

Stent Placement Compared With Balloon Angioplasty for Small Coronary Arteries

In-Hospital and 6-Month Clinical and Angiographic Results

René Koning, MD; Hélène Eltchaninoff, MD; Philippe Commeau, MD; Khalife Khalife, MD; Martine Gilard, MD; Janusz Lipiecki, MD; Pierre Coste, MD; Marc Bedossa, MD; Thierry Lefèvre, MD; Philippe Brunel, MD; Marie-Claude Morice, MD; Luc Maillard, MD; Philippe Guyon, MD; Jacques Puel, MD; Alain Cribier, MD; for the BESMART (BeStent in Small Arteries) Trial Investigators*

Background—Stenting has been demonstrated to be superior to balloon angioplasty in de novo focal lesions located in large native vessels. However, in small vessels, the benefit of stenting remains questionable.

Methods and Results—A total of 381 symptomatic patients with de novo focal lesion located on a small coronary segment vessel (<3 mm) were randomly assigned to either stent implantation (192 patients; 197 lesions) or standard balloon angioplasty (189 patients; 198 lesions). The primary end point was the angiographic restenosis rate at 6 months, as determined by quantitative coronary angiography. On intention-to-treat analysis, angiographic success rate and major adverse cardiac events were comparable: 97.9% and 4.6% versus 93.9% and 5.8% in the stent group and the balloon group, respectively. After the procedure, a larger acute gain was achieved with stent placement (1.35 ± 0.45 versus 0.94 ± 0.47 mm, $P=0.0001$), resulting in a larger minimal lumen diameter (2.06 ± 0.42 versus 1.70 ± 0.46 mm, $P=0.0001$). At follow-up (obtained in 91% of patients), angiographic restenosis rate was 21% in the stent group versus 47% in the balloon group ($P=0.0001$), a risk reduction of 55%. Repeat target lesion revascularization was less frequent in the stent group (13% versus 25%, $P=0.0006$).

Conclusions—Elective stent placement in small coronary arteries with focal de novo lesions is safe and associated with a marked reduction in restenosis rate and subsequent target lesion revascularization rate at 6 months. (*Circulation*. 2001; 104:1604-1608.)

Key Words: arteries ■ balloon ■ angioplasty ■ stents ■ restenosis

Stent implantation has become the major method of percutaneous myocardial revascularization. This is the result of several factors: the use of new antithrombotic regimen, the improvement of implantation techniques and stent designs, and the result of two landmark randomized trials^{1,2} demonstrating the superiority of elective stent placement over balloon angioplasty for new focal lesions in large coronary arteries (>3 mm). However, in current practice, approximately one third of lesions are located on small (<3 mm) coronary arteries,³⁻⁷ a setting known to be associated with poor acute and long-term results after standard balloon angioplasty.^{3,4,8} Although the clinical benefit of stenting remains questionable in these lesions, it has been increasingly used. The analyses of several retrospective or nonrandomized studies show that coronary stenting in small

vessels might lead to better clinical results and lower restenosis rates than balloon angioplasty.^{9,10} To assess this hypothesis, we conducted a multicenter, prospective, randomized trial whose primary end point was to compare the rate of angiographic restenosis after stent implantation and standard balloon angioplasty in coronary arteries of <3 mm.

Methods

Participating Centers and Investigators

This trial was a large-scale multicenter study including 21 centers (see Appendix). The study protocol was approved by the institutional review board at each participating center and was conducted under the auspices of the Interventional Cardiology Board of the French Society of Cardiology.

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From the University Hospital of Rouen, Rouen (R.K., H.E., A.C.); Centre Hospitalier Privé Saint Martin, Caen (P.C.); Hôpital Bon Secours, Metz (K.K.); University Hospital, Brest (M.G.); University Hospital, Clermont-Ferrand (J.L.); University Hospital, Bordeaux (P.C.); University Hospital, Rennes (M.B.); Institut Hospitalier Jacques Cartier, Massy (T.L.); University Hospital, Nantes (P.B.); Clinique du Bois de Verrières, Antony (M.C.M.); University Hospital, Tours (L.M.); Centre Cardiologique du Nord, Saint Denis (P.G.); University Hospital, Toulouse (J.P.), France.

*Additional participants in the BESMART Trial are listed in the Appendix.

Correspondence to René Koning, MD, Service de cardiologie; Hôpital Charles-Nicolle, 1 rue de Germon, 76031 Rouen Cedex, France. E-mail r.koning@wanadoo.fr

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Patient Selection

Were included patients with symptoms of ischemic heart disease (angina pectoris, objective evidence of myocardial ischemia, or both) with de novo lesions on small native coronary arteries. The angiographic inclusion criteria were a lesion with $\geq 50\%$ stenosis according to the estimate of the investigator; a lesion located on a coronary segment with a diameter < 3 mm after intracoronary administration of 0.3 mg of nitroglycerin; and a lesion < 15 mm long, able to be covered by a single stent crimped over a ≤ 2.5 -mm or a noncompliant 2.75-mm-diameter balloon exclusively. The angiographic exclusion criteria were the presence of an ostial and/or bifurcation lesion and a left ventricular ejection fraction of $\leq 30\%$. The clinical exclusion criteria were a myocardial infarction within the previous 3 days or a contraindication to aspirin or ticlopidine. A maximum of 2 lesions located on 2 different main native coronary arteries or branches could be treated in the same patient. Additional angioplasty of other lesions on coronary segments > 3 mm in diameter was allowed if located on other coronary artery branches.

Randomization

After the eligible patients had given their written informed consent, they were randomly assigned to either stent placement (stent group) or balloon angioplasty (PTCA group). To ensure an equal distribution of each treatment at each center, a randomization stratification on-site was designed in blocks of 8 treatment assignments. The randomization was carried out by phone. When 2 lesions had to be treated in the same patient, they were randomly assigned to the same treatment.

Procedural Protocol

The procedures were performed by means of the femoral approach, with arterial introducers of size 6F to 8F. In all patients, a bolus of heparin (80 U/kg) was administered before the procedure, eventually supplemented according to the usual investigator's practice. Most patients were pretreated with aspirin (160 to 325 mg daily). In other cases, a dose of 500 mg of aspirin was administered intravenously before the procedure. After the procedure, patients assigned to stenting received a daily dose of aspirin (100 mg) and an additional daily dose of ticlopidine (500 mg) for 1 month and a daily dose of aspirin (250 mg) thereafter. Patients assigned to PTCA received a daily dose of aspirin (250 mg).

Stent Placement

The Bestent Small (Medtronic Inc) designed for 2.5- to 3.0-mm-diameter vessels was used in all cases. Before stenting, each lesion was predilated with a 2.5-mm or noncompliant 2.75-mm balloon, 20 mm in length. Balloon size was chosen to reach a balloon on artery ratio close to 1.

Balloon Angioplasty

Similar balloons were used for PTCA. An optimal angiographic result was defined as a residual stenosis $\leq 30\%$ of the luminal diameter, according to a visual estimate. A crossover to stent placement was restricted to the following situations: (1) as a "bail-out" procedure in the case of abrupt or threatened closure caused by a coronary dissection with compromised antegrade blood flow and (2) in the case of a suboptimal result defined by a residual stenosis $> 50\%$. Any stent other than the Bestent could be used in the case of crossover.

Clinical events, ECG, and creatine kinase-MB were monitored daily during hospitalization.

Follow-Up

Coronary angiography was required at 6 months in all patients with angiographic procedural success and no target lesion revascularization during hospital stay. Coronary angiography could be prematurely performed on the basis of clinical indications; it was used as the follow-up angiogram in the case of restenosis or if performed after 4 months. In other cases, another angiographic control was repeated at 6 months. Clinical follow-up was obtained at the time of repeated angiography or by phone at 6 months for other patients.

Quantitative Angiographic Analysis

Angiographies were recorded on 35-mm cinefilm or CD-ROM. Matched orthogonal views were used for quantitative analysis at each control. Dye-filled guiding catheters were used for magnification calibration. Angiograms were analyzed in an independent angiographic core laboratory (Corisis, France). Quantitative analysis was performed with the use of the validated CMS 4.0 (Medis-H) edge-detection system.

End Points and Definitions

The primary end point was the restenosis rate defined as a stenosis $\geq 50\%$ measured by quantitative coronary angiography (QCA) on the follow-up angiogram. Secondary end points included (1) the clinical procedural success defined as angiographic success without major adverse cardiac events (MACE): death, myocardial infarction, or myocardial revascularization by repeat angioplasty or coronary bypass surgery; (2) the rate of major adverse clinical events during the 6-month follow-up period.

The angiographic procedural success was defined as a reduction in stenosis to $< 50\%$ by QCA in the absence of dissection $\geq D1$ according to the National Heart, Lung, and Blood Institute criteria¹¹ and a TIMI grade 3 flow. Myocardial infarction was defined by the presence of new Q waves or creatine kinase level or MB fraction at least twice the upper limit of normal.

Collection of Data and Statistical Analysis

Clinical and angiographic data were forwarded to the Data Coordinating Center of Medtronic for statistical analysis. Adverse events were audited and reviewed by members of the Safety Committee.

The primary analysis of angiographic and procedural outcomes was based on the intention-to-treat principle. A secondary analysis was performed to assess the rate of restenosis according to the treatment received. The target sample size (340 patients) was based on an assumed restenosis rate of 45% in the balloon group and 30% in the stent group, a 33% reduction in restenosis rate with stent implantation. To compensate crossover and losses for follow-up, the sample was enlarged by 10% to 380 patients (2-sided test with an α error of 0.5 and a power of 0.95). For comparisons between groups, the χ^2 test (or, if there were fewer than 5 expected observations, Fisher's exact test) was used. For comparisons of continuous variables, ANOVA was used according to the type of data and their distribution. Statistical significance was considered to be indicated by a 2-tailed P value of < 0.05 . Relative risks were calculated with 95% confidence intervals. Kaplan-Meier survival curves for MACE were obtained by means of the log-rank test.

Results

Baseline Clinical and Angiographic Characteristics

Between August 1997 and August 1999, 389 patients were enrolled in the study. Of these patients, 8 were excluded from further analysis because of violation of the protocol in 6 (use of a 3.0-mm balloon in 1, acute myocardial infarction in 2, lesion with major side branch in 2, and tandem lesion in 1) or inadequate quality of QCA in 2. Thus, the final study group comprised 381 patients, 192 (197 lesions) in the stent group and 189 (198 lesions) in the PTCA group. Baseline clinical and angiographic characteristics are shown in Tables 1 and 2, respectively. There was a higher incidence of diabetes and hypertension in the stent group and a higher incidence of 3-vessel disease in the PTCA group. The majority of lesions were simple, type A, or type B1 by American College of Cardiology/American Heart Association classification.¹² The type and distribution of lesions was equivalent in the 2 groups.

TABLE 1. Baseline Clinical Characteristics of the 381 Patients Included in the Intention-to-Treat Analysis

	Stent Group (n=192)	PTCA Group (n=189)	P
Age, y	62±10	61±10	NS
Male sex, %	73.4	79.3	NS
Hypertension, %	51	40	0.034
Diabetes mellitus, %	22	12	0.008
Hypercholesterolemia, %	55.7	57.6	NS
Current smoking, %	57.2	61.3	NS
Family history, %	32.2	29.6	NS
Q-wave MI, %	21.3	27.5	NS
Non-Q-wave MI, %	10.4	15.8	NS
CABG, %	6.7	3.1	NS
PTCA, %	23.9	18.5	NS
Clinical status, %			
Stable angina	38.5	41.2	NS
Unstable angina	50.0	42.8	
Silent ischemia	11.4	15.8	
No. of diseased vessels, %			
1	58.3	43.3	0.032
2	36.4	43.9	
3	5.2	12.6	
Patients treated for another vessel, %	22.9	26.9	NS
Patients randomized for 2 lesions <3 mm	2.6	4.0	NS
Ejection fraction, %	62±9	63±9	NS

MI indicates myocardial infarction.

Procedural Outcome

In the 2 groups, a 2.5-mm balloon was used in 90% of cases, and the balloon-to-artery ratio and maximal balloon inflation pressure were comparable (Table 2). In the PTCA group, 2 procedural failures were noted: In one case the balloon could not cross the lesion and in the other case the artery occluded despite a cross-over to stent placement. In the stent group, 2 of the 197 lesions could not be crossed by the wire. A cross-over to the stent was required in 45 of 198 lesions (22.7%) in the PTCA group and in 6 of 197 lesions (3%) in the stent group because of failure to cross the lesion with the stent. Angiographic procedural success rate was 97.9% in the stent group and 93.9% in the PTCA group, a nonsignificant difference.

The composite rate for all in-hospital MACE was similar in both groups (Table 3). There were no in-hospital deaths. There was no difference in the incidence of Q-wave and non-Q-wave infarctions or in the need for urgent or elective heart surgery or repeat angioplasty during the hospital stay. Documented stent thrombosis during the hospital stay occurred in 2 lesions (1%). Incidence of bleeding and vascular complications was similarly low in the 2 groups. Clinical procedural success rate was comparable: 93.4% in the stent group and 89.9% in the PTCA group. The mean hospital stay was similar (2.70±5.0 versus 2.4±3.0 days in the stent and PTCA groups, respectively).

TABLE 2. Baseline Angiographic and Procedural Characteristics (395 Lesions)

	Stent Group (n=197)	PTCA Group (n=198)	P
Lesion dilated, %			
LAD	24.3	25.7	NS
Dg	14.2	11.1	
LCX	18.7	22.2	
OM	25.3	19.1	
RCA	9.6	13.1	
Other	7.9	8.8	
Type of lesion, %			
A	23.2	19.7	NS
B1	52.7	55.6	
B2	20.8	18.2	
C	3.0	6.5	
Balloon/artery ratio	1.05±0.11	1.02±0.11	NS
Maximum inflation pressure, atm	10.5±2.7	10.2±3.2	NS

LAD indicates left anterior descending coronary artery; Dg, diagonal artery; LCX, left circumflex artery; OM, obtuse marginal artery; and RCA, right coronary artery.

Angiographic Analysis

The QCA results are shown in Table 4. At baseline, there were no differences in stenosis severity or minimal lumen diameter (MLD) in the 2 groups. Mean vessel size was 2.23±0.36 mm in the stent group and 2.24±0.34 mm in the PTCA group. After the procedure, a larger acute gain was achieved with stent placement, resulting in a larger MLD.

Follow-up angiography was performed in 91% (325/356) of eligible patients at a mean of 6±1 month after the initial procedure. At 6 months, there was an overall greater net gain in the stent group, resulting in a larger MLD at 6 months. The late loss in MLD was not significantly different between the 2 groups but was slightly higher in the stent group, and the loss index was comparable. Cumulative frequency curves of MLD at baseline, after the procedure, and at follow-up are plotted in Figure 1.

Restenosis was observed in 21% of lesions in the stent group and in 47% in the PTCA group ($P=0.0001$), a risk reduction of 55%. The risk reduction was independent of the vessel size; it was 70%, 56%, and 50%, respectively, in the 3 subgroups, with a reference diameter of 1.5 to 1.9 mm, 2 to 2.4 mm, and 2.5 to 2.9 mm.

TABLE 3. In-Hospital Clinical Events (381 Patients)

	Stent Group (n=192)	PTCA Group (n=189)	P
Death	0	0	NS
Q-wave MI	1 (0.5)	1 (0.5)	NS
Non-Q-wave MI	7 (3.6)	8 (4.2)	NS
CABG	0	1 (0.5)	NS
Repeat PTCA	3 (1.5)	3 (1.6)	NS
Total MACE*	9 (4.6)	11 (5.8)	NS
Hematoma	1 (0.5)	1 (0.5)	NS

MI indicates myocardial infarction. Values are n (%).

*Patients with ≥1 MACE.

TABLE 4. Quantitative Comparison of Immediate and 6-Month Angiographic Results

	Stent Group (n=197)	PTCA Group (n=198)	P
At baseline			
Reference diameter, mm	2.23±0.36	2.24±0.34	NS
MLD, mm	0.71±0.29	0.76±0.29	NS
Stenosis, %	68±12	66±12	NS
Lesion length, mm	9.1±4.0	9.6±4.6	NS
After procedure			
Reference diameter, mm	2.45±0.35	2.38±0.37	.04
MLD, mm	2.06±0.42	1.70±0.46	0.0001
Stenosis, %	16±14	29±15	0.0001
Acute gain, mm	1.35±0.45	0.94±0.47	0.0001
At 6 mo			
Reference diameter, mm	2.30±0.33	2.33±0.33	NS
MLD, mm	1.43±0.53	1.19±0.58	0.0001
Stenosis, %	38±21	50±24	0.0001
Net gain, mm	0.72±0.58	0.43±0.58	0.0001
Late loss, mm	0.65±0.58	0.57±0.67	NS
Loss index	0.46±0.50	0.56±0.81	NS
Restenosis, %	21	47	0.0001

Values are mean±SD or as indicated.

According to the effective treatment, the restenosis rate was 24% in the stent group versus 50% in the PTCA group ($P=0.0001$), a risk reduction of 50%.

Six-Month Clinical Follow-Up

Major cardiac events at 6 months are shown in Table 5. Clinical follow-up was available in 342 of the 361 (94.7%) eligible patients. Repeat target lesion revascularization was significantly less frequent in the stent group (13% versus 25%, $P=0.006$), a risk reduction of 50%. Survival without MACE was better in the stent group than in the balloon group (Figure 2). Five patients died during follow-up (all cardiac-related deaths): 1 in the stent group and 4 in the angioplasty group.

Discussion

In this trial, compared with balloon angioplasty, stent implantation in de novo focal lesions on coronary arteries <3 mm was

TABLE 5. Major Cardiac Events 6 Months After the Procedure (Follow-Up in 342 Patients)

	Stent Group (n=176)	PTCA Group (n=166)	P
Death	1 (0.6)	4 (2.4)	NS
Myocardial infarction	1 (0.6)	2 (1.2)	NS
Target lesion revascularization	23 (13)	41 (24.6)	0.006
By PTCA	22 (12.5)	39 (23.4)	
By CABG	1 (0.6)	2 (1.2)	
Total MACE*	24 (13.6)	45 (27.1)	0.002
Non-target lesion revascularization	19 (10.7)	22 (13.2)	NS

Values are n (%).

*Patients with ≥1 MACE.

associated with a 55% risk reduction of restenosis at 6 months and a 50% risk reduction of target lesion revascularization. These results have an important impact, considering the increasing use of stenting as a primary strategy in small vessels.³⁻⁷

Conflicting results have been previously reported in this setting. The American College of Cardiology Consensus reported that stenting in small vessels did not improve the long-term outcome in comparison to balloon angioplasty.¹³ In a retrospective study on 2602 patients, Elezi et al⁵ found that small vessel size was an independent factor of restenosis. Several other reports failed to show a beneficial effect of stenting in small vessels.^{14,15} On the other hand, in a subset analysis of the Stent Restenosis Study (STRESS) I-II trial, Savage et al⁹ reported a restenosis rate of 34% after stenting versus 55% after balloon angioplasty in coronary arteries <3 mm. In a French prospective pilot study on stenting in vessels <3 mm,¹⁰ the angiographic restenosis rate was similarly found to be 30%.

Two recent randomized trials failed to show any beneficial effect of stenting over PTCA in coronary arteries <3 mm. In the randomized ISAR-SMART (Intracoronary Stenting or Angioplasty for Restenosis Reduction in Small Arteries Trial),¹⁶ Kastrati et al, using the MULTI-LINK stent (Guidant, Advanced Cardiovascular System, Inc), found a restenosis rate of 35.7% after stenting and 37.4% after PTCA. Comparable results (35.7% versus 30.9%, respectively) were reported by Park et al¹⁷ with the NIR stent (Boston Scientific Corp). Numerous differences in patient selection and techniques may explain the divergent results. In the ISAR-SMART trial, 75% of lesions were complex, including total occlusions (7%) and multiple lesions (34.3%), and longer stents were used (20.8±10.9 mm), all features associated with less favorable outcome after stenting.^{5,14} The Park et al¹⁷ study was a monocentric, small, randomized trial (120 patients), in which QCA analysis was limited to on-line measurements. In these studies, a more aggressive approach was used (higher balloon-to-artery ratio and higher balloon pressure), which might explain the higher late loss after stenting and the better PTCA results at follow-up than in our study. The results obtained after balloon angioplasty in our study could explain the higher cross-over rate (22.7%). The different stent designs might also play a role in the contradictory results.

In the present study, coronary stenting was safe and the in-hospital events were comparably low in the two groups, despite the reported increased risk of acute or subacute thrombosis in these lesions.¹⁸

The rate of major adverse cardiac events during the 6-month follow-up period was markedly reduced in the stent group (13.6% versus 27.1%) and compares favorably with all previous findings from nonrandomized or randomized studies.^{5,9,14-16} The rate of adverse event in the balloon angioplasty arm is coherent with previous reports in this setting.^{5-7,9,15}

In conclusion, elective stent placement in small coronary arteries is feasible and safe and is highly effective in reducing the incidence of restenosis and the need for subsequent revascularization of the target lesion. These results were obtained in de novo focal lesions and cannot be extrapolated to other lesion characteristics such as complex or long lesions.

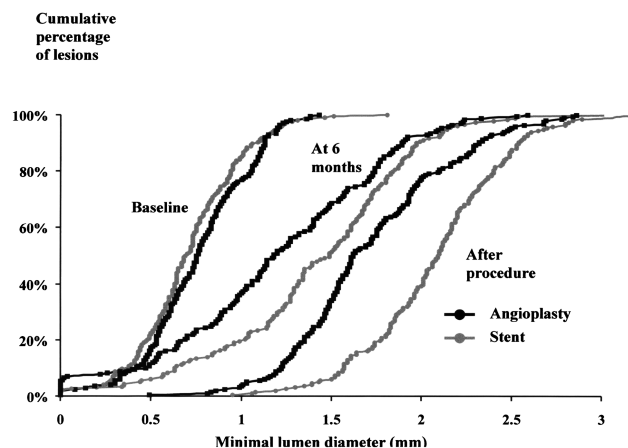


Figure 1. Cumulative frequency distribution curves for the two study groups showing MLD measured at baseline, after procedure, and at 6 months.

Appendix

The following institutions and investigators participated in the BESMART study. The number of patients enrolled is given in parentheses.

Center Hospitalier Privé Saint Martin, Caen (48): B. Huret; Hôpital Bon Secours, Metz (46): K. Khalifé; Center Hospitalier Universitaire, Brest (43): J. Boschat; Center Hospitalier Universitaire, Rouen (36): A. Cribier; Center Hospitalier Universitaire, Clermont-Ferrand (34): B. Citron; Center Hospitalier Universitaire, Toulouse (33): J. Puel; Center Hospitalier Universitaire, Bordeaux (23): P. Coste; Center Hospitalier Universitaire, Rennes (21): H. Le Breton; Institut Hospitalier Jacques Cartier, Massy (19): Y. Louvard; Center Hospitalier Universitaire, Nantes (14): D. Crochet; Clinique du Bois de Verrières, Antony (14): P. Dumas; Center Hospitalier Universitaire, Tours (13): P. Raynaud; Center Hospitalier Universitaire, Nancy (6): N. Danchin; Center Hospitalier Universitaire, Besançon (5): J-P. Bassand; C.M.C.O Schiltigheim, France (5): M. Zupan; Center Hospitalier René Dubos, Pontoise (4): F. Funck; Clinique Saint Laurent, Rennes (4): C. Pico-Bourdonnec; Center Hospitalier Universitaire, Marseille (3): J-L. Bonnet; Hôpital Cochin, Paris (3): C. Spaulding; Hôpital Broussais, Paris (3): J-L. Guermontprez; Center Médical Chirurgical Parly (2), Le Chesnay (2): X. Favereau.

Steering Committee

A. Cribier (chairman), J. Puel, N. Danchin, P. Commeau, and M-C Morice.

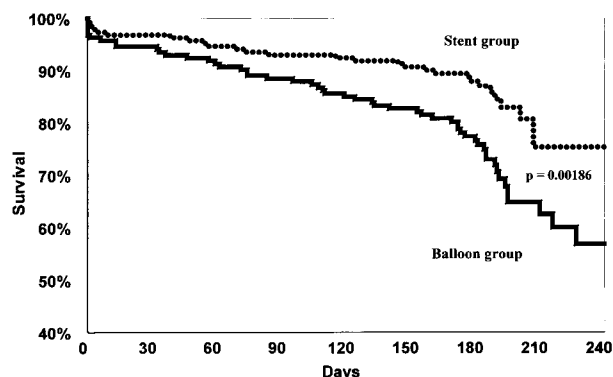


Figure 2. Survival curves for major adverse cardiac events in the 2 groups.

Safety Committee

P. Barragan, P. Meyer, and J-M Lablanche.

Quantitative Angiographic Core Laboratory

Corisis Saint Denis, France: P. Guyon, B. Chevalier, B. Glatt, and T. Royer.

Data Coordinating Center

Bakken Research Center Maastricht, The Netherlands: C. Cassiram (study manager) and E. Kerkhof.

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