Sex differences in long-term outcomes of patients with percutaneous coronary intervention: the Armenian experience

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Abstract

The present study aimed at assessing sex differences in perioperative characteristics and 3-year event-free survival from major adverse cardiac and cerebrovascular events (MACCE) in patients with percutaneous coronary intervention (PCI) in Armenia. The study utilized an observational, retrospective cohort design enrolling patients who underwent PCI from 2006 to 2008 at a single center in Yerevan, Armenia. Major adverse cardiac and cerebrovascular events included all-cause mortality, myocardial infarction (MI), repeat revascularization, or stroke/transient ischemic attack. Among 485 participants included in the analysis, 419 (86%) were men. Women were older, more hypertensive, more obese, and had significantly higher rates of diabetes. At the end of follow-up, the incidence of MACCE was 37% for men and 33% for women (P=0.9). Based on the results from the adjusted Cox proportional hazards model, the independent predictors of MACCE included acute MI [hazard ratio (HR)=1.43, 95% confidence interval (CI): 1.02-2.00], arrhythmia (HR=1.64, 95% CI: 1.07-2.50), sex (HR=2.46, 95% CI: 1.08-5.61), diabetes (HR=5.65, 95% CI: 2.14-14.95), and the interaction between sex and diabetes (HR=0.16; 95% CI: 0.05-0.47). Among diabetic patients, men had better event-free survival from MACCE (HR=0.40, 95% CI: 0.19-0.85) than women, whereas in patients without diabetes men had worse outcomes than women (95% CI: 1.08-5.62). In Armenia, the baseline profile of women undergoing PCI differed considerably from that of men. In patients with diabetes, women had worse outcomes at long-term follow-up, while the opposite was noted in patients without diabetes.

Introduction

Coronary artery disease (CAD) is the leading cause of morbidity and mortality among both men and women worldwide.[1] Although historically considered a *man's disease* because of its earlier manifestation in a man's life, recent studies have indicated that more females die from CAD than males.[2,3] Nonetheless, women are referred less frequently for invasive interventions such as percutaneous coronary intervention (PCI), comprising only one-third of all PCIs performed in the US.[4] Such a discrepancy may be explained by the belief that women do not benefit from invasive strategies as much as men do.[2] Studies have documented that women have worse clinical outcomes such as myocardial infarction (MI), stroke, and vascular complication after PCI than men.[2,5] Poor outcomes can be attributed to a higher prevalence of risk factors and comorbidities such as older age, obesity, hypertension, diabetes mellitus, and congestive heart failure in women than in men at the time of the intervention.[2,5,6] After adjustment for these factors, several studies reported a persistent survival disadvantage for women.[2,4] Several other studies, however, reported that the sex differences disappeared after adjustments[5-9] or that women had better outcomes.[10-12]

Armenia, located in the Caucasus, has a population of approximately 3 million people.[13] The burden of CAD in Armenia is significant. According to Armenia's Ministry of Health, in 2009 CAD morbidity was 1967/100,000 and mortality was 247/100,000 population.[14] Given the conflicting evidence on gender differences and the paucity of information on CAD in Armenia, this study assessed sex differences in the long-term clinical outcomes of PCI patients in Armenia treated at the Nork Marash Medical Center (NMMC) in Yerevan. The Nork Marash Medical Center is the largest tertiary cardiac surgery center in Armenia and boasts outcomes comparable to those observed in other international cardiac centers.[15] In this study we evaluated sex differences in average patient-reported 3-year event-free survival from the composite major adverse cardiac and cerebrovascular events (MACCE) in patients with CAD who had PCI at NMMC.

Materials and Methods

The study utilized an observational, retrospective cohort design. The sample included all patients with CAD who had undergone PCI at NMMC from 1 January 2006 to 31 December 2008. Patients with missing contact information, missing medical records, residing outside of Armenia at the time of the study, or who did not speak Armenian were excluded. Patient contact information was abstracted from the NMMC PCI dataset. Telephone surveys were conducted from February to April 2011 to evaluate patients' long-term outcomes and to obtain consent to review patients' medical records for perioperative information. The study protocol was approved by the Institutional Review Board at the American University of Armenia and by the NMMC Administrative Board.

The main outcome of interest was the 3-year average survival rate from the composite MACCE that included all-cause mortality, MI, repeat revascularization, or stroke/transient ischemic attack (TIA) established by patient self-reports. All patient-reported repeat hospitalizations to NMMC were verified using the NMMC database. We also assessed patients' hospital length of stay, prescription of discharge medications, and in-hospital and early operative complications and mortality. A repeat revascularization was defined as a repeat surgical (coronary artery bypass grafting) or percutaneous coronary intervention (target or new vessel). Operative complications were defined as all major events occurring within 30 days after the PCI.

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Statistical analysis

Continuous variables are presented as means and standard deviations and compared between groups using Student's *t*-test; categorical variables are presented as counts and percentages and compared using a chi-square test or Fisher's exact test. The event-free survival rate from MACCE was estimated by the Kaplan-Meier product-limit method. Cox proportional hazard models were used to estimate unadjusted and adjusted hazard ratios (HR) of MACCE at the end of follow-up. Backward stepwise elimination was used for the multivariable Cox proportional hazards model. All variables found significant in univariate analyses ($P<0.05$) and those found predictive from past studies were entered together into the model at once and eliminated using the likelihood ratio test. The final model was checked for effect modifiers and for conformity with the proportionality assumption. All statistical analyses were performed using the Stata10 software package (Stata Statistical Software, College Station, TX, USA).

Results

Overall, 894 patients underwent PCI from 2006 to 2008 at NMMC. Of these, 839 were residents of Armenia. We could not reach 315 patients for various reasons (*i.e.* phone number not provided, wrong number/number changed, patient was out of the country at the time of contact, no response to call). In total, 524 patients were contacted for the phone interview. Of these, 23 refused to participate, 3 were found to be ineligible, and, after the interviews, medical records were not available for 13 patients. If the patient was reported as dead (n=38) at the time of the interview, information about the MACCE and consent to access the medical records was obtained from an immediate family member. The final total sample included 485 patients.

Patient baseline and procedural characteristics

The study sample (n=485) included 419 (86%) men and 66 women. Patients' baseline characteristics stratified by sex are presented in Table 1. Women were on average 5 years older than men and had a higher prevalence of hypertension, obesity, and diabetes and more often presented with stable angina. A significantly higher proportion of men smoked and at admission presented with acute MI more frequently than women.

No differences were observed in the number of diseased vessels and the number and types of stents implanted (Table 1). In men and women, the most frequently stented vessel was the left anterior descending (LAD) artery. No statistically significant differences were seen between women and men in discharge medication, except for a higher rate of angiotensin-converting enzyme inhibitors (ACEi)/angiotensin receptor blockers (ARB) prescribed to women.

Acute in-hospital and 30-day operative outcomes

Thirty-day operative complications were observed in 3 women (4.5%) and in 23 men (5.5%, P=0.7). Overall, the following complications were observed: ventricular tachycardia/ventricular fibrillation (n=4); complete atrioventricular block (n=2); hematoma at the intervention site (n=1); coronary artery dissection (n=1); reperfusion syndrome (n=1); stent thrombosis (n=2); TIA (n=1); acute renal failure (n=1); acute heart failure (n=1); LAD occlusion during coronary angiography (n=1); recurrent MI (n=2); and repeat revascularization (n=4). In-hospital deaths occurred in 2 men. Death within 30 days after PCI occurred in 1 woman and 3 men. The hospital length of stay did not differ between sexes and was on average 4.5±3.6 days for the total sample.

Table 1. Baseline patients' characteristics.

Patients' characteristics°	Men (n=419)	Women (n=66)	P
Risk factors and comorbidities			
Age (years, mean±sd)	54.7±9.5	59.9±8.6	<0.01
Family history of CAD (%)	210 (53.4)	41 (65.1)	0.09
Current smoker (%)	258 (63.9)	4 (6.2)	<0.01
Diabetes (%)	58 (13.9)	24 (36.3)	<0.01
Hypertension (%)	292 (69.6)	57 (86.4)	<0.01
BMI (kg/m^2, mean±sd)	28.6±4.1	30.4±5.3	<0.01
Stroke/TIA (%)	33 (7.9)	8 (12.1)	0.26
Renal failure (%)	3 (0.7)	0 (0.0)	0.49
Cardiac status (%)			
Acute MI	148 (35.3)	16 (24.2)	0.08
Prior MI	155 (37.2)	19 (28.7)	0.19
Unstable angina	183 (43.7)	32 (48.5)	0.46
Stable angina	56 (13.4)	17 (25.7)	0.01
Previous PCI	10 (2.4)	0 (0.0)	0.20
Previous CABG	24 (5.7)	2 (3.0)	0.36
Arrhythmia	59 (14.2)	11 (16.7)	0.59
Angiographic profile			
EF (%, mean±sd)	45.1±7.1	47.2±6.9	0.03
Number of diseased vessels (%)			
Single vessel	123 (30.2)	20 (31.8)	0.40
Double vessel	161 (39.6)	20 (31.8)	
Triple vessel	123 (30.2)	23 (36.5)	
Number of stents implanted (%)			
One	303 (72.3)	41 (62.1)	0.21
Two	101 (24.1)	21 (31.8)	
Three	15 (3.6)	4 (6.1)	
Type of stented vessel (%)			
LCX	130 (31.2)	19 (28.8)	0.45
LAD	221 (53.0)	45 (68.0)	0.02
RCA	125 (29.9)	18 (27.3)	0.65
Stent type (%)			
DES	339 (81.9)	58 (87.9)	0.48
BMS	67 (16.2)	7 (10.6)	
Both	8 (1.9)	1 (1.5)	
Discharge medications (%)			
Aspirin	384 (97.5)	63 (100.0)	0.20
Tienopiridine derivatives	382 (96.9)	62 (98.4)	0.50
Beta blockers	330 (83.7)	56 (88.9)	0.30
ACEi/ARB	259 (65.7)	50 (79.3)	0.03
Statins	340 (86.0)	52 (82.0)	0.40

CAD, coronary artery disease; BMI, body mass index; TIA, transient ischemic attack; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; EF, ejection fraction; LCX, left circumflex; LAD, left anterior descending; RCA, right coronary artery; DES, drug eluting stent; BMS, bare metal stent; ACEi/ARB, angiotensin converting enzyme inhibitors/angiotensin receptor blockers. °Results are presented as frequencies and percentages, unless specified otherwise. All percentages were calculated after excluding missing values.

Event-free survival rates at long-term follow-up

The median follow-up of the total sample was 1148 days, ranging from 3 to 1917. The mean follow-up was 1267±321 days for women and 1232±321 days for men (P=0.4). During the follow-up period, the total number of MACCE (n=180) did not significantly differ between men and women (37.0 *vs* 33.3%, P=0.9) (Table 2). The most frequently observed MACCE in both groups was repeat revascularization. The event-free survival from MACCE at the median follow-up was 0.79 (95% CI: 0.66-0.87) for women and 0.74 (95% CI: 0.69-0.78) for men (P>0.05).

The unadjusted predictors of long-term survival (MACCE) were identified using univariate Cox proportional hazard models. Significant predictors (P<0.05) of event-free survival were acute MI at admission, arrhythmia, left ventricular ejection fraction, number of diseased vessels, and stent type.

The final, multivariable model included sex (HR=2.46, 95% CI: 1.08-5.61), diabetes (HR=5.65, 95% CI: 2.14-14.95), arrhythmia (HR=1.64, 95% CI: 1.07-2.50), acute MI at admission (HR=1.43, 95% CI: 1.02-2.00), and the interaction between sex and diabetes (HR=0.16; 95% CI: 0.05-0.47) (Table 3).

In patients without diabetes, after adjusting for arrhythmia and acute MI at admission, men had worse event-free survival from MACCE (HR=2.46, 95% CI: 1.08-5.62) than women (Table 4, Figure 1A). After adjusting for arrhythmia and acute MI at admission, in patients with diabetes, men had better event-free survival from MACCE (HR=0.40, 95% CI: 0.19-0.85) than women (Table 4, Figure 1B).

Discussion

This observational study sought to evaluate sex differences in 3-year event-free survival from MACCE in patients with CAD who had PCI in a single center in Armenia. We observed significant differences in several baseline factors between men and women. For example, women on average were older than men, more hypertensive, more obese, and had a significantly higher rate of diabetes. In contrast, men were more likely to be smokers. Similar differences were observed in several past studies.[2,5,11,16,17] For example, a recent observational study conducted by Duvernoy *et al.* found that women were more obese (47.9 *vs* 43.1%) and more often had diabetes mellitus (38.5 *vs* 29.2%) and hypertension (82.5 *vs* 71.0%), and that men were more likely to smoke (27.3 *vs* 21.7%).[2]

In the current analysis, the unadjusted event-free survival at the end of follow-up was

Table 2. Distribution of major adverse cardiac and cerebrovascular events between sexes.

Events, n (%)	Total sample (n=485)	Men (n=419)	Women (n=66)	P
MI	31 (6.4)	26 (6.2)	5 (7.6)	0.8
RR	102 (21.0)	92 (22.0)	10 (15.2)	0.3
PCI	71 (14.6)	64 (15.3)	7 (10.6)	
CABG	32 (6.6)	29 (6.9)	3 (4.5)	
Death	38 (7.8)	31 (7.4)	7 (10.6)	0.4
Stroke/TIA	9 (1.9)	9 (2.2)	0 (0.0)	0.4
Total MACCE	180 (37.1)	158 (37.7)	22 (33.3)	0.9

MI, myocardial infarction; RR, repeat revascularization; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; TIA, transient ischemic attack; MACCE, major adverse cardiac and cerebrovascular events.

Table 3. Unadjusted and adjusted Cox proportional hazard models of survival from major adverse cardiac and cerebrovascular events.

	Unadjusted			Adjusted		
Predictors	Hazard ratio	95% CI	P	Hazard ratio	95% CI	P
Sex	1.12	0.69-1.81	0.652	2.46	1.08-5.61	0.032
Diabetes	1.28	0.85-1.94	0.241	5.65	2.14-14.95	0.000
Acute MI	1.51	1.09-2.10	0.014	1.43	1.02-2.00	0.036
Arrhythmia	1.66	1.09-2.53	0.018	1.64	1.07-2.50	0.022
Sex*diabetes	-	-	-	0.16	0.05-0.47	0.001

CI, confidence interval; MI, myocardial infarction; sex*diabetes, interaction between sex and diabetes.

Table 4. Interaction between sex and diabetes in survival from major adverse cardiac and cerebrovascular events after controlling for acute myocardial infarction and arrhythmia.

	Patients (n)	MACCE (n)	Hazard ratio (95% CI)	P
Diabetes				
Male	58	15	0.40 (0.19-0.85)	0.02
Female	24	15	1.0 (reference)	
No diabetes				
Male	361	143	2.46 (1.08-5.61)	0.03
Female	42	7	1.0 (reference)	

MACCE, major adverse cardiac and cerebrovascular events; CI, confidence interval.

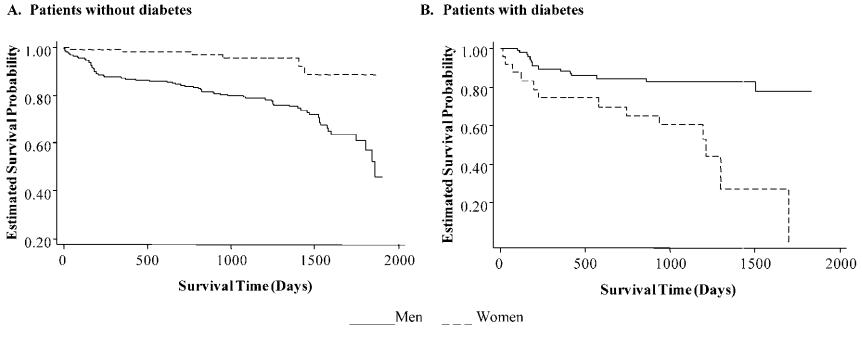

Figure 1. Survivor functions by sex, adjusted for acute myocardial infarction and arrhythmia.

similar between sexes, despite the differences in baseline profiles. These results agree with past studies that also had a retrospective design, followed patients 3 years or longer, and similarly enrolled patients with stable and unstable angina and acute MI.[7,9,18] However, these studies demonstrated that after the adjustment for baseline differences the rates of major adverse cardiac events (MACE) were no longer different between the sexes. Overall, compared to studies in the early 1990s, recent studies have mostly shown that with improved care and technologies, the gap between men and women in complication rates and rates of MACE at long-term follow-up is disappearing.[19]

The evidence of the impact of diabetes status on sex differences in PCI outcomes is still contradictory. In our sample of patients, the prevalence of diabetes was almost 2.5 times higher among women than men (36 and 14%, respectively). After adjusting for acute MI and arrhythmia, we found that women with diabetes had a higher risk of MACCE than men. In contrast, a recent study that enrolled only patients with diabetes in Japan found that at 4-year follow-up after PCI, the cumulative incidence of MACE was similar between the sexes, despite the fact that women had a worse baseline profile.[20] Similar to our study, a significant interaction was observed by Mehilli *et al.*, who evaluated the impact of sex on mortality after PCI in a cohort of patients with stable and unstable angina.[12] They reported that diabetic women had almost twice the mortality hazard in comparison to diabetic men, whereas no significant difference was observed in mortality among the non-diabetic population.

Further analysis of our data revealed that among men, diabetes status did not significantly affect the risk of developing MACCE. Among women, diabetes was a significant predictor of MACCE after adjusting for acute MI and arrhythmia (data not shown). Our finding is supported by a recent meta-analysis of 37 studies that evaluated the risk of fatal coronary events among a diabetic population.[21] It demonstrated that the rate of adverse outcomes was higher among diabetic than non-diabetic patients, but the difference was more pronounced among women than men. The study concluded that the relative risk for fatal CAD associated with diabetes is overall 50% higher in women than in men, most likely due to differences in baseline risk profiles and disparities in treatment approaches.

In our study, we did not evaluate the severity of diabetes (insulin dependent or not; effectively managed or not) that might explain the observed variability in the impact of diabetes on the outcomes by sex. A study that evaluated the effectiveness of drug-eluting stents in acute coronary syndrome patients with diabetes reported a higher prevalence of insulin-dependent diabetes among women compared to men.[22] The sex differences in our study may also be explained by unequal access to or utilization of health care services in Armenia. The 2005 Armenian demographic and health survey found that although a higher proportion of women reported having health problems than men (13.8 *vs* 11.2%), men had overall higher hospitalization rates than women (2.6 *vs* 2.3%).[13]

The limitations of the study merit discussion. In the studied sample, the male female ratio was almost six to one (419 to 66), thus limiting the number of independent predictors that could have been studied and potentially their precision. Another important limitation of our study was that the follow-up data about MACCE were collected retrospectively through telephone interviews, which could introduce recall and report biases. To minimize that bias, we verified self-reported outcomes with the NMMC medical records where possible. Another source of potential bias came from inaccuracies in medical records where, for example, heart failure status and blood lipid levels were not consistently reported and were excluded from the analyses. About one-third of the patients from the original sample were unreachable, either because of inaccurate contact information or absence from the country. The comparison of these non-responders with the final study population using NMMC patient registry information indicated that non-responders were on average 2 years younger ($P<0.05$) than the enrolled patients, and the difference was mainly attributed to the difference among the male population. Thus, the non-response bias suggests that our detected differences would probably be of a larger magnitude if the total sample had been included.

Conclusions

In conclusion, we found that in Armenia, women with CAD differed from men in several baseline risk factors and comorbidities. Women were older than men and had higher prevalence of hypertension, obesity, and diabetes. A significantly higher proportion of men smoked. The differences in the long-term outcomes of PCI between men and women were dependent on the diabetes status. Future studies should investigate the nature, extent, and causal mechanism of the excess risk of diabetes on PCI outcomes, and targeted strategies should be developed to decrease this risk and improve patient outcomes.

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