Four-Year Experience With Palmaz-Schatz Stenting in Coronary Angioplasty Complicated by Dissection With Threatened or Present Vessel Closure

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Background Abrupt vessel closure after percutaneous transluminal coronary angioplasty (PTCA) is associated with major adverse events. Different surgical and nonsurgical approaches have been advocated to treat or prevent this complication. This study summarizes our 4-year experience with Palmaz-Schatz stenting for the management of 339 patients with present or threatened occlusion after PTCA.

Methods and Results Stent implantation was attempted in a total of 339 of 4959 patients with PTCA during the study period and was successful in 327 (96.5%). During the follow-up, events like death, myocardial infarction, need for revascularization (bypass surgery and repeat-in-stent angioplasty), and major vascular complications were recorded. Angiographic follow-up at 6 months was performed in 89.3% of the eligible patients. As part of an initial policy, stenting was intended as a bridge to nonemergency bypass surgery in 26 patients. In 301 patients for whom stenting was intended as permanent treatment, early clinical course (first 4 weeks) was characterized by a 1.3% cardiac mortality and a 4.0% nonfatal myocardial infarction rate; bypass surgery was necessary in 1%, and 6.3% required early repeat PTCA. Surgical repair for peripheral vascular complications was required in 5.6%, and major bleeding events were encountered in 9%. The incidence of subacute stent closure was 6.9%, with subsequent recanalization successful in 86%; subacute stent closure was predicted by presence of vessel occlusion before stenting and localization of the stent in a vessel other than the right coronary artery. Survival rate at 2 years was 95.4%, survival without myocardial infarction was 91.1%, and event-free survival was 70.7%. Survival at 2 years was lower for patients with stents in bypass vein grafts and with myocardial infarction after stenting. Six-month control angiography revealed a restenosis rate of 29.6%.

Conclusions Patients with present or threatened occlusion after PTCA may benefit from Palmaz-Schatz stenting. It is associated with a low mortality and myocardial infarction rate and with a long-term event-free rate comparable to that of uncomplicated PTCA. (Circulation. 1994;90:2716-2724.)

Key Words • stents • angioplasty • surgery • coronary disease

Abrupt vessel closure is a serious complication of percutaneous transluminal coronary angioplasty (PTCA) occurring in up to 11% of patients.1-8 It bears a mortality rate of 8% and a 20% rate of myocardial infarction, as reported in a recent study.6 Coronary wall dissection during PTCA is the strongest predictor of subsequent vessel closure.9-11 For many years, emergency coronary bypass surgery (CABG) has been the only approach for patients with acute coronary occlusion after PTCA. Emergency CABG, however, bears a substantially higher perioperative risk than elective surgery,12-16 with a recently reported 6.4% mortality rate and a myocardial infarction rate of 40%.17 Furthermore, maintaining a standby for emergency CABG during PTCA is associated with high costs.18

As an alternative to emergency CABG, thrombolytic therapy,19 prolonged inflations with oversized balloons,20 perfusion balloon catheters,21,22 atherectomy,23 and laser angioplasty24 have been advocated to treat major coronary dissections and abrupt vessel closure after PTCA.6,25 Sigwart et al26 were the first to report a promising efficacy of coronary stenting as a bailout for present or threatened vessel closure after PTCA. Since then, a number of clinical studies have confirmed these favorable initial results, with primary success rates >90% for Gianturco-Roubin stents27 and Palmaz-Schatz stents.28 Despite these promising initial results, concern remains about the early complications and the uncertain long-term clinical outcome of patients with coronary stents. In the present study, we therefore intended to evaluate the short- and long-term utility of the Palmaz-Schatz stent in patients with dissection and present or threatened occlusion after PTCA, extending the clinical follow-up of a large group of patients to 2 years.

Methods

Study Population A total of 4959 PTCA procedures were performed within a 4-year study period from June 1989 to June 1993 at the three centers (Heidelberg, June 1989 through April 1992; the Tech-
nische Universität München, May 1992 through June 1993; and the Ludwig-Maximilians-Universität München, January 1991 through June 1993). Three hundred thirty-nine patients without acute myocardial infarction had PTCA in vessels >2.5 mm complicated by a coronary dissection with progressive lumen narrowing of >75% or by complete vessel closure despite repeated balloon inflations. In all of them, the placement of at least one Palmaz-Schatz stent (Johnson & Johnson) was attempted. Before every angioplasty procedure, detailed information was given to all patients about stenting as an alternative approach for dealing with a complicated PTCA, the special management required, and the inherent risks. All patients enrolled had given written consent for the potential use of this device.

**Coronary Angioplasty and Stenting Procedure**

PTCA was performed with standard fixed-wire or “monorail” balloon catheters. The selection of the type was at the operator’s discretion, with a priority for “monorail” catheters for lesions considered to have a higher risk for dissection and closure. Standard medication for the intervention included an initial intra-arterial dose of 1.5 mg of Hept in addition 5000 IU uro procedures longer than 1 hour. Aspirin 500 mg was injected during angioplasty.

Once a significant dissection was noted on the angiogram, repeat balloon dilations with longer inflation time and eventually bigger balloon size were used. The decision to stent was taken only if these measures had failed to ensure a stable and satisfactory result. The guide wire was left in situ, and the operator proceeded with the preparation of the stent balloon assembly. A commercially available stent delivery system (Johnson & Johnson) was used in only 2%. The stent was otherwise hand-crimped onto the angioplasty balloon. The balloon-stent assembly was advanced through 8F and ultimately 7F guiding catheters appropriately selected to offer a sufficient backup support. To ensure exact positioning despite the low radiographic opacity of the Palmaz-Schatz stent, specially designed balloons with radiopaque markers at both balloon ends were used after 1991 (Dual Express, Scimed Life Systems). After initial deployment, the stent was frequently further dilated by an additional balloon inflation(s). After removal of the balloon catheter and the guide wire, contrast injections were performed to assess the final result of the stent implantation in multiple projections. The arterial sheath was removed within the first 3 hours after the intervention. Manual compression of the groin was carried out as long as necessary for local hemostasis, followed by pressure bandage. Heparin infusion was restarted immediately after pressure bandage application and titrated to maintain the partial thromboplastin time (PTT) >100 seconds. Therapy with a vitamin K antagonist (Marcumar, Hoffmann-La Roche) was begun on the day of the intervention. Heparin infusion was continued for 7 to 10 days until a stable level of oral anticoagulation was achieved (an international normalized ratio [INR] between 3.5 and 4.5 for protrombin time). The vitamin K antagonist was given for 6 to 8 weeks. All patients were taking aspirin 100 mg/d indefinitely, while continuing their usual therapy.

**Follow-up Protocol After Stenting**

A bed rest regimen was enforced for 72 hours after the intervention. The pressure bandage was then removed from the groin. Patients remained under close clinical, ECG, and laboratory (for enzymatic and coagulation status control) observation for at least 14 days. During the in-hospital stay, control angiography was performed in patients with suspected myocardial ischemia. The femoral puncture site was routinely monitored to assess local vascular complications, and color-flow Doppler ultrasonography was regularly performed on the third and the last hospital days. After discharge, patients were scheduled to return after 8 weeks for exercise testing and at 6 months for control angiography.

Early repeat angiography was performed in case of recurrent symptoms and/or signs of ischemia during exercise testing. Patients were contacted at least twice yearly, either during a regular visit or by phone. All adverse events (see definitions below) such as death, myocardial infarction, subacute stent occlusion, hemorrhagic complications, local vascular complications, and repeated revascularization procedures occurring within a period up to 2 years after stent placement were entered into a computer database.

**Definitions**

Marked irregularity of the vessel wall, a luminal filling defect suggestive of intimal flap, or extravasation of contrast outside the lumen after dilatation were interpreted as angiographic evidence of coronary dissection. Threatened occlusion was considered when contrast material injections in the coronary artery disclosed a progressive lumen narrowing with a residual stenosis >75% despite multiple balloon inflations. Vessel closure was defined angiographically as TIMI grade 0 or 1 flow. The intervention was considered successful when the stent could be deployed at the desired site, leaving a residual stenosis <50%. Any death for which an extracardiac cause could not be identified was considered of cardiac origin. The diagnosis of myocardial infarction was made in the presence of new pathological Q waves (>0.04 second) in ECG or an increase of creatine kinase (CK) more than twice the upper normal limit with an elevated CK-MB fraction, or both. Subacute stent occlusion was defined as occlusion of the stented vessel occurring within the first 4 weeks after the intervention. Hemorrhagic complications included intracranial bleeding and all bleedings requiring transfusion of any other origin recorded during the period of anticoagulation. The diagnosis of late neointimal hyperplasia and arteriovenous fistula was always based on color-flow Doppler ultrasonography. The early poststenting period was defined as the first 4 weeks after the procedure.

**Quantitative Coronary Angiography**

Quantitative analysis was performed as previously described with an automated computer-based system. This technique has an inherent variability for serial measurements of 0.06±0.30 mm for minimal luminal diameter and 0.09±0.28 mm for normal reference diameters. For analysis, the projection was chosen before and after the intervention, which showed the highest grade of stenosis. Acute lumen gain was defined as the difference between the minimal luminal diameter before and after the intervention. Late lumen loss was measured as the difference between the minimal luminal diameter immediately after the intervention and at control angiography. The loss index was calculated as ratio of late lumen loss to acute lumen gain. Restenosis was defined as a diameter stenosis ≥50% at control angiography.

**Statistical Analysis**

Continuous variables are expressed as mean±SD. To define the clinical, angiographic, and procedural variables for subacute occlusion, univariate and multivariate analyses were performed. Univariate analysis consisted of a two-tailed t-test for categorical variables and two-tailed t-test for continuous data. Variables with a value of P<.15 from univariate testing were entered into stepwise logistic regression analysis (SPSS for Macintosh version 4.0). Overall survival and event-free survival (no myocardial infarction or repeat revascularization) were assessed by the Kaplan-Meier method. Cox model analysis was used to identify the correlates of survival (BMDP Statistical Software). Values of P<.05 were considered significant.

**Results**

Stent implantation was attempted in 6.8% of the PTCA procedures. Table 1 lists the main characteristics
TABLE 1. Characteristics of Patients With Stent as Definitive Therapy

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of Patients</th>
</tr>
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<tbody>
<tr>
<td>No. of patients</td>
<td>301</td>
</tr>
<tr>
<td>Sex, M/F</td>
<td>229/72</td>
</tr>
<tr>
<td>Age, y, mean±SD (range)</td>
<td>60.6±9.8 (36-83)</td>
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<tr>
<td>Active smokers, n</td>
<td>99</td>
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<tr>
<td>Hypercholesterolemia, n</td>
<td>181</td>
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<tr>
<td>Systemic hypertension, n</td>
<td>168</td>
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<tr>
<td>Diabetes mellitus, n</td>
<td>57</td>
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<tr>
<td>Prior myocardial infarction, n</td>
<td>121</td>
</tr>
<tr>
<td>Reduced LV function (ejection fraction &lt;50%), n</td>
<td>43</td>
</tr>
<tr>
<td>Unstable angina, n</td>
<td>116</td>
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<tr>
<td>Multivessel disease, n</td>
<td>172</td>
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<tr>
<td>Prior PTCA, n</td>
<td>80</td>
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<tr>
<td>Vessel occluded before stenting, n</td>
<td>42</td>
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<tr>
<td>Stent localization, n</td>
<td></td>
</tr>
<tr>
<td>LCA</td>
<td>1</td>
</tr>
<tr>
<td>LAD</td>
<td>138</td>
</tr>
<tr>
<td>LCx</td>
<td>38</td>
</tr>
<tr>
<td>RCA</td>
<td>105</td>
</tr>
<tr>
<td>Bypass</td>
<td>19</td>
</tr>
<tr>
<td>Multiple-stent patients, n</td>
<td>38</td>
</tr>
</tbody>
</table>

LV indicates left ventricular; PTCA, percutaneous transluminal coronary angioplasty; LCA, left main coronary artery; LAD, left anterior descending coronary artery; LCx, left circumflex coronary artery; and RCA, right coronary artery.

of these patients. In 85%, the indication for stenting was progressive dissection; in 15%, the preceding angioplasty had led to acute vessel closure. The majority of patients had multivessel disease, and the target lesion was situated predominantly in the left anterior descending artery (LAD).

Failures of Stent Deployment

The attempt to place the stent at the desired position was unsuccessful in 12 patients (3.5%; mean age, 61.6±8.1 years; 75% males; Fig 1). The vessel involved was the LAD in 6 patients, the left circumflex artery in 3, and the right coronary artery in 3; other baseline characteristics did not differ from the whole group. In 7 patients, the undeployed stent could be withdrawn successfully. In 1 patient, the stent was dislodged from the balloon catheter before reaching the lesion in the mid LAD; entrapped in the proximal LAD, the stent had to be dilated in this position, still protruding into the left main stem. In the remaining 4 patients, a peripheral embolization of the stent was not associated with clinical sequelae during the follow-up.

Ten of the 12 patients were managed with conservative treatment, while 2 were sent to emergency CABG (1 died the day after surgery, and 1 suffered nonfatal myocardial infarction after operation). A total of 5 patients demonstrated signs of nonfatal myocardial infarction; 4 were treated conservatively, and 1 was sent to CABG. In this patient, the stent had been dislodged in the proximal LAD/main stem as described above; he was the patient who died the day after surgery. The later course of all surviving patients was uneventful. In summary, a failed intervention was associated with a 50% rate of major events.

Stenting With Adjunct Bypass Surgery

Successful stent implantation was achieved in 327 patients (96.5%). Although the stenting was considered successful according to our definition, 26 (8%) of these patients were sent to nonemergency bypass surgery, generally within the first week after the placement of the stent(s), for two reasons. (1) During the initial period of this study, the uncertainty about the risk of subacute stent occlusion led us to use stenting as a bridge to bypass operation for patients with proximal lesions (mostly in the LAD) with substantial jeopardized myocardial area. (2) In a few patients, the decision for bypass surgery was made because the angiographic appearance of the stented lesion suggested a higher risk of occlusion: coronary dissection not covered in its full length by the stent, a hazy appearance of the stented segment, or evidence that a substantial portion of the stent protruded into the left main coronary artery. The patients with adjunct surgery constituted 16.7% of those with successful stent implantation for the first 2 years and only 2.9% for the last 2-year period of the study. The mean age of this group was 61.2±7.5 years, and 85% were men. In 77% of the patients, the stented lesion was situated in the LAD (as a consequence of our initial strategy). Two or more consecutive stents were placed in 4 patients. Otherwise, these patients did not differ from the whole group. During the interval to surgery, no signs of stent occlusion and/or myocardial infarction were encountered. Three patients presented evidence of postoperative myocardial infarction (11.5%); 1 died 5 days after surgery (4.0%). One noncardiac death due to sepsis after surgery for a renal tumor was noted during the later 2-year follow-up.

Stenting as Stand-Alone Therapy

In 301 patients with successful placement, no adjunct bypass surgery was planned the day of the intervention. These patients were a mean of 60.6±9.8 years old, and 76% were men. In 38 patients, two or more stents were needed to cover the dissection.
Clinical, angiographic, and procedural characteristics of the patients with subacutec occlusion are illustrated in Table 2, together with the results of univariate analysis regarding the incidence of subacute closure. Stepwise logistic regression (final model with a value of P = .02) demonstrated that vessel occlusion before stenting increased the likelihood of subacute closure after stenting, whereas the localization of the stent in the right coronary artery was associated with a lower risk for this event.

**Vascular Complications**

Bleeding, pseudoaneurysm, or arteriovenous fistula was encountered in 91 patients (30.2%), requiring surgical correction in 17 (5.6%); 3 for bleeding, 4 for pseudoaneurysm, and 10 for a combination of both. Bleeding events were found in 27 patients (9%) (Table 3). These complications or the intended surgery compelled discontinuation of the anticoagulation therapy in 5 patients, with subsequent stent occlusion in 3. There were 2 intracranial bleedings with permanent neurologic sequelae in 1 patient. Pseudoaneurysm was diagnosed by duplex sonography in 70 patients (23%), and arteriovenous fistula was observed in 5 (1.7%).

In summary, major cardiac events after successful stenting in this early phase were noted only in the 21 patients with subacute stent occlusion: in total, there were 4 deaths (early cardiac mortality rate, 1.3%); 12 nonfatal myocardial infarctions (early myocardial infarction rate, 4.0%), 3 nonemergency bypass surgical interventions (1%), and 19 repeated angioplasty procedures (6.3%). Seventeen patients needed a surgical intervention for vascular complications (5.6%). One additional noncardiac death was documented (occlusive mesenteric infarction, with autopsy confirming patency of the stented vessel).

**Late Follow-up**

Clinical data on follow-up were collected for up to 2 years; the median observation period was 566 days.

**Fatal Events**

After the first 4 weeks, there were an additional 8 deaths, 5 of cardiac and 3 of noncardiac origin. Autopsy in the latter 3 patients confirmed ruptured aneurysm of the abdominal aorta 6 weeks after stenting in 1, bronchial carcinoma with diffuse metastases 8 months after stent placement in another, and ischemic stroke 10 months after stenting in the third. Thus, for the whole observation period, there were, in total, 13 deaths, 4 with documented extracardiac origin. The overall survival rate was 96.7% at 6 months and 95.4% at 2 years (Fig 4). Variables such as age, sex, risk factors for coronary artery disease, multivessel involvement, unstable angina before stenting, previous PTCA, previous myocardial infarction, vessel occlusion before stenting, stent location, multiple stenting, subacute occlusion, and vascular complications were tested for association with survival by means of the Cox proportional-hazards model. The event of death was more likely to occur in patients with the stent located in bypass vein grafts (P = .006) and those with acute myocardial infarction after stenting (P = .001).

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**Early Poststenting Period**

Subacute stent occlusion occurred in 21 patients (6.9%) 2 to 22 days after the procedure (Fig 2). In 19 patients, diagnosis was confirmed by angiography. In the 2 others, the localization of associated myocardial infarction corresponded to the stented vessel; this was confirmed by autopsy in 1 of them. The immediate clinical course of these 21 patients is illustrated in Fig 3. Recanalization of the occluded vessel with PTCA or PTCA plus intracoronary thrombolysis was attempted in 19 patients. In 3 of 17 surviving patients, early nonemergency coronary bypass operation was performed. Four of 21 patients with subacute occlusion died; nonfatal myocardial infarction was observed in 12 patients. In 3 patients, stent occlusion occurred after anticoagulation therapy was discontinued because of bleeding complications; in 6, PTT and INR suggested a suboptimal anticoagulation level; and in 12, PTT and INR were within the desired range. Angiography demonstrated stent thrombosis in 17 of 19 patients, while in the remaining 2, progression of the initial dissection had led to vessel closure located outside the stent body.

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**Fig 2.** Chart displaying the occurrence of subacute stent occlusions and bleeding complications. The hatched bars present the patients in whom progression of dissection outside the stent body was considered to be the cause of occlusion.

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**Fig 3.** Chart showing recanalization attempts for subacute closure. Pts indicates patients; PTCA, percutaneous transluminal coronary angioplasty; AMI, acute myocardial infarction; and Σ, summation.
### TABLE 2. Univariate Analysis for Occurrence of Subacute Stent Occlusion: Clinical, Angiographic, and Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>With Subacute Occlusion (n=21)</th>
<th>Without Subacute Occlusion (n=280)</th>
<th>Univariate P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men, %</td>
<td>91</td>
<td>75</td>
<td>.109*</td>
</tr>
<tr>
<td>Age, y, mean±SD</td>
<td>61.3±11.5</td>
<td>60.5±9.7</td>
<td>.733</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>19</td>
<td>34</td>
<td>.168</td>
</tr>
<tr>
<td>Hypercholesterolemia, %</td>
<td>62</td>
<td>60</td>
<td>.843</td>
</tr>
<tr>
<td>Systemic hypertension, %</td>
<td>67</td>
<td>55</td>
<td>.283</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>19</td>
<td>19</td>
<td>.962</td>
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<tr>
<td>Prior myocardial infarction, %</td>
<td>57</td>
<td>39</td>
<td>.101*</td>
</tr>
<tr>
<td>Reduced LV function, %</td>
<td>25</td>
<td>18</td>
<td>.420</td>
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<tr>
<td>Unstable angina, %</td>
<td>43</td>
<td>51</td>
<td>.468</td>
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<td>Multivessel disease, %</td>
<td>62</td>
<td>57</td>
<td>.684</td>
</tr>
<tr>
<td>Prior PTCA, %</td>
<td>19</td>
<td>27</td>
<td>.418</td>
</tr>
<tr>
<td>Vessel occluded before stenting, %</td>
<td>29</td>
<td>13</td>
<td>.040*</td>
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<tr>
<td>LAD, %</td>
<td>67</td>
<td>44</td>
<td>.047*</td>
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<tr>
<td>LCx, %</td>
<td>14</td>
<td>13</td>
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<tr>
<td>RCA, %</td>
<td>14</td>
<td>37</td>
<td>.037*</td>
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<tr>
<td>Bypass, %</td>
<td>5</td>
<td>6</td>
<td>.762</td>
</tr>
<tr>
<td>Multiple-stent patients, %</td>
<td>19</td>
<td>11</td>
<td>.245</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>12.3±5.7</td>
<td>12.4±5.9</td>
<td>.978</td>
</tr>
<tr>
<td>Original RD, mm</td>
<td>3.1±0.4</td>
<td>3.3±0.6</td>
<td>.159</td>
</tr>
<tr>
<td>Original MLD, mm</td>
<td>0.85±0.36</td>
<td>0.84±0.41</td>
<td>.899</td>
</tr>
<tr>
<td>Balloon/RD ratio</td>
<td>1.07±0.14</td>
<td>1.02±0.16</td>
<td>.211</td>
</tr>
<tr>
<td>MLD after stenting, mm</td>
<td>2.7±0.3</td>
<td>2.8±0.4</td>
<td>.451</td>
</tr>
</tbody>
</table>

LV indicates left ventricular; PTCA, percutaneous transluminal coronary angioplasty; LAD, left anterior descending coronary artery; LCx, left circumflex coronary artery; RCA, right coronary artery; RD, reference diameter; and MLD, minimal luminal diameter.

*Variables entered into multivariate analysis.

### Nonfatal Events

During the follow-up, there was 1 nonfatal myocardial infarction in addition to the 12 in the early phase. As seen in Fig 4, survival rate free of myocardial infarction was 92.3% at 6 months and 91.1% at 2 years. Twelve patients required coronary bypass surgery during the late follow-up. Eight of these patients had restenosis of the stented segment, while the remaining 4 had progression of disease in other vessels without restenosis of the stented segment. The survival rate free of myocardial infarction and bypass surgery was 91.0% at 6 months and 87.1% at 2 years (Fig 4). Forty-eight

### TABLE 3. Bleeding Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intracranial</td>
<td>2</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>5</td>
</tr>
<tr>
<td>Hematuria</td>
<td>3</td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>1</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>1</td>
</tr>
<tr>
<td>Retroperitoneal</td>
<td>4</td>
</tr>
<tr>
<td>Local hematoma</td>
<td>11</td>
</tr>
</tbody>
</table>

FIG 4. Kaplan-Meier curves presenting the event-free rate of the patients with stent implantation for the four defined end points: death, myocardial infarction (MI), bypass surgery (CABG), and repeat balloon angioplasty in stent (PTCA).
patients needed repeat PTCA of the stented segment for restenosis. Event-free survival at 6 months (no myocardial infarction or any repeated revascularization procedure) was 80.0% and at 2 years, 70.7% (Fig 4).

Angiographic Follow-up

Angiography at 6 months was performed in 250 of the 280 stented patients without subacute occlusion, representing 89.3% of the eligible patients. Restenosis was present in 74 patients (29.6%) (Fig 5). Quantitative analysis of the stented segments documented a late loss of 0.84±0.79 mm after an initial acute gain by stenting of 1.95±0.57 mm, demonstrating a loss index of 0.45±0.43.

Discussion

The present study summarizes the experience of three centers with Palmaz-Schatz stenting for coronary dissections with threatened or present vessel closure and reports the data of 339 consecutive patients. To the best of our knowledge, it represents the largest published experience, with an almost 90% angiographic follow-up at 6 months and long-term clinical follow-up of 2 years.

Success of the Intervention

The stent could be deployed successfully in 96.5% of the attempts, which is comparable to other studies using the same or other stent models in emergency or elective situations.38,39,40,41 Eight percent of the patients with successful stent deployment received adjunct nonemergency bypass surgery. This figure does not represent the real need for bypass surgery after stenting, because it is biased by our initial policy to use stenting as a bridge to bypass surgery in selected patients. A similar initial management strategy with the emergent use of stenting has been described by other authors.42,43 The incidence of adjunct bypass surgery declined from 16.7% in the first 2 years to 2.9% for the last 2-year period, reflecting the evolving experience with stenting. Herrmann et al44 recommended early elective bypass surgery for patients with "imperfect results" during emergency stenting due to the high risk of stent closure and of associated adverse events. Emergency bypass surgery was indicated in 4.3% of the patients with successful Gianturco-Roubin stent placement after complicated PTCA.45 The typical course after stenting can be assessed better by the outcome of the 301 patients for whom adjunct bypass surgery after successful stent placement was not planned.

Early Outcome

In these 301 patients, cardiac events were noted in 6.9%. Cardiac mortality rate was 1.3%, nonfatal myocardial infarction rate was 4.0%, the need for bypass surgery emerged in 1%, and 6.3% of the patients required early repeated angioplasty. Comparable results were recently reported with the use of the Gianturco-Roubin stent.46 Our data seem to be more favorable than those obtained with emergency CABG17 or with a multi-interventional approach including prolonged balloon inflations, thrombolysis, and perfusion balloons.6 In the present study, all cardiac events were associated with subacute stent occlusion. All occurred within the first 22 days after the procedure; 86% were verified in the first 2 weeks. Three of the 5 patients with discontinued anticoagulation therapy because of vascular complications had stent thrombosis. This confirms observations made previously by other investigators.28,37,38 The rate of subacute closure in the present study (6.9%) was considerably higher than the 3.4% and 3.5% reported for elective Palmaz-Schatz stenting48,39 but lower than the 16% for emergency use28; the latter patients, however, more often had discontinuation of the anticoagulant therapy and occlusion of the vessel before stenting. Our data for subacute closure are comparable to the 8.7% rate reported for emergency stenting with the Gianturco-Roubin stent42,43 but lower than the 11.7% observed with the Wiktor stent40 or the 24% reported for the Wallstent.41

George et al32 and Herrmann et al28 observed a higher incidence of early adverse events in patients with occlusion present compared with those with threatened occlusion before stenting. Our data confirm these observations; 14.3% of patients with vessel closure before stenting revealed subacute occlusion. This was an independent predictor of stent thrombosis by multivariate analysis. It has been shown that the incidence of subsequent myocardial infarction is dependent on time to stent placement in bailout situations.43 For this reason, decisions to stent were made early once the risk of vessel closure during PTCA appeared to be relevant. This explains our relatively low rate of total coronary occlusion before stenting.

The placement of stents in the right coronary artery was associated with a lower risk for subacute thrombosis (2.9%) in comparison to the LAD (10.1%) and left circumflex coronary artery (7.9%). The paucity of side branches of this artery may create more favorable flow characteristics in the stented area, preventing thrombus formation.

Repeated angioplasty without or in combination with intracoronary lysis achieved a high rate (86%) of successful recanalization in patients with stent closure in
our study. This success rate is markedly higher than the 41% reported recently with another type of stent.37

Vascular complications associated with the strong anticoagulation required after stenting remain a major drawback of this intervention. Blood transfusion and surgical repair were required in 9% and 5.6% of our patients, respectively. Although our target INR was relatively high, these figures are comparable to those reported by Schatz et al33 and the recent Benestent trial36; they are more favorable than those of George et al32 but higher than the results reported for the STRESS study.39

On an intention-to-treat basis, including patients with failed stent delivery and patients with stent intended as a bridge to bypass surgery, there were 6 patients (1.8%) with cardiac death and 19 patients (5.6%) with acute myocardial infarction (Fig 1). These cardiac events have to be evaluated in comparison with possible complications of alternative therapeutic strategies. A combined analysis of 14 studies on emergency CABG for failed coronary angioplasty17 comprising 1042 patients revealed an average death rate of 6.4% (range, 0% to 12.5%) and an infarction rate of 40.0% (range, 18% to 63%). Angiographic follow-up studies have shown that 10% to 18% of vein grafts are already occluded within the first month after CABG.44,45 Moreover, 15% of the patients undergoing emergency bypass surgery suffer from noncardiac complications such as stroke, bleedings, and sepsis.17

Late Outcome

Follow-up data with an observation period up to 6 months are reported only in one large-scale study with emergency stenting using another type of stent.35 It reported a probability of 97% of surviving and of 93% of surviving free of myocardial infarction. Our corresponding figures of 96.7% and 92.3%, respectively, are almost identical. These results are more favorable than those reported for the Wallstent35 and comparable to those characterizing the elective use of the Palmaz-Schatz stent.35

At 2 years, the patients of the present study had a 95.4% rate of surviving, a 91.1% rate of surviving without myocardial infarction, and a 70.7% event-free survival rate (free of myocardial infarction and revascularization procedures). Accordingly, an additional mortality and infarction rate of 1.2% is encountered in the period between 6 months and 2 years. Furthermore, the majority of the revascularization procedures were necessary within the first 6 months, yielding an event-free survival rate of 80.0% at 6 months. Hence, beyond this time and up to 2 years, the rate of revascularization procedures is <10%. These data indicate that the vast majority of cardiac events occur within the first 6 months. Comparable to PTCA,46 the later course appears to be dominated by the natural history of coronary artery disease rather than by the intervention, with myocardial infarction becoming the most important predictor of survival. These findings may be interpreted as the clinical correlate to the findings of our previous serial angiographic study.31 This study indicated that restenosis after stenting develops predominantly within the first 6 months, with only minimal changes occurring between 6 and 12 months.

The 1985-1986 NHLBI Registry of coronary angioplasty showed a 2-year survival rate of 96% for patients with uncomplicated PTCA, of 92% for patients with transient occlusion, and of only 89% for patients with abrupt vessel closure treated medically.3 The same registry revealed that 56% of the patients with transient occlusion and only 32% of those with vessel closure on medical therapy alone were event-free at 2 years.3 The long-term outcome of patients in our study is more favorable and not different from the results for patients without abrupt vessel closure in the NHLBI registry.3

The angiographic restenosis rate of 29.6% in this study is comparable to the 22%,38 31.6%,39 and 36%-47 that had been reported for elective Palmaz-Schatz stenting and lower than those of 53%39 and 39%-42 achieved with the Gainturco-Roubin stent in emergency situations. The calculated loss index of 0.45 is comparable to that reported in the literature for various angioplastical procedures.35,48

Limitations of the Study

Comparisons with previous reports on other surgical and nonsurgical approaches indicate favorable results for coronary stenting. Inferences may be limited, however, by differences in patient characteristics and technical state of the art. Therefore, controlled randomized studies are needed to define the best strategy for the management of acute ischemic complications of PTCA. The merit of the present study is that it shows that coronary stenting is one of the most promising options for dealing with inappropriate results after PTCA and therefore deserves further attention. However, the optimal anticoagulation regimen has yet to be defined. As a result of initial reports of high rates of subacute stent thrombosis,42 patients were put on a strict anticoagulation regimen for 6 to 8 weeks. This high level of anticoagulation adversely affected the rate of bleeding and access site complications. Optimal deployment of the stent and minimization of the residual stenosis, possibly with the aid of intravascular ultrasound, may reduce or even obviate the need for strict anticoagulation49,50 and reduce the rate of bleeding complications.

Conclusions

In the majority of patients with large vessel wall dissections, occlusion of the coronary artery can be prevented by Palmaz-Schatz stenting, and an adequate vessel lumen can be restored and consecutively maintained. Nevertheless, the first 4 weeks after stenting are complicated by a 6.9% rate of subacute stent thrombosis and bear an increased risk of bleeding and access site complications because of the strict anticoagulation. The early course after coronary stenting is more favorable than that reported for emergency CABG or other nonsurgical approaches to complicated PTCA, with a lower mortality and myocardial infarction rate. In fact, from 4 weeks to 6 months, the rate of cardiac events and repeat revascularization procedures resembles that after conventional PTCA. Beyond 6 months, cardiac death, myocardial infarction, and revascularization procedures are rare, with event rates similar to those known for chronic stable coronary artery disease.47 Hence, the late course after coronary stenting appears to be dominated by the primary disease itself rather than the previous intervention. In this respect, coronary stenting
does not differ from uncomplicated PTCA either. Therefore, the data of the present study strongly suggest that the implantation of Palmaz-Schatz stents is a safe and effective treatment for progressive dissections during coronary angioplasty and should always be considered as an approach for complicated balloon angioplasty.

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