

One-Month Results of Coronary Stenting in Patients ≥ 75 Years of Age

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Coronary artery bypass operations are associated with increased morbidity and mortality in the elderly. Similarly, it has been shown that coronary angioplasty is associated with a higher risk of complications in the elderly than in younger patients. The purpose of this study was to evaluate the 1-month outcome of elderly patients (>75 years old) who were included in the Stenting without Coumadin French Registry. From December 1992 to March 1995, 2,900 patients (mean age 61 ± 11 years) were included in this registry. All patients were treated with ticlopidine (250 to 500 mg/day) for 1 month from the day of percutaneous transluminal angioplasty, aspirin (100 to 250 mg/day) for >6 months, and low-molecular-weight heparin (antiXa 0.5 to 1 IU/ml) for 1 month in phase II, 15 days in phase III, and 7 days in phase IV. No heparin was given in phase V. The study group included 233 patients (8.0%) >75 years old (mean age 79 ± 4), 44 (18%) of whom were women. All patients underwent dilatation of a native coronary vessel. One hundred seventeen had unstable angina (50.2%), 20 had postmyocardial infarction ischemia (8.6%), and 6 had acute myocardial infarction (2.6%). Indications for stenting were de novo lesion in 63 pa-

tients (27.0%), restenosis in 38 (16.3%), suboptimal result in 48 (20.6%), nonocclusive dissection in 56 (24.0%), and occlusive dissection in 28 (12.0%), respectively. Stented coronary arteries were the left anterior descending in 109 (46.8%), the right in 80 (34.3%), the left circumflex in 40 (17.2%), and the left main in 4 (1.7%). Palmaz-Schatz stents were used in 228 patients (82.0%), AVE microstents in 38 (13.7%), and other stents in 12 (4.3%). More than 1 stent was used in 48 patients (17.3%). The mean diameter of the balloon used for stenting was 3.31 ± 0.38 mm and maximal inflation pressure was 12.2 ± 2.9 atm. At one-month follow-up, vascular complications occurred in 5 patients, requiring surgery in 2 (1.3%), acute closure occurred in 1 (0.4%), subacute closure in 3 (1.3%), emergency or planned coronary artery bypass graft surgery in none, acute myocardial infarction in 4 (1.7%), stroke in 1 (0.4%), and death in 8 (3.4%). The composite end point of a major cardiac event was observed in 13 cases (5.6%). Coronary stenting using ticlopidine and aspirin appears to be a particularly safe approach in this high-risk subset. ©1998 by Excerpta Medica, Inc.

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Percutaneous transluminal coronary angioplasty is associated with an increased risk of complications in elderly patients.¹⁻⁹ However, advances in coronary angioplasty equipment and greater operator experience have led to a gradual improvement in the acute and midterm results. The recent development of coronary stenting has played a major role in the decrease of the complication rate related to coronary angioplasty in this setting.¹⁰

The present study assesses retrospectively the outcome of coronary stenting in the subgroup of patients >75 years old included in the Stenting without Coumadin French Registry.¹¹

METHODS

In all, 2,900 consecutive patients were included between December 1992 and March 1995. Twenty-five centers participated in this nonrandomized study. Patients with unstable angina, acute or recent myocardial infarction, reduced ejection fraction, previous history of myocardial infarction, coronary artery bypass graft

surgery, or previous coronary angioplasty were not excluded from this study. Conversely, patients with contraindications to anticoagulation or antiplatelet treatment such as uncontrolled arterial hypertension, gastroduodenal ulcer, documented bleeding complications, or allergy to aspirin or ticlopidine were not eligible for stent placement and were therefore excluded from the study. The study included elective stenting (de novo lesion, restenosis, angioplasty of vein graft) and nonelective stenting (dissection, elastic recoil, emergency procedure). No specific selection was made as to morphology, lesion location, or type of artery stented; the decision was left entirely to the clinician's judgment. The only restriction involved stent placement in arteries <3 mm except in emergency cases. This study was performed in the form of a multicenter registry not providing for independent angiographic analysis. However, because most of the centers were equipped with quantitative coronary angiography, optimal balloon size was adapted to the dilated artery and to the percentage of residual stenosis after stent implantation.

Definitions: Unstable angina was defined as rest angina or recent aggravation of stress angina. Stable angina was documented by stress test and/or thallium scan. Nonocclusive dissections were defined as type A,B,C, or D1 of the National Heart, Lung, and Blood

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Institute classification. Bailout situations were defined as clinical or angiographic ischemia associated with type D2, E, F dissection or Thrombolysis In Myocardial Infarction trial flow <2. Major complications at 1-month follow-up included death, Q- or non-Q-wave myocardial infarction with creatine phosphokinase elevation >3 times the normal value, urgent or elective coronary artery bypass graft surgery, and repeat coronary angioplasty at the same site. In the absence of angiographic control of the stented artery, subacute occlusion was defined as the occurrence of sudden death or clinical symptoms of infarction associated with changes in the electrocardiogram or with a significant creatine phosphokinase elevation during the first month of follow-up. Severe local complications were defined as the occurrence of hematoma, pseudoaneurysm, arteriovenous fistula, or retroperitoneal hematoma requiring surgical repair or blood transfusion.

Protocol: Angioplasty was performed using the standard technique. When starting the procedure, a bolus of 7 to 10,000 IU of heparin was given intravenously in combination with 250 mg of aspirin in patients not pretreated with aspirin. The femoral approach was selected in most of the patients using 6Fr to 9Fr guiding catheters. The radial approach was used in only 2.6% of the patients with 6Fr guiding catheters. Pre- and postprocedural intracoronary vasodilators were routinely administered.

The lesion was predilated with a balloon of appropriate size and the stent was delivered using a balloon with a 1.1 to 1.2 ratio to the vessel reference size. In most patients, a Palmaz-Schatz stent was hand-crimped onto the predilation balloon. Stents were deployed at a minimal inflation pressure of 10 atm. The arterial sheath was removed 4 to 24 hours after the procedure depending on the activated clotting time level.

The primary objective of this registry was to assess the benefit of replacing antithrombotic treatment with an optimal antiplatelet treatment combining ticlopidine and aspirin. Low-molecular-weight heparin therapy was initially associated with this treatment, but its duration was gradually reduced from phase 2 to phase 5. After the procedure, 250 mg of ticlopidine per day was administered to patients <85 kg body weight and 500 mg/day to patients >85 kg body weight for 1 month. One hundred mg of aspirin was administered daily. One hundred units per kg of low-molecular-weight heparin were administered twice a day for 1 month in phase 2, 15 days in phase 3, and 7 days in phase 4. In phase 5 of the study, patients did not receive any low-molecular-weight heparin treatment. In patients treated with low-molecular-weight heparin, antiXa activity was measured at day 3 and 1 week later with an objective of 0.5 to 1 IU/ml. Hematologic control including blood count, platelet count, and liver enzymes was performed at 15 days in all patients.

Statistical analysis: Data included baseline characteristics of patients, information on coronary angioplasty procedure, and in-hospital follow-up. One-month follow-up was obtained in all patients. Detailed audit charts were sent to the coordinating center at

TABLE I Indication, Type, and Location of Stent Implantation

| | |
|----------------------------|-------------|
| Indication | |
| De novo lesion | 63 (27.0%) |
| Restenosis | 38 (16.3%) |
| Nonocclusive dissection | 56 (24.0%) |
| Occlusive dissection | 28 (12.0%) |
| Suboptimal result | 48 (20.6%) |
| Stented coronary arteries | |
| Left anterior descending | 109 (46.8%) |
| Right coronary artery | 80 (34.3%) |
| Circumflex coronary artery | 40 (17.2%) |
| Left main trunk | 4 (1.7%) |
| Stent number and type | |
| Stent (per patient) | 1.23 ± 0.47 |
| 1 stent | 230 (82.7%) |
| 2 stents | 43 (15.5%) |
| >2 stents | 5 (1.8%) |
| Palmaz-Schatz | 228 (82.0%) |
| AVE microstent | 38 (13.7%) |
| Cook stent | 9 (3.2%) |
| Wiktor stent | 3 (1.1%) |
| Balloon diameter (mm) | 3.31 ± 0.38 |
| Maximal pressure (atm) | 12.2 ± 2.9 |

1-month follow-up or in the case of major events. Statistical analysis was performed using SAS 6.08 software. Data were summarized using the means and SDs for continuous variables and frequency for categorical variables.

RESULTS

Of the 2,900 patients included in the registry, 233 (8.0%) ≥75 years of age (mean age 79 ± 4) underwent dilatation of a native coronary vessel; 44 (18.9%) were female. Ninety patients had stable angina (38.6%), 117 had unstable angina (50.2%), 20 had postmyocardial infarction ischemia (8.6%), and 6 had acute myocardial infarction (2.6%). Indications, type, and location of stent implantation are listed in Table I. Stents were used mainly for “de novo” lesions (27.0%) and 82.0% were Palmaz-Schatz stents. The mean diameter of balloons used for stent delivery was 3.31 ± 0.38 mm and maximal pressure for stent deployment was 12.2 ± 2.9 atm. Stented arteries were the left anterior descending in 46.8% of patients, the right in 34.3%, the circumflex in 17.2%, and the left main in 1.7%.

Patients’ baseline characteristics across the various phases are summarized in Table II. The proportion of patients with unstable angina and the proportion of stenting procedures in de novo lesions increased during the course of the study, whereas a significant decrease was observed in emergency stenting for occlusive dissection.

The 1-month outcome is shown in Table III. Mean hospital stay was 5.7 ± 5.6 days (5.1 ± 3.8 in patients without major complications). Major cardiac events (combining death, myocardial infarction, elective or urgent coronary artery bypass graft surgery, subacute or acute occlusion) occurred in 5.6% of patients.

Patient inclusion rate, use of Palmaz Schatz stents, and selection of guiding catheter size for angioplasty through the various phases are summarized in Figure

TABLE II Major Characteristics of Patients Included in the Various Phases

| | Phase* | | | |
|--------------------------|------------|------------|------------|-------------|
| | 2 | 3 | 4 | 5 |
| Patients | 9 (3.9%) | 28 (12.0%) | 76 (32.6%) | 116 (49.8%) |
| Age (yr) | 77.5 ± 2.1 | 78.7 ± 2.8 | 79.4 ± 4.1 | 78.8 ± 3.5 |
| Unstable angina (%) | 4 (44.4%) | 12 (42.9%) | 42 (55.3%) | 59 (50.1%) |
| De novo stenting (%) | 1 (11.1%) | 3 (10.7%) | 14 (18.4%) | 45 (38.8%) |
| Occlusive dissection (%) | 2 (22.2%) | 8 (28.6%) | 13 (17.1%) | 5 (4.3%) |

*Phase 2 = low-molecular-weight heparin for 1 month; phase 3 = low-molecular-weight heparin for 15 days; phase 4 = low-molecular-weight heparin for 7 days; phase 5 = no low-molecular-weight heparin.

TABLE III Clinical Outcome (1-month follow-up)

| | |
|------------------------------|-----------|
| Leukopenia | 0 |
| Allergy to ticlopidine | 1 (0.4%) |
| Access site complication | 5 (2.1%) |
| Blood transfusion | 2 (0.9%) |
| Surgery | 3 (1.3%) |
| Acute closure | 1 (0.4%) |
| Subacute closure | 3 (1.3%) |
| Acute myocardial infarction | 5 (2.1%) |
| Q-wave MI | 4 (1.7%) |
| Non-Q-wave MI | 1 (0.4%) |
| Emergency CABG | 0 |
| Stroke | 1 (0.4%) |
| Death | 8 (3.4%) |
| Composite end point | 13 (5.6%) |
| Hospital stay after PTCA (d) | 5.7 ± 5.6 |

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

1. The rate of Palmaz Schatz stents decreased significantly from 92% in phase 2 to 69% in phase 5 ($p < 0.001$). The rate of < 8 Fr guiding catheters used during the procedure increased from 41% in phase 3 to 86% in phase 5 ($p < 0.001$). Data regarding complications and hospital stay through the various phases are shown in Figure 2. The rate of access site complications decreased from 5.4% in phase 2 + 3 to 1.5% in phase 4 + 5. The composite end point decreased significantly from 11.1% in phase 2 to 1.7% in phase 5 ($p < 0.01$). Similarly, the hospital stay after stent placement decreased from 8.3 ± 2.4 days in phase 2 to 4.0 ± 3.6 days in phase 5 ($p < 0.01$). A similar trend was observed in patients without in-hospital complications (8.24 ± 5.04 in phase 2 vs 3.95 ± 3.54 days in phase 5, $p < 0.01$).

DISCUSSION

We are increasingly faced with the problem of elderly patients^{12,13} showing more severe, complex, multiple, and calcified coronary artery lesions than young patients.^{14–16} Numerous studies have shown that coronary angioplasty in this subset involves a higher risk of acute complications than found in younger patients. The risk of acute Q-wave myocardial infarction in patients > 75 years ranges from 1.3% to 6.7%, and the risk of emergency coronary artery bypass graft surgery between 0.9% to 3.6%.^{17–24} The in-hospital death

rate ranges from 1.9% to 6.2%, whereas the 30-day mortality rate was 5.8% in the more recent series of Peterson et al²⁵ including 61,449 patients. Surgical treatment in this high-risk setting is associated with an in-hospital death rate between 5% and 8% and a risk of myocardial infarction or stroke of 5%.^{26–28} The 30-day mortality rate was 8.4% in the Peterson series including 94,481 patients.

The present study demonstrates that coronary stenting in elderly patients results in a dramatic improvement of the midterm outcome, with a 5.6% cumulative complication rate at 1-month follow-up. This good 1-month outcome will probably be reflected in the 6-month follow-up, with a lower event rate, especially for the target vessel revascularization rate as in other studies using stents. The population of patients involved in this study was not selected because most patients had unstable or post-myocardial infarction angina and a mean age of 79 ± 4 years. This population is very comparable to those of previous studies on coronary angioplasty.

The vascular complication rate was extremely low in this series probably due to the frequent use of small-size guiding catheters and to the absence of anticoagulation with warfarin. Comparison between the various phases of the study showed a significant decrease in the access site complication rate and the duration of hospital stay in parallel with reduction in the duration of low-molecular-weight heparin treatment. This was also probably related to the increasing use of small-size guiding catheters (6Fr: 59% in phase 3, 86% in phase 5; $p < 0.01$). The ticlopidine-aspirin combination also resulted in a reduction in the risk of subacute occlusion (down to 1.3%) and of acute myocardial infarction (Q-wave myocardial infarction, 1.7%; non-Q-wave myocardial infarction, 0.4%). Adverse effects associated with ticlopidine were negligible. No cases of leukopenia were observed at 30-day follow-up. A cutaneous rash related to ticlopidine was observed in 1 patient (0.4%), but it was reversible despite maintenance of the treatment.

Throughout the registry, the inclusion rate of elderly patients gradually increased from 5% to 10% (Figure 2). Conversely, the proportion of de novo stent implantation increased from 11% to 39%, whereas indications for occlusive dissections decreased from 22% to 4%. This was associated with a progressive shortening of hospital stay.

APPENDIX

Participating centers and principal investigators: Clinique Bois de Verrières: Antony Marie Claude Morice, MD, Pierre Dumas, MD; Centre Cardiologique du Nord, Saint Denis: Bernard Chevalier, MD, Thierry Royer, MD, Bernard Glatt, MD; Clinique Volney, Rennes: Claude Bourdonnec, MD, Yves Biron, MD, Christian Descaves, MD, Philippe Druelles, MD; Clinique Pasteur, Toulouse: Jean Marco, MD, Jean Fajadet, MD; GCV, Lyon: Philippe Gaspard, MD, Yves Lienhart, MD, Edgar Benveniste, MD; UCV, Marseille: Bernard Valeix, MD, Pierre Labrunie, MD; Clinique Saint Vincent, Besançon: René Faivre, MD, Pierre-Yves Petiteau, MD; Résidence du Parc, Marseille: Patrick

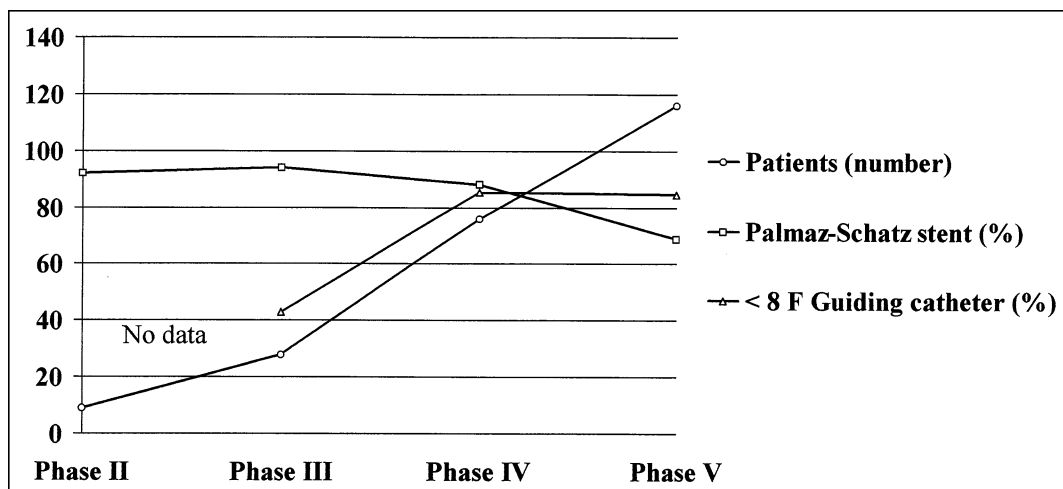


FIGURE 1. Number of patients, proportion of Palmaz-Schatz stents, and <8Fr guiding catheters through the various phases.

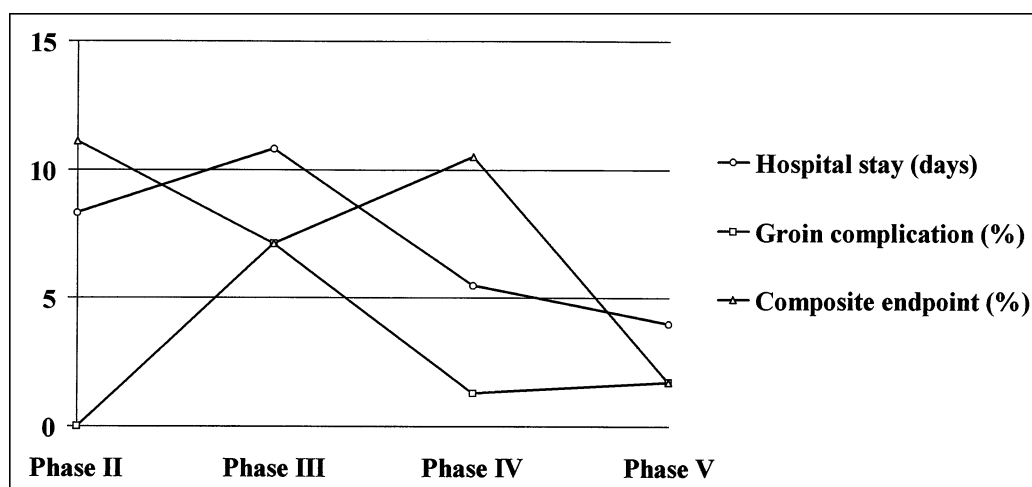


FIGURE 2. Results through the various phases.

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