Sex difference in clinical outcomes after percutaneous coronary intervention in Korean population

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Background Conflicting data on sex-based differences in outcomes after percutaneous coronary intervention (PCI) among Western population exist. Little is known about the nature of sex-specific PCI outcomes in an Asian population.

Methods We performed a pooled analysis using 23,604 patients from 11 prospective PCI clinical studies performed in Korea. The primary outcome was a *major cardiovascular event*, defined as composite of cardiovascular death, myocardial infarction, stent thrombosis, or stroke. Secondary outcomes were all-cause mortality and target vessel revascularization.

Results Thirty-day and 2-year rates of major cardiovascular events were more frequent in women than in men, mainly because of a higher incidence of periprocedural myocardial infarction in women (30-day: 9.2% vs 7.1%; 2-year: 11.2% vs 8.9%). After multivariable adjustment, women had significantly higher risks of 30-day (hazard ratio [HR] 1.27, 95% CI 1.19-1.36) and 2-year major cardiovascular events (HR 1.21, 95% CI 1.13-1.30). Unadjusted 30-day and 2-year all-cause mortality was similar between women and men (30-day: 0.5% vs 0.4%; 2-year: 2.8% vs 2.8%). However, after multivariable adjustment, women had a lower adjusted risk of 2-year death (HR 0.82, 95% CI 0.77-0.87). No sex-based difference was observed for target vessel revascularization (HR 1.07, 95% CI 0.91-1.25). Overall, sex-specific findings for outcomes were consistent across multiple patient subgroups.

Conclusion Among Korean population undergoing contemporary PCI, women have a significantly higher risk of short- and long-term major cardiovascular events than do men but have better long-term survival. (Am Heart J 2014;167:743-52.)

Although procedural success rates are similar between women and men, it remains still unclear whether disparities of early and late outcomes after percutaneous coronary intervention (PCI) exist between the sexes. Several studies have shown conflicting data on sex-specific outcomes after PCI.[1-4] Owing to compelling evidence regarding differential sex-based results after use of medical devices, the Food and Drug Administration proposed the recommendations to achieve representative enrollment of women in medical device clinical studies and, therefore, to enhance the quality and consistency of sex-specific data.[5]

Because most of these studies have been conducted in populations of Western origin, however, the relationship between sex and PCI-related outcomes among Asians, who account for more than 60% of the world population, remains unclear. It has been suggested that there are considerable differences in the prevalence of coronary artery disease and the rates of procedural complications and mortality according to ethnicity and sex.[6]

The purpose of the present study was to investigate whether there are gender-associated differences in short- and long-term outcomes of PCI with stenting in Korean women and men. To accomplish this, we pooled and analyzed data from available randomized clinical trials and registries with similar methods, including case report forms, definitions, and adjudication procedures.

Methods

Study population

For the present analysis, databases from 11 independent, prospective clinical studies (8 randomized trials and 3 observational studies) were pooled to provide a patient-level data. The individual study designs and results have been previously published.[7-17] These studies contain information on patient demographics, cardiac or coexisting risk factors, clinical manifestations, left ventricular function, angiographic and procedural characteristics, and in-hospital and follow-up clinical

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outcomes. Relevant data were prospectively collected using a dedicated, electronic case report form by specialized personnel at each center, and all databases were maintained at the Clinical Research Center of the Asan Medical Center, Seoul, Korea. All studies were approved by the local institutional review board, and all patients provided written informed consent. This study was supported, in part, by the Cardiovascular Research Foundation, Seoul, Korea, and by a grant from the Korea Health 21 R&D Project, Ministry of Health & Welfare, Korea (A090264).

Among studies, PCI was performed according to current standard guidelines. Antiplatelet therapy and periprocedural anticoagulation were administered according to standard regimens.

Outcomes, definitions, and follow-up

The primary outcome was a *major cardiovascular event*, defined as a composite of death from cardiovascular causes, myocardial infarction (MI), stent thrombosis, or stroke. Secondary outcomes were all-cause mortality and target vessel revascularization (TVR).

All deaths were considered to be from cardiovascular causes, unless an unequivocal noncardiovascular cause could be established. The diagnosis of MI was based on the universal definition of MI.[18] *Stent thrombosis* was defined as the definite or probable events, according to the Academic Research Consortium criteria.[19] Stroke, as detected by the occurrence of a new neurologic deficit, was confirmed by a neurologist and on imaging. *Target vessel revascularization* was defined as any percutaneous or surgical revascularization of the target vessel. Information on bleeding events was not available in the ESSENCE-Diabetes trial and in the ASAN-PCI registry. Therefore, bleeding risk was assessed in the remaining 9 clinical studies, according to the Thrombolysis In Myocardial Infarction criteria.[20] For each study, an independent clinical events committee adjudicated all clinical end points of the study.

Among studies, clinical follow-up was performed via office visit or telephone contact at 1, 6, and 12 months and then every 6 or 12 months thereafter, according to the each study protocol. For validation of complete follow-up data, information on vital status was obtained from the National Population Registry of the Korea National Statistical Office with the use of a unique personal identification number.

Statistical analysis

Continuous variables are described as mean and SD, and categorical variables are described as counts and percentages. Baseline clinical, angiographic, and procedural characteristics were compared between women and men using Student t test or the Mann-Whitney U test for continuous variables and the χ^2 test or Fisher exact test for categorical variables, as appropriate.

The number and percentages of clinical outcomes at 30 days and 2 years were presented for women and men. Cumulative incidence and survival curves between groups were constructed from Kaplan-Meier estimates and compared using the log-rank test. Cox proportional hazards regression models were used to estimate the effect of sex on clinical outcomes. After crude analyses were initially performed, multivariable Cox proportional hazards regression modeling was performed to adjust potentially confounding factors, which were significantly associated with outcomes ($P < .05$) or clinically relevant, irrespective of their statistical significance. The following variables were entered into the final multivariable models: study, age, body mass index (BMI), diabetes, hypertension, prior MI, previous stroke, peripheral vascular disease, renal dysfunction, acute coronary syndrome, ejection fraction, multivessel disease, left main disease, bifurcation disease, total occlusion, stent type, number of stents, and use of abciximab. To account for between-study heterogeneity and within-study clustering, because patients at the same study may have similar profiles of characteristics, P value and 95% CI were calculated by using robust SEs based on sandwich estimators.[21] Adjusted survival curves comparing women vs men were constructed for study outcome with the use of the Cox proportional hazards models and methods for calculating adjusted survival.[22]

We also assessed whether sex-based differences exist in subgroups based on clinical, angiographic, procedural, and study characteristics (age, diabetes, clinical presentation, left ventricular function, angiographic disease severity, type of stents, and study type). All reported P values are 2 sided, and P values less than .05 were considered to indicate statistical significance. SAS software, version 9.1 (SAS Institute, Cary, NC), was used for all statistical analyses.

The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

Results

Population and patient characteristics

A total of 23,604 subjects were pooled from 11 clinical studies. The number of patients (women and men) enrolled, types of study design, types of patients or lesions evaluated, and main objective of each study are shown in Table I.

Of the 23,604 patients enrolled in this analysis, 7,180 (30%) were women. Baseline clinical characteristics for women and men are shown in Table II. Women were older, had a higher BMI, and had a higher prevalence of diabetes, hypertension, hyperlipidemia, and prior heart failure. Men were more likely to be smokers and had a higher prevalence of prior MI, prior PCI, and peripheral vascular disease. Mean ejection fraction was lower in men than in women. Angiographic and procedural characteristics between women and men are shown in Table III. Left main disease, long lesion, or total occlusions were less common in women than in men. Women were more likely to have use of drug-eluting stent (DES) and have a slightly lower mean number of stents used and shorter total stent length. Mean stent diameter was smaller in women than in men. Use of intravascular ultrasound (IVUS) during PCI was less common in women than in men.

Short- and long-term outcomes by sex

The median follow-up was 2.1 years in women (interquartile range 1.2-3.8 years) and 2.1 years in men (interquartile range 1.2-3.9 years). During follow-up, a total of 2,421 major cardiovascular events (402 cardiovascular

Table I. Summary of clinical studies used in pooled analysis

Source	No./Total no. (%) of patients enrolled: Women	Men	Type of study design	Type of patients or lesions evaluated	Main objective
ZEST[7]	886/2645 (33.5)	1759/2645 (66.5)	Multicenter, randomized trial	All-comer PCI patients	Comparison of zotarolimus-, sirolimus-, and paclitaxel-eluting stents
ZEST-AMI[8]	58/328 (17.7)	270/328 (82.3)	Multicenter, randomized trial	STEMI	Comparison of zotarolimus-, sirolimus-, and paclitaxel-eluting stents
LONG-DES II [9]	179/500 (35.8)	321/500 (64.2)	Multicenter, randomized trial	Long (≥25 mm) native coronary lesions	Comparison of sirolimus- and paclitaxel-eluting stents
LONG-DES III[10]	136/450 (30.2)	314/450 (69.8)	Multicenter, randomized trial	Long (≥25 mm) native coronary lesions	Comparison of everolimus- and sirolimus-eluting stents
LONG-DES IV [11]	135/500 (27.0)	365/500 (73.0)	Multicenter, randomized trial	Long (≥25 mm) native coronary lesions	Comparison of zotarolimus- and sirolimus-eluting stents
ESSENCE-Diabetes [12]	123/300 (41.0)	177/300 (59.0)	Multicenter, randomized trial	Diabetic patients	Comparison of everolimus- and sirolimus-eluting stents
DECLARE-LONG II[13]	146/499 (29.3)	353/499 (70.7)	Multicenter, randomized trial	Long (≥25 mm) native coronary lesions	Evaluation of cilostazol impact to reduce restenosis after zotarolimus-eluting stents
REAL-LATE [14]	469/1625 (28.9)	1156/1625 (71.1)	Multicenter, randomized trial	All-comer PCI patients	Evaluation of duration of dual antiplatelet therapy after DESs
ASAN-PCI [15]	2089/7221 (28.9)	5132/7221 (71.1)	Multicenter, prospective registry	All-comer PCI patients	Comparison of DESs and bare-metal stents
ASAN-VERIFY[16]	924/3370 (27.4)	2446/3370 (72.6)	Single-center, prospective registry	All-comer PCI patients	Evaluation of clinical use of on-site platelet function test and C-reactive protein after DESs
IRIS-DES[17]	2035/6166 (33.0)	4131/6166 (67.0)	Multicenter, prospective registry	All-comer PCI patients	Comparison of everolimus- and sirolimus-eluting stents
Total	7180/23,604 (30.4)	16,424/23,604 (69.6)			

Abbreviation: *STEMI*, ST-segment elevation MI.

deaths, 1,985 MIs, 184 stent thromboses, and 169 strokes) were reported. Overall, 1,023 all-cause deaths and 1,060 TVR occurred.

Event rates and unadjusted and adjusted risks of clinical outcomes between women and men are shown in Table IV. At 30 days, major cardiovascular events were more frequent in women than in men, which was mainly driven by a higher incidence of periprocedural MI in women. After multivariable adjustment, women remained at a higher risk for 30-day major cardiovascular events. Among each component of primary composite outcome, the adjusted risk of MI and stent thrombosis at 30-day was significantly higher in women than in men. However, there were no significant differences in the unadjusted and adjusted risks of 30-day all-cause mortality and TVR.

At 2 years, cumulative rates and unadjusted risk of major cardiovascular events were significantly higher in women than in men (Figure 1 and Table IV). After multivariable adjustment, women still had a higher risk of major cardiovascular events (Figure 2 and Table IV). When the risk of major cardiovascular events was assessed after eliminating periprocedural MI, unadjusted and adjusted risks of major cardiovascular events were similar in women and men (unadjusted hazard ratio [HR] 1.06 [95% CI 0.85-1.32] and adjusted HR 1.04 [95% CI 0.95-1.13]). As secondary outcomes, unadjusted 2-year risk of all-cause mortality was not significantly different between women and men (Figure 1 and Table IV). However, after multivariable adjustment, women had significantly a lower risk of all-cause mortality compared with men (Figure 2 and Table IV). This difference was mainly driven by a lower risk of noncardiovascular death (HR 0.70, 95% CI 0.63-0.77) in women without a difference of cardiovascular death (HR 1.05, 95% CI 0.93-1.19). There were no gender-specific differences regarding the outcome of TVR.

In the limited population of 9 clinical studies (ZEST; ZEST-AMI; LONG-DES II, III, and IV; DECLARE-LONG II; REAL-LATE; ASAN-VERIFY; and IRIS-DES; N = 16,083), unadjusted and adjusted risks of bleeding events (all types and major bleeding) were significantly higher in women than in men (Table IV).

Subgroup analyses

Consistent with the results of the total population, women had a significantly higher adjusted risk of major cardiovascular events, but a lower adjusted risk of all-cause mortality in several subgroups analyses according to

Table II. Baseline clinical characteristics

Characteristics	Women (n = 7180)	Men (n = 16,424)	*P*
Age (y)	65.8 ± 9.2	59.9 ± 10.2	<.001
BMI (kg/m^2)	25.0 ± 3.2	24.8 ± 2.9	<.001
Diabetes			
Any diabetes	2551 (35.5)	4444 (27.1)	<.001
Insulin dependent	530 (7.4)	656 (4.0)	<.001
Hypertension	4726 (65.8)	8375 (60.0)	<.001
Current smoker	471 (6.6)	6740 (41.0)	<.001
Hyperlipidemia	3218 (44.8)	6534 (39.8)	<.001
Prior MI	541 (7.5)	1708 (10.4)	<.001
Prior PCI	778 (10.8)	2120 (12.9)	<.001
Prior CABG	116 (1.6)	303 (1.8)	.22
Prior CHF	126 (1.8)	189 (1.2)	<.001
Previous stroke	405 (5.6)	922 (5.6)	.93
Peripheral vascular disease	78 (1.1)	312 (1.9)	<.001
Chronic lung disease	115 (1.6)	297 (1.8)	.26
Renal dysfunction	156 (2.2)	357 (2.2)	>.99
Clinical presentation*			.06
Non-ACS	3092 (43.1)	6856 (41.7)	
ACS	4088 (56.9)	9568 (58.3)	
Ejection fraction (%)			<.001
<40	238 (3.3)	628 (3.8)	
40-50	624 (8.7)	2025 (12.3)	
>50	6318 (88.0)	13,771 (83.9)	
Mean	60.3 ± 8.9	58.6 ± 8.9	<.001

Data are shown as mean ± SD or numbers (percentage). Abbreviations: *CABG*, Coronary artery bypass grafting; *CHF*, congestive heart failure; *ACS*, acute coronary syndrome.
*ACS encompasses an acute MI (ST-segment elevation and non–ST-segment elevation MI) and unstable angina.

Table III. Lesion and procedural characteristics and cardiac-related medications

Characteristics	Women (n = 7180)	Men (n = 16424)	*P*
Multivessel disease	3662 (51.0)	8342 (50.8)	.77
Left anterior descending artery disease	4557 (63.5)	9649 (58.8)	<.001
Left main disease	399 (5.6)	1042 (6.3)	.02
Bifurcation lesion	1593 (22.2)	3800 (23.1)	.11
Long lesion (>20 mm)	4833 (67.3)	11,374 (69.3)	.003
Total occlusion	633 (8.8)	2068 (12.6)	<.001
Stent type			.001
DESs	6002 (83.6)	13,438 (81.8)	
Bare-metal stents	1178 (16.4)	2986 (18.2)	
No. of stents			<.001
1	3929 (54.7)	8728 (53.1)	
2	2005 (27.9)	44,777 (27.3)	
≥3	1246 (17.4)	3219 (19.6)	
Mean	1.7 ± 1.0	1.8 ± 1.0	.001
Total stent length (mm)			<.001
<10	101 (1.4)	153 (0.9)	
10-19	1541 (21.5)	3350 (20.4)	
20-29	1493 (20.8)	3350 (20.4)	
≥30	4045 (56.3)	9571 (58.3)	
Mean	40.4 ± 26.8	41.7 ± 27.5	<.001
Average stent diameter (mm)	3.15 ± 0.39	3.26 ± 0.41	<.001
Guidance of IVUS	3829 (57.1)	9418 (61.7)	<.001
Use of abciximab	996 (13.9)	2310 (14.1)	.69
Use of cilostazol	2486 (34.6)	5787 (35.2)	.37
Clopidogrel loading at preprocedure*			.17
75 mg/d for >5 d	1415 (33.9)	3263 (35.1)	
300 mg ≥12 h before PCI	2173 (52.1)	4671 (50.3)	
600 mg ≥12 h before PCI	586 (14.0)	1351 (14.6)	
In-hospital medications			
Aspirin	6702 (99.6)	15,488 (99.5)	.27
Clopidogrel	6694 (99.5)	15,496 (99.5)	.60
ACE inhibitor or ARB	2871 (42.7)	6587 (42.3)	.63
β-Blocker	4712 (69.9)	10,865 (69.8)	.74
Calcium-channel blocker	4402 (65.4)	10,034 (64.4)	.17
Statin	4592 (68.2)	10,409 (66.8)	.06

Data are shown as mean ± SD or numbers (percentage). Abbreviations: *ACE*, Angiotensin-converting enzyme; *ARB*, angiotensin II receptor antagonist.
*Information on clopidogrel loading dose was available in 13,459 patients (57% of overall population).

major clinical, angiographic, or procedural characteristics and study type (Figure 3). Although our analysis merged data from randomized clinical trials and observational registries, overall findings were consistent in a cohort of randomized trials and a cohort of observational studies.

Discussion

In this large-sized pooled analysis involving Korean patients undergoing contemporary PCI, women had a significantly higher adjusted risk of major cardiovascular events than did men, mainly because of a higher incidence of periprocedural MI in women. However, women had a lower adjusted, 2-year risk of all-cause mortality. The risk of TVR was similar between women and men.

In our study, as a specific end point for PCI-related events, a primary composite outcome of cardiovascular death, MI, stent thrombosis, or stroke was significantly higher in women than in men. This difference was mainly driven by a higher incidence of periprocedural MI in women. There are conflicting data regarding the prognostic impact of periprocedural MI. Our previous analysis showed that periprocedural MI was significantly associated with an increased risk of morality during follow-up.[23] Some studies of Western population showed similar findings indicating increased rates of in-hospital complications after PCI among women[3,4]; another studies showed a significantly higher adjusted risk of 30-day composite of death or MI for women but no difference in 1-year outcome[1]; and other studies suggested no difference of in-hospital and 1-year death or MI.[24] Although conflicting results exist, there have been more evidence predisposing women to worse PCI-specific outcomes. The plausible explanations of this excess of risk are suggested by older age at disease onset and interventions, a greater burden of comorbidities, smaller body size or BMI, delays in seeking medical care, and less aggressive pharmacologic therapy.[1,4,25]

Contrary to sex-based difference in major cardiovascular events, adjusted risk of all-cause mortality was significantly lower in women than in men, and this

Table IV. Incidence rates, with unadjusted and adjusted HRs of 30-day and 2-year clinical outcomes according to sex*

	No. of events		Cumulative event rate†		Unadjusted risk		Adjusted risk‡	
Clinical outcome	**Women**	**Men**	**Women**	**Men**	**HR (95% CI)**	***P***	**HR (95% CI)**	***P***
30-d outcomes								
Major cardiovascular events	661	1161	9.2	7.1	1.32 (1.24-1.40)	<.001	1.27 (1.19-1.36)	<.001
Death from cardiovascular causes	31	58	0.4	0.4	1.22 (0.95-1.58)	.13	1.11 (0.83-1.49)	.47
MI	645	1115	9.0	6.8	1.34 (1.27-1.42)	<.001	1.29 (1.21-1.39)	<.001
Stent thrombosis	31	64	0.4	0.4	1.11 (0.92-1.33)	.27	1.25 (1.07-1.45)	.006
Stroke	12	20	0.2	0.1	1.37 (0.58-3.27)	.47	1.10 (0.50-2.41)	.81
All-cause death	36	68	0.5	0.4	1.21 (0.94-1.56)	.13	1.07 (0.83-1.38)	.58
TVR	16	31	0.2	0.2	1.18 (0.70-2.01)	.54	1.29 (0.82-2.07)	.27
Bleeding§								
All types	178	246	3.6	2.2	1.64 (1.06-2.52)	.03	1.59 (0.99-2.56)	.05
Major	30	38	0.6	0.3	1.70 (1.35-2.13)	<.001	1.92 (1.31-2.81)	<.001
2-y outcomes								
Major cardiovascular events	787	1411	11.2	8.9	1.25 (1.14-1.37)	<.001	1.21 (1.13-1.30)	<.001
Death from cardiovascular causes	89	185	1.4	1.3	1.09 (0.94-1.27)	.27	1.05 (0.93-1.19)	.41
MI	685	1208	9.6	7.5	1.28 (1.18-1.39)	<.001	1.27 (1.16-1.39)	<.001
Stent thrombosis	45	108	0.7	0.7	0.92 (0.71-1.18)	.50	1.22 (0.98-1.52)	.08
Stroke	58	85	0.9	0.6	1.45 (1.16-1.82)	.001	1.03 (0.81-1.30)	.82
All-cause death	170	395	2.8	2.8	0.97 (0.92-1.02)	.19	0.82 (0.77-0.87)	<.001
TVR	296	611	4.4	4.0	1.08 (0.93-1.25)	.31	1.07 (0.91-1.25)	.43
Bleeding§								
All types	225	303	4.7	2.8	1.66 (1.32-2.09)	<.001	1.56 (1.24-1.98)	<.001
Major	45	61	0.9	0.6	1.59 (1.26-2.02)	<.001	1.52 (1.15-2.00)	.003

Major cardiovascular event was defined as a composite of death from cardiovascular causes, MI, stent thrombosis, or stroke.
* The HRs are for women relative to men.
† Cumulative event rates (%) are derived from Kaplan-Meier estimates.
‡ Models were adjusted for study, age, BMI, diabetes, hypertension, prior MI, previous stroke, peripheral vascular disease, renal dysfunction, acute coronary syndrome, ejection fraction, multivessel disease, left main disease, bifurcation disease, total occlusion, stent type, number of stents, and use of abciximab.
§ All types (major, minor, or minimal) and major bleedings were assessed according to the Thrombolysis In Myocardial Infarction criteria.[20]

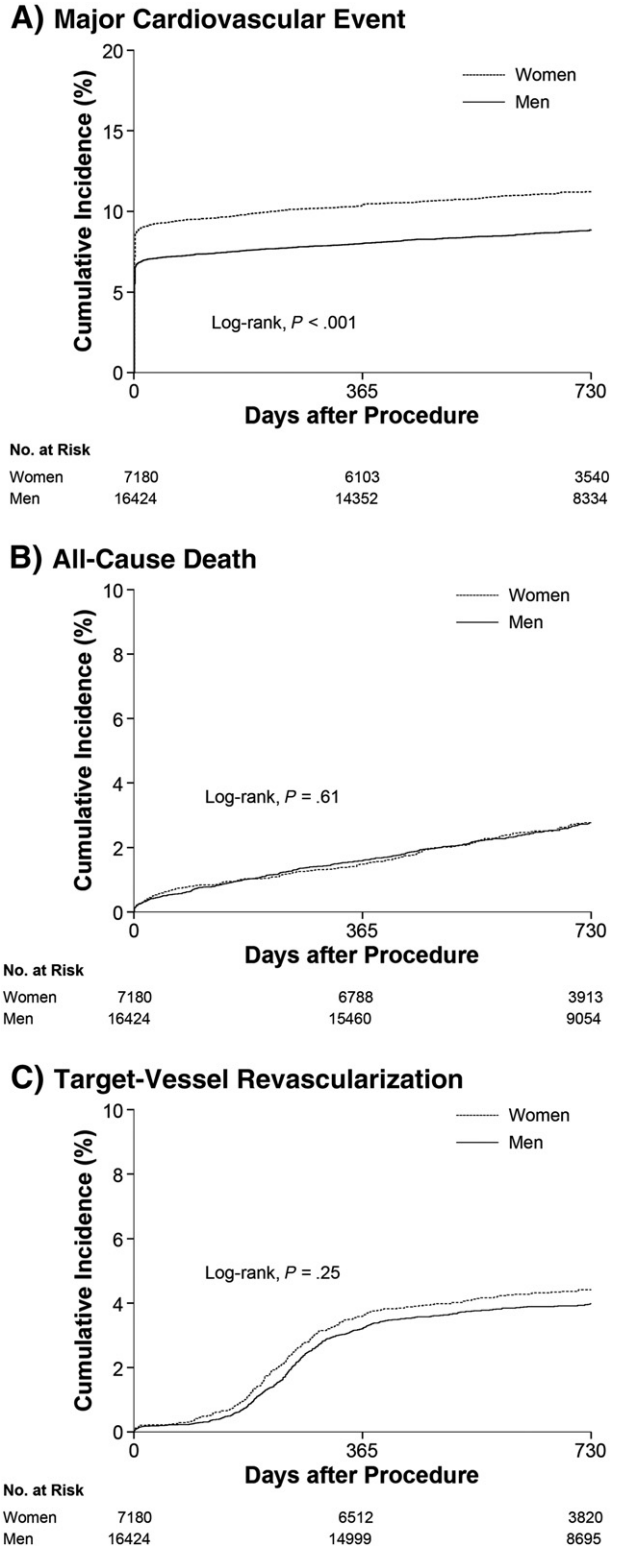
difference was mainly driven by a lower risk of noncardiovascular death in women. Consistent with these findings, several epidemiologic studies have shown that noncardiovascular mortality is better in women than in men in Korea.[26,27] Some studies suggested that women had higher in-hospital or short-term mortality after PCI,[2,28] and other study showed that adjusted risk of 30-day and 1-year all-cause mortality was not significantly different between women and men.[29] However, many of these studies were conducted in the pre-DES era. Similar to our findings, recent data from the National Cardiovascular Data Registry CathPCI Registry showed that women had a lower adjusted risk of long-term all-cause mortality.[4]

From a clinical standpoint, it is important to note that most devices and adjunctive drug therapies used in PCI have been designed to work in women and men equally, without a specific sex indication. Although the exact mechanism linking women with poorer PCI outcomes is still unclear, future studies are needed to determine whether smaller stent–based therapies, smaller vascular access devices, and sex-based guidelines for weight-based antiplatelet and anticoagulation therapy for women with smaller body size and BMI may eliminate sex-based differences in PCI outcomes.[25]

Although other studies of Western population have shown a consistent treatment bias against women with respect to use of DES and use of IVUS,[30] in our merged analysis, women had more DES use but had less use of IVUS, for reasons that remain unclear. This disparity might be explained in part by differences in clinical or lesion characteristics, interventional practice, or race or ethnic group between our population of patients and those enrolled in other studies.

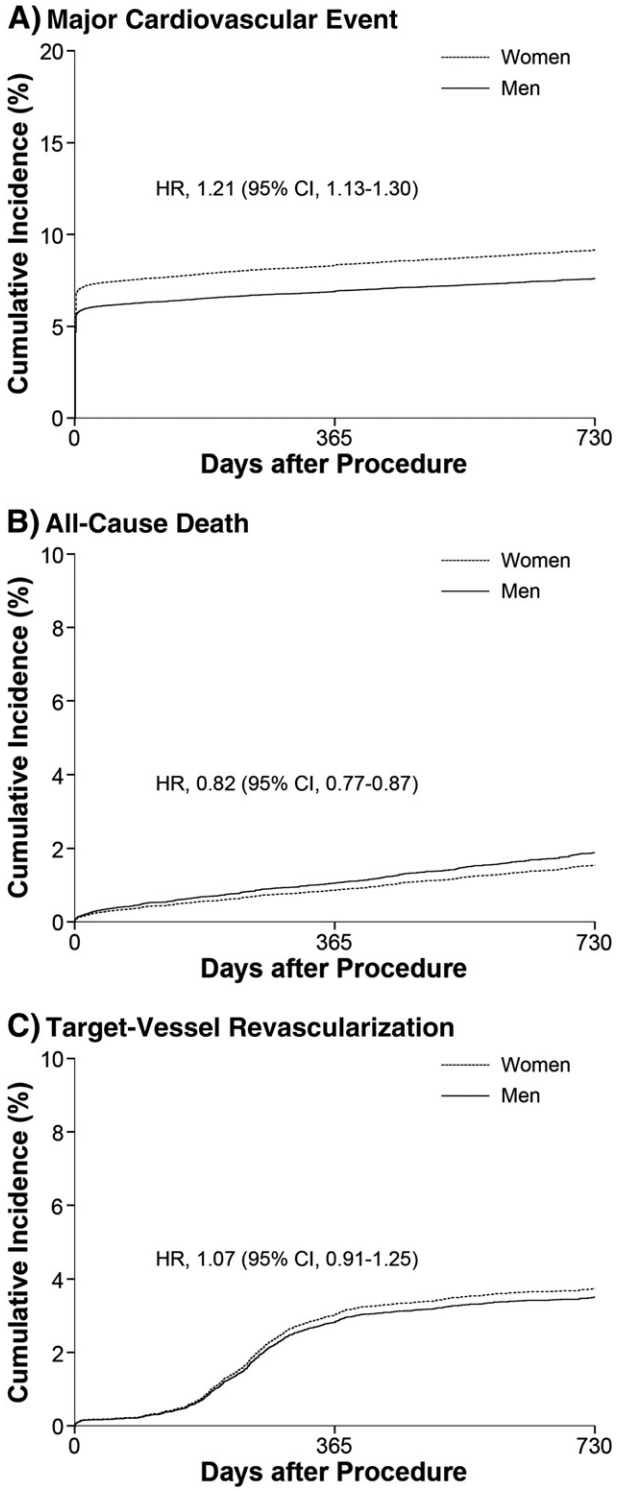
Potential limitations of the present study warrant discussion. First, unmeasured confounding factors and selection bias cannot be completely excluded, and it can have contributed to the differences observed. Second, our analysis merged data from randomized trials and observational registries, which are different in terms of the nature of study designs. Therefore, we conducted sensitivity analyses to account for potential differences between randomized trials and observational registries, and major findings were overall consistent without interactions between sex and study type. Third, the database merged several clinical studies, and so inter-study variability in care may have influenced the results of the pooled population. Fourth, because this analysis was performed in an Asian population, it is uncertain whether these findings can be applied to other ethnic groups.

Figure 1



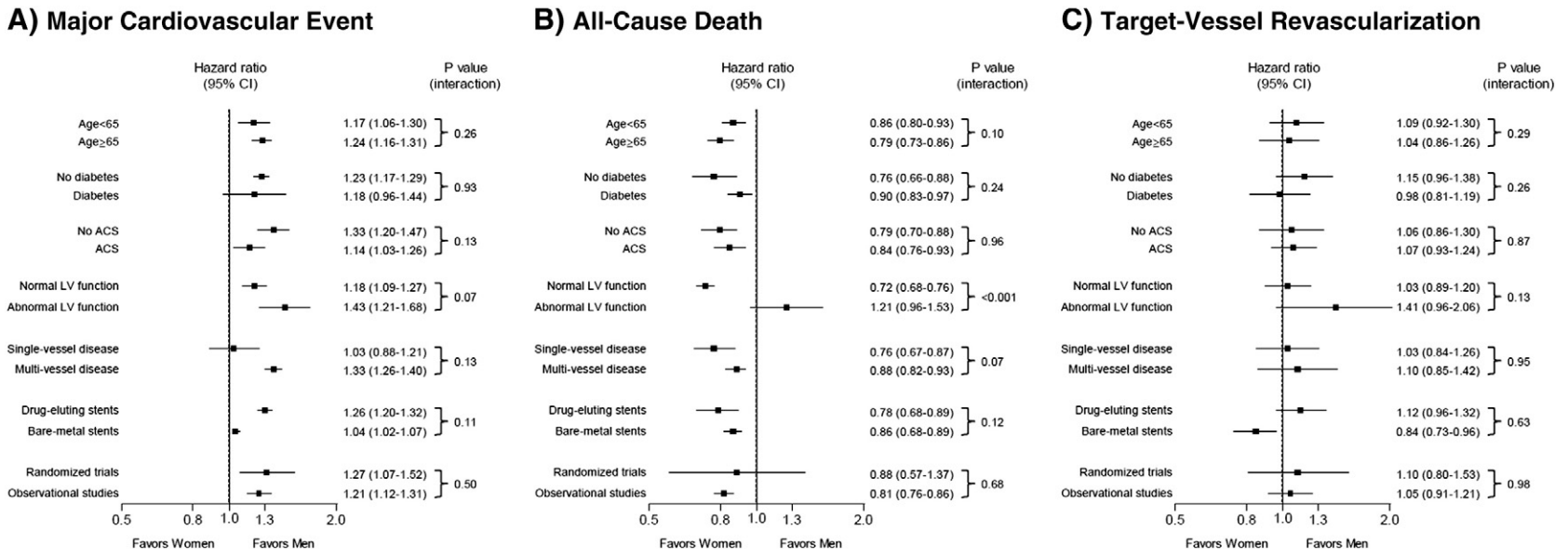
Kaplan-Meier curves of the cumulative probability of primary and secondary outcomes in women and men. Cumulative incidence curves are shown for the primary outcome of major cardiovascular events (cardiovascular death, MI, stent thrombosis, or stroke; **A**) and for the secondary outcome of all-cause mortality (**B**) and TVR (**C**).

Figure 2



Adjusted event curves for primary and secondary outcomes in women and men. Adjusted events curves are shown for the primary outcome of major cardiovascular events (cardiovascular death, MI, stent thrombosis, or stroke; **A**) and for the secondary outcome of all-cause mortality (**B**) and TVR (**C**). The adjusted HRs are for women relative to men.

Figure 3



Adjusted HRs for primary and secondary outcomes in women and men according to patient subgroups. Adjusted HRs are shown for the primary outcome of major cardiovascular events (cardiovascular death, MI, stent thrombosis, or stroke) and for the secondary outcome of all-cause mortality and TVR. The adjusted HRs are for women relative to men.

Finally, because this is a secondary data analysis, results should be considered hypothesis generating only, and it raises unresolved questions. These findings need to be confirmed in additional dedicated studies.

Conclusions

In our study, women showed a significantly higher risk of short- and long-term major cardiovascular events than did men after PCI, mainly because of a higher incidence of periprocedural MI with women. By contrast, women had better long-term survival. Further studies are needed to understand the underlying mechanisms of sex-based PCI outcomes and to determine whether Asian women with a smaller body size, BMI, and vessel size may specifically need tailored PCI devices and adjunctive pharmacotherapies.

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