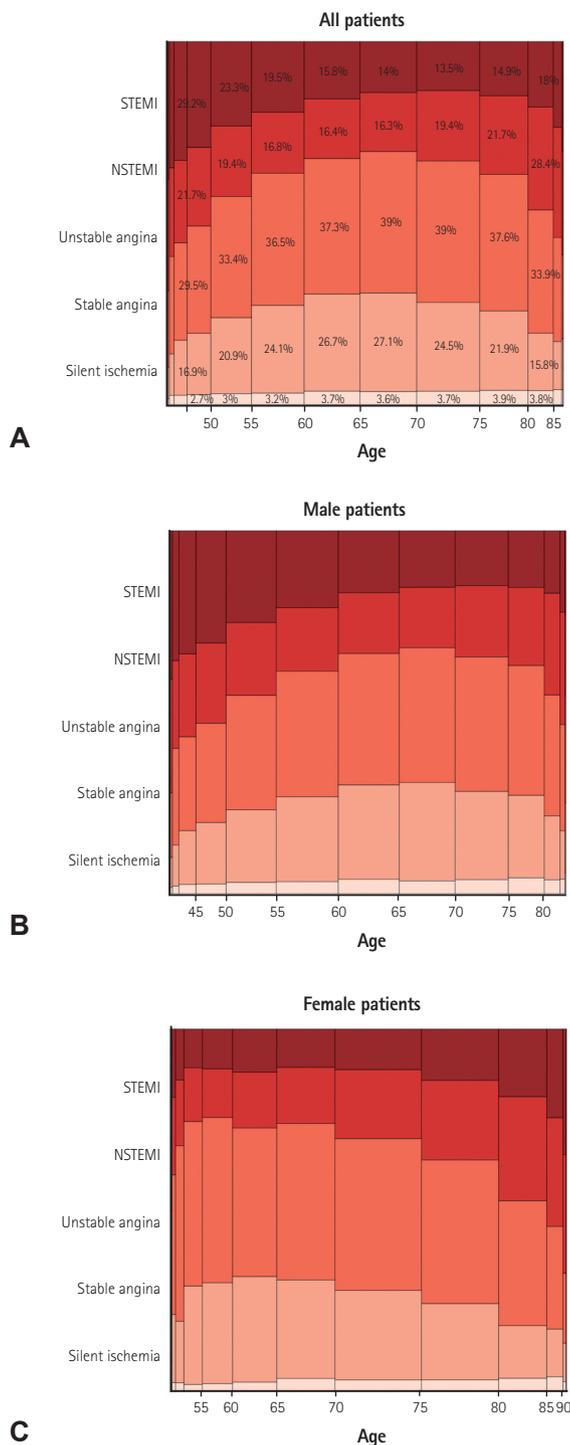
All patients

A

Male patients

B

Female patients

C

Fig. 5. Age-specific clinical indications for PCI. The width of the bars in the histogram indicates the number of patients. NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, PCI: percutaneous coronary intervention.

years and the proportion of male patients was 70.3% (Fig. 3). Among patients undergoing PCI, 35.9% had diabetes mellitus, 9.2% had

history of prior myocardial infarction, 24% had history of PCI, 1.3% had prior coronary artery bypass surgery, 6.4% had renal failure, 8.8% had prior history of cerebrovascular disease, and 2.7% had peripheral vascular disease. Unstable angina was the most common initial presentation (35.9%) that was a clinical indication for PCI, followed by stable angina (22.6%), NSTEMI (19.7%), STEMI (18.4%), and silent ischemia (3.5%) (Fig. 4). Patients that were between 60-80 years, were more likely to present with stable angina compared with other age groups, whereas patients in younger groups and elderly groups were more likely to present with acute coronary syndrome (ACS) (Fig 5A). However, when this age-diagnosis interaction was sorted by gender, there was a trend toward a higher incidence of ACS in young male patients and elderly female patients (Fig. 5B, C). Cardiogenic shock was identified in 3.1% and cardiac arrest was present in 2.3% of patients in the 24 hours prior to admission. Beta blocking agents were the most frequently prescribed antianginal medication (53.5%) within 2 weeks of the procedure, followed by calcium channel blockers (36.5%), nicorandil (24.1%), long-acting nitrates (17.6%), and trimetazidine (15.2%).

Non-invasive test and imaging studies

From the total number of patients undergoing PCI, only 13.9% (9.8% in ACS patients, 25.8% in non-ACS patients) underwent certain types of non-invasive tests before the PCI (Table 1). The treadmill test (TMT) was the dominant stress test (6.7% in ACS patients, 19.5% in non-ACS patients). Of the non-ACS patients who underwent different types of non-invasive stress tests, 13.3% demonstrated positive TMT and 5.1% demonstrated positive thallium single-photon emission computed tomography. Stress echocardiography and stress magnetic resonance imaging studies were done in less than 1% of patients in this registry. Coronary computed tomography (CT) angiography was performed in 13.7% (10.0% in ACS, 24.1% in non-ACS) of patients and 42.7% of those patients had one vessel involved. Pre-PCI evaluation of left ventricular function was performed in 67.6% of patients and the mean left ventricular ejection fraction was 60.0%.

Procedural characteristics

Angiographic and procedural characteristics for each PCI procedure are presented in Table 2. More than half of the patients had multi-vessel CAD, whereas 42.7% of patients had single vessel involvement. The left anterior descending artery was the most frequently involved vessel (70.1%), followed by the right coronary artery (35.4%), left circumflex artery (27.3%), and left main coronary artery (4.9%). Among patients that underwent PCI, a chronic total occlusion lesion was present in 10.5% and an in-stent restenosis lesion was present in 7.6%. Graft vessel PCI was done in only 0.2 % of all procedures. Two-thirds of the PCI procedures were performed in an elective setting. In this registry the trans-radial approach was more frequently (56.1%)

Table 1. Baseline patient and clinical characteristics

Variables	All (n=44967)	Men (n=31590)	Women (n=13377)	p
Demographics				
Age, years (IQR)	66.0 (57.0-74.0)	63.0 (55.0-72.0)	72.0 (65.0-78.0)	<0.001
Risk factors				
Diabetes				<0.001
Any	16139 (35.9)	10710 (33.9)	5429 (40.6)	
Insulin-dependent	1601 (9.92)	956 (8.92)	645 (11.9)	
Hypertension	27828 (61.9)	18154 (57.5)	9674 (72.3)	<0.001
Dyslipidemia	17823 (39.6)	12486 (39.5)	5337 (39.9)	0.748
Current/recent smoker	14376 (31.96)	13499 (42.76)	877 (6.55)	<0.001
Family history of CAD	2518 (5.60)	1893 (5.99)	625 (4.67)	<0.001
Prior myocardial infarction	4132 (9.19)	3170 (10.0)	962 (7.19)	<0.001
Prior PCI	10798 (24.0)	7792 (24.7)	3006 (22.5)	<0.001
Prior CABG	598 (1.33)	437 (1.38)	161 (1.20)	0.278
Renal failure*				<0.001
Any	2877 (6.40)	1931 (6.11)	946 (7.07)	
Dialysis-dependent	1134 (2.52)	718 (2.27)	416 (3.11)	
Cerebrovascular disease	3943 (8.77)	2695 (8.53)	1248 (9.33)	0.023
Peripheral arterial disease	1198 (2.66)	937 (2.97)	261 (1.95)	<0.001
Clinical indication for PCI				<0.001
Silent ischemia	1553 (3.45)	1114 (3.53)	439 (3.28)	
Stable angina	10166 (22.6)	7085 (22.4)	3081 (23.0)	
Unstable angina	16127 (35.9)	10729 (34.0)	5398 (40.4)	
NSTEMI	8839 (19.7)	6192 (19.6)	2647 (19.8)	
STEMI	8282 (18.4)	6470 (20.5)	1812 (13.5)	
Cardiogenic shock	1395 (3.10)	1015 (3.21)	380 (2.84)	0.114
Cardiac arrest	1034 (2.30)	803 (2.54)	231 (1.73)	<0.001
Non-invasive stress or imaging test				
Stress test performed				
Done	6269 (13.9)	4688 (14.8)	1581 (11.8)	<0.001
Negative (any stress test)	1799 (4.0)	1321 (4.2)	478 (3.6)	
Positive (any stress test)	4470 (9.94)	3367 (10.7)	1103 (8.25)	<0.001
TMT positive	2972 (6.61)	2301 (7.28)	671 (5.02)	<0.001
Thallium positive	1307 (2.91)	931 (2.95)	376 (2.81)	0.817
Stress echo positive	271 (0.60)	201 (0.64)	70 (0.52)	0.288
Stress MR positive	36 (0.08)	28 (0.09)	8 (0.06)	0.611
Pre-PCI LVEF†				
Done	30383 (67.6)	20908 (66.2)	9475 (70.8)	<0.001
Mean (±SD)	60.0 (50.0-66.0)	60.0 (50.0-65.0)	61.0 (51.0-67.0)	<0.001
Coronary CTA performed				0.009
Done	6164 (13.7)	4243 (13.4)	1921 (14.4)	
1 vessel disease	2632 (42.7)	1777 (41.9)	855 (44.5)	0.107
2 vessel diseases	1855 (30.1)	1293 (30.5)	562 (29.3)	
3 vessel diseases	1457 (23.6)	1019 (24.0)	438 (22.8)	
Undetermined	71 (1.15)	56 (1.32)	15 (0.78)	
Antianginal medications (within 2 weeks)				
Beta-blockers	13146 (53.3)	9184 (54.4)	3962 (50.9)	<0.001
Ca-channel- blockers	8999 (36.5)	5952 (35.3)	3047 (39.1)	<0.001
Long-acting nitrates	4339 (17.6)	2989 (17.7)	1350 (17.3)	0.493
Nicorandil	5934 (24.1)	4062 (24.1)	1872 (24.0)	0.987
Trimetazidine	3745 (15.2)	2602 (15.4)	1143 (14.7)	0.141
Others	4544 (18.4)	3078 (18.2)	1466 (18.8)	0.270

Values are presented as number (%) if not otherwise specified. *GFR ≤60 mL/min/1.73 m², †can be assessed via invasive (i.e. left ventriculography) or non-invasive (i.e. echocardiography, magnetic resonance, computed tomography, or nuclear) testing. IQR: interquartile range, CAD: coronary artery disease, PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft, NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, TMT: treadmill test, MR: magnetic resonance, LVEF: left ventricular ejection fraction, SD: standard deviation, CTA: computed tomography angiography

Table 2. Baseline angiographic and procedural characteristics

Variables	All (n=44967)	Men (n=31590)	Women (n=13377)	p
Disease extent				<0.001
1 vessel disease	19210 (42.7)	13641 (43.2)	5569 (41.6)	
2 vessel diseases	14674 (32.6)	10352 (32.8)	4322 (32.3)	
3 vessel diseases	10664 (23.7)	7310 (23.1)	3354 (25.1)	
Lesion location				
Left main	2216 (4.93)	1629 (5.16)	587 (4.39)	0.001
Proximal LAD	14327 (31.9)	10083 (31.9)	4244 (31.7)	0.697
Mid to distal LAD	17200 (38.3)	11468 (36.3)	5732 (42.8)	<0.001
LCX	12294 (27.3)	8732 (27.6)	3562 (26.6)	0.028
RCA	15925 (35.4)	11392 (36.1)	4533 (33.9)	<0.001
Graft	100 (0.22)	75 (0.24)	25 (0.19)	0.352
ISR lesion	3421 (7.61)	2426 (7.68)	995 (7.44)	0.351
CTO lesion	4740 (10.5)	3561 (11.3)	1179 (8.81)	<0.001
Procedural characteristics				
PCI status				<0.001
Elective	29971 (66.7)	20536 (65.0)	9435 (70.5)	
Urgent	5458 (12.1)	3836 (12.1)	1622 (12.1)	
Emergent	8981 (20.0)	6836 (21.6)	2145 (16.0)	
Salvage	158 (0.35)	116 (0.37)	42 (0.31)	
PCI approach				
Trans-radial	25213 (56.1)	17884 (56.6)	7329 (54.8)	<0.001
Trans-femoral	20396 (45.4)	14146 (44.8)	6250 (46.7)	<0.001
Mechanical support tool				0.505
Not done	43954 (97.7)	30861 (97.7)	13093 (97.9)	
Done (IABP or EBS)	1002 (2.23)	721 (2.28)	281 (2.10)	
Adjunctive support tool				
IVUS use	12846 (28.6)	9339 (29.6)	3507 (26.2)	<0.001
FFR use	1675 (3.72)	1234 (3.91)	441 (3.30)	0.006
Angioplasty device				
BMS	483 (1.07)	327 (1.04)	156 (1.17)	0.237
DES	41077 (91.3)	28909 (91.5)	12168 (91.0)	0.060
DEB	2666 (5.93)	1866 (5.91)	800 (5.98)	0.780
POBA	8611 (19.1)	5953 (18.8)	2658 (19.9)	0.012
Number of BMS				0.144
1	372 (0.83)	254 (0.80)	118 (0.88)	
2	81 (0.18)	57 (0.18)	24 (0.18)	
≥3	30 (0.06)	16 (0.05)	14 (0.1)	
Number of DES				0.121
1	27406 (60.9)	19361 (61.3)	8045 (60.1)	
2	9784 (21.8)	6841 (21.7)	2943 (22.0)	
≥3	3887 (8.64)	2707 (8.53)	1180 (8.81)	

Values are presented as number (%) and percent if not otherwise specified. LAD: left anterior descending, LCX: left circumflex, RCA: right coronary artery, ISR: in-stent restenosis, CTO: chronic total occlusion, PCI: percutaneous coronary intervention, IABP: intra-aortic balloon pump, EBS: emergency bypass system, IVUS: intravascular ultrasound, FFR: fractional flow reserve, BMS: bare-metal stents, DES: drug-eluting stents, DEB: drug-eluting balloon, POBA: plain old balloon angioplasty

Table 3. In-hospital outcomes

Variables	All (n=44967)	Men (n=31590)	Women (n=31590)	p
Death	1023 (2.28)	629 (1.99)	394 (2.95)	<0.001
Cardiac death	704 (1.57)	432 (1.37)	272 (2.03)	<0.001
Nonfatal myocardial infarction	701 (1.56)	516 (1.63)	185 (1.38)	0.075
Stent thrombosis	172 (0.38)	139 (0.44)	33 (0.25)	0.003
Stroke	90 (0.20)	58 (0.18)	32 (0.24)	0.426
Urgent repeat PCI	118 (0.26)	96 (0.30)	22 (0.16)	0.015
Transfusion	978 (2.17)	589 (1.86)	389 (2.91)	<0.001

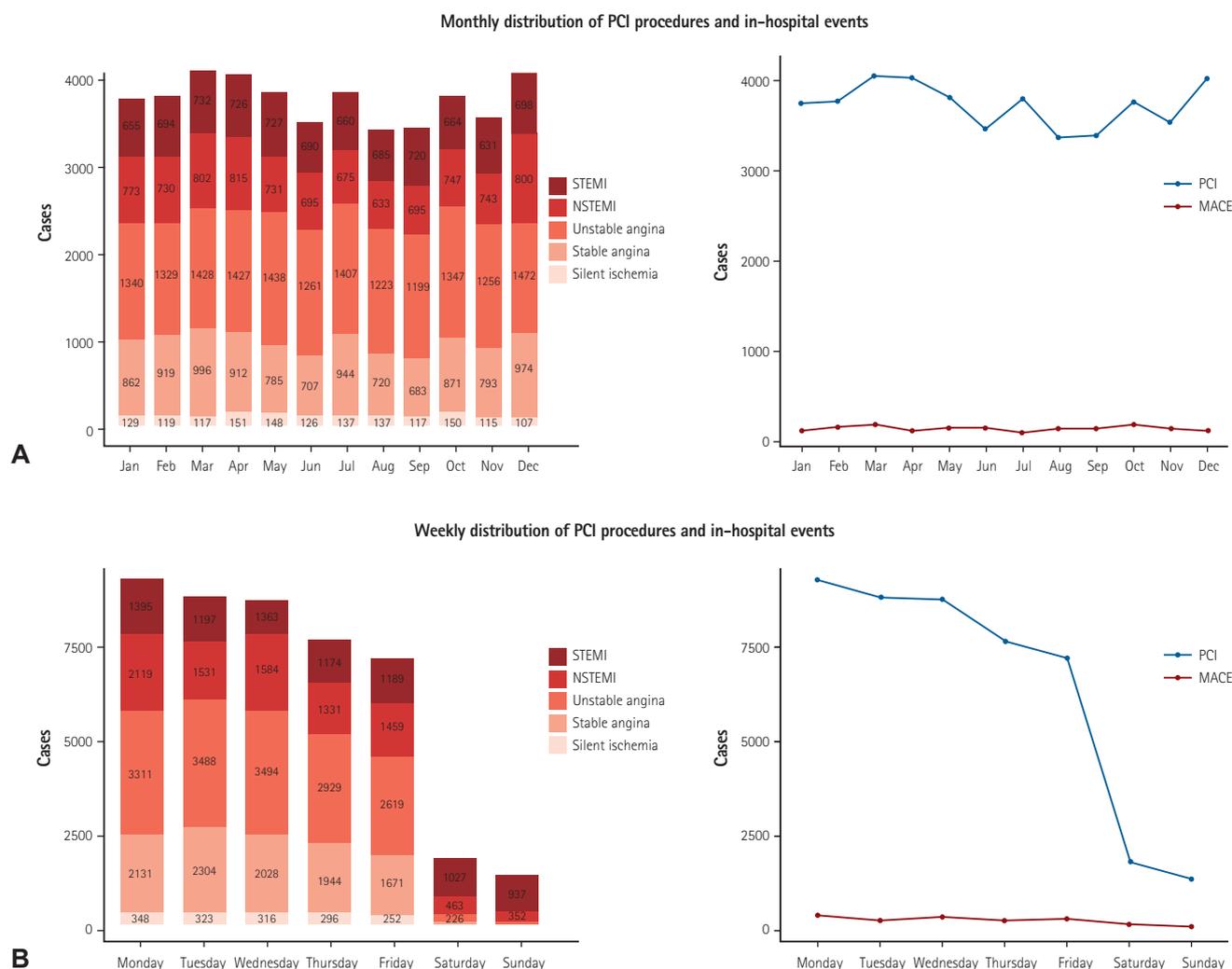Values are presented as number (%). PCI: percutaneous coronary intervention

Fig. 6. Temporal distribution of PCI procedures and in-hospital events. (A) Monthly distribution of PCI procedures and in-hospital cardiac events. (B) Weekly distribution of PCI procedures and in-hospital cardiac events. STEMI: ST-elevation myocardial infarction, NSTEMI: non-ST-elevation myocardial infarction, PCI: percutaneous coronary intervention, MACE: major adverse cardiac events.

used for PCI procedures, compared to the trans-femoral approach (45.4%). Even among ACS patients, more than half (52.7%) of procedures were performed via the trans-radial approach.

Mechanical support devices, such as an intra-aortic balloon pump

or emergency bypass system, were used in 2.2% of all PCI procedures. Data on the use of PCI devices was also collected. At least one drug-eluting stent (DES) was placed in 91.3% of procedures, plain old balloon angioplasty (POBA) without stent implantation was done in

19.1%, and drug-eluting balloon (DEB) was used in 5.9% of patients. A bare-metal stent was placed in only 1.1% of all patients. Intravascular ultrasound (IVUS) was used in 28.6% of patients (27.1% in ACS patients, 32.7% in non-ACS patients) as an adjunctive PCI support tool, whereas fractional flow reserve (FFR) was only performed in 3.7% of patients (2.5% in ACS patients, 7.2% in non-ACS patients).

Clinical outcomes during hospitalization

Patient clinical outcomes during hospitalization are summarized in Table 3. The in-hospital, all-cause mortality for the entire cohort was 2.3% (1023 patients), of which 68.8% (704 patients) experienced cardiac-related deaths (Table 3). In-hospital mortality ranged from 0.2% in patients with stable angina to 6.9% in STEMI patients. Other in-hospital event rates were low including, non-fatal MI 1.6%, stroke 0.2%, urgent repeat revascularization 0.3%, and stent thrombosis in 0.4% (172 patients). There were significantly higher rates of all-cause mortality (3.0 vs. 2.0; p<0.001) and cardiac mortality (2.0 vs. 1.4%; p<0.001) in women undergoing PCI. The rates for transfusion during hospitalization were 2.2%, which was higher in women (2.9 vs. 1.9%; p<0.001). Although the number of PCI procedures peaked in March and December, the incidence of in-hospital events was evenly distributed throughout the year. However, the rates of in-hospital cardiac events were significantly higher when PCI cases were performed during weekends than for procedures performed during weekdays (9.4 vs. 3.8%; p<0.001; Fig. 6), this is likely because most cases performed over the weekend were in emergency settings.

Centers patterns and results

To understand differences in demographics, procedural characteristics and clinical outcomes between high vs. low PCI volume centers, we divided all PCI centers into three tertiles based on the number of PCIs performed during the collection period (1st tertile: 41-493; 2nd tertile: 494-780; 3rd tertile: 781-1794). Patients in high-volume centers were more likely to have a history of hypertension, dyslipidemia, renal failure, peripheral vascular disease, prior PCI, and coronary artery bypass graft than patients from lower volume centers (Table 4). High volume centers had more stable patients, used non-invasive pre-tests more frequently, and more frequently performed elective PCI with a trans-radial approach using IVUS/FFR (Table 5). In contrast, low volume centers had higher incidences of acute myocardial infarction, cardiogenic shock or cardiac arrest. Thus, these centers performed emergency PCI more frequently (24.4 vs. 14.9%; p<0.001) without IVUS/FFR and were less likely to conduct non-invasive pre-tests. Consequently, low volume centers showed higher in-hospital mortality (2.7 vs. 2.3 vs. 1.8%; p<0.001) (Table 6).

Discussion

This study represents the first nationwide database for PCI in Korea that was collected and analyzed by the KSC/KSIC K-PCI registry. Key findings were as follows: 1) thirty-eight percent of patients presented with acute myocardial infarction and one-third of all PCI procedures were performed in urgent or emergency settings, 2) non-invasive stress tests were performed in 13.9% of cases, while coronary CT angiography was used in 13.7% of cases before PCI, 3) radial artery access was used in 56.1% of all PCI procedures, 4) devices used in PCI included DES, POBA, DEB, and BMS (91.3%, 19.1%, 5.9%, and 1.1% of all procedures, respectively), 5) the incidences of in-hospital death, non-fatal myocardial infarction, and stroke were 2.3%, 1.6%, and 0.2%, respectively, 6) depending on the case volume of each center, there were differences in the baseline demographics, clinical characteristics, and in-hospital clinical outcomes after PCI.

The National Cardiovascular Data Registry (NCDR) of the American College of Cardiology Foundation (ACCF) is a representative database that was developed to assist healthcare providers document their processes and quality of care in the cardiac catheterization laboratory.[14)15] This registry records data on patient and hospital characteristics, clinical presentation, length of hospital stay, treatment information, and in-hospital outcomes for PCI procedures from >1000 sites across the United States. Several European countries are now conducting nationwide interventional registries that are organized either by a scientific society or the government.[16-20] However, patterns for Korean PCI practice have differed, compared to western countries, therefore a Korean database that reflects relevant situations in Korea is needed.

After FDA approval, the use of DES rapidly increased by up to 89% of all stents that were implanted in 2005. However, after research presented in 2006 suggested that there was an increase in adverse events in patients that received DES, use declined to 66% of all stents and was recorded as 73% in 2011.[21] In the US, physicians were less likely to use DES for patients that presented with myocardial infarction and were at high risk for stent thrombosis compared to unstable angina. In this cohort, DESs were used in 91.3% of all procedures, whereas only 1.1% of patients received bare-metal stents. Moreover, physicians consistently used DES across clinical diagnoses at initial presentation. Even in STEMI patients that underwent primary PCI, 92.2% received DES. Although the position of DES during primary PCI was not extensively established and increased risk of late stent thrombosis was indicated,[22] the practice pattern of DES use might reflect a gap in knowledge between actual and alleged benefits of DES, thus representing a possibility to improve clinical outcomes and quality of care for patients with different clinical presentations.

In this cohort, IVUS was used in 32.7% and FFR was used in 7.2%

Table 4. Baseline patient and clinical characteristics by PCI case-volume

Variables	All (n=44967)	Low-tertile volume centers [41–493]* (n=15105)	Mid-tertile volume centers [494–780]* (n=15286)	High-tertile volume centers [781–1794]* (n=14576)	p
Demographics					
Age, years (IQR)	66 (57–74)	66 (57–75)	66 (57–74)	65 (57–74)	<0.001
Gender					<0.001
Men	31590 (70.3)	10498 (69.5)	10572 (69.2)	10520 (72.2)	
Women	13377 (29.7)	4607 (30.5)	4714 (30.8)	4056 (27.8)	
Risk factors					
Diabetes					
Any	16139 (35.9)	5335 (35.3)	5296 (34.6)	5508 (37.8)	<0.001
Insulin-dependent	1601 (9.92)	524 (9.82)	511 (9.65)	566 (10.3)	<0.001
Hypertension	27828 (61.9)	9165 (60.7)	9492 (62.1)	9171 (62.9)	<0.001
Dyslipidemia	17823 (39.6)	5065 (33.5)	5531 (36.2)	7227 (49.6)	<0.001
Current/recent smoker	14376 (31.96)	4763 (31.57)	4927 (32.21)	4686 (32.10)	<0.001
Family history of CAD	2518 (5.60)	762 (5.04)	663 (4.34)	1093 (7.50)	<0.001
Prior myocardial infarction	4132 (9.19)	1328 (8.79)	1470 (9.62)	1334 (9.15)	<0.001
Prior PCI	10798 (24.0)	3298 (21.8)	3692 (24.2)	3808 (26.1)	<0.001
Prior CABG	598 (1.33)	123 (0.81)	167 (1.09)	308 (2.11)	<0.001
Renal failure†					<0.001
Any	2877 (6.40)	1012 (6.70)	858 (5.62)	1007 (6.91)	
Dialysis-dependent	1134 (2.52)	427 (2.83)	307 (2.01)	400 (2.74)	
Cerebrovascular disease	3943 (8.77)	1357 (8.98)	1350 (8.83)	1236 (8.48)	<0.001
Peripheral arterial disease	1198 (2.66)	307 (2.03)	390 (2.55)	501 (3.44)	<0.001
Clinical Indication for PCI					<0.001
Silent ischemia	1553 (3.45)	347 (2.30)	540 (3.53)	666 (4.57)	
Stable angina	10166 (22.6)	2862 (18.9)	2780 (18.2)	4524 (31.0)	
Unstable angina	16127 (35.9)	5752 (38.1)	5966 (39.0)	4409 (30.2)	
NSTEMI	8839 (19.7)	3095 (20.5)	2998 (19.6)	2746 (18.8)	
STEMI	8282 (18.4)	3049 (20.2)	3002 (19.6)	2231 (15.3)	
Cardiogenic shock	1395 (3.10)	642 (4.25)	443 (2.90)	310 (2.13)	<0.001
Cardiac arrest	1034 (2.30)	446 (2.95)	333 (2.18)	255 (1.75)	<0.001
Non-invasive stress or imaging test					
Stress test performed					
Done	6269 (13.9)	1775 (11.8)	1997 (13.1)	2497 (17.1)	<0.001
Negative (any stress test)	1799 (3.96)	497 (3.34)	594 (3.92)	708 (4.8)	
Positive (any stress test)	4470 (9.94)	1278 (8.46)	1403 (9.18)	1789 (12.3)	<0.001
TMT Positive	2972 (6.61)	979 (6.48)	829 (5.42)	1164 (7.99)	<0.001
Thallium positive	1307 (2.91)	201 (1.33)	566 (3.70)	540 (3.70)	<0.001
Stress echo positive	271 (0.60)	108 (0.71)	29 (0.19)	134 (0.92)	<0.001
Stress MR positive	36 (0.08)	3 (0.02)	3 (0.02)	30 (0.21)	<0.001
Pre-PCI LVEF‡					
Done	30383 (67.6)	10657 (70.6)	9984 (65.3)	9742 (66.8)	<0.001
Mean (±SD)	60.0 (50.0–66.0)	60.0 (50.0–65.0)	60.0 (49.5–65.3)	60.0 (52.0–66.0)	<0.001
Coronary CT performed					<0.001
Done	6164 (13.7)	1649 (10.9)	1260 (8.24)	3255 (22.3)	
1 vessel disease	2632 (42.7)	752 (45.6)	559 (44.4)	1321 (40.6)	<0.001
2 vessel diseases	1855 (30.1)	474 (28.7)	385 (30.6)	996 (30.6)	
3 vessel diseases	1457 (23.6)	359 (21.8)	265 (21.0)	833 (25.6)	
Undetermined	71 (1.15)	22 (1.33)	8 (0.63)	41 (1.26)	
Antianginal medications (within 2 weeks)					
Beta-blockers	13146 (53.3)	3564 (46.2)	4499 (54.3)	5083 (58.6)	<0.001
Ca-channel-blockers	8999 (36.5)	2525 (32.8)	2897 (35.0)	3577 (41.2)	<0.001
Long-acting nitrates	4339 (17.6)	1283 (16.6)	1393 (16.8)	1663 (19.2)	<0.001
Nicorandil	5934 (24.1)	1908 (24.8)	1741 (21.0)	2285 (26.3)	<0.001
Trimetazidine	3745 (15.2)	1316 (17.1)	1328 (16.0)	1101 (12.7)	<0.001
Others	4544 (18.4)	1783 (23.1)	1781 (21.5)	980 (11.3)	<0.001

Values are presented as number and percent if not otherwise specified. *Centers were divided into three tertiles based on PCI case-volume (1st tertile: 41–493; 2nd tertile: 494–780; 3rd tertile: 781–1794), †GFR ≤60 mL/min/1.73 m², ‡can be assessed via invasive (i.e. left ventriculography) or non-invasive (i.e. echocardiography, magnetic resonance, computed tomography, or nuclear) testing. IQR: inter-quartile range, CAD: coronary artery disease, PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft, NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, TMT: treadmill test, MR: magnetic resonance LVEF: left ventricular ejection fraction, VD: vessel disease, SD: standard deviation

Table 5. Baseline angiographic and procedural characteristics by PCI case-volume

Variables	All (n=44967)	Low-tertile volume centers [41–493]* (n=15105)	Mid-tertile volume centers [494–780]* (n=15286)	High-tertile volume centers [781–1794]* (n=14576)	p
Angiographic characteristics					
Disease extent					<0.001
1 vessel disease	19210 (42.7)	6795 (45.0)	6249 (40.9)	6166 (42.3)	
2 vessel diseases	14674 (32.6)	4782 (31.7)	5016 (32.8)	4876 (33.5)	
3 vessel diseases	10664 (23.7)	3371 (22.3)	3872 (25.3)	3421 (23.5)	
Lesion location					
Left main	2216 (4.93)	586 (3.88)	718 (4.70)	912 (6.26)	<0.001
Proximal LAD	14327 (31.9)	4694 (31.1)	5002 (32.7)	4631 (31.8)	0.008
Mid to distal LAD	17200 (38.3)	5373 (35.6)	6047 (39.6)	5780 (39.7)	<0.001
LCX	12294 (27.3)	4101 (27.1)	4370 (28.6)	3823 (26.2)	<0.001
RCA	15925 (35.4)	5453 (36.1)	5612 (36.7)	4860 (33.3)	<0.001
Graft	100 (0.22)	20 (0.13)	29 (0.19)	51 (0.35)	<0.001
ISR lesion	3421 (7.61)	998 (6.61)	1080 (7.07)	1343 (9.21)	<0.001
CTO lesion	4740 (10.5)	1648 (10.9)	1204 (7.88)	1888 (13.0)	<0.001
Procedural characteristics					
PCI status					<0.001
Elective	29971 (66.7)	9005 (59.6)	9963 (65.2)	11003 (75.5)	
Urgent	5458 (12.1)	1991 (13.2)	2115 (13.8)	1352 (9.28)	
Emergent	8981 (20.0)	3681 (24.4)	3123 (20.4)	2177 (14.9)	
Salvage	158 (0.35)	44 (0.29)	77 (0.50)	37 (0.25)	
PCI approach					
Trans-radial	25213 (56.1)	8117 (53.7)	8536 (55.8)	8560 (58.7)	<0.001
Trans-femoral	20396 (45.4)	7123 (47.2)	6969 (45.6)	6304 (43.2)	<0.001
Mechanical support tool					0.034
Not done	43954 (97.7)	14743 (97.6)	14951 (97.8)	14260 (97.8)	
Done (IABP or EBS)	1002 (2.23)	354 (2.34)	332 (2.17)	316 (2.17)	
Adjunctive support tool					
IVUS use	12846 (28.6)	3770 (25.0)	4278 (28.0)	4798 (32.9)	<0.001
FFR use	1675 (3.72)	296 (1.96)	382 (2.50)	997 (6.84)	<0.001
Angioplasty device					
BMS	483 (1.07)	70 (0.46)	106 (0.69)	307 (2.11)	<0.001
DES	41077 (91.3)	13912 (92.1)	14117 (92.4)	13048 (89.5)	<0.001
DEB	2666 (5.93)	993 (6.57)	719 (4.70)	954 (6.55)	<0.001
POBA	8611 (19.1)	5041 (33.4)	2153 (14.1)	1417 (9.72)	<0.001
No. of BMS					<0.001
1	372 (0.83)	53 (0.35)	87 (0.57)	232 (1.59)	
2	81 (0.18)	8 (0.05)	12 (0.08)	61 (0.42)	
≥3	30 (0.06)	9 (0.06)	7 (0.05)	14 (0.0)	
No. of DES					<0.001
1	27406 (60.9)	9578 (63.4)	9320 (61.0)	8508 (58.4)	
2	9784 (21.8)	3207 (21.2)	3347 (21.9)	3230 (22.2)	
≥3	3887 (8.64)	1127 (7.47)	1450 (9.48)	1310 (8.99)	

Values are presented as number (%) if not otherwise specified. *Centers were divided into three tertiles based on PCI case-volume (1st tertile: 41–493; 2nd tertile: 494–780; 3rd tertile: 781–1794). LAD: left anterior descending, LCX: left circumflex, RCA: right coronary artery, ISR: in-stent restenosis, CTO: chronic total occlusion, PCI: percutaneous coronary intervention, IABP: intra-aortic balloon pump, EBS: emergency bypass system, IVUS: intravascular ultrasound, FFR: fractional flow reserve, BMS: bare-metal stents, DES: drug-eluting stents, DEB: drug-eluting balloon, POBA: plain old balloon angioplasty

Table 6. In-hospital outcomes by PCI case-volume

Variables	All (n=44967)	Low-tertile volume centers [41–493]* (n=15105)	Mid-tertile volume centers [494–780]* (n=15286)	High-tertile volume centers [781–1794]* (n=14576)	p
Death	1023 (2.28)	403 (2.67)	352 (2.30)	268 (1.84)	<0.001
Cardiac death	704 (1.57)	274 (1.81)	240 (1.57)	190 (1.30)	0.001
Nonfatal myocardial infarction	701 (1.56)	260 (1.72)	237 (1.55)	204 (1.40)	0.171
Stent thrombosis	172 (0.38)	86 (0.57)	59 (0.39)	27 (0.19)	<0.001
Stroke	90 (0.20)	32 (0.21)	30 (0.20)	28 (0.19)	0.984
Urgent re-PCI	118 (0.26)	38 (0.25)	60 (0.39)	20 (0.14)	<0.001
Transfusion	978 (2.17)	246 (1.63)	338 (2.21)	394 (2.70)	<0.001

Values are presented as number (%). *Centers were divided into three tertiles based on PCI case-volume (1st tertile: 41-493; 2nd tertile: 494-780; 3rd tertile: 781-1794). PCI: percutaneous coronary intervention

of non-ACS cases as adjunct PCI support tools in patients undergoing PCI. These rates are higher than reported in US patterns of IVUS and FFR use.[23] However, there was a significant increase in the use of FFR and IVUS, according to the Nationwide Inpatient Sample (NIS) database of patients undergoing left heart catheterization between 2009 and 2011 in the US. Specifically, the number of in-hospital FFR utilization in US increased from 1173 cases in 2008 to 21365 cases in 2012, representing an 18-fold rise.[24] Further research studies are needed to elucidate the implementation of adjunct PCI support tools in lesions with different locations and different severities in our cohort.

The overall in-hospital mortality rate for PCI patients in this report was somewhat higher than previous registries.[25)26] In-hospital mortality among 181775 PCI procedures performed from January 2004 through March 2006 in US NCDR was 1.27%, ranging from 0.65% in elective PCI to 4.81% in STEMI patients.[25] In our registry, in-hospital mortality ranged from 0.2% in patients with stable angina to 6.9% in STEMI patients. Higher overall in-hospital mortality in our registry can be partly explained by older age, more female patients, higher proportion of diabetes mellitus, and greater likelihood of undergoing emergency PCI in subjects included in our registry. Although the exact mechanism of higher mortality in the K-PCI registry has not been fully elucidated, additional mortality risk model assessment is needed to accurately measure patient risks in order to improve quality of care and shared decision making.[27]

We found significant variations between high vs. low PCI volume centers in terms of baseline demographic, clinical characteristics and in-hospital clinical outcomes. For example, the frequency of non-invasive tests before PCI was 12% in low-tertile volume centers while 17% in high-tertile volume centers. The frequency of IVUS/FFR use during PCI was 27% in low-volume centers while 40% in high-volume centers. These actual differences, particularly the lower utilization of IVUS or FFR during procedures in low-tertile volume centers, suggest an important opportunity to improve the consistency

of care for patients undergoing PCI because evidence indicates that adjunct PCI support tools can reduce repeat revascularization and stent thrombosis rates after PCI with DES implantation.[28-30] The lower utilization of IVUS/FFR during PCI or non-invasive tests before PCI in low-volume centers could be related to critical care or patient emergencies. The low-volume centers had fewer patients with stable angina (20 vs. 35% in high-volume) and that underwent less elective PCI (60 vs. 75% in high-volume centers) than high-volume centers. In other words, low-volume centers more frequently performed urgent/emergency PCI for patients with ACS than high-volume centers. This could affect the ability of centers to use non-invasive tests before PCI or IVUS/FFR during PCI, which is possible in more stable patients or in PCI situations. This analysis was not designed to formulate definite conclusions from this observation. Therefore, additional research efforts are needed to elucidate how the differences in quality of care have affected clinical outcomes in high- vs. low-volume centers.

Performance measures and outcome implementation information from the K-PCI registry could provide data for creating and developing Korean guidelines for PCI, acute myocardial infarction, and unstable angina/non-ST-elevation myocardial infarction. The K-PCI registry will support improvements in catheterization laboratory performance around the country and assist in the acquiring and maintaining individual physician certification for KSIC. The K-PCI registry committee is currently planning to capture catheterization data in 2016 and this report will be the most comprehensive database for PCI in Korea.

Limitations

There were some limitations to this study that should be considered when interpreting the results. First, patients and hospitals participating in the K-PCI registry may not have been representative of all Korean PCI procedures. However, the K-PCI registry represents 92 PCI-capable hospitals across Korea and captures the majority of PCI procedures performed nationally. Second, several factors

may have influenced the decision-making of the interventional cardiologists represented in different region or different hospitals, in regards to procedural features, such as use of adjunct PCI tools and pre-PCI non-invasive test selection. Third, the K-PCI registry dataset only records clinical outcomes that occurred before hospital discharge prior to PCI. Moreover, given that our data were analyzed retrospectively, clinical outcomes associated with the clinical or procedural characteristics of patients or catheterization laboratories are observational and causality cannot be established. Fourth, data collection and reports lagged behind PCI procedures by 1 year, thus limiting rapid feedback of contemporary practices to implement quality improvement processes for the participating centers.

Conclusion

This study presents the first Korean PCI data collected and analyzed by the KSC/KSIC K-PCI registry. These data may provide an opportunity to understand current PCI practices and in-hospital outcomes in Korea and could be used as a foundation for developing treatment guidelines and nationwide clinical research.

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Supplementary Material

The online-only Data Supplement is available with article at https://doi.org/10.4070/kcj.2017.0071.

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