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FOCUS ISSUE: DRUG-ELUTING STENTS: TAXUS-IV

Gender-Based Outcomes After Paclitaxel-Eluting Stent Implantation in Patients With Coronary Artery Disease

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OBJECTIVES We sought to determine whether gender influences the results of paclitaxel-eluting stent implantation.

BACKGROUND The TAXUS-IV trial demonstrated the safety and effectiveness of the slow-release, polymer-based, paclitaxel-eluting TAXUS stent compared to bare-metal stents in patients undergoing elective coronary intervention. Whether these results are generalizable to women is not known.

METHODS A total of 1,314 patients with coronary lesions 10- to 28-mm long in 2.5- to 3.75-mm vessels were randomized to TAXUS stent versus bare-metal EXPRESS stents (Boston Scientific Corp., Natick, Massachusetts). Outcomes examined were stratified by gender.

RESULTS A total of 662 patients (including 187 women) were assigned to the TAXUS stent, and 652 (180 women) received the control stent. Women were older than men, and had more hypertension, diabetes, renal insufficiency, unstable angina, and heart failure, but less smoking. Among patients receiving the TAXUS stent, women compared with men had higher unadjusted one-year rates of target lesion revascularization (TLR) (7.6% vs. 3.2%, p = 0.03), though female gender was not an independent predictor of TLR (odds ratio [OR] = 1.72 [95% confidence interval (CI) 0.68 to 4.37], p = 0.25). Moreover, restenosis rates were similar in men and women treated with the TAXUS stent (8.6% vs. 7.6%, respectively, p = 0.80), as was late loss (0.22 vs. 0.23 mm, p = 0.90). Compared to control stents, treatment with the TAXUS stent in women resulted in a significant reduction in nine-month restenosis (8.6% vs. 29.2%, p = 0.0001) and one-year TLR (7.6% vs. 14.9%, p = 0.02). The only independent predictor of freedom from restenosis in women was randomization to the TAXUS stent (OR = 0.28 [95% CI 0.11 to 0.74], p = 0.01).

CONCLUSIONS The benefits of the paclitaxel-eluting stent in reducing clinical and angiographic restenosis are generalizable to women. (J Am Coll Cardiol 2005;45:1180–5) © 2005 by the American College of Cardiology Foundation

Stents reduce clinical and angiographic restenosis compared to balloon angioplasty and other devices (1–3). Specific gender-based comparisons were not reported from these earlier randomized clinical trials, yet the results with bare-metal stents have been generalized to the female population. Despite stent implantation, a considerable number of patients still develop restenosis and require repeat revascularization within 6 to 12 months (4–6). Drug-eluting stents that deliver bioactive agents directly to the site of vascular injury have demonstrated superior results in the elective treatment of de novo coronary lesions compared to bare-metal stents (7–16). Whether these devices are as safe and effective in men and women is unknown. We report the gender-based outcomes with the slow-release, polymer-based, paclitaxel-eluting TAXUS stent as evaluated in the TAXUS-IV clinical trial (12,16).

METHODS

The TAXUS-IV study design, major inclusion and exclusion criteria, end point definitions, and principal results have been reported in detail previously (12). In brief, 1,314 patients undergoing elective coronary intervention of a single de novo coronary lesion were prospectively randomized in double-blind fashion to the TAXUS stent, or an identical-appearing bare-metal EXPRESS stent (Boston Scientific Corp., Natick, Massachusetts). By visual estimation the lesion lengths were 10 to 28 mm, with reference vessel diameters of 2.5 to 3.75 mm. Patients were stratified during randomization according to the presence or absence of diabetes mellitus and vessel size. Diabetes, hyperlipid-

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Abbreviations and Acronyms

CI = confidence interval
MACE = major adverse cardiac events
OR = odds ratio
TLR = target lesion revascularization
TVR = target vessel revascularization

emia, and hypertension were defined based on the requirement for therapy with medications.

The recommended adjunctive pharmacologic regimen included 325 mg aspirin per day (continued indefinitely), and 300 mg of clopidogrel started before the procedure and continued for at least six months. The procedural antithrombotic agent used was unfractionated heparin, and glycoprotein IIb/IIIa inhibitors were used at the operator's discretion.

Clinical follow-up was planned at 1, 4, and 9 months, and then yearly for 5 years. The primary end point was the rate of ischemia-driven target vessel revascularization (TVR) adjudicated by an independent clinical events committee. Other adjudicated clinical end points included death, myocardial infarction, target lesion revascularization (TLR), target vessel failure, major adverse cardiac events (MACE), and stent thrombosis, as previously defined (12). Angiographic follow-up was pre-specified in 732 patients at nine months. All baseline and follow-up angiograms were analyzed at an independent core laboratory.

Statistical analysis. Examination of gender-based outcomes was a pre-specified subset analysis. Categorical variables were compared with chi-square test for trend (for four-way comparisons) or with the Fisher exact test (for two-way comparisons). Continuous variables are presented as means ± 1 SD or median with interquartile ranges and were compared by the Wilcoxon two-sample test. Survival estimates were created using Kaplan-Meier methodology, and compared using the log-rank test. The influence of baseline variables on the nine-month rates of angiographic restenosis was evaluated with logistic regression, using entry and stay criteria of <0.20 and <0.10, respectively. A Cox proportional hazard regression was used to identify the independent determinates of TLR and TVR. The variables entered into these models included age, smoking status, diabetes, epicardial coronary artery, previous myocardial infarction, hypertension, hyperlipidemia, left ventricular ejection fraction, unstable angina, creatinine clearance, ostial location, bend $\geq 45^{\circ}$, tortuosity, calcification, lesion length, baseline reference vessel diameter, and baseline minimal luminal diameter, with gender forced into the models. All p values are two-sided.

RESULTS

Baseline and procedural characteristics. Of the 1,314 randomized patients, 662 were assigned to the paclitaxel-eluting stent (including 475 [71.8%] men and 187 [28.2%] women), and 652 were assigned to the bare-metal control stent (including 472 [72.4%] men and 180 [27.6%] women). Gender differences in baseline demographic characteristics according to randomization are detailed in Table 1. In the TAXUS group, women were older than men, and had more hypertension, diabetes, baseline renal insufficiency, unstable angina, and prior congestive heart failure, but less smoking. These findings were similar in the angiographic subset.

Angiographic characteristics are detailed in Table 2. Left ventricular ejection fraction was greater in women than men despite more prior congestive heart failure. Women had smaller vessel diameters, but similar lesion lengths compared to men. Procedure-related complications including dissections, abrupt vessel closure (0.3%), and no-reflow (0.7%) were infrequent in both groups. The post-procedural angiographic diameter stenosis was similar in men and women, and in both randomized groups.

Gender-based differences in the discharge medical regimen included less use of beta-blockers (63.1% vs. 71.2%, $p = 0.05$)

Table 1. Baseline Demographic Features According to Gender and Randomization Arm

	TAXUS Stent			Control Stent			TAXUS vs. Control	
	Women	Men	p Value	Women	Men	p Value	Women p Value	Men p Value
n	187	475		180	472			
Mean age, yrs	66.1 ± 11.4	61.6 ± 10.8	<0.001	65.2 ± 10.9	60.9 ± 10.7	<0.0001	0.45	0.33
Body surface area, m^2	1.82 ± 0.19	2.07 ± 0.19	<0.0001	1.80 ± 0.18	2.08 ± 0.20	<0.0001	0.48	0.76
Hypertension, %	78.5	67.7	0.006	80.0	65.5	0.0003	0.79	0.49
Hyperlipidemia, %	68.0	65.5	0.58	64.2	67.3	0.46	0.50	0.58
Diabetes, %	33.7	19.4	0.0001	29.4	23.3	0.11	0.43	0.15
Prior heart failure, %	9.1	4.1	0.01	11.7	5.8	0.01	0.49	0.23
Peripheral vascular disease, %	10.1	9.4	0.78	14.9	8.7	0.02	0.19	0.73
Renal insufficiency, %	7.1	3.2	0.03	4.6	3.4	0.49	0.37	1.00
History of coronary artery disease, %	77.0	64.6	0.005	73.7	63.5	0.02	0.51	0.77
Prior myocardial infarction, %	27.8	31.6	0.34	24.4	32.0	0.06	0.47	0.94
Previous smoker, %	29.8	45.4	0.0003	35.8	51.7	0.0004	0.25	0.06
Unstable angina, %	42.2	33.3	0.03	41.7	29.2	0.003	0.91	0.18

Table 2. Baseline and Post-Procedure Angiographic Findings According to Gender and Randomization Arm

	TAXUS Stent			Control Stent			TAXUS vs. Control	
	Women	Men	p Value	Women	Men	p Value	Women p Value	Men p Value
n	187	475		180	472			
Baseline								
Lesion location								
Right coronary artery	33.2%	30.2%	0.51	38.3	29.7	0.03	0.38	0.89
Left circumflex coronary artery	30.5%	28.3%	0.63	21.1	28.2	0.06	0.04	1.00
Left anterior descending coronary artery	36.4%	41.4%	0.25	40.6	41.7	0.79	0.39	0.95
Left ventricular ejection fraction, %	57.0 ± 11.1	54.5 ± 9.5	0.008	57.1 ± 10.0	54.9 ± 10.6	0.01	0.97	0.62
Lesion length, mm	13.25 ± 5.82	13.43 ± 6.49	0.72	12.67 ± 5.79	13.64 ± 6.32	0.08	0.34	0.63
Reference vessel diameter, mm	2.63 ± 0.43	2.80 ± 0.48	<0.0001	2.66 ± 0.43	2.79 ± 0.50	0.001	0.50	0.61
Minimal luminal diameter, mm	0.87 ± 0.31	0.94 ± 0.34	0.008	0.93 ± 0.34	0.95 ± 0.34	0.51	0.06	0.62
Diameter stenosis, %	67.0 ± 10.5	66.4 ± 10.7	0.54	65.0 ± 10.9	65.83 ± 10.6	0.38	0.08	0.42
Post-procedure								
Minimal luminal diameter, mm								
In-stent	2.57 ± 0.39	2.70 ± 0.44	<0.0001	2.61 ± 0.39	2.67 ± 0.43	0.08	0.31	0.24
Analysis segment	2.15 ± 0.45	2.30 ± 0.47	0.0003	2.18 ± 0.44	2.29 ± 0.51	0.007	0.45	0.95
Diameter stenosis, %								
In-stent	3.2 ± 10.9	4.3 ± 10.9	0.24	2.1 ± 11.6	5.0 ± 11.3	0.003	0.34	0.38
Analysis segment	19.5 ± 9.8	19.2 ± 9.4	0.72	18.7 ± 9.3	19.0 ± 10.4	0.68	0.42	0.83

and lipid-lowering (65.2% vs. 75.8%, p = 0.007) agents in women, but greater use of angiotensin-converting enzyme inhibitors (57.8% vs. 46.3%, p = 0.01). Protocol-mandated aspirin and thienopyridine use was equally high in men and women at discharge (>99%) and at 30 days (>97%); at 9 months aspirin use was also similar (95%), but thienopyridine use was lower in women (35.4% vs. 47.7%, p = 0.005). There were no differences in medication use in patients randomized to paclitaxel-eluting versus bare-metal stents.

Gender-specific clinical outcomes. The 30-day rates of MACE were similar in men compared to women, randomized to either the paclitaxel-eluting stent or the bare-metal stent (Table 3). At one year, among patients randomized to the bare-metal stent, the rates of cardiac death, TLR, and TVR were similar between men and women. Women assigned to the control stent had a higher incidence of myocardial infarction at one year than men, though the overall composite incidences of MACE were similar in men and women. Among patients randomized to the paclitaxel-eluting stent, the one-year rates of TLR and TVR were significantly higher in women than men, though there were no differences in cardiac death, myocardial infarction, or composite MACE. By multivariate analysis, female gender was not an independent predictor of either TLR or TVR among patients randomized to the paclitaxel-eluting stent after adjustment for differences in baseline characteristics between men and women (Fig. 1).

Among women, randomization to the paclitaxel-eluting stent rather than the control stent resulted in lower one-year rates of myocardial infarction (66% reduction) and TLR (54% reduction), with a strong trend toward reduced TVR (41% reduction) (Table 3). As a result, target vessel failure (44% reduction) and composite MACE (45% reduction) were significantly reduced in women assigned to the TAXUS stent. Men randomized to the paclitaxel-eluting stent rather than the bare-metal stent had reduced one-year rates of TLR (80% reduction), TVR (69% reduction), target vessel failure (55% reduction), and MACE (51% reduction).

Gender-specific angiographic outcomes. Follow-up angiography at nine months demonstrated that the amount of late loss was similar in women and men treated with the paclitaxel-eluting stent, both within the stent and the entire analysis segment. As a result, the binary rates of in-stent and analysis segment restenosis were also similar in men and women after TAXUS stent implantation (Table 4). Randomization to the TAXUS stent rather than the bare-metal control stent in both men and women resulted in markedly less late loss and, therefore, highly significant reductions in both in-stent and analysis segment restenosis. Both men and women experienced a 70% relative reduction in analysis segment restenosis with assignment to the TAXUS stent rather than the control stent. Among women, the only independent predictor of freedom from analysis segment restenosis at nine months was randomization to the paclitaxel-eluting stent (odds ratio [OR] = 0.28 [95% confidence interval (CI) 0.11 to 0.74], p = 0.01). In men,

Table 3. Clinical Outcomes at 30 Days and 1 Year

	TAXUS Stent			Control Stent			TAXUS vs. Control	
	Women	Men	p Value	Women	Men	p Value	Women p Value	Men p Value
n	187	475		180	472			
30 days, %								
Major adverse cardiac events	2.1	3.2	0.48	3.3	2.1	0.37	0.48	0.32
Cardiac death	0.0	0.4	0.37	0.0	0.6	0.28	—	0.65
Myocardial infarction	2.1	2.7	0.66	3.3	1.9	0.28	0.48	0.39
Target vessel revascularization	0.0	0.0	—	0.0	0.4	0.38	—	0.16
Stent thrombosis	0.0	0.4	0.37	0.0	0.8	0.22	—	0.41
1 year, %								
Major adverse cardiac events	13.5	9.9	0.24	22.7	19.0	0.35	0.02	<0.0001
Target vessel failure	13.0	8.8	0.15	21.6	18.6	0.45	0.03	<0.0001
Cardiac death	0.5	1.7	0.25	1.8	1.1	0.53	0.30	0.41
Myocardial infarction	2.7	3.8	0.48	7.9	3.4	0.02	0.03	0.73
Target lesion revascularization	7.6	3.2	0.03	14.9	15.2	0.88	0.02	<0.0001
Target vessel revascularization	10.8	5.7	0.03	17.5	17.0	0.95	0.07	<0.0001
Repeat coronary intervention	9.2	4.1	0.02	15.2	13.4	0.69	0.08	<0.0001
Bypass graft surgery	2.2	1.6	0.54	2.2	4.7	0.15	0.95	0.0044
Stent thrombosis	0.0	0.8	0.21	0.0	1.1	0.17	—	0.73

randomization to the TAXUS stent was also a powerful independent correlate of freedom from restenosis (OR = 0.19 [95% CI 0.09 to 0.37], $p < 0.0001$).

DISCUSSION

The present analysis from the TAXUS-IV trial demonstrates that the overall beneficial effects of the paclitaxel-eluting stent in reducing clinical and angiographic restenosis are generalizable to female patients. Women assigned to the TAXUS stent, however, did have higher absolute revascularization rates compared to men, a difference that by multivariate analysis was driven by the increased incidence of covariate risk factors for restenosis in women, including diabetes, smaller reference vessel diameter and body surface area, and not by female gender per se. Moreover, the relative reduction in angiographic restenosis with the TAXUS stent compared to the bare-metal control stent was virtually identical in women and men.

The influence of gender on the rates of angiographic restenosis has not been frequently reported from prior randomized studies, partly due to the under-representation of women in prospective trials incorporating systematic angiographic follow-up. Paradoxically, observational registry data have generally reported women to have similar or lower TLR rates compared to men after balloon angioplasty (17–23) and stenting (23–26), despite their consistently smaller vessel size and higher prevalence of diabetes mellitus, factors that are typically associated with higher restenosis and revascularization rates after coronary interventions (21–25). In the absence of systematic angiographic and clinical follow-up, this counterintuitive finding is of uncertain clinical significance. Referral bias, in which women are less likely to be referred or undergo follow-up angiography or revascularization due to gender-based discrepancies in either patient or physician interpretation of symptoms or noninvasive tests may explain the lower observed TLR rates in women compared with men in uncontrolled studies. Two studies of elective stenting, in contrast, found female gender to be predictive of higher rates of restenosis and revascularization (27,28).

A pooled analysis of seven prospective, controlled investigational device exemption stent trials has been performed that included 7,171 patients (2,179 women and 4,992 men) undergoing elective bare-metal stent implantation in 3.0 to 4.0 mm vessels (23). Systematic angiographic and clinical follow-up was mandated by individual protocols. This study demonstrated no differences in TVR one year after bare-metal stenting between men and women (12% women vs. 11% men, p = NS).

Given the potential for referral bias, the higher unadjusted one-year rates of TLR and TVR in women compared to men treated with the paclitaxel-eluting stent in the TAXUS-IV trial (a trend not seen with the bare-metal stent) is at first glance a notable finding. However, by multivariate analysis, gender was not an independent predictor of TLR or TVR after TAXUS stent implantation. Rather, the higher repeat revascularization rates in women receiving the TAXUS stent were explained by the more frequent presence of confounding variables in female patients, including diabetes, smaller reference vessel diameter and body surface area, that were more directly responsible for clinical restenosis. Moreover, the TAXUS stent resulted in a nearly identical 70% reduction in angiographic restenosis in both men and women. Indeed, among women, randomization to the TAXUS stent was the only independent determinate predicting a reduction in restenosis.

Importantly, the benefits of the paclitaxel-eluting stent in women in terms of reducing restenosis were achieved without evident safety issues such as stent thrombosis. On the contrary, the one-year rates of myocardial infarction were reduced in

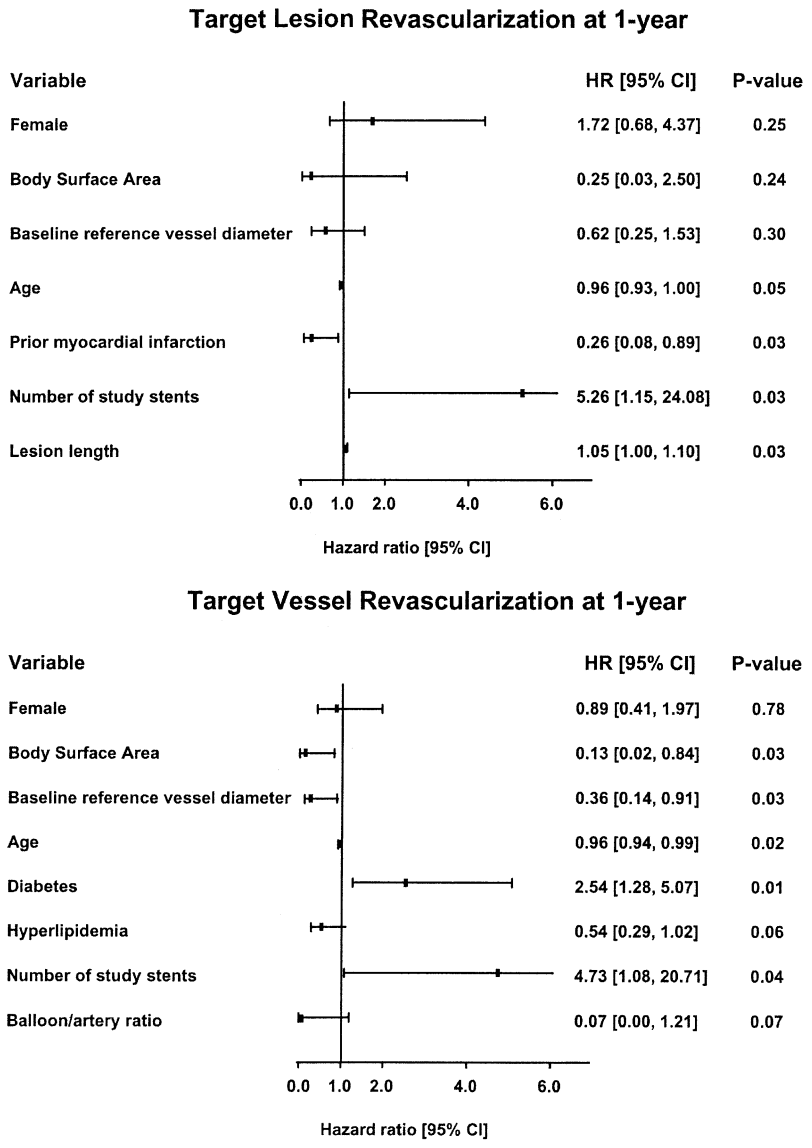

Figure 1. Multivariate predictors of one-year target lesion revascularization **(top)** and target vessel revascularization **(bottom)** in patients randomized to the paclitaxel-eluting stent. CI = confidence interval; HR = hazard ratio.

women receiving the TAXUS stent rather than a bare-metal stent, which, along with reductions in TLR and TVR, contributed to significantly lower rates of target vessel failure and composite MACE in women. Thus, although additional studies would be welcome to investigate the gender-based impact of clinical and angiographic restenosis after drug-eluting stents, the results of the present analysis suggests that the paclitaxel-eluting stent is effective in reducing restenosis and enhancing event-free survival in women as well as men.

Study limitations. Though pre-specified, the present post-hoc subset analysis must be considered hypothesis-generating. The numbers of women studied were insufficient, and the study was underpowered to definitively determine whether the TAXUS stent reduces clinical revascularization in women, which may contribute to why women compared to men treated with the TAXUS stent had higher clinical but not angiographic revascularization rates. In addition, the results of this analysis apply only to the patient cohort defined by the protocol of the TAXUS trial. For example, no conclusions can be drawn regarding optimal treatment of women with more diffuse disease, acute myocardial infarction, or those requiring multivessel intervention. Furthermore, whether drug-eluting stents other than the polymer-based paclitaxel-eluting stent would be more or less effective in women is unknown.

Conclusions and clinical implications. The TAXUS stent safely reduces clinical and angiographic restenosis, and improves survival free from MACE in both men and women. Absolute clinical restenosis rates may be higher in women than men receiving the TAXUS stent, though such an observation is explained by the presence of other risk factors for restenosis after drug-eluting stents in women, rather than gender per se. Moreover, as the only variable identifiable as being predictive of freedom from restenosis was assignment to the paclitaxel-

Table 4. Angiographic Results at Nine Months

	TAXUS Stent			Control Stent			TAXUS vs. Control	
	Women	Men	p Value	Women	Men	p Value	Women p Value	Men p Value
n	81	211		72	194			
In-stent								
Minimal luminal diameter, mm	2.16 ± 0.53	2.30 ± 0.60	0.07	1.62 ± 0.62	1.80 ± 0.65	0.04	<0.0001	<0.0001
Late loss, mm	0.43 ± 0.51	0.38 ± 0.49	0.38	1.03 ± 0.53	0.88 ± 0.59	0.055	<0.0001	<0.0001
Diameter stenosis, %	17.9 ± 17.7	17.2 ± 17.76	0.77	39.7 ± 19.1	36.3 ± 20.0	0.12	<0.0001	<0.0001
Restenosis, %	7.4	4.8	0.39	27.8	23.2	0.52	0.001	<0.0001
Analysis segment								
Minimal luminal diameter, mm	1.98 ± 0.51	2.05 ± 0.56	0.31	1.54 ± 0.55	1.73 ± 0.62	0.02	<0.0001	<0.0001
Late loss, mm	0.22 ± 0.46	0.23 ± 0.43	0.90	0.63 ± 0.50	0.61 ± 0.60	0.77	<0.0001	<0.0001
Diameter stenosis, %	25.3 ± 15.2	26.7 ± 15.5	0.53	42.4 ± 17.5	38.8 ± 18.7	0.16	<0.0001	<0.0001
Restenosis, %	8.6	7.6	0.80	29.2	25.6	0.63	0.001	<0.0001

eluting stent rather than its bare-metal counterpart, this device should be preferentially used in women (as well as men) with lesions meeting the enrollment criteria of the TAXUS-IV trial.

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