Emergency Polytetrafluoroethylene-Covered Stent Implantation to Treat Coronary Ruptures

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Background—Coronary perforation is a life-threatening complication of percutaneous interventions. In the past few years, the implantation of covered stents has emerged as a strategy for treatment when the traditional conservative approach (ie, prolonged balloon inflation and reversal of anticoagulation) fails.

Methods and Results—Since May 1997 (when polytetrafluoroethylene [PTFE]-covered stents were available at our institutions), 11 of the 12 consecutive patients who had coronary ruptures that were unsuccessfully sealed with prolonged balloon inflation and reversal of anticoagulation were treated with 12 PTFE-covered stents (PTFE group). The efficacy of the PTFE-covered stent was compared with that of noncovered stents, which were used to treat 17 perforations (non-PTFE group). One patient sustained a very distal perforation that was not suitable for covered stent sealing and underwent emergency surgery. All vessel ruptures treated with PTFE-covered stent implantation were successfully sealed. The time necessary to deploy the stent was 10±3 minutes (range, 4 to 15 minutes). All patients but one were discharged from the hospital and had an optimal early clinical outcome. One patient underwent emergency bypass surgery and died in the intensive care unit. The occurrence of cardiac tamponade and the necessity for emergency surgery was significantly lower in the PTFE group than in the non-PTFE group. At 14±4 months, the 10 discharged patients had not experienced any major adverse cardiac events.

Conclusions—This preliminary study supports the utility of the PTFE-covered stent for the nonsurgical treatment of vessel ruptures. (Circulation. 2000;102:3028-3031.)

Key Words: angioplasty ■ coronary disease ■ hemorrhage ■ stents

Coronary artery perforation during percutaneous transluminal coronary angioplasty remains a rare but life-threatening complication. A surgical approach to treat the coronary perforations is necessary in 37% to 63% of cases. The implantation of covered stents has emerged as a strategy to treat perforation. Polytetrafluoroethylene (PTFE)-covered stents are easy and rapid to deploy, and they have emerged as a new tool for the nonsurgical treatment of this life-threatening complication.

Methods

Patient Population
Since March 1993, 49 coronary perforations have occurred at the authors’ institutions during 10,945 percutaneous interventions (0.45%). Using May 1997 (when PTFE-covered stents were available at our institutions) as the cutoff time, we separated patients into the non-PTFE group (25 perforations occurred during 6567 procedures [0.40%] before May 1997), and the PTFE group (24 coronary perforations occurred during 4378 percutaneous interventions [0.5%] after May 1997). According to the efficacy of conventional nonsurgical treatment, patients were classified as those who (1) achieved adequate sealing of the perforation with a conventional method (n=12 in PTFE group and n=17 in non-PTFE group; P=0.16) with a conventional method. This report deals with the patients in whom adequate sealing of the perforation was not achieved with conventional conservative management.

Coronary perforations were classified according to method of Ellis et al. Two-dimensional echocardiography and pulsed-wave Doppler were performed to assess the presence and severity of pericardial effusion.

Management of Vessel Perforation

A conventional strategy to treat perforation includes prolonged perfusion balloon inflation and reverse-heparin anticoagulation with protamine to reach an activated clotting time <130 s; a platelet transfusion is also administered if abciximab was given. If cardiac tamponade occurs, pericardiocentesis is performed.

When the conventional strategy was not able to seal perforations, the eventual nonsurgical strategy was, in the non-PTFE group, noncovered stent implantation when the patient did not already have a stent at the perforation site and the procedure seemed feasible and, in the PTFE group, PTFE-covered stent implantation.

We used the JOSTENT stent (JOMED), a balloon-expandable, slotted-tube stent manufactured by sandwiching a layer of PTFE between 2 stents, as our PTFE-covered stent. The potential diameter of the stent is 2.5 to 5.0 mm. The stent is currently Prior to European Community approval (CE mark), but the protocol was approved by the local ethics committees. After stent implantation, angiographic optimization was performed with high-pressure balloon dilatation to
achieve <20% residual stenosis by visual estimate. In 6 patients (50%), the final stent apposition was evaluated by intravascular ultrasound (3.2-F monorail system with a 30-MHz transducer-tipped catheter; Ultracross Cardiovascular Imaging System, Boston Scientific Co.). Angiographic measurements were performed with an automated computer-based system (Cardiovascular Measurement System, MEDIS).

Monitoring After Successful Nonsurgical Management
Antiplatelet therapy consisted of 325 mg/d aspirin indefinitely and 250 mg of ticlopidine BID for 3 months. Serial echocardiography was performed to detect pericardial effusion. Major adverse cardiac events (MACEs), which included death, Q- and non–Q-wave myocardial infarction, and coronary bypass surgery, were assessed. Non–Q-wave myocardial infarction was defined as chest pain or ST-segment or T-wave abnormalities associated with an increase of total creatine kinase $\geq 2$ times above normal values, with a positive creatine kinase-MB fraction without any new pathological Q waves. Clinical follow-up was obtained by an interview or a telephone conversation with the patient. Exercise tests were routinely performed at 1 to 2 months after the procedure. Repeated angiography was performed at 6 months after stent placement or earlier if clinically indicated. Restenosis was defined as a stenosis $\geq 50\%$ at the angiographic follow-up.

Statistical Analysis
Differences between groups were assessed by $\chi^2$ analysis for categorical variables and Student’s $t$ test for continuous variables. $P<0.05$ was significant.

Results
PTFE Group
Eleven of the 12 cases were deemed suitable for PTFE-covered stent implantation (Tables 1 and 2). In one case, in which a perforation occurred during guidewire distal migra-
Angiographic evidence of perforation has been reported in 0.1% to 3.0% of the lesions treated with various intervention techniques.1–4 Nonsurgical management of coronary perforation (that is, prolonged balloon inflation at the site of contrast extravasation and immediate reversal of anticoagulation) often fails, and emergency surgery is necessary.1,2

Covered Stents
In the past few years, covered stents have become an alternative to surgery when conservative approaches fail. Some case reports have shown promising results with autologous venous-covered stents.6,8 However, this strategy is technically demanding and may be difficult to perform in emergency situations like coronary rupture. Of note, the time interval from vein harvest to covered stent deployment has been reported as between 20 and 45 minutes.6,8 In contrast, PTFE-covered stent implantation is easy, rapid, and does not require extensive training.

In our study, PTFE-covered stents successfully sealed 91% of coronary perforations after other conservative approaches failed. Compared with the non-PTFE group, PTFE-covered stent significantly reduced the necessity for emergency surgery. Time to deploy the PTFE-covered stent and, subsequently, to seal the perforation was relatively short, and this may explain why cardiac tamponade occurred in only one patient. Furthermore, none of the 10 patients effectively treated with the PTFE-covered stent implantation experienced any MACEs at follow-up, and angiographic restenosis was 29% (2 of 7 patients). The lack of late thrombo-occlusive events9 in the PTFE group could be due to (1) the frequent use (50%) of intravascular ultrasound to assess proper stent implantation, (2) the routine use of final high pressure balloon inflation, (3) the prolonged (3 months) ticlopidine administration after the procedure, and (4) the fact that this event has a very low frequency of occurrence and it was evaluated in a small group.

Study Limitations
Because of the small sample size and the nonrandomized nature of the study, no firm conclusions can be drawn about the incidence of restenosis and late stent thrombosis. The limited flexibility of this stent restricts its implantation to
lesions accessible with no or moderate tortuosity. Furthermore, this device prevents any access to side branches.

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References
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