Journal of the American College of Cardiology
© 2001 by the American College of Cardiology
Published by Elsevier Science Inc.

Vol. 37, No. 6, 2001
ISSN 0735-1097/01/$20.00
PII S0735-1097(01)01207-4

Interventional Cardiology

Continued Benefit of Coronary Stenting Versus Balloon Angioplasty: Five-Year Clinical Follow-Up of Benestent-I Trial

Ferdinand Kiemeneij, MD,* Patrick W. Serruys, MD, FACC,† Carlos Macaya, MD,‡ Wolfgang Rutsch, MD,§ Guy Heyndrickx, MD, FACC,‖ Per Albertsson, MD,¶ Jean Fajadet, MD,# Victor Legrand, MD,** Pierre Materne, MD,†† Jorge Belardi, MD,‡‡ Ulrich Sigwart, MD, FACC,§§ Antonio Colombo, MD, FACC,‖‖ Jean-Jacques Goy, MD,¶¶ Clemens M. C. Disco, MSc,## Marie-Angèle Morel, BSc,## on behalf of the Benestent I Study Group

Amsterdam and Rotterdam, the Netherlands; Madrid, Spain; Berlin, Germany; Aalst, Belgium; Göteborg, Sweden; Toulouse, France; Liège, Belgium; Buenos Aires, Argentina; London, United Kingdom; Milan, Italy; and Lausanne, Switzerland

OBJECTIVES This study sought to establish whether the early favorable results in the Benestent-I randomized trial comparing elective Palmaz-Schatz stent implantation with balloon angioplasty in 516 patients with stable angina pectoris are maintained at 5 years.

BACKGROUND The size of the required sample was based on a 40% reduction in clinical events in the stent group. Seven months and one-year follow-up in this trial showed a decreased incidence of restenosis and clinical events in patients randomized to stent implantation.

METHODS Data at five years were collected by outpatient visit, via telephone and via the referring cardiologist. Three patients in the stent group and one in the percutaneous transluminal coronary angioplasty (PTCA) group were lost to follow-up at five years. Major clinical events, anginal status and use of cardiac medication were recorded according to the intention to treat principle.

RESULTS No significant differences were found in anginal status and use of cardiac medication between the two groups. In the PTCA group, 27.3% of patients underwent target lesion revascularization (TLR) versus 17.2% of patients in the stent group ($p = 0.008$). No significant differences in mortality (5.9% vs. 3.1%), cerebrovascular accident (0.8% vs. 1.2%), myocardial infarction (9.4% vs. 6.3%) or coronary bypass surgery (11.7% vs. 9.8%) were found between the stent and PTCA groups, respectively. At five years, the event-free survival rate (59.8% vs. 65.6%; $p = 0.20$) between the stent and PTCA groups no longer achieved statistical significance.

CONCLUSIONS The original 10% absolute difference in TLR in favor of the stent group has remained unchanged at five years, emphasizing the long-term stability of the stented target site. (J Am Coll Cardiol 2001;37:1598–603) © 2001 by the American College of Cardiology

This study sought to establish whether the early favorable results in the Benestent-I randomized trial comparing elective Palmaz-Schatz stent implantation with balloon angioplasty in 516 patients with stable angina pectoris are maintained at five years.

The Benestent-I trial is a randomized study comparing elective Palmaz-Schatz (Cordis, Warren, New Jersey) stent implantation (1) with balloon angioplasty in patients with stable angina pectoris and a single de novo lesion in a native coronary artery. At seven months, a lower incidence of restenosis, as well as a lower incidence of major adverse cardiac events, was found in the stent group (2). A reduced need for repeat interventions was found at one year (3). However, stent implantation does not address the underlying disease process. Detrimental mechanisms, such as accelerated atherosclerosis at the stented site, metal corrosion and endothelial dysfunction have all been proposed as potential mechanisms of late deterioration but have, so far, not been documented.

This study sought to answer these questions from the five-year clinical follow-up status of patients included in the Benestent-I trial.

METHODS

Study patients. In the Benestent-I trial, patients with stable angina pectoris and a single de novo lesion <15 mm

From *Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands; †Erasmus University, Rotterdam, the Netherlands; ‡Hospital Clinico San Carlos, Madrid, Spain; §Universitätsklinikum Charité, Berlin, Germany; ‖Onze Lieve Vrouw Ziekenhuis, Aalst, Belgium; ¶Sahlgrenska University Hospital, Göteborg, Sweden; #Clinique Pasteur, Toulouse, France; **CHU Sart Tilman, Liège, Belgium; ††CHR Hôpital de la Citadelle, Liège, Belgium; ‡‡Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina; §§Royal Brompton & National Heart Hospital, London, United Kingdom; ‖‖Centro Cuore Columbus, Milan, Italy; ¶¶Centre Hospitalier Universitaire, Lausanne, Switzerland; and ##Cardialysis, Rotterdam, the Netherlands.
Supported by Cordis, a Johnson & Johnson Company, Warren, New Jersey.

Manuscript received June 12, 2000; revised manuscript received January 9, 2001, accepted January 24, 2001.

Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CI = confidence interval
CVA = cerebrovascular accident
MI = myocardial infarction
PTCA = percutaneous transluminal coronary angioplasty
RR = relative risk
STRESS = Stent Restenosis trial
TLR = target lesion revascularization

in length suitable for coronary stent implantation in a native coronary artery >3 mm in diameter were included.

Eligible patients were randomized to either Palmaz-Schatz stent implantation or balloon angioplasty. The stent was deployed at 10 ± 8 atm, and the stent artery ratio was 1.12 ± 0.15. A total of 516 patients were included—257 in the balloon group and 259 in the stent group. Clinical and angiographic characteristics have been previously described (2,3). The distribution of baseline characteristics was well balanced in both groups.

Procedure. The procedural technique has been described in previous reports (2,3). The 15-mm long articulated Palmaz-Schatz stent (PS 153) was used. Patients undergoing stent implantation received an infusion of Dextran (1,000 ml over 6 to 8 h) and a 10,000 IU bolus of heparin at the start of the procedure. An additional heparin bolus was given each hour during the procedure and continued for 36 h after the procedure. Oral anticoagulation with warfarin was started after sheath removal and continued for three months titrated to an international normalized ratio of 2.5 to 3.5.

Patients randomized to balloon angioplasty received a 10,000 IU bolus of heparin at the start of the procedure, and additional heparin bolus was given during prolonged procedures. Both treatment groups received a calcium antagonist during the hospitalization phase and aspirin 250 to 500 mg daily and dipyridamole, 225 mg daily, for at least six months.

Five-year clinical follow-up. Clinical information was obtained at the outpatient clinic, by telephone interview or via the referring physician. A questionnaire, which included information on occurrence and date of a primary clinical end point, anginal status according to the Canadian Cardiovascular Society classification (4) and antianginal medication, was completed.

End points. The primary clinical end points included death (regardless of cause) cerebrovascular accident (CVA) (considered hemorrhagic unless demonstrated otherwise), Q-wave myocardial infarction (MI) (new pathological Q-wave) (5) or non-Q-wave MI (an increase in serum creatine kinase levels to more than twice the upper limit of normal with a concomitant increase in myocardial isoenzyme levels), coronary artery bypass surgery or a second percutaneous coronary intervention involving the previously treated lesion for demonstrated myocardial ischemia between the time of the initial procedure and the follow-up performed at five years. All events were reviewed by the clinical events committee. When more than one clinical end point occurred in a patient, only the first event was counted for survival analysis.

Secondary clinical end points were anginal class and current medication use (calcium antagonist, beta-adrenergic blocking agent, nitrate, angiotensin-converting enzyme inhibitor and statin).

Statistical analysis. The main clinical analysis consisted of a single comparison between the two study groups (stent and balloon) with respect to primary clinical end points, regardless of the time of occurrence of these events. This analysis included all patients according to the intention to treat principle. At the outset of the study, the size of the required sample (428 patients) was based on an assumed rate of clinical events of 30% in the angioplasty group and a reduction of that by 40% in the stent group (by a two-sided test with an alpha error of 0.05 and a power of 0.80). To compensate for unsuccessful interventions and losses to follow-up, the sample was enlarged by 10% (to 470 patients). In addition, to adjust for a loss of power due to a planned interim analysis, the sample size was increased by another 10%, reaching a final size of 520 patients.

Discrete variables are expressed as counts, and percentages and were compared in terms of relative risks (RR) for stented lesions compared with balloon-dilated lesions, including 95% confidence intervals calculated by the method of Greenland and Robins (6) and Fisher's exact test. Event-free survival after stent placement or balloon angioplasty was determined by Kaplan-Meier techniques and displayed as survival curves. Comparison between curves was performed using the log-rank method.

RESULTS

Follow-up to one year. Results of the Benestent-I trial have previously been reported (2). There were no differences in baseline clinical and angiographic characteristics between the two study groups. Acute angiographic and procedural success rates were similar in the two groups. There was also no difference in the incidence of major clinical events between the groups during the hospital stay. However, bleeding and vascular complications were more frequently seen in the stent group (13.5% vs. 3.1%; RR: 4.34; 95% confidence interval (CI): 2.05 to 9.18; $p = 0.001$), who received full anticoagulation with coumadin.

At seven months, a primary clinical end point was reached in 29.6% of patients in the percutaneous transluminal coronary angioplasty (PTCA) group versus 20.1% of patients randomized to stent implantation (RR: 0.68, 95% CI: 0.50 to 0.92; $p = 0.02$). Repeat coronary angioplasty involving the treated segment was more frequent in the PTCA group (20.6% vs. 10%; RR: 0.49; 95% CI: 0.31 to 0.75; $p = 0.001$).

JACC Vol. 37, No. 6, 2001
May 2001:1598–603

At a mean follow-up of 12 months, there was no significant difference in mortality (0.8% vs. 0.8%), stroke (0% vs. 0.8%), MI (5.5% vs. 4.7%) or coronary bypass graft surgery (7.4% vs. 5.9%) between the stent and PTCA groups. A continued reduced need for repeat angioplasty procedures was found in the stent group (15.2% vs. 24.2%, p = 0. 01). No difference was found between the two groups with respect to anginal status and prescribed medication.

Five-year follow-up. Information was obtained from 511 patients included in the study who were alive at one-year follow-up. Three patients in the stent group (1.2%) and one in the PTCA group (0.4%) were lost to follow-up.

Information was obtained by visits to the outpatient clinic (77 patients; 15%), by telephone (302 patients; 60%), via the referring cardiologist (101 patients; 20%) and by other means (27 patients; 5%). All data were collected five years after the initial interventional procedure (range: 1,540 to 2,775 days).

Of the 256 patients randomized to stent implantation (three lost to follow-up), 168 (65.6%) were free of major adverse cardiac and cerebrovascular events versus 153 of the 256 (59.8%) patients randomized to PTCA (one lost to follow-up).

The rankings for major events and total counts for events are presented in Table 1. A primary clinical end point was reached in 40.2% of 256 patients in the PTCA group versus 34.4% of 256 patients randomized to stent implantation (RR: 0.85; 95% CI: 0.68 to 1.07; p = 0.20) (Fig. 1). Thus, the difference in the overall incidence of end points, which was significant at one year, did not reach statistical significance at five years.

However, the reduced need for repeat PTCA (17.2% vs. 27.3%; RR: 0.63; 95% CI: 0.45 to 0.88; p = 0.008) was maintained in the stent group. Between seven months and five years after the procedure, there were 22 additional cases of target lesion revascularization (TLR) in the PTCA group versus 21 in the stent group (total count of events).

The total mortality rate was somewhat higher in the stent group than it was in the PTCA group (5.9% vs. 3.1%; p = 0.20). While the difference in cardiac mortality was 2.7% versus 1.2% (p = 0.34), the difference in noncardiac mortality was 3.1% versus 2.0% (p = 0.58) (Table 2).

The distribution of anginal class was similar in both groups as was the use of cardiac medications at five years, except for the use of nitrates, which was significantly lower in the stent group (p = 0.002).

Table 1. Major Adverse Cardiac and Cerebrovascular Events in Descending Order of Severity and Followed by the Total Number of Events

Event	Angioplasty (n = 256)		Stent (n = 256)		Relative Risk (95% CI)
	n	%	n	%	
Death					
1 yr*	2	0.8	2	0.8	
5 yrs	8	3.1	15	5.9	
All events†	8	3.1	15	5.9	1.88 (0.81–4.34)
CVA					
1 yr*	2	0.8	0		
5 yrs	3	1.2	1	0.4	
All events†	3	1.2	2	0.8	0.67 (0.11–3.96)
Q-wave MI					
1 yr*	6	2.3	11	4.3	
5 yrs	9	3.5	18	7.0	
All events†	10	3.9	20	7.8	2.00 (0.90–4.19)
Non-Q-wave MI					
1 yr*	5	2.0	3	1.2	
5 yrs	6	2.3	4	1.6	
All events†	6	2.3	4	1.6	0.67 (0.19–2.33)
CABG					
1 yr*	14	5.5	16	6.3	
5 yrs	21	8.2	25	9.8	
All events†	25	9.8	30	11.7	1.20 (0.73–1.98)
Repeat PTCA					
1 yr*	52	20.3	28	10.9	
5 yrs	56	21.9	25	9.8	
All events†	70	27.3	44	17.2	0.63 (0.45–0.88)
Any event					
1 yr*	81	31.6	60	23.4	0.74 (0.56–0.99)
5 yrs	103	40.2	88	34.4	0.85 (0.68–1.07)

*In the paper of Macaya et al. (3), the one-year results at a mean follow-up were presented, whereas the one-year data presented in this Table are censored at 400 days.

†"All events" refers to the total count of events at five years (i.e., if a patient required repeat angioplasty and later coronary artery bypass grafting, "all events" at five years would reflect both events, not just the first that occurred).

CABG = coronary artery bypass grafting; CI = confidence interval; CVA = cerebrovascular accident; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

DISCUSSION

Summary of findings. Only four patients (0.8%) of the 511 patients included in the original Benestent study who were alive at one year were lost to follow-up at five years. Due to a change in the organization at one institution, three patients from this institution were lost to follow-up at five years, although they were seen at the outpatient clinic at one year.

This relatively large study population allows a reliable comparison in long-term outcome between coronary stent implantation and PTCA. Questionnaires were used to document and verify clinical events and symptomatic status.

In this study no significant differences were found in death, CVA, MI and coronary artery bypass grafting (CABG) rates after five years. The 10% absolute difference in TLR rate in favor of stenting versus balloon angioplasty remained unchanged at five years.

Long-term follow-up of patients treated with Palmaz-Schatz stents. RANDOMIZED TRIALS. The longest follow-up of patients randomized to PTCA or Palmaz-Schatz stent implantation reported so far has been one year for the Benestent-I study (3) and one year for the Stent Restenosis (STRESS) trial (7).

After one year, the Benestent-I study showed no significant differences in mortality, stroke, MI or CABG between the stent and PTCA groups. However, the need for a repeat

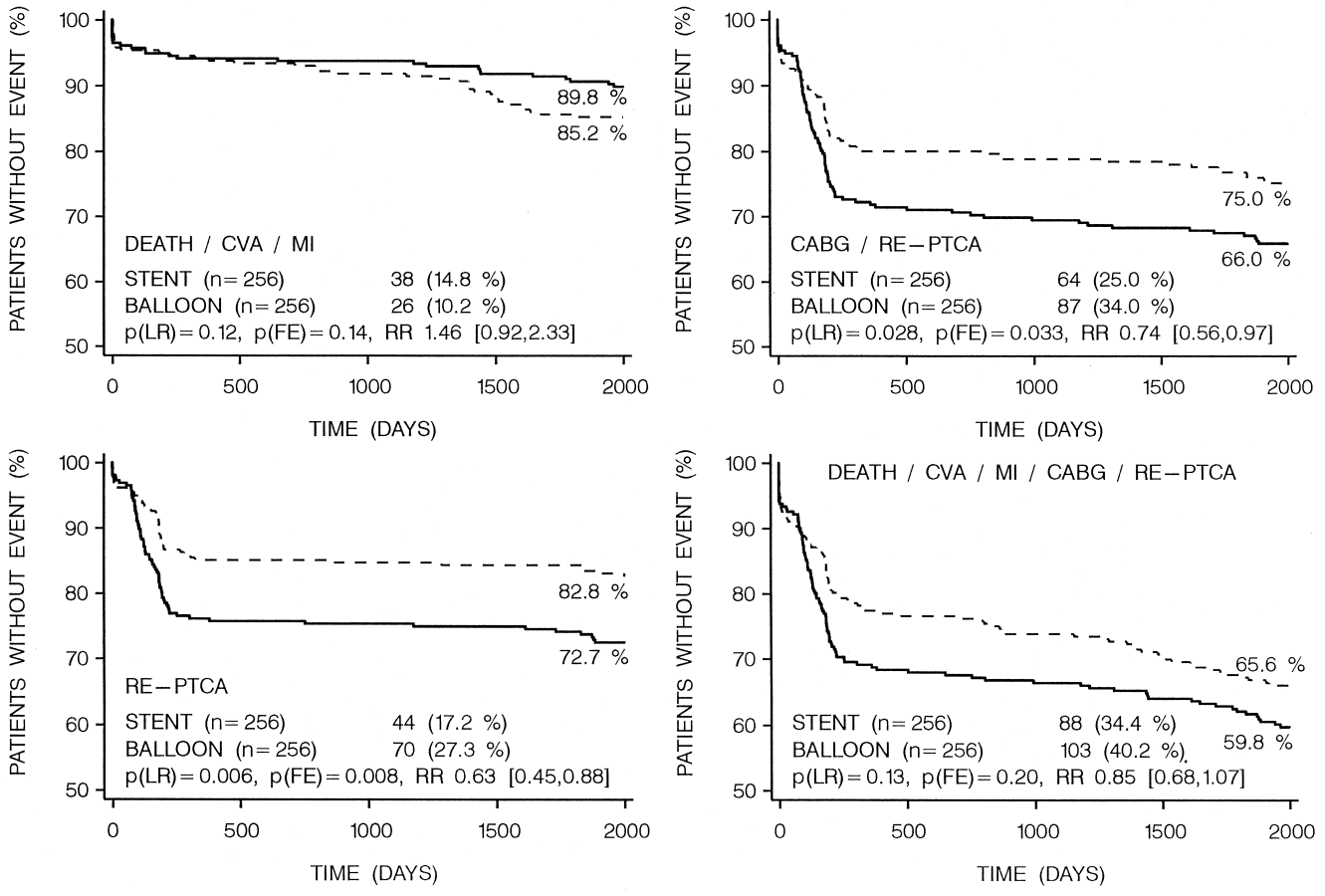

Figure 1. Five-year event-free survival of patients enrolled in the Benestent-I trial. **Left upper panel:** Kaplan-Meier event-free survival curves for death, cerebrovascular events or myocardial infarction of patients assigned to stenting **(dashed line)** versus balloon angioplasty **(solid line)**. **Right upper panel:** Kaplan-Meier event-free curves for any revascularization (CABG and re-PTCA of the target lesion) of patients assigned to stenting **(dashed line)** versus balloon angioplasty **(solid line)**. **Left bottom panel:** Kaplan-Meier event-free curves for re-PTCA of the target lesion of patients assigned to stenting **(dashed line)** versus balloon angioplasty **(solid line)**. **Right bottom panel:** Kaplan-Meier event-free survival for death, cerebrovascular events, myocardial infarction or any revascularization of patients assigned to stenting **(dashed line)** versus balloon angioplasty **(solid line)**. CABG = coronary artery bypass grafting; CVA = cerebrovascular accident; FE = Fisher's exact test; LR = Log Rank test; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; RR = relative risk.

angioplasty procedure was significantly lower in the stent group than it was in the PTCA group (15% vs. 24%, p = 0.01), and overall primary end points were less frequently reached by patients in the stent group than they were by those in the PTCA group (23.4% vs. 31.6%; p = 0.04).

In the original STRESS I (7), 407 patients with symptomatic ischemic heart disease and new lesions of the native coronary circulation were randomly assigned to treatment with either the Palmaz-Schatz coronary stent or PTCA. Ninety-seven percent of all patients had complete follow-up beyond eight months, and 94% beyond 11 months. Anginal status between 9 and 15 months after the procedure was available for 78% of patients. At one year, 154 patients (75%) assigned to stent implantation and 141 (70%) assigned to PTCA were free of all clinical events (death, MI or any revascularization procedure), and 162 stent patients (79%) and 149 PTCA patients (74%) were free from death, MI or TLR. Symptom-driven TLR occurred in 12% of the stent group versus 17% of the PTCA group. None of these differences in clinical events, which favored the stent group, reached statistical significance. Freedom from angina at one year was reported with equal frequency in both groups (84%).

Long-term follow-up of patients treated with Palmaz-Schatz stents. NONRANDOMIZED TRIALS. Klugherz et al. (8) reported on three-year clinical follow-up after Palmaz-Schatz stenting in a cohort of 65 consecutive patients who electively received Palmaz-Schatz intracoronary stents.

At a mean follow-up of 39 ± 17 months, absolute survival and event-free survival at three years were 88% and 56%, respectively. Three-year freedom from stent-site revascularization was 66%. Predictors of decreased long-term survival included diabetes and a high angina score (Canadian Cardiovascular Society class III/IV) at 6 and 12 months after stenting. Predictors of decreased event-free survival included a high angina score at 3, 6 and 12 months after stenting, smaller stent deployment balloon size and a greater number of stents implanted. Freedom from adverse events by six months after stenting also correlated with long-term event-free survival. Eighty-five percent of stent-site revascularizations occurred within one year. During

JACC Vol. 37, No. 6, 2001
May 2001:1598–603

Table 2. Causes of Death

Event	Angioplasty (n = 256)	Stent (n = 256)
Cardiac	3 (1.2%)	7 (2.7%)
Subacute occlusion	0	1 (within 30 days)*
Arrest	0	1 (acute pulmonary edema)
Myocardial Infarction	1†	2†
Sudden death	1	1
Hypovolemic shock	0	1*
Unknown	1	1
Noncardiac	5 (2.0%)	8 (3.1%)
Malignancy	1 (metastatic, unknown origin)	6 (3 lung, 1 breast, 2 ORL cancer)
Pulmonary embolism	1	1
CVA	1	1
Pulmonary disease	1	0
Suicide in prison	1*	—

*These patients have been described in detail in the original publication of Benestent-I trial (N Engl J Med 1994;331:489–95); †Clinical assessment without electrocardiogram localization.

CVA = cerebrovascular accident; ORL = othorinolaryngo carcinoma.

follow-up, the majority of adverse events and stent-site revascularizations occurred early after stenting, and disease progression in nonstented vessels accounted for the majority of late revascularization events.

Laham et al. (9) published data on the long-term (four- to six-year) outcome of Palmaz-Schatz stenting in native coronary arteries and saphenous vein coronary bypass grafts.

The study cohort consisted of 175 consecutive patients who underwent elective placement of 194 Palmaz-Schatz stents in 185 vessels. Clinical events (death, MI, recurrent angina or any revascularization) were assessed at six weeks, two, four and six months, one year and yearly thereafter. Clinical follow-up was available on all patients at a mean of 54 ± 17 months. Angiographic success was achieved in 173 patients (98.9%); angiographic restenosis was observed at six months in 26.1% of target sites. The survival rate was 86.7% at five years, with a five-year event-free survival rate decreasing progressively to 50.7%, reflecting primarily repeat revascularization procedures (41.2% at five years). However, the TLR rates were 14.4%, 17.7% and 19.8% at one, three and five years, respectively, with late (one-year) TLR for in-stent restenosis in only three patients (1.7%). Rates of both five-year survival (70.5% vs. 93.4%) and event-free survival (21.1% vs. 63.3%) were lower for patients who underwent saphenous vein graft stenting than for those with native coronary artery stenting. However, five-year TLR rates were similar for saphenous vein grafts (21.9%) and native vessels (19.2%), indicating that the higher incidence of repeat revascularization for saphenous vein grafts was due to an increase in non-TLR for progressive disease at other sites.

These studies show that the progressive increase in repeat revascularization over longer periods as well as most ongoing late events can largely be attributed to the progression of coronary disease at other sites, rather than to late deterioration of the stent result itself. These observations are concordant with our own observations in this trial.

Conclusions. The high proportion of noncardiac deaths and Q-wave MIs, potentially unrelated to the stented vessel, obscures the long-term benefit of stent implantation. Although not statistically significant, a higher percentage of patients in the stent group developed cancer. A relation between the development of malignant diseases and stent implantation seems to be very unlikely, although fluoroscopy times were probably longer in the stent group. However, beyond the censored date of 2,000 days, three cases of malignant disease were found in the PTCA group, thereby decreasing the apparent difference in the incidence of malignant disease between the two groups.

Although late migration of the stent, metal fatigue, endarteritis, late restenosis and accelerated atherosclerosis at the site of stenting have all been proposed as potential late clinical complications of coronary stent implantation, none of these putative complications manifested themselves in the current study population or in other long-term studies involving implantation of metallic coronary stents.

The long-term follow-up results of the Benestent-I trial show that the original difference of 10% in TLR observed at seven months has remained unchanged at five years, emphasizing the extraordinary long-term stability of the dilated or stented target site. However, the relatively high frequency of noncardiac deaths and Q wave MIs in the stent group, potentially unrelated to the deterioration of the target lesion, result in the difference in freedom from major cardiovascular and cerebrovascular events no longer achieving statistical significance at five years (RR: 0.85; CI: 0.68 to 1.07, p = 0.20).

APPENDIX

PRINCIPAL INVESTIGATORS AND PARTICIPATING INSTITUTIONS FOR THE BENESTENT-I TRIAL—FIVE-YEAR FOLLOW-UP

Argentina: Instituto Cardiovascular de Buenos Aires, Buenos Aires: J. Belardi, MD, R. Henquin, MD.

Belgium: CHR Hôpital de la Citadelle, Liège: P. Materne, MD, J. Boland, MD; Cliniques Universitaires de Saint-Luc, Brussels: J. Renkin, MD; Onze Lieve Vrouw Ziekenhuis, Aalst: G.R. Heyndrickx, MD; Academisch Ziekenhuis Middelheim, Antwerp: P. van den Heuvel, MD; CHU Sart Tilman, Liège: V. Legrand, MD.

France: Centre Cardiologique du Nord, Saint Denis: B. Chevalier, MD, B. Glatt, MD, P. Guyon, MD; Clinique Pasteur, Toulouse: J. Fajadet, MD, J. Marco, MD; Polyclinique Volney, Rennes: C. Bourdonnec, MD; CHR Nancy, Vandoeuvre les Nancy: N. Danchin, MD.

Germany: Christian Albrechts Universität, Kiel: R. Simon, MD; Universitätsklinikum Charité, Berlin: W. Rutsch, MD.

Ireland: St. James's Hospital, Dublin: P. Crean, MD.

Italy: Centro Cuore Columbus, Milan: A. Colombo, MD; Ospedale Maggiore, Trieste: A. Salvi, MD, L. Dreas, MD.

Spain: Hospital Clinico San Carlos, Madrid: C. Macaya, MD, L. López Ferrero, MD; Hospital Universitario Gregorio Maranon, Madrid: E. Garcia Fernandez, MD.

Sweden: Sahlgrenska Hospital, Göteborg: P. Albertsson, MD.

Switzerland: Faculté de Médécine FMH, Geneve: P. Delafontaine, MD, E. Camenzind, MD; Centre Hospitalier Universitaire de Vaudois, Lausanne: J.J. Goy, MD, E. Eeckhout, MD.

The Netherlands: Catharina Ziekenhuis, Eindhoven: J.J.R.M. Bonnier, MD; St. Antonius Ziekenhuis, Nieuwegein: E.G. Mast, MD; Onze Lieve Vrouwe Gasthuis, Amsterdam: F. Kiemeneij, MD; AZR Dijkzigt, Rotterdam: P.W. Serruys, MD, A. Wardeh, MD; Academisch Medisch Centrum, Amsterdam: K. Koch, MD; Ziekenhuis De Weezenlanden, Zwolle: H. Suryapranata, MD; Academisch Ziekenhuis Groningen, Groningen: A. J. van Boven, MD.

United Kingdom: Royal Brompton & National Heart Hospital, London: U. Sigwart, MD.

Reprint requests and correspondence: Dr. Patrick W. Serruys, Department of Interventional Cardiology, Thoraxcenter Bd 418, University Hospital Dijkzigt, Rotterdam, the Netherlands. E-mail: serruys@card.azr.nl.

REFERENCES

1. Schatz RA, Baim DS, Leon M, et al. Clinical experience with the Palmaz Schatz coronary stent: initial results of a multicenter study. Circulation 1991;83:148–61.
2. Serruys PW, de Jaegere PP, Kiemeneij F, et al. for the Benestent Study Group. A comparison of balloon expandable stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489–95.
3. Macaya C, Serruys PW, Ruygrok P, et al., for the Benestent Study Group. Continued benefit of coronary stenting versus balloon angioplasty: one-year clinical follow-up of Benestent trial. J Am Coll Cardiol 1996;27:255–61.
4. Goldman L, Hashimoto B, Cook F, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. Circulation 1981; 64:1227–34.
5. Blackburn H, Keys A, Simonson E, Rautaharju P, Punsar S. The electrocardiogram in population studies: a classification system. Circulation 1960;21:1160–75.
6. Greenland S, Robins JM. Estimation of a common effect parameter from sparse follow-up data. Biometrics 1985;41:55–68.
7. George CJ, Baim DS, Brinker JA, et al. One-year follow-up of the Stent Restenosis (STRESS I) study. Am J Cardiol 1998;81:860–5.
8. Klugherz BD, De Angelo DL, Kim BK, Herrmann HC, Hirshfeld JW, Kolansky DM. Three-year clinical follow-up after Palmaz-Schatz stenting. J Am Coll Cardiol 1996;27:1185–91.
9. Laham RJ, Carrozza JP, Berger C, Cohen DJ, Kuntz RE, Baim DS. Long-term (four- to six-year) outcome of Palmaz-Schatz stenting: paucity of late clinical stent-related problems. J Am Coll Cardiol 1996; 28:820–6.