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Elective sirolimus-eluting stent implantation for left main coronary artery disease: six-month angiographic follow-up and 1-year clinical outcome

C. A. Arampatzis, *et al.*

Department of Interventional Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands.

The effectiveness of sirolimus-eluting stent (SES) implantation in patients treated electively for left main (LM) stenoses has not been yet ascertained. The present study reports on the clinical and angiographic outcome of 16 consecutive patients treated electively for de novo stenoses in the LM. The impact of SES implantation on major adverse cardiac events was evaluated. Mean age was 65 +/- 11 years. Unprotected LM was present in nine (56%), and eight patients (50%) received stents extending into both the left anterior descending and circumflex arteries for stenoses of the distal left main bifurcation. In-house mortality and reintervention rate was zero. One patient developed a non-Q-wave myocardial infarction related to the index procedure. At 1-year clinical follow-up, there were no deaths or further myocardial infarctions; one (6%) patient required target lesion revascularization. A total of 12 patients (75%) underwent 6-month angiographic follow-up with a late lumen loss of 0.04 +/- 0.65 mm and one focal restenosis (8% of patients). Elective SES implantation for LM disease was associated with zero mortality and a very low incidence of additional major adverse events at 1 year.

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Early and mid-term results of drug-eluting stent implantation in unprotected left main

A. Chieffo, *et al.*

San Raffaele Hospital, Milan, Italy.

BACKGROUND: The safety and efficacy of percutaneous coronary intervention in unprotected left main (ULM) coronary arteries are still a matter of debate. **METHODS AND RESULTS:** All consecutive patients who had a sirolimus-eluting stent (Cypher, Cordis, Johnson and Johnson Co) or a paclitaxel-eluting stent (Taxus, Boston Scientific) electively implanted in de novo lesions on unprotected left main were analyzed. Patients treated with a drug-eluting stent (DES) were compared with the historical group of consecutive patients treated with bare metal stent (BMS). Eighty-five patients were treated with DES; 64 had BMS implantation. Patients treated with DES had lower ejection fractions (51.1 +/- 11% versus 57.4 +/- 13%, P=0.002) and were more often diabetics (21.2% versus 10.9%, P=0.12) with more frequent distal left main involvement (81.2% versus 57.8%, P=0.003). Furthermore, in the DES group, smaller vessels (3.33 +/- 0.6 versus 3.7 +/- 0.7 mm, respectively; P=0.0001) with more lesions (2.94 +/- 1.6 versus 2.25 +/- 1.3, P=0.004) and vessels (2.03 +/- 0.69 versus 1.8 +/- 0.72, P=0.05) were treated with longer stents (24.3 +/- 12 versus 15.8 +/- 8.6 mm, P=0.0001). Despite the higher-risk patients and lesion profiles in the DES group, the incidence of major cardiac events at a 6-month clinical follow-up was lower in the DES than in the BMS group (20.0% versus 35.9%, respectively; P=0.039). Moreover, cardiac deaths occurred in 3 DES patients (3.5%), as compared with 6 (9.3%) in the BMS group (P=0.17).

CONCLUSIONS: In this early experience with DES in unprotected left main, this

procedure appears safe with favorable and improved clinical results as compared with historical control subjects with a BMS. A randomized study comparing surgery appears justified at present.

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Rapamycin-eluting stents for the treatment of unprotected left main coronary disease
J. S. de Lezo, *et al.*

Reina Sofia Hospital, University of Cordoba, Cordoba, Spain. grupo_corpal@arrakis.es

BACKGROUND: Conventional bare stents have been used to treat unprotected left main (LM) coronary artery stenosis. However, restenosis remains the main limitation. Since rapamycin-eluting stents (RES) appear to inhibit neointimal proliferation, their application to this specific site seems promising. **METHODS:** Since May 2002, we have studied a series of 52 patients with LM lesions treated with RES. Forty-seven patients presented with de novo stenoses, and 5 had in-stent restenosis; 19 patients required combined stent treatment for other remote lesions in the coronary tree, 6 of them at the level of proximal right coronary artery. The RES was implanted directly at the LM in 39 patients; 13 others needed predilation. Once deployed, the RES was overexpanded with short balloons adjusted to the LM length in 44 patients. Quantitative coronary angiograms were analyzed in the same view before and immediately after treatment and at follow-up. Patients were followed-up closely and new cardiac catheterization was scheduled at 6-month evaluation or earlier in the presence of symptoms. At follow-up study, quantitative coronary angiography and motorized intravascular ultrasound analyses were performed in 35 (67%) patients. **RESULTS:** Primary success was obtained in 50 patients (96%). Two patients (4%) developed a non-Q-wave myocardial infarction. All patients were symptom-free at discharge. After a mean follow-up of 12 +/- 4 months, 50 patients (96%) remain asymptomatic. No late death or acute thrombosis have been recorded. Two patients became symptomatic 2 and 4 months after treatment, respectively. One had restenosis at a remote site, while the other had in-segment restenosis. None of the remaining 33 angiographically evaluated patients developed restenosis at any site. Target lesion revascularization was 1/52 (2%). **CONCLUSIONS:** Although longer-term follow-up studies are needed, the tailored treatment of coronary lesions located at the LM by overexpanded RES is feasible and safe. Midterm results seem promising, which might help to shift the orientation of patient management from surgical to percutaneous revascularization.

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Correlations between fractional flow reserve and intravascular ultrasound in patients with an ambiguous left main coronary artery stenosis

V. Jasti, *et al.*

Division of Cardiology, University of Louisville, Louisville, KY 40292, USA.

BACKGROUND: Intravascular ultrasound (IVUS) is being used to assess the significance of a left main coronary artery stenosis (LMCS). However, the cutoff values of IVUS parameters at which to predict a fractional flow reserve (FFR) of 0.75 are

unknown. METHODS AND RESULTS: In 55 patients with an angiographically ambiguous LMCS, a pressure guidewire was used to calculate FFR, and IVUS parameters were calculated after automatic pullback. FFR averaged 0.86±0.13 (range, 0.55 to 1.0). IVUS minimum lumen diameter (MLD), minimum lumen area (MLA), cross-sectional narrowing (CSN), and area stenosis (AS) were 3.8±0.61 mm, 7.65±2.9 mm², 59±13%, and 47±19%, respectively. Regression analysis demonstrated strong correlations between FFR and MLD (r=0.79, P<0.0001) as well as between FFR and MLA (r=0.74, P<0.0001). There were inverse, moderate correlations between FFR and CSN (r=0.69, P<0.0001), followed by those between FFR and AS (r=0.54, P<0.0001). Compared with FFR as the "gold standard," an MLD of 2.8 mm had the highest sensitivity and specificity (93% and 98%, respectively) for determining the significance of an LMCS, followed by an MLA of 5.9 mm² (93% and 95%, respectively). Based on an FFR <0.75 and an FFR ≥0.75, the 38-month survival and event-free survival estimates (EFSEs) were both 100% and 100% versus 90%, respectively (P=NS). CONCLUSIONS: We conclude that (1) an IVUS MLD and MLA of 2.8 mm and 5.9 mm², respectively, strongly predict the physiological significance of an LMCS and (2) among patients with an LMCS, an FFR of 0.75 is a strong predictor of survival and EFSE.

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Sirolimus-eluting stent implantation for unprotected left main coronary artery stenosis: comparison with bare metal stent implantation

S. J. Park, *et al.*

Department of Medicine, University of Ulsan College of Medicine, Asan Medical Center, 388-1 Pongnap-dong, Songpa-gu, Seoul 138-736, Korea. sjpark@amc.seoul.kr

OBJECTIVES: This study was designed to compare the clinical and angiographic outcomes of sirolimus-eluting stent (SES) and bare metal stent (BMS) implantation for unprotected left main coronary artery (LMCA) stenosis. BACKGROUND: The safety and effectiveness of SES implantation for unprotected LMCA stenosis have not been ascertained. METHODS: Elective SES implantation for de novo unprotected LMCA stenosis was performed in 102 consecutive patients with preserved left ventricular function from March 2003 to March 2004. Data from this group were compared to those from 121 patients treated with BMS during the preceding two years. RESULTS: Compared to the BMS group, the SES group received more direct stenting, had fewer

complications and is more effective in preventing restenosis compared to BMS implantation.

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