Percutaneous transluminal coronary revascularization in women: higher risk of dissection and need for stenting

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Dissection; Stent; Women.

Background. **Even though success rates of percutaneous transluminal coronary angioplasty (PTCA) are influenced by gender, women are at higher risk for adverse procedural events. Plaque dissection has been demonstrated to cause more adverse cardiac events during PTCA in the female gender than the male, but it is not clear how much it could influence stent implantation and procedural complications in the stent era. This study sought to evaluate whether the prevalence of dissection is equal in men and women with similar vessel size, which factors are associated with the risk of this complication and whether stenting has modified the immediate outcome.**

Methods. **Three hundred thirty-nine lesions were studied in 100 consecutive women and 128 men with a vessel diameter 3.5 mm, who underwent PTCA in our catheterization laboratory between March 1998 and March 1999.**

Results. **Procedural success rates were similar in the two groups (93.9% women vs 97.6% men). Complications were one coronary artery bypass graft and five acute myocardial infarctions. In the group of women, however, there was a significant increase in the incidence of plaque dissection during the procedure (37.9 vs 21.7%, p = 0.001), with consequent increased need for stenting (70.4 vs 52.2%, p < 0.05) to achieve adequate final results. Moreover, dissection was strongly associated (p = 0.03) with procedural complications. Multivariate analysis of the whole patient cohort showed the risk of dissection to be associated only with the female gender (p = 0.009), diabetes (p = 0.029), and type C lesion morphology (p = 0.019).**

Conclusions. **Women are at higher risk of plaque dissection, which is associated with adverse procedural events and an increased need for stenting.**

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Introduction

Prior studies have reported significant gender differences in the initial experience of percutaneous transluminal coronary angioplasty (PTCA)[1-7]. Women undergoing PTCA had a lower clinical and angiographic success rate, higher in-hospital mortality, and complication rate than men. These differences have been attributed to older age, worse clinical characteristics (unstable angina, hypertension, diabetes), smaller vessel size, and body surface area in women rather than to gender alone[4-7]. Several factors influence the risk of abrupt coronary closure and major adverse cardiac events; coronary dissection is the major cause of the procedural complications affecting the female population treated with PTCA[2,8-17]. Limited intimal dissection often occurs after balloon inflation. However, when dissection deeply extends to the media the risk of major adverse cardiac events increases[18,19]. Plaque dissection is usually and successfully treated with stent deployment which decreases cardiac complications from 10 to 3%, improving the overall procedural outcome[20-22]. Following the BENESTENT and STRESS trials, stenting is indicated electively in a vessel diameter 3 mm and in short lesions, given that the restenosis rate has been proven to be lower than in PTCA without stenting[23,24]. Coronary stenting is also used when suboptimal PTCA results are present[24-27].

Although stenting is diffusely used, it has not been clearly determined whether stents have influenced procedural differ-

ences by gender and which is the rate of stenting in the female population[28,29].

In our study, we aimed at evaluating whether the prevalence of dissection is equal in men and women with similar vessel size, which factors are associated with the risk of this complication and whether stenting has modified the immediate outcome.

Methods

Study population. The series consists of 339 lesions in 100 consecutive women (132 lesions) and 128 men (207 lesions) with a vessel diameter 3.5 mm who underwent PTCA with or without stenting in our catheterization laboratory between March 1998 and March 1999.

Baseline clinical characteristics and in-hospital complications were collected from hospital documentation. All patients underwent 12-lead ECG pre- and postoperatively to detect procedure-related ischemic changes or the appearance of a new pathological Q wave. Blood samples to check CPK-MB were routinely acquired at 6 and 12 hours after the procedure. The diagnosis of myocardial infarction was based on CPK-MB elevation 5 times normal values with or without new pathological Q waves on postoperative ECGs. Patients were excluded from analysis if they presented acute myocardial infarction, bleeding diathesis and coagulation problems or debulking procedures (rotablator, directional atherectomy).

Qualitative angiographic analysis. Angiography was performed in two projections (30 difference) for every given lesion to be dilated; it was further repeated during and after the procedure. Maximal inflation balloon pressure during PTCA and balloon/artery ratio were also recorded for each treated lesion.

Two independent observers identified occlusive and non-occlusive dissections and the quantitative analysis was done on the angiogram recorded on CD-ROM.

Quantitative coronary angiography. Angiographic data were quantified on end-diastolic frames, with the on-line and off-line quantitative coronary analysis (Automatic Coronary Analysis ACA, Interim, Philips, Eindhoven, The Netherlands). A contrast-filled catheter tip was used for calibration. Measurements were taken from the angiogram before and immediately after PTCA. Minimal lumen diameter, reference diameter, percent diameter stenosis and lesion length were measured at each step by the quantitative coronary analysis system.

Angioplasty procedure. The femoral artery approach was used in all cases. A 6F guiding catheter was used and the guidewire type was selected according to the physician s preference. Balloon size was chosen in relation to the reference diameter (balloon/artery 1.1:1) measured by quantitative coronary analysis. Inflation balloon pressure was based on balloon size, vessel diameter and response of the stenosis to the balloon inflation. Stents were always deployed after predilation with a balloon. The reasons for stent placement were classified into three categories: 1) plaque dissection (occlusive and non-occlusive), 2) suboptimal PTCA result, 3) elective stenting in a vessel diameter 3 mm. Anterograde blood flow was graded using the Thrombolysis in Myocardial Infarction (TIMI) study group classification[30]. Occlusive dissection was defined as a vessel occlusion with TIMI grade 0 or 1 flow (type E and type F of the NHBLI)[31]. Angiographically visible dissection (type A to type D of the NHBLI) was considered non-occlusive when associated with normal blood flow. Stent implantation was indicated when grade C or higher dissections were present. The presence of visually estimated residual stenosis 30% after balloon dilation was considered a suboptimal result.

Elective stenting was considered the stenting decided before the procedure for lesions in vessels with a diameter 3 mm, when a stent-like result was not reached.

The stent size was matched to arterial diameter. Long stents or multiple stents were deployed to cover the full lesion, if necessary, or the dissection.

The stents used were the NIR Primo stent (Boston Scientific, Medinol, Israel), Multilink stent (Guidant, Advanced Cardiovascular Systems, Temecula, CA, USA), the Crossflex stent (Cordis, Johnson and Johnson, Miami, FL, USA), Avenger ACS stent (Guidant, Advanced Cardiovascular Systems, Temecula, CA, USA) and Div Ysion stent (Biocompatibles, Galway, Ireland).

All patients received aspirin 160 mg/die and ticlopidine (500 mg) the day before the procedure; a bolus of heparin (10 000 IU) was administered before PTCA and 2500 to 5000 IU were administered, if necessary, during the procedure, to maintain an activated clotting time 300 s.

PTCA was considered successful when the residual luminal narrowing in the dilated segment immediately after angioplasty was < 30%, or < 10% after stenting, without occurrence of major adverse cardiac events (ECG or enzymatic evidence of myocardial infarction, need for emergency coronary artery bypass graft - CABG - or death). Total complications (major adverse cardiac events, ventricular fibrillation, cardiac tamponade and groin problems) were taken into account. At discharge, the patients who had undergone conventional balloon angioplasty received aspirin alone, whereas the patients who had coronary stent implantation received a combination of aspirin (160 mg) and ticlopidine (500 mg) daily for 4 weeks and then aspirin alone.

Statistical analysis. Data are presented as means – SD for continuous variables and as proportions of all the modalities for qualitative variables. Comparisons of mean values of quantitative variables between two groups

were made by Student s t test. Comparisons or proportions of events between two or more groups were made resorting to χ^2 test, and relative p values are reported. The Kruscal Wallis test was done to compare the percentage of stenosis.

The risk of dissection was identified as the dependent variable possibly associated with all variables listed in figure 1. The first step of the analysis was done by univariate logistic regression in order to identify the variables significantly associated with the dependent one. The second step of the analysis was done by multivariate logistic regression including those variables found to be significantly associated with the dissection at the first step. A stepwise selection of variables completed the analysis. A p value of 0.05 was considered statistically significant. Figure 1 shows the odds ratios and their confidence intervals both for univariate and multivariate analysis.

Table I. Clinical characteristics in women and men.

	Women (n=100)	Men (n=128)	p
Age (years)	64 – 9	61 – 10	NS
Diabetes mellitus	23 (23.0%)	19 (14.8%)	NS
Hypercholesterolemia	44 (44.0%)	57 (44.5%)	NS
Systemic arterial hypertension	50 (50.0%)	57 (44.5%)	NS
Smoking	24 (24.0%)	85 (66.4%)	< 0.001
Angina	77 (77.0%)	91 (77.1%)	NS
Previous myocardial infarction	56 (56.0%)	69 (53.9%)	NS
Previous PTCA	5 (5.0%)	12 (9.4%)	NS
Previous CABG	3 (3.0%)	7 (5.5%)	NS
BSA (kg/m^2)	1.64 – 0.14	1.82 – 0.15	< 0.001
EF	61 – 10	62 – 9	NS

BSA = body surface area; CABG = coronary artery bypass graft; EF = ejection fraction; PTCA = percutaneous transluminal coronary angioplasty.

Results

Baseline characteristics are summarized in table I. Mean age was 64 – 9 years in women and 61 – 10 years in men. No significant gender imbalances were found in history of angina, remote myocardial infarction, previous PTCA or CABG, diabetes, hypercholesterolemia, systemic arterial hypertension, and left ventricular function indexes. In the group of women there was a significantly lower percentage of smokers than in men (24.0 vs 66.4%, p < 0.001). Body surface area was 1.64 – 0.14 kg/m^2 in women and 1.82 – 0.15 kg/m^2 in men (p < 0.001).

Multivessel disease was more frequent in men than women (72.9 vs 51.5%, p < 0.001) (Table II). Overall, procedural success rates were similar in women and men (93.9 vs 97.6%, p = NS). Reference diameter was 2.9 – 0.4 mm in the female group and 2.8 – 0.4 mm in the male population. The percentage of diameter stenosis was significantly higher in the female than in the male population (84.1 – 11.5 vs 81.5 – 10.2, p < 0.05) but no difference was found in type of lesions, minimal lumen diameter before and after the procedure, balloon/artery ratio, and maximal balloon pressure in the two groups (Table II).

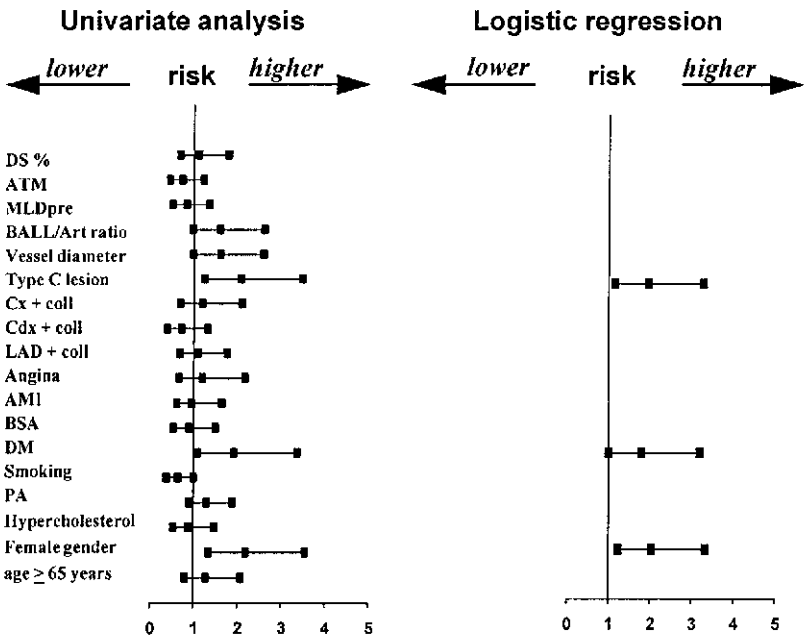

Figure 1. *Graphic presentation of the results of the univariate and multivariate analysis of the potential risk factors for plaque dissection. AMI = acute myocardial infarction; ATM = atmosphere > 9; BALL/Art = balloon/artery ratio > 1.2; BSA = body surface area; Cdx = right coronary artery; Cx = circumflex coronary artery; DM = diabetes mellitus; DS% = percent diameter stenosis > 80%; LAD = left anterior descending coronary artery; MLDpre = minimal lumen diameter before procedure > 0.7 mm; PA = systemic arterial hypertension.*

Table II. Angiographic and procedural characteristics of 339 lesions in women and in men.

	Women (n=100)	Men (n=128)	p
Total lesions	132	207	
Success rate	124 (93.9%)	202 (97.6%)	NS
Multivessel disease	68 (51.5%)	151 (72.9%)	< 0.001
LAD + side branch	74 (54.5%)	115 (55.6%)	NS
Cx + side branch	27 (20.4%)	50 (24.1%)	NS
Cdx + side branch	31 (23.5%)	42 (20.3%)	NS
Type A, B1, B2 lesions	91 (68.9%)	157 (78.8%)	NS
Type C lesion	41 (31.1%)	50 (24.1%)	NS
%DS	84.1 – 11.5	81.5 – 10.2	< 0.05
MLD pre (cm)	0.77 – 0.3	0.75 – 0.4	NS
MLD post (cm)	2.8 – 0.4	2.7 – 0.5	NS
Ball/art	0.97 – 0.2	0.99 – 0.1	NS
ATM (atm)	9.8 – 2.7	9.5 – 2.8	NS

ATM = atmosphere of balloon inflation; Ball/art = balloon/artery ratio; Cdx = right coronary artery; Cx = circumflex coronary artery; %DS = percent diameter stenosis; LAD = left anterior descending coronary artery; MLD pre = minimal lumen diameter before the procedure; MLD post = minimal lumen diameter after the procedure.

Of the overall 339 treated lesions, plaque dissection was more frequent in the female than in the male population (37.9 vs 21.7%, p = 0.001). However, occluding dissection was 3.0% in women and 1.0% in men without reaching statistical significance. There was a trend toward more complications in women (7.0 vs 3.1% in women and men respectively, p = NS) and women had more acute myocardial infarctions than men (5.0 vs 0.8% respectively, p < 0.05). One woman underwent emergency CABG and there were no deaths in either group (Table III). On univariate analysis total complications were associated with plaque dissection (p = 0.03) but not with vessel size (p = NS) and body surface area (p = NS).

Overall there was a more frequent need for stenting in the female group. Out of the 132 lesions treated in the female group, 93 (70.4%) lesions were treated with stenting, whereas stents were used in 108 lesions of the 207 (52.2%) males (p < 0.05). More stents were used in the female population due to plaque dissection during the procedure (49.5 vs 41.7 % women and men, p < 0.05) and in only 4 cases a stent was not applied even if a plaque dissection was present. Stenting for suboptimal result (18.2 vs 24.0% in women and in men, p = NS), and the elective stenting rate (32.3 vs 34.3% in women and in men, p = NS) were similar in the two sexes (Table IV).

At univariate analysis of the whole lesion series, the risk of dissection was associated with the female gender (p = 0.001), diabetes (p = 0.014), type C lesion morphology (p = 0.005), vessel diameter < 2.5 mm (p = 0.028), and balloon/artery ratio > 1.2 (p = 0.032). However, at the logistic regression only the female gender (p = 0.009), diabetes (p = 0.029), and type C lesion morphology (p = 0.019) remained independent predictors of dissection (Fig. 1). As shown in table V the female gender is the major risk factor for plaque dissection since the level of significance is much higher for the female gender than for the other two predictors of dissection.

Discussion

Our data show that procedural plaque dissection is more frequent in the female than in the male population. This increases the rate of procedural complications, par-

Table III. Acute complications in women and in men.

	Women (n=100)	Men (n=128)	p
Total complications	7 (7.0%)	4 (3.1%)	NS
MACE			
AMI	5 (5.0%)	1 (0.8%)	< 0.05
CABG	1 (1.0%)	0	NS
Death			

AMI = acute myocardial infarction; CABG = emergency coronary artery bypass graft; MACE = major adverse cardiac events; Total complications = MACE, ventricular fibrillation, cardiac tamponade, congestive heart failure, and groin problems.

Table IV. Reasons for coronary stenting in 132 lesions in women and 207 lesions in men.

	Women (n=100)	Men (n=128)	p
Stent	93 (70.4%)	108 (52.2%)	< 0.05
Dissection	46 (49.5%)	45 (41.7%)	< 0.05
Suboptimal result	17 (18.2%)	26 (24.0%)	NS
Elective	30 (32.3%)	37 (34.3%)	NS

Table V. Multivariate logistic regression analysis of 339 lesions associating plaque of dissection with gender, diabetes, and type C lesion.

Dissection	Odds ratio	SE	Z	p > | Z |	95% CI
Female	2.041984	0.5125659	2.844	0.004	1.248501-3.339762
Diabetes	1.796756	0.5274497	1.996	0.046	1.010679-3.194221
Type C	1.949085	0.5206081	2.499	0.012	1.154706-3.289955

CI = confidence interval; SE = standard error.

ticularly acute myocardial infarction, even though these events are very infrequent. Prior studies reported that women undergoing conventional balloon angioplasty had a lower clinical and angiographic success rate, a higher mortality during hospitalization and many more complications than men[1-7]. Risk factors for a worse outcome in the female population were identified as age, and more severe clinical conditions (unstable angina, hypertension, diabetes). In our series, the mean age was similar in both sexes (64 – 9 vs 60 – 10 years in women and in men respectively, p = NS). The prevalence of diabetes and hypertension was higher in women but without reaching statistical significance. For this reason the two populations in our series seemed to be more homogeneous than in previous studies.

In many surgical coronary revascularization series the worst postoperative outcome reported in women was attributed to smaller vessel size[4-6]. Small vessel size has also been reported by some authors as one of the major factors associated with abrupt vessel closure and complications during PTCA. In our study, reference diameter was similar (2.9 – 0.4 mm in the female group and 2.8 – 0.4 mm in the male population); however the incidence of dissection remained higher in women than in men. Moreover, in our study a vessel size < 2.5 mm itself was not associated with dissection on multivariate analysis and it was not correlated with total complications on univariate analysis. In our opinion, vessel size is not a risk factor for dissection when balloon/artery ratio is < 1.2.

In the literature several other factors have been associated with abrupt coronary closure and procedural complications[8-19]. Out of all these factors, listed in figure 1, only the female gender, type C morphology of the lesion and diabetes remain statistically significant on multivariate analysis.

In our study, the higher incidence of dissection led to a higher number of stent implantation in the female population undergoing PTCA. Out of the 95 coronary dissections 91 (46 in women) were treated with stenting and only 4 dissected lesions were not covered by a stent, because they were considered grade B of the NHBLI classification. This finding is in contrast to previous reports. Gowda et al.[32] have reported significantly fewer intracoronary stents placed in female patients. According to these authors these data were due to the smaller female vessel diameter, which did not allow utilization of the stents available at the time of the study. The introduction of stents with low profile and higher tractability and pushability, in fact, has allowed an extensive use of these devices in those tortuous and small vessels typical of the female gender. These devices have improved the outcome of PTCA that nowadays achieves success rates of 94-98%[20-27]. This improvement has been higher in women than in men thus equalizing the immediate outcome between the two sexes. Moreover, acute complications, particularly mortality and need for urgent revascularization, have become extremely low with no gender difference. Gowda et al.[32] reported, in fact, more acute repeated PTCA procedures and a trend toward a higher in-hospital mortality in the female population. In our series no patient died. Only one woman underwent emergency CABG due to an acute intrastent thrombosis in a coronary artery with an extremely difficult access. The reduced incidence of complications in the stent era makes percutaneous transluminal coronary revascularization an appealing option in patients with coronary artery disease, especially in women. Jacobs et al.[33] reported a better acute and long-term outcome in women undergoing coronary revascularization than men. They observed a similar low incidence of death and myocardial infarction in both sexes treated with PTCA. Moreover, among patients undergoing an initial surgery strategy of revascularization a subsequent procedure was significantly more likely in women than in men, whereas it was less likely in women undergoing initial percutaneous coronary revascularization. Furthermore, no significant difference was found among diabetic and non-diabetic women treated with PTCA at 5-year survival.

Although stenting has greatly decreased emergency CABG and death, in our series Q and non-Q wave myocardial infarction remained more frequent in the female population (5.0 vs 0.8% in women and men, $p < 0.05$) and this was due to coronary dissection. The reason for a higher incidence of plaque dissection and cardiac complications in women is not clear. Our hypothesis is that the plaque composition could be different in the two sexes. Some authors have assessed that the plaques in women are hypercellular with less dense connective tissue as compared with the male plaques[34,35]. Atherosclerosis in women starts in the menopausal period and grows quicker than in men; probably this different composition makes the plaques more prone to rupture. However, this hypothesis needs further anatomo-pathologic evaluation.

For this reason, when PTCA is performed in women, we should expect more plaque dissection with a higher incidence of acute myocardial infarction and we should be ready to use stents more extensively.

In conclusion, comparable procedural results can be obtained in women and men after PTCA. Women, however, have a higher risk of plaque dissection associated with a higher incidence of myocardial infarction and an increased need for stenting. Nevertheless, all these findings need to be confirmed by prospective studies in larger series of patients.

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