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Comparison of clinical outcomes of Chinese men and women after coronary stenting for coronary artery disease: a multi-center retrospective analysis of 4,334 patients

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Abstract

The outcome differences between Chinese male and female patients within one-year follow-up after percutaneous coronary intervention (PCI) with stent remain unclear. The present study was aimed to compare clinical outcomes in such two populations. From May 1999 to December 2009, 4,334 patients with acute myocardial infarction (MI), unstable angina, stable angina, or silent ischemia, who underwent PCI, were registered at our centers. Among these, 3,089 were men and 1,245 were women. We compared these groups with respect to the primary outcomes of MI and secondary outcomes including a composite of major adverse cardiac events (MACE) including cardiac death, MI, target lesion revascularization, target vessel revascularization (TVR), stent thrombosis (ST), definite ST and probable ST at one-year follow-up. Chinese male patients had a higher MACE rate (13% vs. 10.7%, $P = 0.039$), mainly led by TVR (9.09% vs. 6.98%, $P=0.024$) at one year, which was significantly different than female patients. Chinese male and female patients showed a significant difference on MACEs. However, there was no sig–nificant difference with respect to MI between these groups.

Keywords: interventional cardiology, ischemic heart disease, drug-eluting stent, major adverse cardiac event, coronary stenting, gender difference

INTRODUCTION

Percutaneous coronary intervention (PCI), first introduced as percutaneous transluminal coronary angioplasty (PTCA) by Andreas Gruntzig in 1997, is a catheter-based therapy alternative to open heart sur–gery. After several decades of explosive development in this field, PCI has become the most effective

approach to rescue patients with coronary heart dis-ease, leading to successful and safe advances of heart disease treatment. However, PCI still needs to be per-fected and numerous issues remain to be resolved[1]. PCI has developed from PTCA to bare-metal stents (BMS) and drug-eluting stents (DES). With the use of DES, the use of PCI dominates over coronary bypass operations and results in reduced rates of rest-enosis and mortality[2,3]. In the quest for perfection, there have been many studies on gender outcome dif-ferences after PCI procedure. Many studies have sug-gested that female patients are more likely to have postoperative complications than male patients[3,4]. However, large scale data are lacking for analyzing and understanding the relationship between genders and outcome differences after the implantation of stents in Chinese patients. Therefore, this study attempts to compare differences in one-year outcomes between genders after PCI by using a large cohort of patients.

PATIENTS AND METHODS

We included symptomatic patients older than 18 years, from May 1999 to December 2009. A total of 4,334 patients with acute myocardial infarction (AMI), unstable angina, stable angina, or silent ische-mia who had PCI in our centers were registered. Among these, 3,089 patients were men and 1,245 patients were women.

PCI procedures

All PCI procedures and peri-procedure medications followed the American Heart Association/American College of Cardiology (AHA/ACC) guidelines. Coronary angiography and PCI with stent implantation were performed through a transfemoral or transradial approach. The use of intravascular ultrasound and the selection of stents were totally dependent on an experienced operating physician. All patients were pretreated with 300 mg clopidogrel and 100 mg aspirin. Life-long aspirin therapy was recommended to all patients. Clopidrogrel was prescribed for at least 9-12 months according to clinical guidelines. Angiographic success was defined as a residual steno-sis $\leq 30\%$ by visual estimation in the presence of thrombolysis in myocardial infarction (TIMI) flow grade of 3. Procedural success was defined as the achievement of angiographic success in the absence of in-hospital events. The primary endpoint was myo-cardial infarction (MI) at one-year follow-up. Secondary endpoints included composite major adverse cardiac events (MACE), such as cardiac

deaths, MI, target lesion revascularization (TLR), tar-get vessel revascularization (TVR), stent thrombosis (ST), definite ST and probable ST at one-year fol-low-up. Cardiac death was diagnosed for any unex-plained death unless a non-cardiac cause was identified. The diagnosis of MI was based on the ACC/AHA guideline[5,6]. TLR was defined as a repeat intervention of the stented segment, including the 5-mm segments proximal or distal to the stent. TVR was defined as a repeat revascularization of the same vessel that was treated in the index procedure. ST was defined according to ARC definition[7]. Definite ST was diagnosed by angiographic or pathologic con-firmation of partial or total thrombotic occlusion within the peri-stent region and at least one of the additional criteria, including acute ischemia symptoms, ischemic ECG changes and elevated cardiac enzymes. Probable ST was defined as any unexplained death within 30 days of stent implantation and any MI related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of ST and any other obvious causes.

Follow-up

All patients were followed-up at one month and 12 months after discharge. Follow-up was done on an outpatient clinic basis either through telephone contact or through patients′ relatives. If patients had visited other medical centers, the records from those centers were also recorded. All clinical and imaging data were recorded in our database. Patients were advised to repeat angiography once within a year of the procedure but angiography was not done routinely for every patient. Earlier angiographic surveillance was per-formed if clinically indicated. Clinically driven TLR or TVR was performed if there was at least $> 50\%$ in-stent restenosis coupled with the presence of typical angina or a new onset of exertional dyspnea.

Statistical analysis

Continuous variables were expressed as mean $\pm$ standard deviation (SD) and were compared with the use of two-tailed Student′s t test. Categorical variables were expressed as percentages and compared using chi-square test or Fisher′s exact test. All statistical analyses were two-tailed, and a P value < 0.05 was considered statistically significant. MACE-free survi-val was calculated using the Kaplan-Meier curve and compared by log-rank test. Binary regression was con-ducted by applying variables including age, gender, hypertension, diabetes, heart failure, stable angina, unstable angina, non-ST segment elevation myocardial

infarction (NSTEMI), ST segment elevation myocardial infarction (STEMI), hyperlipidemia, left ventricle ejection fraction (LVEF), creatinine, renal function, diseased vessel numbers, stent number, stent length, transradial approach, chronic total occlusion (CTO) lesions, LMcto, LADcto, RCActo, left circumflex artery (LCXcto), post PCI TIMI flow, presence of bifurcation, presence of thrombus and complete revascularization. Statistical analysis was performed using SPSS version 16.0 for Windows.

RESULTS

Baseline characteristics

Of the 4,334 patients, 3,089 were men and 1,245 were women (71.2% vs. 28.7%). Baseline characteristics of both patient groups are shown in ***Table 1***. Women were older than men but were shorter in height, lower in body weight, and had increased blood pressure, blood glucose level and increased serum cholesterol levels ($P < 0.05$) for all the values. Male patients were found to have a greater incidence of STEMI ($P < 0.05$) and NSTEMI, whereas stable angina and unstable angina incidence was found to be greater in female patients ($P < 0.05$). Other characteristics like LVEF, renal function and the use of medicine were not significantly different between the two groups.

Angiographic and procedural features

A higher prevalence of diseased vessel was seen in male patients than in female patients ($P < 0.000$). A higher incidence of CTO of LCXcto ($P = 0.007$) with an increased stent length ($P = 0.000$), stent number ($P = 0.000$) and thrombus ($P = 0.000$) was seen in male patients whereas complete revascularization was higher in female patients ($P = 0.013$). PCI was performed through the trans-radial approach in 1,501 male patients and 585 female patients without a difference in the rate between male and female patients (48.5%

Table 1 **Baseline demographic and clinical characteristics**

Baseline levels	Men (*n*=3,089)	Women (*n*=1,245)	*P* value
Age (year)	63.93±10.75	66.41±9.29	0.000
Height (cm)	167.55±5.97	159.67±3.69	0.000
Weight (kg)	67.93±10.80	60.80±9.01	0.000
Hypertension, n (%)	2108(68.2)	931(74.8)	0.000
Systolic blood pressure	134.11±20.72	136.90±20.71	0.291
Diastolic blood pressure	81.14±12.71	80.12±11.38	0.000
Diabetes mellitus, n (%)	612(19.8)	316(25.38)	0.000
Insulin	112(3.6)	62(4.9)	0.400
Oral medication	420(13.59)	225(18.0)	0.000
Hyperlipidemia, n (%)	543(17.57)	305(24.49)	0.000
CHF, n (%)	429(13.88)	117(14.21)	0.778
Presentation, n (%)			
Stable angina	475(15.37)	266(21.36)	0.000
Unstable angina	1,652(53.4)	759(60.96)	0.000
STEMI	735(23.79)	154(12.36)	0.000
NSTEMI	230(7.4)	63(5.06)	0.150
LVEF (%)	56.53±11.94	61.36±32.26	0.342
Creatinine	98.59±49.73	79.93±40.94	0.537
Renal dysfunction, n (%)	48(4.8)	11(2.7)	0.700
Medication, n (%)			
Statin	311(10.06)	120(9.6)	0.669
Beta-blocker	374(12.10)	171(13.73)	0.144
Diuretics	122(3.94)	56(4.49)	0.410
CCB	620(20.0)	282(22.65)	0.138
ACEI	357(11.55)	131(10.5)	0.281
ARB	167(5.40)	78(6.26)	0.268

CHF: congestive heart failure, STEMI: ST-elevation myocardial infraction, NSTEMI: non-ST-elevation myocardial infraction, LVEF: left ventricular ejection fraction, ACEI: angiotensin converting enzyme inhibitor, ARB: angiotensin receptor blocker, CCB: calcium channel blocker.

Table 2 Angiographic and procedural features

Angiographic and PCI	Men (n=3,089)	Women (n=1,245)	P value
No. of diseased vessel (n)	1.35±0.59	1.30±0.56	0.000
1-vessel disease no, n (%)	2,191(70.9)	923(74.13)	
2-vessel disease no, n (%)	712(23.04)	256(20.56)	
3-vessel disease no, n (%)	181(5.85)	65(5.22)	
Infarct related artery, n (%)			
LAD	2,062(66.75)	854(68.5)	0.419
LCX	860(27.84)	339(27.22)	0.684
RCA	919(29.75)	326(26.18)	0.190
LM	343(11.1)	117(9.4)	0.099
Chronic total obstruction (cto), n (%)	247(8.10)	76(6.10)	0.320
LAD cto	99(3.2)	33(3.0)	0.337
LCX cto	78(2.52)	15(1.20)	0.007
RCA cto	107(3.50)	35(3.00)	0.275
LM cto	1	-	0.525
TIMI flow after PCI, n (%)			0.469
0	26(0.84)	5(0.40)	
1	5(0.16)	2(0.16)	
2	28(0.90)	10(0.80)	
3	3,030(98.0)	1,228(99.0)	
Bifurcation lesion, n (%)	963(31.1)	340(27.30)	0.120
Thrombus, n (%)	267(8.64)	63(5.06)	0.000
Complete-revascularization, n (%)	2,184(71.0)	927(74.4)	0.0130
Stent number	2.26±1.51	2.01±1.39	0.000
Stent diameter	3.02±0.73	3.00±0.695	0.650
Stent length	55.03±4.20	47.78±36.81	0.000
Transradial approach, n (%)	1,501(48.5)	585(47.0)	0.339

PCI: percutaneous coronary intervention, LAD: left anterior descending artery, LCX: left circumflex artery, RCA: right coronary artery, LM: left main artery.

vs. 47.0%, $P = 0.339$). The two groups did not differ with respect to infarct-related artery, bifurcation lesion or TIMI flow (**Table 2**).

One-year follow-up

Approximately 63.1% of all patients received repeat angiography. There was a significant difference in the rate of repeat angiography between male and female patients (65.1% vs. 61.1%, $P = 0.012$) (**Table 3**). Although there was no statistical significance in MI between the two groups during in-hospital follow-up (0.64% in men vs. 0.24% in women, $P = 0.096$), the rate of MI at one-month follow-up was significantly higher in male patients than female patients (0.87% in men vs. 0.24% in women, $P = 0.023$) and was seen still increasing at one-year follow-up, but was not sig–nificantly different between the two groups (1.23% in men vs. 0.72% in women, $P = 0.145$).

The rate of MACE during in-hospital follow-up was not significantly different in the two groups (2.10% in men vs. 1.84% in women, $P = 0.587$), with a slight increase in the one-month follow-up in the two groups

(3.20% in men vs. 2.81% in women, $P = 0.498$). However, a significant difference was detected between the two groups in the one-year follow-up (13.0% in men vs. 10.7% in women, $P = 0.039$). There was a significant difference in TLR between the two groups at one-month follow-up (0.32% in men vs. 0% in women, $P = 0.044$) and TVR at the one-year follow-up (9.09% in men vs. 6.98% in women, $P = 0.024$). Definite and probable ST was comparable in the two groups. On the other hand, there was no significant difference in cardiac death, coronary artery bypass grafting (CABG) and stent thrombosis between male and female patients. However, there was a trend for an increase in MACE in one-year fol–low-up, with greater significant increase in male patients.

Binary regression analysis revealed that diabetes (odds ratio [OR] = 0.22, 95% confidence interval [CI] = 0.06−0.75, $P = 0.01$) and the presence of bifurcation (OR = 0.30, 95% CI = 0.08−1.02, $P = 0.05$) were significantly associated with the occurrence of MI at one-year. Conversely, LVEF (OR = 0.97,

***Table 3* Cumulative major adverse cardiac events during one-year follow-up**

Parameters	Men (*n*=3,089)	Women (*n*=1,245)	*P* value
Repeat angiography, n (%)	2,013(65.1)	761(61.1)	0.012
In hospital, n (%)			
Myocardial infarction	20(0.64)	3(0.24)	0.096
Cardiac death	34(1.10)	14(1.12)	0.946
Target lesion revascularization	8(0.25)	-	0.072
Target vessel revascularization	25(0.80)	6(0.48)	0.247
Coronary artery bypass graft	16(0.51)	6(0.48)	0.880
Stent thrombosis	9(0.29)	3(0.24)	0.775
Major adverse cardiac event	65(2.10)	23(1.84)	0.587
One month, n (%)			
Myocardial infarction	27(0.87)	3(0.24)	0.023
Cardiac death	66(2.1)	26(2.0)	0.921
Target lesion revascularization	10(0.32)	-	0.044
Target vessel revascularization	30(0.97)	7(0.56)	0.185
Coronary artery bypass graft	16(0.51)	7(0.56)	0.856
Stent thrombosis	14(0.45)	3(0.24)	0.312
Definite	10(0.32)	1(0.08)	0.150
Probable	4(0.12)	2(0.16)	0.803
Major adverse cardiac event	99(3.20)	35(2.81)	0.498
12 months, n (%)			
Myocardial infarction	38(1.23)	9(0.72)	0.145
Cardiac death	95(3.07)	36(2.89)	0.749
Target lesion revascularization	198(6.40)	68(5.4)	0.239
Target vessel revascularization	281(9.09)	87(6.98)	0.024
Coronary artery bypass graft	24(0.77)	11(0.88)	0.723
Stent thrombosis	26(0.84)	5(0.40)	0.120
Definite	10(0.32)	1(0.08)	0.150
Probable	4(0.12)	2(0.16)	0.803
Major adverse cardiac event	403(13.0)	134(10.7)	0.039

95% CI = 0.95–0.99, *P* = 0.02) and LADcto (OR = 0.29, 95% CI = 0.09–0.85, *P* = 0.02) were signifi–cantly associated with occurrence of MACE at one-year post PCI (***Fig. 2***) .

Survival

Kaplan-Meier analysis is shown in ***Fig. 1*** for MI patients at the one-year follow-up after PCI by using Log rank test. It was determined that there was no sig–nificant difference between male and female patients (*P* = 0.144). However, there was a significant differ–ence between the two groups with respect to one-year MACE during the follow-up period (*P* = 0.041).

DISCUSSION

We were able to derive several major findings from the present study. Chinese female patients were found to be older and have a lower body weight than male patients. They also had more risk factors including hypertension, diabetes and high cholesterol levels, but were found to have lower rates of thrombosis and MI than male patients. However, there was no sig–nificant difference between male and female patients during the hospital stay in the rates of MI, mortality or MACE. There was a significant difference in MI and TLR between male and female patients during one-month follow-up. A significant difference in MACE between male and female patients was found during one-year follow-up. There was a slight increase in definite ST and MI in men rather than women, and there was also a significant difference in TVR between male and female patients during one-year follow-up.

Many studies have shown a higher prevalence for female patients with these risk factors than male patients because women are older than men at the time of presentation of ACS[8,9] and female patients have a higher incidence of postoperative MACE than male patients[10]. Some studies[11,12,13] showed that patients with risk factors, such as diabetes, are most likely to
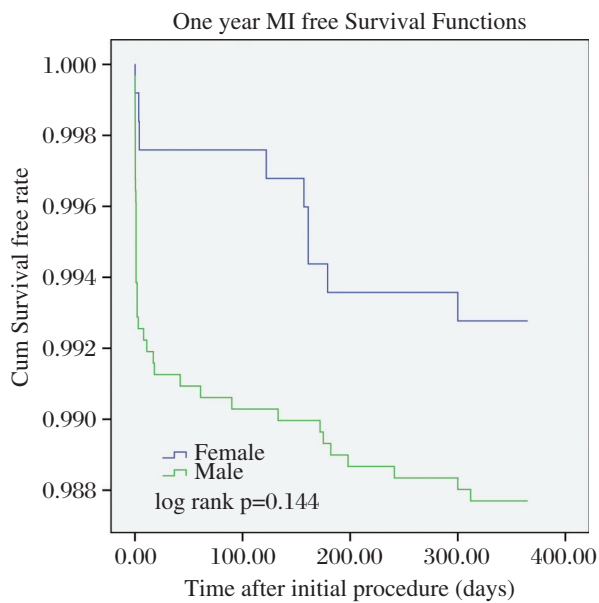
One year MI free Survival Functions

Fig. 1 One-year myocardial infarction free survival functions.
Kaplan-Meier free survival curves for one-year MI between male and female patients undergoing percutaneous coronary intervention.

have negative outcomes than patients without risk factors. Mehilli et al.[14,15] suggested that diabetes may have a greater adverse impact on female patients than male patients. The study by Ogita et al.[16] on diabetic patients post DES showed no significant difference
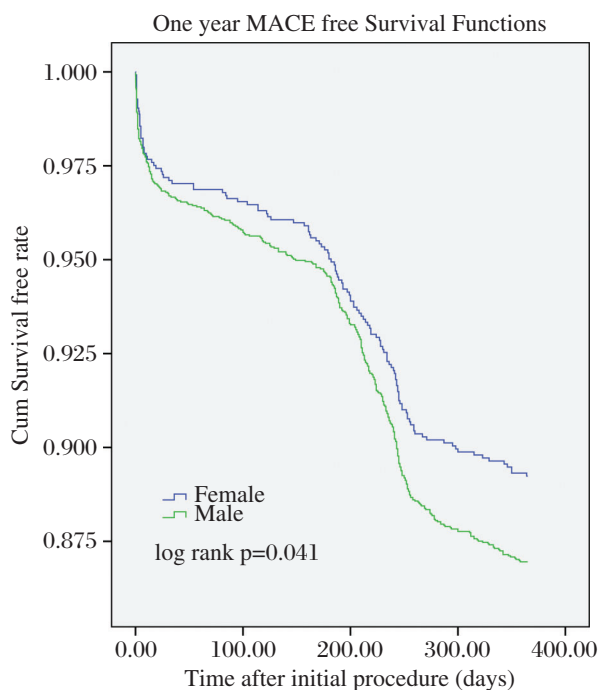
One year MACE free Survival Functions

Fig. 2 One-year major adverse cardiac events MACE free survival functions. Kaplan-Meier free survival curves for one-year MACE between male and female patients undergoing percutaneous coronary intervention.

between patients of different genders after elective PCI. In our present study, many female patients were older than male patients and had diabetes with other risk factors including hypertension and high cholesterol, but their follow-up results were totally opposite and showed that male patients had a higher incidence of MACE than female patients. In our study, Chinese male patients having a higher incidence of MACE at one-year due to their LVEF, renal function and creatinine levels were much worse in outcome than Chinese female patients, although they were not statistically significantly different. Spinler [17] reported that, from a large database of the SYNERGY trial, chronic kidney disease derived from estimated glomerular filtration rate was predictive of 30-day mortality, myocardial infarction and bleeding.

Lansky [18] reported that women have increased in-hospital mortality after both elective and primary PCI compared to men in the majority of reports, but that such differences are smaller after adjustment for women's greater age, smaller body surface area and comorbidities at the time of presentation. In our study, we did not find any difference between female and male patients during the in-hospital stay, which can be explained by the improvement in the PCI technique and in-hospital management. KAMIR[19] investigators suggested that one-month MACE was higher in female patients although there was no gender difference for invasive treatment. Welty[20] did not find any difference between genders for the procedural outcome of PCI and both genders had a similar success rate in their study. Schuhlen et al.[21] also found that female gender had no excess risk for MACE after PCI. Our study showed that there was a gender difference, but male patients were having a higher rate of MACE than female patients. MI and TLR were found to be significantly higher in male patients. This can be explained as there were a higher number of male patients who had longer and a higher number of stents. The increase in the number and length of stents contributed to an increase in TLR and in stent restenosis causing MI and an increase in MACE[22]. The other main reasons for all MACE at one-year follow-up are discontinuation of dual antiplatelet therapy by patients themselves. The study of Brener et al.[23] suggested that prolonged dual antiplatelet therapy reduces MACE after PCI. We know many male patients discontinued dual antiplatelet therapy from our data. Another study reported by Harmsze et al.[24] concluded that many patients are resistant to anti-coagulation medication. This can be the major cause of MACE after PCI and patient's reaction to stents. In our study, there are more male patients than

female patients, like the study reported by Nguyen et al.[25], who suggested that there may be a gender bias for referral of patients for coronary angiography.

This study is subject to the limitations of a non-randomized study. The significant difference between genders in terms of baseline demographics and the smaller female patient population may result in bias in the interpretation of the data. Further studies of DES and BMS need to be performed to clarify difference in gender-based outcomes in Chinese patients.

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