Elective stenting in small coronary arteries: results of the Italian prospective multicenter registry MICROSCOPE

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Coronary stenosis; Stenting.

Background. **The role of stent implantation in small coronary arteries is still controversial. The MICROSCOPE study (Ministenting in small coronary arteries, a prospective evaluation) is a multicenter registry addressed to prospectively evaluate the immediate and mid-term clinical and angiographic results of elective stenting of lesions located in coronary arteries with an angiographic reference diameter ≤ 2.75 mm.**

Methods. **A total of 146 patients (160 lesions) were included in the study. The percentage of complex lesions (B2 and C lesions) was 49.3%. The clinical indications for stent implantation were: stable angina (55.0%), unstable angina (24.6%), and clinical evidence of myocardial ischemia in asymptomatic patients (20.4%); 60% of patients had multivessel disease. Stent deployment could be performed in 96.2% of lesions. The baseline reference diameter was 2.12 ± 0.36 mm. In all cases the Ministent (Cordis, a J&J Company, Miami, FL, USA), specifically designed for small coronary arteries, was employed. The stent was pre-mounted on low profile balloons available in three different diameters (2.25, 2.50 and 2.75 mm) and three different lengths (11, 15 e 26 mm).**

Results. **The primary endpoint of successful stent-assisted angioplasty in all study vessels without major adverse cardiac events was achieved in 95.8% of the patients. The minimal lumen diameter increased from 0.64 ± 0.24 to 2.02 ± 0.43 mm and the dimensions of the stenosis (expressed as a percentage of the diameter of the coronary vessel) decreased from 68.6 ± 10.8 to 16.2 ± 10.7% (< 30% standard deviation in all cases). After the procedure all the patients received double antiplatelet therapy for 4 weeks. Post-procedural complications were limited to 2 patients (1.3%) who had a non-Q wave myocardial infarction at 6 months of follow-up; 13 patients (11%) required target lesion revascularization. No patient died following the procedure. Angiographic control was performed in 44% of lesions. The minimal lumen diameter decreased to 1.12 ± 0.47 mm and the percent stenosis increased to 45.9 ± 23.2%. The incidence of binary restenosis (stenosis ≥ 50%) was 41%.**

Conclusions. **Elective stenting of small coronary arteries with the Ministent can be safely performed and is associated with a low incidence of acute or subacute stent thrombosis. The mid-term results indicate a high rate of angiographic restenosis but a low need of target vessel revascularization. These data suggest that stenting cannot be considered the treatment of choice for unselected lesions located in coronary arteries with a small reference diameter, but represents a safe solution if unsatisfactory results are obtained with balloon angioplasty alone.**

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Introduction

Coronary stenting reduces the risk of restenosis and the need of target lesion revascularization in arteries with an angiographic reference diameter ≥ 3.0 mm[1,2]. Approximately 30 to 40% of the lesions treated by means of percutaneous revascularization, however, are located in vessels < 3.0 mm[3-6], and the superiority of stenting in comparison to balloon angioplasty in these vessels has not been confirmed. Several studies have indicated that a small luminal reference diameter at the lesion site is associated with lower rates of procedural success and higher rates of subsequent in-hospital major events[7]. Moreover, a small vessel size is one of the most important predictors of restenosis both after plain old balloon angioplasty as well as after stent implantation[3-8]. Retrospective analyses[9,10] and prospective randomized studies have recently addressed the efficacy of stent implantation in such lesions in reducing restenosis[11-16]. The results of these studies were however conflicting and did not pro-

vide sufficient evidence of an improved long-term outcome compared with conventional balloon angioplasty.

The purpose of this study was to evaluate the immediate and mid-term clinical and angiographic results of elective stenting in vessels with a small reference diameter using a specific stent, characterized by a reduced strut thickness and mounted on low profile, low compliance balloons so as to allow complete stent expansion in small diameter vessels.

Methods

Patients. The study MICROSCOPE (Ministenting in small coronary arteries, a prospective evaluation) was a prospective multicenter registry including 10 Italian centers. The study protocol was approved by the institutional Ethics Committee of each participating center and all patients gave informed consent. Patients were considered eligible for inclusion if they complained of angina and/or presented with objective evidence of myocardial ischemia. Angiographic inclusion criteria were the presence of a lesion with a stenosis diameter > 50% in a native coronary artery with an angiographic reference diameter < 2.75 mm (on-line measurement after intracoronary injection of nitrates, controlled after predilation if needed). Clinical exclusion criteria were limited to acute myocardial infarction (AMI, < 24 hours) and contraindications to combined aspirin and ticlopidine (or clopidogrel) treatment. In-stent restenosis, ostial and bifurcational lesions, chronic total occlusions, a history including the use of rotablator or directional atherectomy, and the location of the lesions on grafts were the main angiographic exclusion criteria.

Additional angioplasty and stent implantation in coronary lesions of other arteries with a reference diameter > 2.75 mm were allowed.

Procedural protocol. At the beginning of the procedure patients received an intravenous bolus of heparin (70-100 IU/kg) eventually supplemented according to the values of the activated clotting time (recommended > 200-250 s). All patients received double oral antiplatelet therapy with aspirin (100 mg) and ticlopidine (250 mg) twice daily (or clopidogrel 75 mg daily) starting at least 3 days before the procedure and continuing for 4 weeks; all patients received aspirin indefinitely. Multiple stent implantation was allowed if required. The stent used (Mini, Cordis, Miami, FL, USA) is a slotted tubular stent characterized by a reduced strut thickness (0.004") and a design that allows complete stent expansion in arteries with a small diameter. The stent is securely crimped on low compliance balloons resulting in a stent-balloon assembly characterized by a low profile (0.044-0.048") and a good flexibility. The device was available in three different lengths (11, 15, 26 mm), and in three different diameters (2.25, 2.50, 2.75 mm).

Direct stenting (without predilation) was discouraged. After predilation, the stents were deployed by inflating the stent delivery balloon in accordance with the investigator's decision (recommended > 10-12 atm). If necessary, adjunct high pressure balloon postdilation was performed to achieve angiographic optimization. The use of balloons > 2.75 mm in diameter for postdilation was discouraged.

Angiography was performed using 6F or 8F guiding catheters. Matched orthogonal views were used for quantitative analysis before and after treatment using contrast filled catheters for calibration. Angiography was performed after nitroglycerine (100-200 μg) or isosorbide dinitrate (1-3 mg) intracoronary infusion. Angiograms were analyzed off-line in an independent core laboratory (Milan Cardiovascular Research, Milan, Italy) with the validated automated edge detection system CMS, version 4.0 (Medis, Medical Imaging System, Leiden, The Netherlands).

Definitions and endpoints. The primary endpoint was the clinical procedural result defined as angiographic success (residual diameter stenosis after Ministent implantation ≤ 30%) without major adverse cardiac events (MACE): death, AMI or in-hospital target vessel revascularization by means of angioplasty or coronary bypass surgery. Secondary endpoints were the restenosis rate, defined as a stenosis ≥ 50% as measured at quantitative coronary angiography performed 6 months after the procedure, and the incidence of MACE within 6 months. Cardiac events were monitored throughout the follow-up period and analyzed at 30 days and 6 months.

The acute lumen gain was defined as the difference between the minimal lumen diameter (MLD) at the end of the intervention and the MLD before balloon dilation; the relative gain as the ratio between the baseline reference diameter and the acute gain; the delayed lumen loss was defined as the difference in the MLD between measurements after the procedure and at follow-up; the loss index and net lumen gain were defined as the ratio between the late lumen loss and the acute lumen gain and the difference between the MLD at follow-up and the MLD before balloon dilation, respectively.

Myocardial infarction was defined as the presence of new pathological Q-waves or of an increase in the creatine kinase (CK) serum levels of at least 3 times the normal upper limit and associated with a similar increase in the serum levels of CK-MB[17].

Statistical analysis. Data are expressed as the mean ± SD for continuous variables and as frequencies for categorical variables. Comparisons were performed using the Student's t test for continuous data and the Pearson's χ^2 test for discrete data. Multiple comparisons among tertiles were performed using the ANOVA test. Statistical significance was accepted for a 2-tailed value of $p < 0.05$. Logistic-regression analysis was per-

formed to test the correlation of the baseline clinical and angiographic characteristics and of the procedural parameters with the immediate success rate, MACE incidence and with the restenosis rate.

Results

Baseline clinical and angiographic characteristics. A total of 146 patients who met the inclusion criteria were enrolled in the study between 1998 and 1999. The baseline clinical characteristics and clinical indications to coronary angioplasty are shown in table I. Two or more lesions in small vessels were treated according to the protocol in 13 patients (8.2%). Table II presents the baseline angiographic characteristics of the 160 lesions included in the registry. Most of the lesions were located in side branches or in distal segments of the main vessels (72.2%). Complex lesions (B2 and C), so defined on the basis of the American College of Cardiology/American Heart Association grading system[18], were the majority of the lesions included in the study.

Procedural data and outcome. The procedural and angiographic characteristics of the 160 lesions treated by means of stent implantation are reported in table III. An overall technical success was reached in all but 5 cases (96.2%). In 2 cases it was impossible to reach the lesion because of the extreme tortuosity of the proximal vessel and because of the presence of calcified deposits; in 2 cases it was not possible to pass the stent beyond the lesion; in 1 case a distal occlusive dissection developed after stent implantation; only in one did we fail to retrieve the stent-balloon assembly within a 6F catheter and an uneventful stent loss occurred in the arteries of the lower limbs. No in-hospital deaths or Q-wave AMI occurred. A non-Q-wave AMI, as defined according to the protocol criteria, was observed in 2 cases (1.3%). Treatment of other vessels not fulfilling the angiographic inclusion criteria was performed in 12

Table I. Baseline clinical characteristics.

Clinical characteristics	
No. patients	146
Age (years)	60.9 ± 9.7
Sex (M/F) (%)	74/24
Diabetes (%)	17.6
Current or previous smokers (%)	55.0
Hypercholesterolemia (%)	61.8
Hypertension (%)	65.7
Family history of CAD (%)	43.5
Previous MI (%)	53.2
Previous PTCA at the same site (%)	3.6
Previous CABG (%)	7.0
LV ejection fraction (%)	59.5 ± 8.2
Clinical indications	
Unstable angina (%)	24.6
Stable angina (%)	55.0
Asymptomatic (%)	20.4

CABG = coronary artery bypass graft; CAD = coronary artery disease; LV = left ventricular; MI = myocardial infarction; PTCA = coronary angioplasty.

Table II. Baseline angiographic characteristics.

No. diseased vessels	160
Single-vessel disease	40.3%
Two-vessel disease	40.3%
Three-vessel disease	19.4%
Location in vessels	
LAD proximal	6.9%
LAD mid or distal	18.7%
Diagonal branch	19.5%
Septal branch	1.3%
CX proximal	5.2%
CX mid or distal	5.3%
Obtuse marginal branch	11.5%
Ramus (intermediate branch)	7.4%
PL-CX	5.3%
RCA proximal	3.9%
RCA mid or distal	4.7%
PL-RCA	5.0%
Posterior descending artery	5.3%
Lesions characteristics*	
A	9.0%
B1	41.7%
B2	39.7%
C	9.6%
Calcified lesions	11.9%
Total occlusions	1.8%
Restenotic lesions	3.6%
Angiographic measurements	
Vessel reference diameter (mm)	2.12 ± 0.36
Minimal lumen diameter (mm)	0.69 ± 0.33
Degree of stenosis before the procedure (%)	68.5 ± 14.0
Lesion length (mm)	10.2 ± 4.2

CX = circumflex coronary artery; LAD = left anterior descending coronary artery; RCA = right coronary artery; PL = posterolateral branch. * = lesions were classified by using the modified ACC/AHA grading system[18].

Table III. Procedural data.

Maximal balloon pressure (atm)	14.0 ± 4.2
Final vessel reference diameter (mm)	2.46 ± 0.38*
Final minimal lumen diameter (mm)	2.06 ± 0.43**
Final diameter stenosis (%)	16.4 ± 10.8**
Acute lumen gain (mm)	1.38 ± 0.51
Stent diameter	
2.25 mm	24.2%
2.50 mm	43.8%
2.75 mm	32.0%
Mean (mm)	2.65 ± 1.4
Stent length	
11 mm	52.1%
15 mm	42.2%
26 mm	5.7%
Mean (mm)	13.2 ± 4.2
No. stents/lesion	1.30 ± 0.21

p values are referred to comparisons vs baseline data; 2-tail paired Student's t test. * = $p = 0.083$; ** = $p < 0.0001$.

cases (7.5%). The primary endpoint of a successful stent-assisted angioplasty in all study vessels without MACE was achieved in 95.8% of the patients.

Late clinical and angiographic results. The clinical follow-up was complete in 81% of patients. During the whole follow-up period no deaths or Q-wave AMI were recorded. In the first 30 days after hospital discharge one additional non-Q-wave AMI (0.6%) occurred and in 1 patient target lesion revascularization with coronary angioplasty was needed. After 6 months no additional AMI was observed and target vessel revascularization was required in 13 (11%) cases (12 lesions treated by means of coronary angioplasty and 1 case treated by means of coronary artery bypass grafting).

Angiography was repeated at 6 months of follow-up in 71 cases (44% of the treated lesions). Restenosis was observed in 41% of cases. Table IV summarizes the angiographic follow-up data, compared with the pre- and post-procedural measurements in the same patients. We performed an additional analysis dividing the lesions into three tertiles according to the baseline reference diameter of the treated vessel (Table V). The three groups with a statistically significant difference in the baseline reference diameter showed no significant differences in the indices of severity of the lesion (baseline MLD and percentage of stenosis). No differences were observed in the acute relative gain and in the late loss or restenosis rates. Logistic regression analysis showed that neither the baseline clinical and angiographic characteristics nor the procedural parameters had a significant effect on the immediate success rate, the MACE incidence and on the restenosis rate.

Discussion

Immediate outcome. The primary endpoint of our study was to evaluate the feasibility and the immediate angiographic results of elective stent implantation performed using a specific stent in small vessels. The outcome indicates that stent implantation is associated with high procedural success and low acute complication rates, similar to those reported for larger vessels[5,19]. Besides, even the absence of symptomatic stent thrombosis in a consecutive group of 146 patients, at 1 month of follow-up, is encouraging. These results are in agreement with those of other reports and can be explained by the use of high pressure balloon expansion and post-procedural double antiplatelet therapy[20]. The number of cases in which it was impossible to reach or

Table IV. Six-month angiographic follow-up.

	Baseline (n=71)	Post-stenting (n=71)	6-month follow-up (n=71)
Vessel reference diameter (mm)	2.07 ± 0.31	2.40 ± 0.34	1.99 ± 0.32
Minimal lumen diameter (mm)	0.64 ± 0.24	2.02 ± 0.43*	1.12 ± 0.47*§
Diameter stenosis (%)	68.6 ± 10.8	16.2 ± 10.7*	45.9 ± 23.2*§
Acute lumen gain (mm)		1.38 ± 0.51	
Late lumen loss (mm)			0.90 ± 0.46
Net lumen gain (mm)			0.47 ± 0.38
Loss index (%)			0.65
Restenosis rate (%)			41.0

* = $p < 0.001$ for comparisons vs baseline data; 2-tail paired Student's t test; § = $p < 0.001$ for comparisons vs post-stenting data; 2-tail paired Student's t test.

Table V. Analysis per tertiles according to baseline vessel reference diameter (n=71).

	1st tertile (n=24)	2nd tertile (n=24)	3rd tertile (n=23)	p
Baseline vessel reference diameter (mm)	1.73 ± 0.13	2.03 ± 0.09	2.44 ± 0.13	< 0.0001
Baseline minimal lumen diameter (mm)	0.57 ± 0.26	0.61 ± 0.24	0.74 ± 0.26	0.044
Baseline diameter stenosis (%)	67 ± 10	67 ± 11	69 ± 11	0.626
Follow-up minimal lumen diameter (mm)	1.07 ± 0.49	1.13 ± 0.46	1.12 ± 0.49	0.915
Follow-up diameter stenosis (%)	44 ± 20	42 ± 21	48 ± 20	0.553
Acute gain (mm)	1.21 ± 0.29	1.46 ± 0.45	1.54 ± 0.39	0.002
Relative gain	0.69 ± 0.25	0.72 ± 0.29	0.63 ± 0.31	0.453
Late lumen loss (mm)	0.62 ± 0.45	0.93 ± 0.54	1.16 ± 0.63	0.005
Net gain (mm)	0.49 ± 0.56	0.52 ± 0.52	0.38 ± 0.57	0.660
Loss index (%)	0.60 ± 0.45	0.66 ± 0.34	0.76 ± 0.36	0.402
Restenosis rate (%)	39.1	34.8	43.5	0.833

cross the lesion (5 cases, 3.1%) is low considering the complexity of the lesions and their distal location. Despite the more favorable lesion characteristics, the percentages of patients allocated in the stent arm of the recent randomized trials and who were submitted to balloon angioplasty alone because of the impossibility to reach or cross the target lesion were 2.4, 3.0, 4.4 and 4.1% in the SISA, BESMART, ISAR-SMART and SISCA trials respectively[11-16].

Restenosis. In our study every attempt has been made to exclude "falsely" small vessels. The possibility to recheck the cut-off value of 2.75 mm after predilation and the recommendation to choose lesions located in the side branches or distal segments of main vessels (72.2% of the lesions treated) confirm that stent placement has been performed in a series of "truly" small vessels. Calcified, complex lesions and recent (< 1 month) total occlusions were also included in the study.

Among the recently published randomized studies comparing elective stenting to balloon angioplasty, restenosis rates vary from 9.0 to 37.5% in the stent arms and from 18.8 to 47.0% in the coronary angioplasty arms. A statistically significant superiority of elective stent implantation was reported in three of these studies (BESMART, RAP and SISCA)[14-16], while in the ISAR-SMART trial, in the SISA trial and in the study by Park et al. the primary endpoint (6-month restenosis rate) was similar in both the two arms[11-13]. A common finding of all these trials is that stent implantation was associated with a significantly larger MLD that was partially counterbalanced by a higher late loss during follow-up.

Differences in target vessel reference diameter, lesion complexity, techniques of stenting and coronary angioplasty, and stent design have been advocated to explain the conflicting results of these trials. In larger vessels a role of stent design on the long-term clinical and angiographic outcomes has been demonstrated[21,22]. We do not have any more information about the use of the Ministent since the only randomized prospective study (CORDIS-MICA) planned with this stent has been stopped after randomization of just 128 out of 600 patients because of the unacceptably high crossover rate (37%) in the coronary angioplasty arm. Besides, the results of this trial are biased, owing to the extremely low number of repeat angiographic controls, mainly performed for the recurrence of symptoms. Furthermore, these controls showed a high but not significantly different restenosis rate (61 vs 63% in the stent and in the coronary angioplasty arms respectively, p = NS)[23].

On a theoretical basis, the initial reference diameter may influence the restenosis rate in small coronary arteries since the same degree of intimal hyperplasia is more likely to induce the development of a critical stenosis in a smaller vessel. However, separate analysis of our lesions after we had divided them into three tertiles on the basis of the baseline reference diameter, did not reveal any significant differences in the restenosis rates. On the basis of this analysis we were unable to select a cut-off value for baseline reference diameter that might have permitted the distinction between a favorable and an unfavorable outcome. A discrepancy between the restenosis rate and the need of target vessel revascularization has been observed and can be explained by the absence of symptoms even in the presence of angiographic restenosis in vessels with a small distribution territory. Obviously, in view of this persistently high restenosis rate, care should be taken to avoid the overtreatment of clinically silent stenosis in small vessels.

Study limitations. The first limitation is that this study is not randomized and hence the outcome of the patients treated cannot be compared with that of a control group of patients submitted to balloon angioplasty alone. Moreover, the low number of angiographic controls at 6 months, performed for only 44% of the treated lesions, increases the restenosis rate since the population undergoing new angiograms is more likely to include symptomatic patients or patients with evidence of recurrent ischemia. Finally, it must be noted that since we employed only one stent design, our findings cannot be extended to other type of stents. Very recently, further improvements in balloon and stent design have reduced the stent profile and increased the stent flexibility and deliverability modifying the technique of stent implantation and allowing direct stenting. Coated and drug-eluting stents are promising new tools[24]. Preliminary results from the randomized study RAVEL suggest the total absence of restenosis and of intimal hyperplasia at follow-up even in small vessels[25].

In conclusion, successful stent implantation in small vessels with a specific stent can be achieved in the vast majority of patients (95.8%) even in case of complex lesions located in secondary branches. The mid-term results are suggestive of a high rate of angiographic restenosis but a low need of target vessel revascularization procedures. Our interpretation of the data of this registry is that stenting cannot be considered a first choice strategy in the setting of unselected lesions located in coronary arteries with a small reference diameter, and should be used as an alternative solution if the results of balloon angioplasty alone are unsatisfactory.

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