



## Results of Coronary Artery Stenting in Women versus Men: A Single Center Experience

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**Key words:** coronary stents, outcome, gender

### Abstract

**Background:** Prior studies have suggested that women are at higher risk for morbidity and mortality during coronary angioplasty, although long-term prognosis is similar after successful procedures.

**Objectives:** To examine the role of gender in coronary stenting, including immediate procedural success as well as early and late outcomes.

**Methods:** The study group comprised 560 consecutive patients (119 women and 441 men) who had undergone stenting over a 3 year period.

**Results:** The indications for coronary stenting were similar among women and men, and stents were successfully deployed at similar rates without complications (92 vs. 90% respectively). Cardiac death or myocardial infarction within 30 days of the procedure was observed in 5% of women and men, whereas none of the women, compared to 1.4% of men, had early revascularization. Bleeding complications occurred in 4% of women and 2% of men. During  $10 \pm 2.8$  months of follow-up, 58% of women and men underwent repeat cardiac catheterization, revealing similar rates of restenosis, 36 vs. 32% respectively. During the study period, 3.3% of women as compared to 0.9% of men had a cardiac death (not significant). Cardiac death or myocardial infarction was observed in 7% of women and 8% of men, and the combined endpoint of death, myocardial infarction or revascularization, was noted in 24% and 26% respectively. Multivariate Cox analyses of the clinical, angiographic and procedural characteristics revealed that multiple stent deployment was the only predictor of major adverse cardiac event among men, whereas none of these characteristics predicted outcome in women.

**Conclusion:** Coronary stenting is performed with similar success rates among women and men, with similar restenosis rates as well as early and late major adverse cardiac events.

*IMAJ 2003;5:398-402*

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Although women develop coronary artery disease at an older age than men do, CAD and stroke are the leading causes of death among elderly women [1]. Prior studies have suggested that women are at higher risk for morbidity and mortality during coronary angioplasty [2-7] and coronary bypass surgery [8,9], although long-

term prognosis is similar to that of men after successful procedures [2-7].

As the frequency of coronary stenting is rapidly increasing, the purpose of our study was to evaluate the procedural success as well as early and late outcome of coronary stenting among women compared to men, and to identify gender-related characteristics that may affect these outcomes.

### Patients and Methods

#### Patients

A total of 560 patients (119 women and 441 men) underwent coronary stenting in our institution from January 1994 through December 1996, and were evaluated for procedural success, early complications and subsequent cardiac events. During this period 1,776 percutaneous coronary interventions were performed in 1,415 patients.

Clinical variables included patients' diagnosis at the time of intervention, risk factors for CAD, prior history of myocardial infarction, and prior revascularization procedures. Angiographic variables included qualitative assessment of coronary disease, and quantitative assessment of the culprit vessel. Off-line QCA was performed using electronic caliper on end-diastolic cine-frames. The maximal stenosis severity before and after intervention on matching views upon termination of the procedure was compared. Vessel size was measured proximal and distal to the lesion site, and minimal luminal diameter, percent stenosis and lesion length were assessed. Two experienced angiographers who were blinded to the patient's clinical outcome reviewed the coronary angiography films. Procedural variables included stent type, number of stents deployed, multivessel intervention, maximal balloon size, maximal pressure utilized, and antiplatelet or anticoagulation therapy following stent deployment.

In all patients, coronary balloon angioplasty preceded stent implantation. The indications for stent implantation included suboptimal result of percutaneous transluminal coronary angioplasty, dissection, threatened or acute occlusion, or as a primary procedure with predilatation. Eight patients underwent rotational atherectomy prior to stent implantation. Stent implantation was

CAD = coronary artery disease

QCA = quantitative assessment of the culprit vessel

performed by standard percutaneous femoral approach. Balloons and stents were chosen by the operators to approximate the size of the reference segment. Multivessel intervention was performed in 10% of patients. The first vessel stented was considered for the analyses. During the study period glycoprotein IIb/IIIa receptor blockers were not used. A few of the study patients were treated with warfarin after the stenting, however most of the patients were treated with ticlopidine for 1 month, in addition to aspirin.

In-hospital complications were entered prospectively into the database for all 560 patients. These included major adverse cardiac events (death, myocardial infarction, or revascularization) and adverse vascular events requiring blood transfusion or surgical repair of the arterial access site. Myocardial infarction was defined by the presence of two of the following conditions: a) chest discomfort of  $\geq 20$  minutes, b) development of new abnormal Q waves, and c) enzyme elevation of creatine-kinase and CK-MB fraction (when available) to more than twice the upper limit of normal. Myocardial enzymes were not routinely measured after PCI, but were obtained when clinically indicated.

### Follow-up

The follow-up was obtained retrospectively from hospital and clinic records, and if missing, patients' questionnaires were distributed by mail, and telephone interviews with patients and their primary physicians were conducted. Follow-up was obtained in 96% of patients and included the patient's symptoms, the results of functional tests for cardiac ischemia, and the presence of major adverse cardiac events after hospital discharge. Major adverse events were defined as cardiac death, myocardial infarction, coronary bypass surgery, and percutaneous target vessel revascularization.

Angiographic follow-up was obtained in 58% of patients with a mean patient follow-up of 5.3 months. Indications for repeat angiography included the recurrence of symptoms, a provocative test suggestive of recurrent ischemia, complex anatomy preceding stenting such as bifurcation lesions and chronic coronary occlusion, procedural complication such as major dissection, stent implantation performed as part of an approved research protocol that included 6 month angiography, and routine angiographic follow-up recommended by the patient's cardiologist.

### Statistical analysis

Results are expressed as mean value  $\pm$  1 SD. The unpaired Student *t*-test was performed in the analysis of continuous variables and the chi-square test was used for categorical data. Stepwise multivariate logistic regression analysis using the SAS system was performed on all variables whose value was less than 0.05 on univariate analysis.

### Results

The clinical characteristics of the 560 patients (119 women and 441 men) by gender are described in Table 1. Women were older than men ( $64 \pm 10$  vs.  $58 \pm 1$  years) and had a higher prevalence of diabetes mellitus, hypertension and hypercholesterolemia, but they

**Table 1.** Clinical characteristics of the study population by gender

	Women (n=119)	Men (n=441)	P
Age (yrs)	64 $\pm$ 10	58 $\pm$ 11	0.02
Diabetes (%)	39	25	0.003
Hypertension (%)	55	37	0.001
Hypercholesterolemia (%)	66	52	0.001
Smokers (%)	28	55	0.001
Prior MI (%)	38	46	NS
Prior PTCA (%)	34	41	NS
Prior coronary artery bypass graft (%)	15	19	NS
Multivessel disease (%)	61	64	NS
<b>Indications for PTCA</b>			
Unstable angina pectoris (%)	27	23	Ns
Acute MI (%)	13	14	Ns
Post-MI angina pectoris (%)	14	19	Ns
Stable angina pectoris (%)	46	44	Ns
<b>Indications for stent deployment</b>			
<i>De novo</i> lesions (%)	39	35	Ns
Restenosis (%)	20	26	Ns
Suboptimal PTCA results (%)	41	39	Ns

smoked less than men (all  $P = 0.05$ ). Women had similar rates of prior myocardial infarction, coronary angioplasty and coronary bypass surgery.

The indications for balloon angioplasties that subsequently led to coronary stenting were unstable angina in 27% of women and 23% of men, evolving myocardial infarction in 13% of women and 14% of men, post-myocardial infarction angina in 14% vs. 19%, stable angina in 46% vs. 44% (all not significant) [Table 1]. Stent deployment was performed in *de novo* lesions in 39% of women and 35% of men, in restenotic lesions in 20% vs. 26%, and due to suboptimal balloon angioplasty results in 41% vs. 39% respectively (not significant) [Table 1].

### Coronary stent deployment

Palmaz-Schatz stents (Johnson & Johnson Interventional Systems, USA) were deployed in 308 patients (55%), NIR Stent (Boston Scientific, USA) in 90 patients (16%), Gianturco-Roubin Flex-Stent (Cook, USA) in 61 patients (11%), Micro Stent (Arterial Vascular Engineering, USA) in 49 patients (9%), Wiktor stent (Medtronic, USA) in 29 patients (5%), Multilink stent (Advanced Cardiovascular Systems, USA) in 11 patients (2%), and other stents, including the Wallstent (Schneider, Switzerland), Cordis stent (Cordis, USA), and BeStent (Medtronic) in 11 patients (2%). Multiple stents were deployed in 126 patients (23%). The first stent used was considered the stent responsible for any subsequent adverse cardiac event. The first lesion stented was located in the left anterior descending artery in 275 patients (49%), in the right coronary artery in 139 patients (25%), in the circumflex artery in 87 patients (16%), in an arterial or saphenous vein graft in 49 patients (9%), and in the left main coronary artery 10 patients (2%). Multivessel intervention was performed in 56 patients (10%). The first vessel stented was considered the target vessel.

Stent deployment results by gender are presented in Table 2. Mean vessel reference diameter, mean percent stenosis, final

PCI = percutaneous coronary intervention

balloon size, mean maximal pressure deployed, final mean luminal diameter, mean length of the stent deployed and the frequency of multiple stenting were all similar between women and men. Successful stent deployment (final percent diameter stenosis of the stented lesion was <50% of the reference diameter at the end of the procedure) without complications was achieved in 92% of women and 90% of men. After the procedure, 90% of the patients were treated with aspirin, 67% with ticlopidine for 1 month and 12% with warfarin, with similar rates in women and men.

### In-hospital complications and late outcome

Among the patients in whom stent deployment was successful, cardiac death within 30 days after the procedure occurred in 2 women and 1 man, and death or myocardial infarction occurred in 6 women (5%) and 24 men (5.4%). None of the women, but six men (1.4%), had early revascularization, repeat balloon angioplasty or coronary bypass surgery within this period (not significant). Vascular or bleeding complications occurred in 4% of women and 2% of men (not significant).

Ninety-six percent of the study patients surviving hospitalization had clinical follow-up of average  $10 \pm 2.8$  months (range 6–12 months).

Repeat coronary angiography was performed in 69 women (58%) and 255 men (58%) 5.3 months following the primary procedure. Significant restenosis was observed in 25 women (36%) and 82 men (32%) of the patients who had angiographic follow-up (not significant).

The clinical outcome of the patients by gender, including the frequency of major adverse cardiac events, i.e., death, myocardial infarction or revascularization, and symptom-free follow-up is presented in Table 3. Cardiac death during the study period occurred in 3.3% of women compared to 0.9% of men, however this difference was not statistically significant. Seven percent of women and 8% of men died or had myocardial infarction after stent deployment and during follow-up (the majority occurred within 30 days of follow-up), whereas 24% of women compared to 26% of men had major cardiac events (death, myocardial infarction or revascularization). Forty-eight percent of women and men were asymptomatic and event-free during the follow-up period.

Univariate Cox analysis for the entire study population revealed that gender had no effect on angiographic results and clinical outcome. The results of univariate Cox analysis of clinical, angiographic and procedural characteristics of major adverse cardiac events stratified according to gender is presented in Table 4. Multivariate analysis revealed that multiple stent deployment was the only predictor of major adverse cardiac event among men, whereas none of the clinical or angiographic variables predicted outcome among women. Variables significantly associated with angiographic restenosis on univariate analysis of the entire study population were not independently predictive of restenosis on multivariate analysis, therefore analyses by gender were not performed. The phenomenon that some of the variables were found significantly correlated with the response variable while taken separately, but lost their significant association while considered in multivariate setup, is feasible in the context of the

**Table 2. Results of stent implantation by gender**

	Women (n=119)	Men (n=441)
Mean vessel ref. diam. (mm)	3.25 $\pm$ 0.66	3.27 $\pm$ 0.73
Mean % stenosis	75 $\pm$ 13	77 $\pm$ 14
Final balloon size (mm)	3.5 $\pm$ 0.5	3.5 $\pm$ 0.5
Mean max. pressure (atm)	18 $\pm$ 3	17 $\pm$ 3
Final minimal luminal diam (mm)	3.1 $\pm$ 0.6	3.2 $\pm$ 0.6
Mean stent length (mm)	17 $\pm$ 7	17 $\pm$ 6
Multiple stents (%)	19	23
Successful stent deployment without complications (%)	92	90

*P* not significant

**Table 3. Clinical outcome of the patients by gender (average follow-up  $10 \pm 2.8$  months)**

	Women (n=119)		Men (n=441)	
	No.	%	No.	%
Death	4	3.3	4	0.9
Death/MI	8	6.7	36	8.2
Death/MI/revascularization	28	23.5	114	25.8
Asymptomatic, event-free	57	47.9	210	47.6

*P* not significant

**Table 4. Univariate predictors of cardiac events by gender**

	Variable	Chi-square	<i>P</i>
Women	Hypertension	4	0.047
	Bifurcation lesion	4.2	0.04
	Diabetes	4.8	0.03
	Multivessel disease	9.7	0.008
	No aspirin	17.6	0.001
Men	Hypertension	4	0.047
	Restenosis	5.9	0.016
	No ticlopidine	11.8	0.001
	Multi-lesions treated	12.5	0.006
	Dissection	14.8	0.001
	Multi-stents deployed	19	0.001

logistic regression technique that was used. The main reason for such occurrence is that the response and each of the explanatory variables have a linear relationship with different slopes (on the logarithmic scale). However, when taken together, the (logarithmic) linear relationship may weaken. A secondary reason for this phenomenon is multi co-linearity between predictors. Such co-linearity may have a masking effect on the significance of association between these predictors and the response.

### Discussion

Previous studies have suggested that women undergoing coronary balloon angioplasty are at higher risk for immediate complications, including death and non-fatal myocardial infarction [2–6]. However, increasing numbers of coronary angioplasties are involving stent deployment, with significant improvement in immediate success

and reduction in complication rates [10–14], therefore the purpose of the present study was to assess if coronary stenting affected the outcome in women compared to men.

### Immediate success rate

We observed a similar success rate of stent deployment in women compared to men (92 vs. 90% respectively). The angiographic success of coronary balloon angioplasties was similar among the 546 women of 2,136 patients of the Angioplasty Registry of NHLBI performed in 1985–1986, as reported by Kelsey et al. [2]. Similar angiographic success between women and men undergoing balloon angioplasties were also demonstrated by other authors [4,5]. In a study by Schuhlen and colleagues [13] female sex was not a predictor of failure for intracoronary stenting.

### 30 day complication rate

Cardiac death or myocardial infarction within 30 days after stent deployment was similar in women and men (5% in both groups). None of the women compared to 1.4% of men required early revascularization (not significant). Vascular or bleeding complications occurred in 4% of women and 2% of men (not significant).

Prior studies have suggested that women are at higher risk for morbidity and mortality during coronary angioplasty [2–6]. Among the 546 women and 1,590 men who participated in the Angioplasty Registry of NHLBI, women had a considerably higher procedural mortality rate – 2.6% compared to 0.3% among men ( $P < 0.001$ ) [2]. Increased in-hospital mortality of 4.2% among 960 women as compared to 2.7% among 2,597 men undergoing coronary angioplasty ( $P = 0.005$ ) was also demonstrated by Bell et al. [3]. A trend toward more Q wave myocardial infarctions (1.1% vs. 0.75%, not significant), and a significantly higher hospital mortality among women compared to men (0.7% vs. 0.1%,  $P < 0.0001$ ) was also reported by Weintraub and co-workers [4] who studied 2,582 women and 7,126 men undergoing coronary angioplasty. Malenka et al. [6], in their study of 12,232 patients who underwent 13,061 coronary angioplasties, found that the mortality rate among women was 1.64 vs. 0.7% among men, with odds ratio of 2.34. However, these studies did not involve coronary stenting.

Worse in-hospital outcome among women undergoing coronary stenting was reported by Mehilli and associates [15], who studied 1,001 consecutive women and 3,263 men. Thirty days after coronary stenting, women presented an excess risk of death or myocardial infarction of 3.1% vs. 1.8% in men ( $P = 0.02$ ). Multivariate analysis of these results revealed a hazard ratio for women of 2.02.

Recently, Watanabe et al. [16] who reviewed 20% of all U.S. hospital discharges for 1997 found that of 118,548 coronary angioplasties, 59% involved stenting. The mortality rates after stenting was 4% for women and 2% for men with acute myocardial infarction ( $P < 0.0001$ ), whereas the rates were 1.1% vs. 0.5% respectively for patients without acute myocardial infarction ( $P < 0.0001$ ). In our study, cardiac death or myocardial infarction within 30 days after stent deployment was 5%, both among women and men. The relatively high 30 day event rate probably reflects early experience with coronary stenting and the utilization of previous generation stents.

### Predictors of restenosis

In our study, none of the clinical, angiographic and procedural variables were independently predictive of stent restenosis on multivariate analysis. By contrast, in a study by Kastrati and colleagues [17] involving 1,349 patients and 1,753 lesions stented, diabetes, multiple stents and smaller final mean luminal diameter were strong predictors of stent restenosis. Bauters et al. [18] did not find any clinical predictor of stent restenosis in their study of 463 patients, however multiple stent deployment, stenosis length, small reference diameter and stents other than Palmaz-Schatz were independent predictors of restenosis. Kastrati's team [19] found that the restenosis rate is significantly higher when stents were implanted in type B2 or C lesions as compared to type A or B1 lesions. The same group also found that long lesions represent an independent risk factor for restenosis after coronary stent deployment [20]. Antoniucci et al. [21] in their study on 258 consecutive non-selected patients found 4 independent predictors of stent restenosis, including age older than 63 years, female gender, lesion length >12 mm, and type C lesions. Restenosis rate was not affected by the utilization of high (15–20 atmospheres) or low (8–13 atmospheres) pressure balloon inflations [22]. However, stent restenosis rate was lower among diabetic patients treated with the glycoprotein IIb/IIIa receptor blocker abciximab [23].

### Predictors of major adverse cardiac event at follow-up

In our study, most cases of death/myocardial infarction occurred within the first 30 days post-procedure. Multiple stent deployment was the only predictor of MACE (death/MI/revascularization) during follow-up among men, whereas none of the clinical or angiographic variables predicted outcome among women. Schuhlen and co-workers [13] found that independent risk factors for MACE were older age, diabetes, acute myocardial infarction, unstable angina, left ventricular dysfunction, residual dissection, stent overlap, longer stented segments, and lack of utilization of ticlopidine after the procedure. Mathew et al. [24], in their research on 1,709 patients who underwent successful stent deployment without any in-hospital MACE, found that death, myocardial infarction or revascularization at follow-up were associated with congestive heart failure, multivessel stent deployment, warfarin therapy, and procedure within 24 hours of acute myocardial infarction. Kastrati et al. [25] demonstrated that stent design has a significant impact on long-term results after coronary stenting.

Mehilli et al. [15] found that at 1 year, the outcome of the 1,001 women and 3,263 men who underwent coronary stenting was similar, with 6% death or myocardial infarction among women compared to 5.8% among men, with a multivariate-adjusted hazard ratio for women of 1.06 (95% confidence interval 0.75–1.48).

### Limitations

The study population included a relatively small number of women. This might have affected our ability to predict factors that might influence procedural success and patient outcome. Recently, the

MACE = major adverse cardiac event  
MI = myocardial infarction

wide utilization of glycoprotein IIb/IIIa receptor blockade has improved the outcome of patients undergoing coronary stenting, as has the introduction of new generations of more flexible stents. In the present study 55% of the stents used were Palmaz-Schatz, which are no longer used. Hence, the results of our study are relevant only to the study period (1994–1996) when stents were deployed mainly in patients with coronary dissection, threatened acute vessel closure or non-satisfactory balloon angioplasty results. Presently, this technique is more refined and elective coronary stenting, rather than provisional stenting, has markedly increased.

## Conclusions

Coronary stenting was performed with similar success among women and men. The major adverse cardiac event rate after the procedure, as well as restenosis, occurred at similar rates in women and men. In multivariate analysis, no predictors of stent restenosis or major adverse cardiac events could be defined among women. Hence, since coronary stenting as compared to coronary angioplasty alone is related to a significant improvement in immediate success and outcome, it should be utilized in women as frequently as in men.

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*I think men talk to women so they can sleep with them and women sleep with men so they can talk to them.*

Jay McInerney (1955- ), U.S. author