Predictors of long-term clinical outcome in patients undergoing multiple vessel stenting for coronary artery disease

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Coronary artery disease; Stent; Coronary angioplasty.

Background. **Coronary artery stenting reduces the restenosis rate compared to coronary angioplasty alone. With the increased number of procedures completed with stent placement there has been a parallel increase in the number of procedures performed in patients with multivessel disease and therefore a rise in the number of patients receiving multiple stents. The clinical outcome and the predictors of the outcome of patients receiving multiple stents are not known.**

Methods. **To evaluate the clinical outcome of patients with multivessel coronary artery disease undergoing multiple stenting we studied 133 consecutive patients who had received > 1 stent in at least two vessels. A total of 375 coronary stents (2.8 stent per patient) were implanted in elective procedure situations. Clinical follow-up was complete in 100%.**

Results. **During follow-up 2 patients (1.5%) died (1 cardiac death), 4 patients (3%) had acute myocardial infarction, 96 patients (72.1%) remained angina-free, and 31 patients (23.3%) had recurrence of angina. Repeat revascularization procedure was performed in 45 patients (33.8%); 43 patients (32.3%) underwent coronary angioplasty; 2 patients (1.5%) underwent coronary artery bypass grafting. The female gender and the presence of diabetes were significant ($p < 0.05$) predictors for coronary angioplasty or coronary artery bypass grafting procedures during follow-up. Recurrence of angina was also significantly ($p < 0.05$) associated with unstable angina at the time of the first procedure as well as diabetes and the female gender. Diabetes, the female gender and unstable angina were highly predictive factors of major adverse cardiac events during follow-up.**

Conclusions. **Multiple vessel stenting in patients with multivessel coronary artery disease is associated with an acceptable immediate and long-term clinical outcome and could be considered as an alternative therapeutic option in these patients. Predictors of an adverse long-term outcome are the female gender and the presence of diabetes mellitus.**

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Introduction

Since the introduction of percutaneous transluminal coronary angioplasty (PTCA)[1], the use of this procedure for coronary revascularization has rapidly expanded. Initially, PTCA was used in patients with single-vessel disease, but as experience and technology have advanced, it has been used in those with multivessel disease as well. A number of randomized trials have compared coronary artery bypass grafting (CABG) to conventional balloon PTCA in the management of multivessel coronary artery disease[2-6]. All these studies have reported a significantly higher (two- to three-fold) rate of repeat revascularization in the PTCA group compared to patients who had undergone coronary artery surgery while there was no significant differences in mortality and incidence of acute myocardial infarction during the follow-up period. These results were confirmed in a large meta-analysis of several trials in which PTCA was compared to CABG in multivessel disease[7]. In the last 3 years the use of coronary stents has improved both procedural angiographic results and late outcome of PTCA. Coronary artery stenting has reduced procedural complications[8,9] and the late restenosis rate in isolated lesions[10,11]. The use of coronary stents improving procedural success and reducing acute and subacute complications has increased the number of procedures of multi-

vessel percutaneous revascularization; as a consequence the number of multivessel coronary artery stenting for the treatment of multivessel disease has increased. However the long-term outcome after the permanent placement of stents in multivessel coronary lesions is still unclear.

The aim of this retrospective non-randomized study was to evaluate the early and long-term clinical outcome of patients who had undergone multivessel coronary stenting and to identify clinical variables associated with an unfavorable outcome.

Methods

From March 1996 to September 1997 we performed 982 consecutive coronary angioplasty procedures in 982 patients: 579 patients (59%) were treated on a single coronary vessel and 403 patients (41%) were treated on two or more coronary vessels. Of these latter 113 patients underwent only balloon angioplasty; the majority of this group had main branch disease associated with side branch disease, 157 patients received only one single stent while the other target lesions were treated by conventional balloon angioplasty and 133 patients (33%) received one or more stent on at least two main coronary vessels and formed the study group. One hundred patients were male and 33 female with a total of 327 lesions suitable for percutaneous revascularization and stenting. Thus, the patient cohort for this analysis includes a consecutive series of patients with multivessel disease treated with stents in our Center over a period of 1.5 years. All patients were treated during a single intervention session on two, three or more vessels. The vast majority of patients (120/133, 90.2%) underwent coronary interventions with stent implantation on two main coronary vessels while the other 13 patients (9.8%) underwent three-vessel stenting. Besides stenting, non-stent interventions were performed in other lesions in 43 patients (33%) during the same session. Patients with restenotic lesions, as well as those with stents implanted in the left main coronary artery or in a bypass graft were excluded from this analysis. Baseline angiographic characteristics of patients are reported in table I. Treated total occlusions were 23 lesions (7%), and 28 lesions were bifurcational (8.6%). GP IIb/IIIa antagonists were used in 16 patients (12%), those who had an angiographic evidence of thrombus in correspondence to at least one target lesion. Intracoronary ultrasound imaging was obtained in only 14 patients (10.5%) and was an operator-dependent decision.

Patients with contraindications to antiplatelet therapy, unprotected left main coronary artery, small (< 2.5 mm) diffusely diseased vessels, and acute myocardial infarction with poor left ventricular function (ejection fraction < 40%) were also excluded.

The majority of these patients (n = 120, 90.2%) had stent implantation in Ž 2 different major native coronary arteries in one session; the other 13 patients (9.8%) in two sessions < 1 month apart. Staged procedures in these cases were motivated by the presence of renal insufficiency in 4 cases, poor left ventricular function (ejection fraction < 30%) in 8 cases and by a prolonged first procedure in 1 case.

Table I. Baseline angiographic characteristics of the study population.

Patients with two-vessel disease	120 (90.2%)
Patients with three-vessel disease	13 (9.8%)
Lesions	327
Left anterior descending	112 (34.3%)
Right coronary	75 (22.9%)
Left circumflex	87 (26.6%)
Diagonal	16 (4.9%)
Obtuse marginal	20 (6.1%)
Posterior descending	17 (5.2%)
Lesion type	
A	19 (5.8%)
B1	87 (26.6%)
B2	152 (46.5%)
C	69 (21.1%)
Preprocedural QCA	
Mean reference diameter of stented vessels (mm)	3.19 ± 0.49
Mean luminal diameter of stented lesions (mm)	1.07 ± 0.39
Mean stenosis diameter (%)	78 ± 15
Mean length of stented lesions (mm)	19 ± 7
Postprocedural QCA	
Mean luminal diameter of stented lesions (mm)	3.06 ± 0.39
Mean stenosis diameter (%)	5 ± 8
Mean length of stented segments (mm)	20 ± 6

QCA = quantitative coronary angiography.

Coronary stenting indication in the vast majority of patients was elective (110/133, 82.7%) and in the other 23 patients (17.3%) stenting was provisional in order to treat the suboptimal results of balloon angioplasty.

All patients underwent preprocedural and postprocedural 12-lead electrocardiogram to detect ischemic changes, appearance of new pathologic Q wave or both. Blood samples were routinely acquired from all patients before the procedure and 12 hours after the intervention for total CK and CK-MB. The diagnosis of non-Q wave myocardial infarction was defined as CK-MB elevation Ž 5 times the normal values (n.v. 0 to 4 ng/ml), in the absence of new pathologic Q waves. A Q wave myocardial infarction was defined as new pathologic Q waves according to the Minnesota Code[12] associated with abnormal cardiac enzyme levels as described above.

Angiographic definitions. Coronary angiography was performed in a routine manner and the angiograms were analyzed by an experienced angiographer. A clinically important lesion was defined as a stenosis > 50% of the diameter of a vessel with a reference diameter of > 2.5 mm as measured by quantitative coronary angiography. The complexity of the lesions was categorized as type A, B, or C according to the criteria of the American College of Cardiology/American Heart Association[13]. Le-

sions were predilated using an undersized angioplasty balloon. After the deployment of the stent, full stent expansion was performed using adjunctive high pressure (14 to 18 atm) balloon dilation. At that time, this represented the strategy of stent deployment followed in our Laboratory by all operators. Angiography was performed at least in two orthogonal views. Dilation of a stenotic vessel was considered successful if the degree of stenosis was reduced by at least 20 percentage points, with residual stenosis of < 50% of the lumen diameter and normal anterograde flow (TIMI grade 3)[14].

All patients received oral aspirin (100 mg once a day) and ticlopidine (250 mg bid) at least 2 days before PTCA. During the procedure a bolus of heparin (70 IU/kg) was administered intravenously, with additional heparin given to maintain an activated clotting time > 250 s.

Clinical success was defined as procedural success with no major in-hospital complications, such as death, myocardial infarction, or the need for repeat revascularization.

Clinical follow-up. Patients were followed up with outpatient visits in order to ascertain health status. Clinical follow-up data were entered in our hospital data base and for patients with > 6 month clinical follow-up telephone contacts were used to ascertain health status. Major clinical events were death, anginal status (Canadian Cardiovascular Society class > 1), occurrence of myocardial infarction, need of subsequent revascularization procedures after the initial revascularization, and were determined by the accompanying documentation. Death was defined as death from any cause. Repeat revascularization included any need for new revascularization (PTCA or CABG) for anyone of the target lesions or target vessels treated.

In-hospital events were included in the analysis of follow-up events. All patients were treated and studied after giving informed consent.

Statistical analysis. Values are expressed as mean ± SD. Multivariate analysis was performed using a Cox proportional hazard model to assess predictor clinical factors of long-term outcome. A p value of < 0.05 was considered statistically significant.

Results

In-hospital outcome. Baseline clinical and angiographic characteristics are shown in tables I and II[15]; 327 lesions were treated in 133 patients (2.45 lesion/patient). The majority of lesions (281, 86%) were treated by stent implantation (291 lesions, 89%). All stented vessels had a reference diameter > 2.5 mm. The other 36 lesions were dilated only by an adequately sized balloon. These subsequent lesions were mostly located on side branches with a reference diameter • 2.5 mm. A total of 375 coronary stents (2.8 ± 0.6 per patient) were implanted. The majority of patients had two-vessel disease as coronary stenting was performed in two vessels in 120 patients (90.2%) and in three vessels in 13 patients (9.8%). The mean number of lesions stented per patient was 2.45 ± 0.4 and the mean number of stents implanted per lesion was 1.3 ± 0.2. Stents were selected according to coronary anatomy and lesion characteristics. Coil and flexible stents were preferred in tortuous arteries. Coil stents were also used when an important side branch was originating from the stented segment. The Multilink coronary stent (Guidant/Advanced Cardiovascular Systems, Indianapolis, IN, USA) was the stent most commonly used (47%). Other stents included Wiktor stent (Medtronic Interventional Vascular, Santa Rosa, CA, USA) 16%, NIR stent (Medinol, Boston Scientific, Tel Aviv, Israel) 12%, Crossflex stent (Cordis-J&J, Miami, FL, USA) 11%, Powergrip stent (J&J, New Brunsuwick, NJ, USA) 6%, Crown stent (J&J) 3%, beStent (Medtronic InStent) 3%, Bard XT (Bard, San Antonio, TX, USA) 2%, and Divysio (Biocompatibles, Famham, UK) 2%. Angiographic success was achieved in 319 treated lesions (97.5%). There were no procedural deaths. No patients required emergency CABG, and neither acute or subacute stent thrombosis was observed. Non-Q wave myocardial infarction occurred in 2 patients (1.5%). Angiographic success was achieved in all stented lesions.

Table II. Baseline clinical characteristics of the study population.

No.	133
Mean age (years)	57 ± 10
Sex (M/F)	100/33
History	
Diabetes	24 (18.1%)
Hyperlipidemia	64 (48.1%)
Hypertension	54 (40.6%)
Family history	50 (37.6%)
Smoking	73 (54.9%)
Previous myocardial infarction	60 (45.1%)
Previous CABG	19 (14.2%)
Unstable angina*	47 (33.9%)
Ejection fraction (%)	52 ± 9

CABG = coronary artery bypass grafting. * patients were classified according to Braunwald's criteria[15].

Clinical follow-up. During a mean clinical follow-up period of 18 ± 8 months (Table III), 2 patients (1.5%) died, one patient had congestive heart failure presumably related to restenosis of a treated lesion and died 5 months following the procedure, and the other patient died in an accident 8 months after the procedure. Two patients had a Q wave myocardial infarction (1.5%) at 4 and 11 months following the procedure. Thirty-one patients (23.3%) had recurrence of angina during the follow-up, while 96 patients (72.1%) remained angina-free (Fig. 1). Repeat revascularization procedure was required in 45 patients (33.8%); in 38 patients repeat revascularization was needed on previously treated lesions and in 7

Table III. In-hospital events and long-term clinical follow-up.

	In-hospital	Follow-up
Q wave myocardial infarction	0 (0%)	2 (1.5%)
Non-Q wave myocardial infarction	2 (1.5%)	0 (0%)
Stent thrombosis		
Acute	0 (0%)	0 (0%)
Subacute	0 (0%)	0 (0%)
Recurrence of angina	0 (0%)	31 (23.3%)
Repeat revascularization		
PTCA	0 (0%)	43 (32.3%)
CABG	0 (0%)	2 (1.5%)

PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass grafting.

patients for de novo lesions. Forty-three patients (32.3%) underwent re-PTCA; 2 patients (1.5%) underwent CABG (both had multiple in-stent restenosis and proximal left anterior descending artery involvement). Thus total repeat target lesion revascularization was performed in 38 patients (28.6%). Predictors of long-term clinical outcome are shown in table IV. The female gender and the presence of diabetes were significant predictors for major cardiac events or for the need of revascularization during follow-up. Recurrence of angina was also significantly associated with unstable angina at the time of the initial procedure as well as diabetes and the female gender.

Discussion

For more than a decade, the value of PTCA as compared to CABG for the treatment of patients with multivessel disease has been largely debated. Several prospective randomized clinical trials have shown that patients randomized to PTCA had a significantly higher need for revascularization either acutely or during follow-up. During long-term follow-up in patients randomized to PTCA the need for target lesion revascularization ranged from 44 to 55% with the need for CABG ranging from 16 to 22.5%[2-6]. These results were also confirmed in a later meta-analysis of eight randomized trials in which balloon PTCA was compared to CABG in both single and multivessel disease[7]. Thus, data from these trials clearly indicate that patients randomized to initial PTCA procedure have a significantly higher recurrence of angina and repeat interventions as compared to patients undergoing CABG. This leads to a better quality of life in the CABG group at 3-year follow-up. Furthermore the increase in cost, due to repeat interventions over 5 years in the PTCA group leads to similar costs as for CABG. Based on these data, it becomes clear that transcatheter interventions require these results to be substantially improved in order to gain a role in the treatment of this important cohort of patients. In the mean time, coronary stenting has been shown to improve the results of PTCA, reducing procedural complications[8,9] and late restenosis in isolated lesions[10,11]. In addition, coronary stenting has expanded the therapeutic window to more complex lesions, such as chronic total occlusions[16,17], ostial lesions[18,19] and calcified lesions[20], with a more favorable immediate and long-term outcome compared to conventional balloon PTCA. This raises the question of whether the benefits of single vessel stenting could be extended to multivessel interventions. In the last 2 years few retrospective, non-randomized single center studies have been reported on multivessel stenting suggesting favorable immediate procedural and clinical outcome[21-25].

In the present study, despite the prevalence of complex coronary lesions treated (type B and C lesions were respectively 73 and 21.2% of cases) the angiographic success rate was 97.5% and the major complication rate was 1.5% (2 patients had non-Q wave myocardial infarction). No in-hospital deaths were observed and no patients required emergency revascularization (CABG or re-PTCA) and neither acute or subacute stent thrombosis was observed. Compared to the

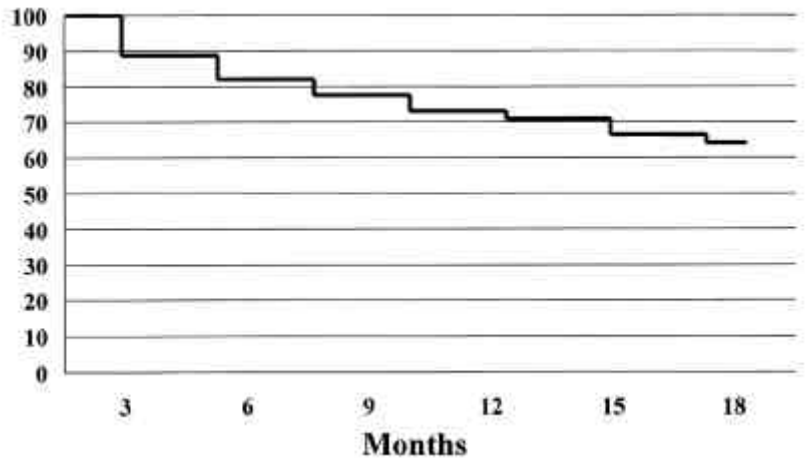

Figure 1. *Event-free survival curve for any adverse event (death, Q wave myocardial infarction, angina, and repeat revascularization).*

Table IV. Predictor clinical factors of long-term outcome (multivariate analysis).

	RR	CI	p
Repeat PTCA			
Diabetes	1.72	(3.06-1.12)	< 0.001
Female gender	1.54	(2.63-1.02)	< 0.01
Hypertension	0.9	(1.62-0.4)	NS
Hypercholesterolemia	1.25	(2.45-0.98)	NS
Cigarette smoking	1.12	(2.61-0.58)	NS
Family history	0.89	(1.67-0.56)	NS
Chronic stable angina	1.03	(1.45-0.34)	NS
Unstable angina	1.14	(1.29-0.46)	NS
Previous AMI	0.82	(1.08-0.37)	NS
Lesion morphology			
A	1.04	(1.48-0.42)	NS
B1	1.28	(2.76-0.73)	NS
B2	0.82	(2.82-0.48)	NS
C	1.42	(2.61-0.82)	NS
Lesion length > 2	1.31	(3.49-0.98)	NS
Repeat revascularization (PTCA or CABG)			
Diabetes	1.64	(3.12-1.16)	< 0.001
Female gender	1.75	(2.86-1.12)	< 0.01
Hypertension	0.84	(1.56-0.47)	NS
Hypercholesterolemia	1.36	(2.64-0.96)	NS
Cigarette smoking	1.06	(2.21-0.72)	NS
Family history	0.87	(1.69-0.62)	NS
Chronic stable angina	1.08	(1.47-0.36)	NS
Unstable angina	1.54	(2.29-0.96)	NS
Previous AMI	0.93	(1.18-0.48)	NS
Lesion morphology			
A	1.24	(1.67-0.53)	NS
B1	1.08	(2.26-0.67)	NS
B2	1.26	(2.72-0.81)	NS
C	1.34	(2.16-0.75)	NS
Lesion length > 2	1.21	(2.84-0.76)	NS
Combined end-points (AMI, recurrence of angina, repeat revascularization)			
Diabetes	1.57	(3.16-1.18)	< 0.001
Female gender	1.62	(2.78-1.16)	< 0.01
Unstable angina	1.36	(2.19-1.04)	< 0.01
Hypertension	0.9	(1.56-0.45)	NS
Hypercholesterolemia	1.35	(2.55-0.98)	NS
Cigarette smoking	1.17	(2.11-0.78)	NS
Family history	0.93	(1.76-0.68)	NS
Chronic stable angina	1.13	(1.55-0.43)	NS
Previous AMI	0.62	(1.06-0.31)	NS
Lesion morphology			
A	1.15	(1.59-0.31)	NS
B1	1.12	(2.65-0.84)	NS
B2	1.2	(2.61-0.97)	NS
C	1.18	(2.04-0.68)	NS
Lesion length > 2	1.12	(2.78-0.74)	NS
Recurrence of angina			
Unstable angina	1.35	(2.92-1.05)	< 0.05
Diabetes	1.06	(1.42-1.02)	< 0.01
Female gender	1.41	(2.82-1.16)	< 0.01
Hypertension	1.36	(2.02-0.64)	NS
Hypercholesterolemia	1.54	(2.56-0.97)	NS
Cigarette smoking	1.31	(2.06-0.38)	NS
Family history	0.81	(1.97-0.22)	NS
Chronic stable angina	0.64	(1.95-0.43)	NS
Previous AMI	0.84	(1.12-0.67)	NS
Lesion morphology			
A	0.98	(2.65-0.32)	NS
B1	1.37	(2.58-0.63)	NS
B2	0.72	(2.61-0.58)	NS
C	1.04	(2.86-0.68)	NS
Lesion length > 2	0.72	(1.78-0.46)	NS

AMI = acute myocardial infarction; CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

immediate clinical outcome reported in above-mentioned clinical trials, in the PTCA group, it seems that coronary stenting, as in patients with single vessel disease, reduces the acute complications and the need for emergency CABG.

Previous studies[21-25] reporting the results of multivessel stenting have shown similar results. Despite the similarity of patients included in these studies (mostly two-vessel disease) long-term clinical outcome was different. Moussa et al.[22] included 100 patients with 243 lesions treated; 84% had two-vessel disease. Angiographic restenosis per patient was 37%. Target lesion repeat revascularization was 30%. Chauchan et al.[23] reported 77 patients with multivessel stenting followed up for 6 months. Repeat revascularization in this study was 20% (12% re-PTCA and 8% CABG). Kornowski et al.[24] reported the largest non-randomized series of 398 consecutive patients undergoing multivessel stenting; 94% of patients had two-vessel disease, and procedural complications were 3.8%. During 500 days of follow-up target lesion revascularization was 15%. The need for either of the two revascularization procedures was 20%. In another recent retrospective study, Hernandez-Antolin et al.[25] reported the results of multivessel stenting in 136 patients followed up to 18 ± 10 months. Survival free from major cardiac events was 75%. The need for target lesion revascularization was 11%. The need for any kind of revascularization was 14%. Angiographic follow-up was available in 86 patients (63%). Restenosis per patient was 35%.

In the present study, the repeat target lesion revascularization rate was 28.6% (38 patients) and the need for any revascularization was 33.8% (45 patients). Of these, 43 patients (32.3%) underwent re-PTCA and only 2 patients (1.5%) underwent CABG. The different need for surgery in the present study compared to the previous published series may be dependent upon the different composition of the study populations and on the different therapeutic approach used in each study. Nevertheless, the majority of patients included in this study had two-vessel disease and ejection fraction > 40%. The extensive use of intracoronary ultrasound during the initial procedures in the study of Kornowski et al.[24] might have contributed to a lower incidence of restenosis and the need for revascularization during the follow-up. In the present study a 6-month angiographic control was not routinely performed since the primary end-point of the study was not angiographic restenosis but clinical variables and clinical follow-up was completed in all patients.

The female gender and the presence of diabetes were significant predictors for the need of PTCA or CABG procedures during follow-up. Recurrence of angina was also significantly associated with unstable angina at the time of the first procedure as well as diabetes and the female gender. Combined end-points were highly predictive in patients with diabetes, female gender and unstable angina at the time of the initial procedure. The different distribution of types of lesions treated in these studies might also have an impact on the long-term outcome. However, all of these studies show that the need for repeat target lesion revascularization and the overall need for revascularization in a relatively long-term follow-up are substantially lower if compared to the historical data from randomized studies on conventional PTCA in multivessel disease[1-7].

This study confirms also the important role of diabetes mellitus as a clinical predictor for a higher restenosis rate and the need for repeat revascularization following successful PTCA even with stent implantation. A recent subanalysis of the Bypass Angioplasty Revascularization Investigation (BARI) trial has shown a worse 5-year survival rate in diabetic patients with multivessel coronary disease treated by PTCA compared with CABG[6]. The impact of diabetes mellitus on in-stent restenosis is not well known. Even with stents, diabetic patients seem to have an increased late loss index and restenosis rate compared with non-diabetic patients[26], although stents may still improve results compared to PTCA in diabetic patients[27]. Late loss seems to be significantly greater in insulin-treated diabetes mellitus as was recently reported by Abizaid et al.[28].

Higher complications and lower success rates of both PTCA and stenting have been reported more in women than in men. In our study the immediate results and complications of coronary artery stenting were similar in both sexes, however women had a higher recurrence of angina and need for revascularization than men. Robertson et al.[29] have reported a similar 1-year prognosis in men and women undergoing coronary artery stenting. Several clinical and anatomic characteristics may explain the different outcome of male and female patients, which include coronary artery diameters and prevalence of risk factors.

In conclusion, the present study confirms the results of previous reports on multivessel stenting[21-25] and demonstrates that this approach is feasible and safe with excellent early results and favorable long-term clinical outcome. Compared with results of multivessel PTCA, our study has shown an important improvement, particularly with regard to the absence of procedural death and emergency revascularization due to PTCA failure during in-hospital stay. The female gender and diabetes mellitus represent unfavorable predictors of the long-term outcome in terms of need for repeat revascularization. Until a more detailed and accurate comparison of multivessel stenting and CABG from the major ongoing randomized trials (ARTS and SOS) is available, data coming from observational and retrospective analysis can be useful in the daily clinical practice.

Study limitation. The most important limitation of this study is that it represents a retrospective study of a single center with a relatively small number of patients. As such our cohort of patients does not include patients

who were considered to be better candidates for surgery, i.e. patients with diffuse three-vessel disease particularly with diffuse left anterior descending coronary artery involvement, those with multiple long lesions (> 20 mm), those with repetitive restenosis and transcatheter interventions. Moreover, it should be emphasized that the vast majority of patients included in this study (89.2%) underwent angioplasty in two vessels. Therefore, the results of the present study are not necessarily applicable to larger groups of patients with three-vessel disease. However, the cohort of patients analyzed in the present study is representative of the routine daily practice in the Interventional Cardiology field and the principal aim of the present study was to verify whether the use of multiple stents in such a cohort of patients has a favorable impact.

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