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A Randomized Comparison of the Value of Additional Stenting After Optimal Balloon Angioplasty for Long Coronary Lesions

Final Results of the Additional Value of NIR Stents for Treatment of Long Coronary Lesions (ADVANCE) Study

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OBJECTIVES We sought to investigate the clinical benefit of additional stent implantation after achieving an optimal result of balloon angioplasty (BA) in long coronary lesions (>20 mm).

BACKGROUND Long coronary lesions are associated with increased early complications and late restenosis after BA. Stenting improves the early outcome, but stent restenosis is also related to both lesion length and stent length.

METHODS A total of 437 patients with a single native lesion 20 to 50 mm in length were included and underwent BA, using long balloons matched to lesion length and vessel diameter (balloon/artery ratio 1.1) to achieve a diameter stenosis (DS) <30% by on-line quantitative coronary angiography (QCA). "Bail-out stenting" was performed for flow-limiting dissections or >50% DS. Patients in whom an optimal BA result was achieved were randomized to additional stenting (using NIR stents) or no stenting. The primary end point was freedom from major adverse cardiac events (MACE) at nine months, and core laboratory QCA was performed on serial angiograms.

RESULTS Bailout stenting was necessary in 149 patients (34%) and was associated with a significantly increased risk of peri-procedural infarction ($p < 0.02$). Among the 288 randomized patients, the mean lesion length was 27 ± 9 mm, and the vessel diameter was 2.78 ± 0.52 mm. The procedural success rate was 90% for the 143 patients assigned to BA alone (control group), as compared with 93% in the 145 patients assigned to additional stenting (stent group), which resulted in a superior early minimal lumen diameter (0.54 mm, $p < 0.001$) and led to reduced angiographic restenosis (27% vs. 42%, $p = 0.022$). Freedom from MACE at nine months was 77% in both groups.

CONCLUSIONS A strategy of provisional stenting for long coronary lesions led to bailout stenting in one-third of patients, with a threefold increase in peri-procedural infarction. Additional stenting yielded a lower angiographic restenosis rate, but no reduction in MACE at nine months. (J Am Coll Cardiol 2002;39:393–9) © 2002 by the American College of Cardiology

Coronary lesion length is an independent risk factor for early complications during balloon angioplasty (BA) (1,2). Furthermore, angiographic restenosis rates of up to 58% have been reported after BA of long lesions, and lesion length is an independent predictor of restenosis (3,4). Long balloons (5), and especially coronary stents, have improved procedural success, but the long-term outcome of stents in long lesions cannot compete with the results of the BElgian NEtherlands STENT (BENESTENT) trial and the STent REStenosis Study (STRESS) in focal lesions (6,7). Restenosis rates of 30% to 63% have been reported for stenting of long lesions, and stented segment length is an independent predictor of restenosis (8–10). The optimal percutaneous approach to long lesions remains unclear thus far.

In focal lesions, the concept of "provisional stenting" (11) has demonstrated that a "stent-like" or "optimal" result using BA achieves clinical and angiographic results equivalent to those of stent implantation, so that stenting could be reserved for lesions in which an optimal result cannot be

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Abbreviations and Acronyms

BA = balloon angioplasty
CK = creatine kinase
DS = diameter stenosis
IVUS = intravascular ultrasound
MACE = major adverse cardiac events
MI = myocardial infarction
MLD = minimal lumen diameter
TIMI = Thrombolysis In Myocardial Infarction
TVR = target vessel revascularization
QCA = quantitative coronary angiography

achieved (12–14). The value of additional stenting after achievement of an optimal BA result in long coronary lesions has not been investigated; therefore, this study was initiated.

METHODS

Study group. Patients with stable or unstable angina or reversible ischemia related to a single, native, primary coronary lesion 20 to 50 mm in length, in a vessel 2.5 to 4.0 mm in diameter, were eligible for inclusion. Exclusion criteria included myocardial infarction (MI) within the five days before enrolment, Q-wave MI with akinesia in the target vessel territory, ejection fraction <30%, history of stroke, gastrointestinal bleeding within six months, severe hepatic disease, serum creatinine >130 μmol/liter, contraindication to or intolerance of aspirin or ticlopidine, unprotected left main coronary artery lesion, total occlusion (Thrombolysis in Myocardial Infarction [TIMI] trial flow grade 0), bifurcation lesion (side branch >2.0 mm), aorto-ostial lesion and large intra-luminal thrombus.

Trial design. This prospective, randomized, multicenter trial assumed a 40% incidence of the primary end point (i.e., cumulative major adverse cardiac events [MACE] at nine months) in the control group (optimal BA result, randomized to no additional stenting) and 26% in the stent group (optimal BA result, randomized to additional stenting). A total of 500 patients (2 × 250) were required to obtain a power of 90% with $\alpha = 0.05$ for a two-tailed test. With an anticipated 20% to 25% rate of bail-out stenting, 650 patients were needed to retain 500 evaluable patients.

Trial procedure and randomization. Suitable patients gave written, informed consent before undergoing angiography before the intervention. Ticlopidine, 250 mg twice daily, or clopidogrel, 75 mg/day, was administered to all patients within 12 h before the intervention and for one month subsequently to those undergoing stent implantation. Heparin (10,000 U) and aspirin (250 mg intravenously) were given according to standard protocol; aspirin, ≥100 mg/day, was continued indefinitely. Use of the platelet glycoprotein IIb/IIIa receptor antagonist was at the discretion of the investigators.

After baseline angiography had established the patients' suitability for inclusion, the allocation service was telephoned to report inclusion and provide patient identity, lesion length, vessel diameter and diameter stenosis (DS) by on-line quantitative coronary angiography (QCA). Target lesion BA was then performed to achieve DS <30% without significant dissection, using balloons of sufficient length to cover the entire lesion with a single inflation and a final balloon/artery ratio of 1.1. When an optimal result had been achieved, whereby in daily practice the procedure would be considered successfully completed, the trial randomization service was again telephoned to report BA procedural success, lesion length, vessel diameter and post-angioplasty diameter stenosis. Then randomization took place, either to no further therapy or to additional stenting. When bail-out stenting had been performed, the allocation service was also called to report this.

In patients randomized to no further therapy, the final post-BA angiographic views were recorded for off-line analysis at the core laboratory. In those randomized to additional stenting, premounted NIR stents (Boston Scientific Corp., Maple Grove, Minnesota) of the appropriate length and diameter were implanted to achieve an optimal result, using the least number of stents possible, while fully covering the lesion (ideally a single stent) (Table 1). So-called "spot stenting" was excluded. The NIR stents were available in diameters from 2.5 to 4.0 mm and lengths of 9, 16, 25 and 32 mm.

Bail-out stenting. Bail-out stenting was reserved for cases where repeated dilations with appropriately sized balloons failed to achieve DS <50% in all views by on-line QCA; for a type C dissection (according to the National Heart, Lung and Blood Institute classification), combined with documented ST segment changes or anginal pain; for type D, E or F dissections; or for a reduction in TIMI flow of at least one grade or TIMI flow grades 0 and 1. All types of stent (preferably premounted NIR) were permitted.

Table 1. Stent Implantation Strategy

Lesion Length (mm)	Stent Lengths (mm)		
	First Choice	Second Choice	Third Choice
20–24	25 or 32	16 + 9, 16 + 16 or 25 + 9	3 × 9 or 2 × 9 + 16
25–30	32 or 25 + 9	25 + 9 or 16 + 16	16 + 9 + 9
31–40	32 + 9, 32 + 16 or 25 + 16	16 + 16 + 9	any combination
41–50	25 + 9, 32 + 16, 25 + 25 or 32 + 25	16 + 16 + 16, 25 + 16 + 9, 9 + 9 + 32, 16 + 16 + 25 or 9 + 16 + 32	any combination

End points and definitions. The primary end point was the occurrence of MACE during nine months of follow-up, defined previously (15) as the occurrence of cardiac death, MI, coronary artery bypass graft surgery or repeat percutaneous transluminal coronary angioplasty (i.e., target vessel revascularization [TVR]).

CARDIAC DEATH. All deaths were considered as cardiac-related, unless unequivocally documented as noncardiac (based, whenever possible, on an autopsy). Myocardial infarction was defined as 1) development of new abnormal Q waves (Minnesota Code) not present at study inclusion (baseline); and 2) an increase of creatine kinase (CK) of more than twice the upper limit of normal and an abnormal level of CK-MB isoenzyme, measured routinely at screening and 6 and 12 h after the intervention and where clinically indicated.

TARGET VESSEL REVASCULARIZATION. The procedure of TVR, defined as the repeat treatment of a lesion in a previously treated vessel, was justified by recurrent symptoms and/or reversible ischemia in advance of repeat catheterization, or diminished coronary flow reserve or fractional flow reserve, combined with DS >50% during repeat catheterization. Telephone notification to the allocation center was required before repeat revascularization, for documentation and justification.

TREATMENT SUCCESS. Core laboratory criteria for angiographic success were DS <50% and TIMI flow grade 3 in the control group and DS <30% and TIMI flow grade 3 in the stent group. Procedural success was measured angiographically and by the absence of MACE during the hospital period. In the group randomized to additional stenting, strategic success was defined by attainment of the "first-choice" stent strategy (Table 1).

Ethical conduct. This study was conducted in accordance with the Declaration of Helsinki. Patients received detailed, written information on the trial and gave written consent according to national requirements. No center started until written approval of the protocol and consent procedure was obtained from the appropriate Ethical Review Committee and Institutional Review Board. The study complied with Good Clinical Practice and European Standard EN 540, governing the conduct of clinical investigations of medical devices. Source data verification was performed.

Angiographic procedures. Coronary angiography was performed in at least two views after intracoronary injection of 0.1 to 0.3 mg of nitroglycerin or 1 to 3 mg of isosorbide dinitrate at baseline and repeated after BA and after stenting and at follow-up angiography for the randomized patients. Standardized procedures were followed to facilitate quantitative analysis at the core laboratory (Cardialysis, Rotterdam, The Netherlands, using the CAAS II system [PIE Medical, Maastricht, The Netherlands]), as extensively described previously (4,6,9,12,15).

Table 2. Baseline Demograpic Data on Intention-to-Treat Patients (n = 437)

Patient Characteristics	Balloon Angioplasty (n = 143)	Stent Implantation (n = 145)	Bailout Stenting (n = 149)
Male	79.0%	67.6%	71.8%
Mean age (yrs)	62.2 ± 9.6	61.1 ± 9.2	60.2 ± 10.3
Previous MI	37.8%	45.5%	36.9%
Previous CABG	6.3%	3.4%	6.0%
Previous PTCA	14.7%	17.2%	9.4%
Hypertension	45.5%	40.7%	47.7%
Diabetes	15.4%	18.6%	9.4%
Insulin-dependent	4.2%	5.5%	4.7%
Hypercholesterolemia	62.2%	63.4%	64.4%
History of stroke	2.8%	2.8%	2.0%
Relevant family history	47.6%	51.7%	44.3%
Peripheral arterial disease	10.5%	9.0%	6.0%
Previous smoker	50.3%	46.9%	43.0%
Current smoker	23.8%	22.8%	22.8%
Anginal status			
Unstable	30.8%	30.3%	29.5%
Stable	58.0%	64.1%	65.1%
Silent ischemia	11.2%	5.5%	5.4%

CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

Follow-up. All patients visited the out-patient clinic at one, six and nine months after the intervention; an exercise tolerance test was also performed at six months, and in randomized patients, follow-up angiography was carried out on the same day or at least within the next two weeks, according to well-described standardized procedures.

Statistical analysis. Primary end points were analyzed according to the intention-to-treat principle. Safety analysis was performed for all patients included. Ordinal variables were analyzed by the Fisher exact test; continuous variables by analysis of variance; MACE-free survival in the primary efficacy group at nine months by the log-rank test; and event-free survival distributions by the Kaplan-Meier method.

RESULTS

Interim analysis. A planned interim analysis after 280 patients completed nine months of follow-up was performed in September 1999. Survival free of MACE was lower in the additional stenting group than in the control group (81% vs. 86%, p = NS). Because the hypothesized advantage of additional stenting over BA (a 14% reduction in MACE) could not be substantiated with the existing trial design, the Safety and Data Monitoring Board recommended that patient recruitment be curtailed and the 437 patients included (Tables 2 and 3) be followed and analyzed, according to the protocol.

Early results (Table 4, Fig. 1). Of the 437 patients, 149 (34%) underwent bail-out stenting because of DS >50% in 65.3%, a type D or F dissection in 63.9%, ischemia with a type C dissection in 16.3% and/or reduced TIMI flow in 11.0%. The remaining 288 patients were randomized: 143 to no stenting and 145 to additional stenting.

Table 3. Baseline Lesion Characteristics

Characteristics	Balloon Angioplasty (n = 143)	Stent Implantation (n = 145)	Bailout Stenting (n = 149)
Calcification (moderate to heavy)	33.3%	31.9%	29.6%
Thrombus	6.5%	5.1%	2.1%
Bifurcation lesion requiring second wire	42%	40%	30.3%
Type A	2.1%	2.8%	4.0%
Type B1	2.1%	2.1%	1.3%
Type B2	27.3%	26.1%	22.1%
Type C	68.5%	69.0%	72.5%
RCA	42.0%	43.4%	38.5%
LAD	42.7%	37.2%	45.3%
LCx	15.4%	19.3%	16.2%

LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery.

The *angiographic success rate* was 95.1% in the control group and 95.9% in the additional stenting group, with success of the first-choice stent strategy in 84%. A single stent was used in 78%; two stents in 10%; and three or more stents in 12%. The mean implanted stent length (by QCA in the core laboratory) was 26.1 ± 7.7 mm. Additional stenting achieved a significantly greater post-procedural minimal lumen diameter (MLD 0.54 mm, $p < 0.001$). The *procedural success rate* was 93.1% in the additional stenting group and 89.5% in the control group (p = NS), and there was no difference in peri-procedural MI. Cardiac enzyme elevation was most marked in the bail-out stenting group (21.4% had elevated CK-MB, with 7.1% more than 5 times elevated), and significantly more patients experienced peri-procedural MI as compared with randomized patients (p = 0.03). Among the patients with side branch occlusion, an increase in CK occurred in 39% (2.8% of the control group, 6.2% of the additional stenting group and 6.7% of those who had bail-out stenting). The proportions of patients treated with glycoprotein IIb/IIIa receptor antagonists in the additional stenting, control and bail-out groups were 7.6%, 10.5% and 10.1%, respectively.

Table 4. Quantitative Coronary Angiographic Analysis

Variable	Balloon Angioplasty (n = 120)	Stent Implantation (n = 124)	p Value
Lesion length (mm)	27 ± 10	26 ± 8	NS
Vessel size (mm)	2.76 ± 0.53	2.80 ± 0.53	NS
MLD (mm)			
Before procedure	0.94 ± 0.29	0.92 ± 0.29	NS
After procedure	1.86 ± 0.40	2.40 ± 0.41	0.001
Follow-up	1.53 ± 0.58	1.61 ± 0.63	0.28
Diameter stenosis (%)			
Before procedure	66 ± 9	66 ± 10	NS
After procedure	35 ± 9	20 ± 7	0.0001
Follow-up	47 ± 16	43 ± 18	0.07
Gain (mm)	0.92 ± 0.39	1.47 ± 0.47	0.001
Loss (mm)	0.33 ± 0.48	0.79 ± 0.58	0.001
Loss index	0.36	0.57	0.066
Restenosis rate	42%	27%	0.022

Data are presented as the mean value ± SD, except where indicated otherwise.
MLD = minimal lumen diameter.

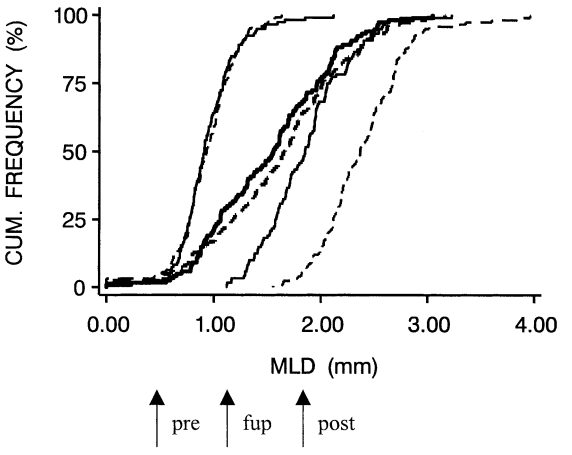

Figure 1. Cumulative distribution of minimal lumen diameter (MLD) before the procedure (pre), after the procedure (post) and at six-month follow-up (fup) for the balloon angioplasty only group (n = 120; **solid line**) and the additional stenting group (n = 124; **dashed line**).

Follow-up (Tables 4, 5 and 6, Fig. 1). The incidence of MACE at nine months was similar between the two groups, at 23%. There was also no difference in MLD at follow-up (0.08 mm, p = NS), although angiographic restenosis was higher in the control group than in the additional stenting group (42% vs. 27%, p = 0.022). The incidence of TVR tended to be higher in the additional stenting group than in the control group (34 vs. 28), and 20% of TVR in the stent group was in lesions with DS <50%, as compared with only 9% in the control group.

DISCUSSION

Trial design issues. The first generation of stent trials (6,7) demonstrated the feasibility, safety and efficacy of elective stenting as compared with BA, despite being "biased" in favor of BA, as bail-out stenting (preventing emergency bypass surgery or worse) was allowed in the BA strategy (6,7). The second generation of stent trials evaluated *addi-*

Table 5. Major Adverse Cardiac Events at 31 Days in Intention-to-Treat Patients (n = 437)*

Adverse Event	Randomized: Balloon Angioplasty (n = 143)	Randomized: Stent Implantation (n = 145)	Not Randomized: Bailout Stenting (n = 149)
Cardiac death	0	0	0
MI	7 (4.9%)	4 (2.8%)	16 (10.7%)
Q-wave	1 (0.7%)	0	3 (2.0%)
Non–Q-wave	6 (4.2%)	4 (2.8%)	13 (8.7%)
CABG	1 (0.7%)	0	2 (1.3%)
TVR	2 (1.4%)	1 (0.7%)	0
MACE-free	133 (93.0%)	140 (96.6%)	131 (87.9%)

*If a patient required repeat angioplasty and later coronary artery bypass graft surgery (CABG), only the worst event (CABG) was counted. Data are presented as the number (%) of patients.
MACE = major adverse cardiac events; MI = myocardial infarction; TVR = target vessel revascularization.

Table 6. Major Adverse Cardiac Events at 300 Days in Intention-to-Treat Patients (n = 437)*

Adverse Event	Randomized: Balloon Angioplasty (n = 143)	Randomized: Stent Implantation (n = 145)	Not Randomized: Bailout Stenting (n = 149)
Cardiac death	0	0	2 (1.3%)
MI	7 (4.9%)	4 (2.8%)	16 (10.7%)
Q-wave	1 (0.7%)	0	3 (2.0%)
Non–Q-wave	6 (4.2%)	4 (2.8%)	13 (8.7%)
CABG, all	5 (3.5%)	4 (2.8%)	4 (2.7%)
CABG, justified†	4 (2.8%)	4 (2.8%)	1 (0.7%)
TVR, all	21 (14.7%)	26 (17.9%)	17 (11.4%)
TVR, justified†	19 (13.3%)	21 (14.5%)	13 (8.7%)
MACE-free, all	110 (76.9%)	111 (76.6%)	110 (73.8%)
MACE-free, justified†	113 (79.0%)	116 (80.0%)	117 (78.5%)

*If a patient required repeat angioplasty and later coronary artery bypass graft surgery (CABG), only the worst event (CABG) was counted. †Target vessel revascularization (TVR) counted as "justified" only if minimal lumen diameter ≤1.55 mm and/or diameter stenosis ≥50% *and* a positive history of recurrent angina pectoris or objective signs of ischemia or an abnormal invasive functional diagnostic test result. Data are presented as the number (%) of patients.

Abbreviations as in Table 5.

tional stenting where an optimal BA result had been achieved (and where bail-out stenting had been eliminated). This "provisional stenting" strategy (11) showed that in focal lesions, a BA-achieved DS <35%, combined with coronary flow reserve >2.5, provided a clinical outcome equivalent to that of additional stenting (12,14,16,17).

The Additional Value of NIR Stents for Treatment of Long Coronary Lesions (ADVANCE) trial was the first to evaluate provisional stenting in longer lesions. Because of the intricacies of combining physiologic and on-line QCA measurements in a multicenter trial, with the complexity of long lesions, optimization of BA would be determined by on-line QCA alone.

The surprising revelation of the interim analysis, that the MACE rate was actually higher in the additional stenting group, led to advice by the independent Safety and Data Monitoring Board to the Steering Committee to terminate inclusion, because the initial trial hypothesis could no longer be demonstrated, which would have rendered continuing inclusion of patients both futile and unethical. What was surprising was the lower than expected rate of MACE of 20% in the BA-only group at that time (23% finally), as compared with an expected rate of 40%. This may partly reflect differences in patient selection for randomized trials, compared with day-to-day practice, and be partly explained by the higher than anticipated bail-out stenting rate of 34%, which may have "removed" many patients at higher risk of late MACE from the BA group.

Clinical implications. When embarking on this trial, three theoretical outcomes were considered. First, the additional value of stenting could have been demonstrated, whereby this policy would have been recommended. Second, stenting could have been found to be detrimental, in which case, its restriction to bailout would have been concluded. The third possibility, and the ultimate finding, was that additional

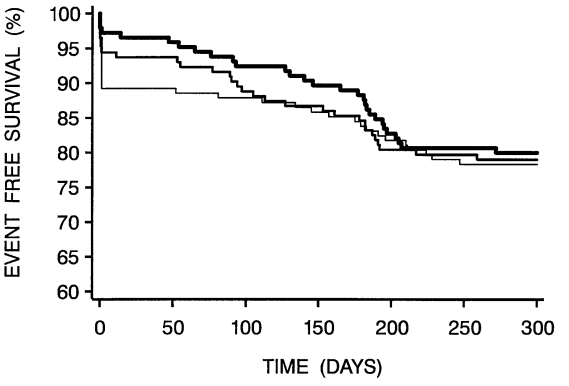

Figure 2. Event-free survival during 300 days after the intervention (by the Kaplan-Meier method). **Thickest line** = additional stenting group (n = 145); **medium-thick line** = balloon angioplasty only group (n = 143); **thin line** = bail-out stenting group (n = 149).

stenting was neither advantageous nor detrimental to the clinical outcome, which brings about a clinical dilemma. This study has not answered the question: should we stent long lesions? It has, however, demonstrated that an initial strategy of attempting optimal BA leads to bail-out stenting in one-third of patients, with a threefold increased risk of peri-procedural infarction, which is detrimental to the long-term clinical outcome (18,19). Accordingly, intentional stenting might be a safer and more effective initial strategy, by avoiding the bail-out situation. In retrospect, inclusion of an additional randomization to intentional stenting at the time of the first allocation might have provided data that would elucidate this possibility. However, the required sample size needed to demonstrate superiority of this strategy would have been cost-prohibitive, so the current design was chosen.

The majority of late events was TVR at follow-up angiography (Fig. 2), which was artificially higher in the stent group, as previously reported in BENESTENT-2 (20), despite our policy of prospective justification for proposed re-interventions. Clinical follow-up, without routine angiography, would likely have led to a lower TVR rate in the stent group and hence a better clinical outcome (immediately before follow-up angiography, 90% of the stent group was MACE-free vs. 85% of the BA group) (Fig. 2). It might have been useful to include such a sub-randomization, but in this scenario, the sample size required would have been excessive, and it was expected that clinical justification of TVR would be followed.

Issues of stent optimization. The MLD after stenting was rather low (2.48 mm), as compared with that in other recent trials, such as BENESTENT-2 (2.69 mm) (20) and Multicentre Ultrasound Stenting in Coronaries (MUSIC) (2.90 mm) (21). However, these trials included only focal lesions and a larger vessel diameter (2.78 mm in ADVANCE) (Table 4). Actually, the late loss in the present stent group (0.79 mm) is comparable to the loss in these trials (0.84 mm) (6,21) and considerably less than that observed in the Magic 5L study of long Wallstents

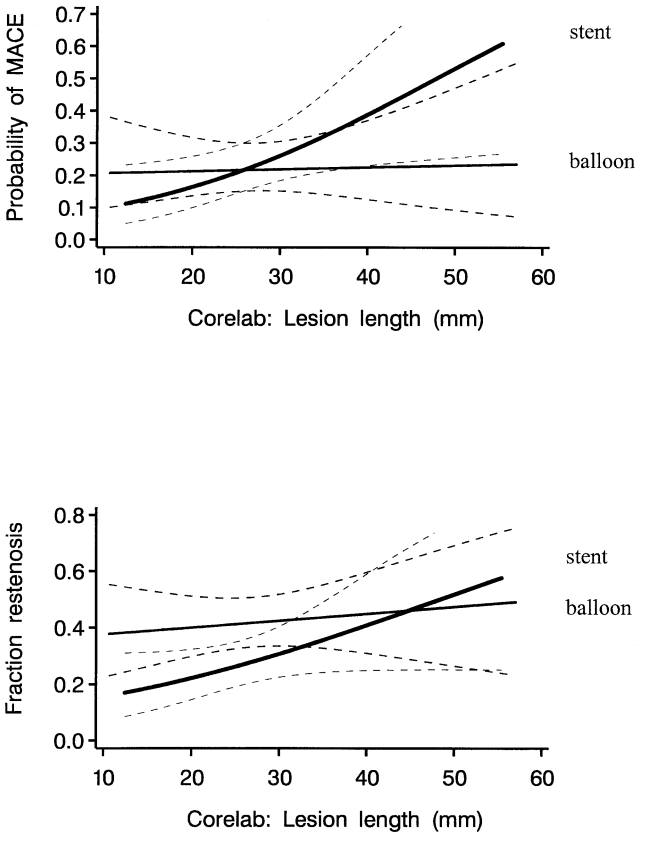

Figure 3. Logistic regression analysis of lesion length versus major adverse cardiac events (MACE) **(top)** and restenosis rate **(bottom)**. Both relationships show an advantage of stenting over balloon angioplasty (BA) for shorter lesions; however, in the additional stenting group, there is a significant incremental increase in restenosis and MACE with increased lesion length, a phenomenon that is not seen with BA.

(1.20 mm) (9). Accordingly, it could be speculated that a more aggressive strategy of post-dilation, possibly guided by intravascular ultrasound (IVUS), could have led to improved early and consequently late results. Guidance of stenting with IVUS in long lesions has been shown to improve the late outcome (22).

Lesion length as a predictor of restenosis: differences between BA and stenting. Logistic regression analysis of lesion length versus restenosis rate and MACE (Fig. 3) suggested that for lesions 20 to 30 mm, additional stenting was superior to BA, but worse for lesions >40 mm. In the additional stenting group, a lower MACE rate (16.0% vs. 20.3%, p = NS) and a larger MLD at follow-up (1.64 vs. 1.50 mm) were observed for lesions <26 mm, as compared with lesions >26 mm. Furthermore, the TVR rate was significantly lower in those with stents <32 mm (13.1% vs. 23.8%; p = 0.13), and use of multiple stents was associated with an almost doubling of the need for TVR (29.6% vs. 16.7%; p = 0.17), as previously reported (23,24).

Potential impact of new developments. Platelet glycoprotein IIb/IIIa antagonists have been shown to significantly improve the clinical outcome one year after stenting in complex lesions (25). At the time this trial was commenced, these data were not available, which may explain the infrequent use of these agents, which seem justified in percutaneous coronary intervention of long lesions, and may have improved the outcome in the stent group. Perhaps of greater interest are developing measures to reduce intimal hyperplasia—specifically, exciting reports of virtual elimination of restenosis by a sirolimus-eluting stent, first in a registry (26) and, more recently, in a randomized trial (27). Evaluation of this technology in long lesions seems mandatory and will be welcomed by all practitioners, who are accustomed to the safety of elective stenting and would be reluctant to return to a strategy of BA (provisional stenting) without compelling evidence. No such evidence is provided in this trial.

Study limitations. Randomization to systematic stenting without an optimal BA result might have added important data to the trial and needs to be addressed in future studies. Lack of adjunctive IVUS guidance has been discussed, but because this is not routine in most clinics, the trial is representative of clinical practice.

Conclusions. A strategy of provisional stenting in long lesions led to bail-out stenting in one-third of the patients, at the cost of a greater than threefold increase in periprocedural MI. Additional stenting improved early MLD and lowered angiographic restenosis, but without improving nine-month MACE-free survival. These results must be weighed against the potential benefit of systematic stenting, which would reduce the risk of bail-out, taking into account the impending availability of drug-eluting stents, which may reduce or eliminate restenosis.

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