Clinical and Angiographic Outcomes After Coronary Artery Stenting for Acute or Threatened Closure After Percutaneous Transluminal Coronary Angioplasty
Initial Results with a Balloon-Expandable, Stainless Steel Design

James A. Hearn, MD; Spencer B. King, III, MD, FACC; John S. Douglas, Jr, MD, FACC; Sherry F. Carlin, RN; Nicholas J. Lembo, MD, FACC; Ziyad M.B. Ghazzal, MD

Background. Acute occlusion after balloon coronary angioplasty is associated with an increased risk of angina, emergency coronary artery bypass grafting (CABG), myocardial infarction (MI), and death. Stents offer a way of restoring patency and avoiding these complications.

Methods and Results. One hundred sixteen patients underwent attempted stent placement for imminent or total acute closure after PTCA. In 163 patients (110 stents, 105 procedures) the stent was successfully deployed (89%). Angiographic success (final diameter stenosis of <50%) was achieved in 94 placements (85%). Seventy-one phase 2 procedures (CABG optional, n=96; phase I, CABG required, n=9) were angiographically successful without complications of death, Q-wave myocardial infarction, or CABG (clinical success 74%). Stent placement was associated with resolution of ST-segment deviation and angina in 84% of patients. Five deaths and 5 Q-wave MIs occurred during hospitalization. Two deaths were related to pulmonary insufficiency from chronic lung disease and one patient died after rescue stent placement for left main coronary artery occlusion during routine angiography. Another patient died after CABG was followed by right ventricular MI. The last death occurred in an elderly patient who suffered a stroke while on intravenous heparin. During hospitalization nine patients developed reocclusion after stent placement (8.6% of procedures) and six had repeat PTCA. CABG was performed after 29 stent procedures (28%). The first nine patients underwent CABG as a mandate of the phase I protocol. In addition, nine patients had CABG after stenting with a good angiographic result but with a large amount of myocardium at risk. Clinical follow-up was obtained in all patients at a median of 14 months (range, 2 to 43). There were three late deaths (3%), two Q-wave myocardial infarctions (2%), 16 repeat PTCAAs (16%), and 15 CABG procedures (15%). Angiographic restenosis (percent diameter ≥50%) using caliper measurements was found in 30 of 57 patients (53%) at a median of 4 months (93% of patients eligible). A total of 41 procedures were successful and unaccompanied by death, emergency or elective coronary artery bypass grafting, or angiographic restenosis in follow-up. Restenosis and/or clinical events (death, MI, CABG, repeat PTCA) were associated with non-Q MI, hypertension, diabetes, left circumflex coronary artery stenting, saphenous vein graft stenting, smaller caliber artery stenting, higher balloon to artery ratios, and shorter inflation times.

Conclusions. Coronary artery stenting for acute closure after PTCA relieves myocardial ischemia and provides an alternate means of treatment. This series includes early learning curve experience; 70% (67 of 96) of patients were spared emergency coronary artery bypass graft surgery when this adverse outcome occurred. Certain clinical and angiographic subsets are at increased risk for restenosis and future cardiac events. (Circulation. 1993;88[part 1]:2086-2096.)

Key Words • coronary artery disease • percutaneous transluminal coronary angioplasty • stents

Acute closure of a recently dilated coronary artery after percutaneous transluminal coronary angioplasty (PTCA) results in a marked increase in morbidity and mortality. In the 1985-1986 National Heart, Lung, and Blood Institute PTCA Registry, periprocedural occlusion occurred in 6.8% of patients and was associated with a fivefold increase in the incidence of death (1% to 5%) and an increase in myocardial infarction incidence from 2% to 27% in those with repeat PTCA and 56% in those undergoing emergency coronary artery bypass grafting (CABG). Despite reopening with PTCA or emergency CABG, the risk of death continued during the first 18 months of follow-up.

See p 2455
One of the most potent predictors of acute closure is
the occurrence of an intimal tear or coronary dissection
after PTCA (odds ratio of 5). Independent risk factors
associated with increased mortality after acute closure
include collateral vessels arising from the dilated artery,
female sex, and multivessel disease. When multiple
repeat inflations fail to resolve an acute closure, pa-
tients have conventionally undergone emergency
CABG. Other strategies for acute closure are prolonged
inflations, perfusion catheters, and laser balloon PTCA.

Investigations using the Wallstent have shown a po-
tential for subsequent acute closure in the weeks after
placement. Thirteen patients undergoing stent place-
ment for acute closure did well in comparison except for
one who developed late acute closure of the stented site
despite antiplatelet and anticoagulant treatment. A
subsequent report of stenting for this indication has
mandated urgent coronary artery bypass grafting.

Coronary artery stents offer the theoretic advantages
of scaffolding intimal/medial flaps away from the lumen
of the artery and maintaining radial support to offset
elastic recoil closure. This offers the possibility of
avoiding the ischemic complications of acute closure
and obviating emergency CABG. We describe the first
experience with a balloon-expandable, stainless steel
stent in the treatment of acute and threatened acute
closure after PTCA.

Methods

Patients

Between September 3, 1987, and December 31, 1990,
103 patients underwent coronary artery stent implanta-
tion with the Gianturco-Roubin stent (Cook, Inc, Flex-
ible Coil) for acute or threatened acute closure after
PTCA. This was carried out under phase 1 and 2
protocols approved by the Emory University Human
Investigations Committee. Phase 1 was a protocol for
stent placement according to the indications below
followed by immediate coronary artery bypass surgery.
The first nine patients constituted phase 1 while the
remaining patients were entered into phase 2 (n=94).
Phase 2 involved stent placement for these indications
followed by further revascularization only if deemed
necessary by the angioplasty operator. Each patient
gave informed consent before a scheduled balloon
PTCA.

Criteria for Stent Placement

Patients selected for this study had lesions that, if
closed after stent placement, would not result in massive
myocardial ischemia and hemodynamic instability. If
closure of the stented site posed a significant chance of
producing a lethal condition, then patients were gener-
ally referred for emergent CABG after stent placement.

The entry criteria included coronary dissections with
arteriographic or hemodynamic evidence of closure,
imminent closure, or threatened closure after repeated
balloon inflations that failed to improve the artery
satisfactorily. Originally stents were placed in large
arteries or vein grafts supplying important areas of
myocardium only if a good collateral system existed.
The use of the stent was expanded to include some
patients without such collaterals. This criterion for

Collaterals was obviated if the vascular distribution
of the stented artery was small or moderate in size.

Exclusions to Stent Placement

Relative exclusion criteria included vessels that were
diffusely diseased, three-vessel disease, multiple steno-
ses in a single vessel, severely impaired left ventricular
function (ejection fraction <25%), akinetic wall motion
in the distribution of the artery to be stented, a vessel
diameter of <2.0 mm, the presence of a bleeding
diathesis or other potentially hemorraghic disorder (eg,
active peptic ulceration or recent cerebrovascular acci-
dent) limiting the use of antiplatelet and anticoagulant
therapy, and the presence of an angiographically evi-
dent thrombus in the proposed stent site.

Stent Procedure and Adjuvant Medical Therapy

Stenting of a coronary artery was considered once a
standard PTCA procedure had been completed and all
other efforts to maintain vessel patency had failed. In
addition to 10 000 IU of intravenous heparin, 325 mg
aspirin and 60 mg diltiazem, patients received 75 mg
oral dipyridamole and intravenous dextran 40 at a rate
of 100 mL/h. Two hundred micrograms of intracoronary
nitroglycerin was given before stenting. Stent sizes were
selected to be similar to the estimated diameter of the
proposed artery. Intravenous fluids and additional hepa-
rin (5000 IU IV each additional hour) were given.
Prestent intracoronary urokinase was given for sus-
ppected intracoronary thrombus.

Poststen Procedure

Femoral artery sheaths were removed when the ac-
tivated clotting time (ACT) reached 1.5 times normal.
After hemostasis, patients received an intravenous bolus
of heparin (2000 to 5000 IU, depending on weight) and
were started on a constant infusion of 1000 IU/h. Partial
thromboplastin times were monitored frequently and a target
of 60 to 90 seconds was main-
tained. Aspirin 80 to 325 mg qd, dipyridamole 75 to 225
mg qd, diltiazem 60 mg p o TID, and transdermal
nitroglycerin were continued. A daily dose of coumadin
was selected to increase the prothrombin time to a
target of 17 to 21 seconds. Poststent creatine kinase
isoenzymes and ECGs were obtained serially. Tele-
metry was maintained for 2 to 3 days, and the patient was
typically discharged on the fifth day after stent
placement.

Follow-up Procedures

Patients were followed up by telephone at 2 and 4
weeks and were asked to undergo coronary angiography
of the stented segment approximately 6 months after
implantation. Some patients underwent repeat angiog-
raphy before discharge or at 2 months after discharge.

Data Collection

Prospectively collected baseline demographic, clini-
cal, and angiographic variables were entered on stan-
dard data sheets by physicians for entry into a main-
frame, computerized data base. A complete review for
this report included the computerized data base, case
report forms, and individual medical records (all re-
viewed and crossvalidated).
Definitions and Measurements

Acute closure is cessation of all blood flow (angiographically determined) at and beyond the dilated segment of the coronary artery at any time after balloon dilatation. Threatened acute closure is defined as angiographic features present in the dilated segment that predispose to, yet have not resulted in, total acute closure, as determined by the operator. This occurrence is an ongoing process rather than a discrete event. The features could include static components (eg, large dissection) or dynamic components (eg, progressive decline in lumen size at the dilated site, or changing TIMI grade flow) and were commonly associated with angina, alterations in blood pressure, and ST-segment deviations. Some previous definitions of acute closure have included a subsequent ischemic outcome or event such as myocardial infarction, repeat PTCA, or emergency CABG.5,6 New Q-wave myocardial infarction is presence of a pathologic Q wave as defined by the Minnesota code13 that occurs after the acute closure syndrome and is not mimicked or obscured by conduction abnormalities (eg, left bundle branch block). New non-Q-wave myocardial infarction is absolute, peak, creatine kinase MB isoenzyme levels ≥50 IU/L after an acute closure syndrome without development of pathologic Q waves.14 Deployment success occurs when the stent is expanded in the artery that produced the acute closure syndrome. Angiographic success occurs when the stent is delivered to the site of the acute or threatened acute closure and the maximum diameter stenosis after stent implantation is <50%. Clinical success is angiographic success obtained after stent deployment and the patient does not experience a Q-wave myocardial infarction or undergo CABG (applicable only to phase 2 patients; phase 1 patients had CABG predetermined). The proximal coronary artery is that portion of the epicardial artery before any major side branch.

Other angiographic definitions include intimal tear or dissection, thrombus, percent diameter stenosis, lesion length, native artery diameter, branch point, eccentricity, and multivessel disease, as previously defined.5 Restenosis was defined as occurrence of a ≥50% narrowing at the site of, or in close proximity to, a previously stented site.

Coronary arterial dimensions were measured with hand-held digital calipers as previously described using digital electronic calipers with known intraobserver and interobserver variability.13,14 Two near-orthogonal views were used if available.

Statistical Analysis

Categorical variables were analyzed using the $\chi^2$ statistic or Fisher's exact test for small data sets. Unpaired, two-sided $t$ tests were used for continuous data. A null hypothesis of no difference between groups compared (two-tailed) was used. A value of $P\leq 0.05$ was accepted as evidence of statistical significance. Kaplan-Meier survival analysis was performed. Analyses were carried out using BMDP statistical software.

Results

Characteristics of the Study Group

The patients had a mean age of 58 years (Table 1). There was a male predominance, 77%, and hypertension was present in 41%, hyperlipidemia in 48%, diabetes mellitus in 18%, and cigarette smoking in 73%. Multivessel disease was present in 42%, and history of prior myocardial infarction was found in 32%. Twenty-two percent of patients had had previous CABG and 41% had undergone prior PTCA in the same coronary artery segment. Left ventricular function was preserved with a mean ejection fraction of 56% (qualitative results omitted in sixteen).

Deployment Success

One-hundred twenty-three stent placements were attempted in 116 patients with acute closure syndrome (Fig 1). Successful deployment occurred in 9 patients in phase 1 (9 procedures and 9 stents) and in 94 patients in phase two (96 procedures and 101 stents). Of the 13 stents not deployed, failures were due to failure to get the stent to the artery in 6 and inability to cross the
proximal artery or the lesion site in 7. Of these 13 cases, 2 could not be advanced through the guide catheter because of size mismatch (eg, a 3.5-mm stent requires a 9F, large-lumen catheter). Guide wire dislodgment and separation of the guide wire and extension wire occurred in one each. One was not used because of the inability to recross with the guide wire after an acute closure, and one was considered and then not used. Two would not pass the proximal portion of the artery. Five were not deployed because of failure to cross the lesion.

Twenty-nine 2.5-mm stents (26%), 62 3.0-mm stents (56%), 11 3.5-mm stents (10%), and 7 4.0-mm stents (6%) were deployed.

**Angiographic Characteristics**

Acute closure was the indication for stent placement in 46 procedures (44%), and threatened acute closure was antecedent to stenting in 59 procedures (56%) (Table 2). This threatened closure group was characterized by angiina in 78% of procedures with ST-segment changes in 68%, dissections in 80%, thrombi in 32%, a TIMI flow average of 2.68, and an average length of 8.4 mm. In both groups, the stented coronary artery distribution was: left main coronary artery in 2 (1 protected by bypass graft, 1 not [see discussion under in-hospital outcomes]), left anterior descending coronary artery in 38 (36%), left circumflex coronary artery in 23 (22%), and right coronary artery in 44 (42%). Fourteen procedures were carried out in saphenous venous bypass grafts (13%), and 12 procedures (11%) were performed in patients with total occlusions before balloon angioplasty. Lesions were eccentric in 60% of cases, across branch points in 31%, contained dissections in 79%, and had an intraluminal filling defect in 36%. The average stent size (nominal size stated by manufacturer) was 2.97 mm and was well matched to the artery (3.03 mm) or vein graft (3.09 mm). The mean lesion length before balloon angioplasty was 7.9 mm, with a range of 0.4 to 33.7 mm. The mean present TIMI perfusion grade was 1.4.

**In-Hospital Outcomes**

Angiographic and clinical success. Angiographic success was achieved in 94 procedures (89.5%), and hospital discharge without death, MI, or CABG surgery was obtained in 71 of 96 phase 2 procedures (74%) (Table 3). Twelve patients underwent CABG for reasons other than ongoing myocardial ischemia or inadequate lumen result (residual stenosis ≥50%). There were 9 poststent CABGs mandated by the phase 1 protocol. Of these, 3 had no evidence of potential ischemia, and 3 had residual stenosis ≥50%, 2 had large dissections extending beyond the stent, and 1 had a separate lesion in the same artery remaining ≥50%. In phase 2, 9 patients went to CABG after successful stenting (mean poststent stenosis of 15%) with no ongoing ischemia but with potential for ischemia or a large area of myocardium at risk. Two had bleeding complications necessitating heparin withdrawal, and 7 had evidence of extensive myocardium at risk (2 due to hypotension with balloon inflations and 5 due to proximal location in very large arteries). The success rate of stent placement for chronologic quartiles of procedures is shown in Fig 2.

**Benefits of stent placement.** Angina after acute closure was present in 64 procedures, and its subsequent resolution after stenting was recorded in 54 procedures, (84%) (Fig 3). ST-segment deviation after closure occurred in 61 procedures, and its resolution occurred in 51 procedures, (84% resolution). The percent diameters are shown in Fig 4. The diameter stenosis was calculated before stenting (73%) and compared with the pre- and postballoon diameters (P<.0001). The poststent mean diameter stenosis in 104 procedures was 21%
Table 3. In-Hospital Outcomes

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No.</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiographic success (n=105)</td>
<td>94</td>
<td>89.5</td>
</tr>
<tr>
<td>Clinical success (n=96)</td>
<td>71</td>
<td>74</td>
</tr>
<tr>
<td>Death (n=103)</td>
<td>5</td>
<td>4.9</td>
</tr>
<tr>
<td>Q-wave MI (n=105)</td>
<td>5</td>
<td>4.8</td>
</tr>
<tr>
<td>Non-Q-wave MI (n=101)</td>
<td>28</td>
<td>27.7</td>
</tr>
<tr>
<td>Emergent/urgent CABG (n=105)</td>
<td>29</td>
<td>27.6</td>
</tr>
<tr>
<td>Repeat PTCA (n=105)</td>
<td>6</td>
<td>5.7</td>
</tr>
<tr>
<td>Repeat threatened or actual closure (n=105)</td>
<td>9</td>
<td>8.6</td>
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</table>

Peak isoenzymes

<table>
<thead>
<tr>
<th>Enzyme</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>CK</td>
<td>558</td>
<td>814</td>
<td>20-5064</td>
</tr>
<tr>
<td>CK-MB</td>
<td>9</td>
<td>7</td>
<td>0-27</td>
</tr>
<tr>
<td>CK-MB</td>
<td>75</td>
<td>136</td>
<td>0-709</td>
</tr>
</tbody>
</table>

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

*See text for definitions; tincludes only phase 2 procedures in which CABG was optional.

(P<.0001). In the clinically successful procedures, the mean poststent diameter stenosis was 14%.

Deaths. Five patients died while in the hospital (4.9%) (Table 3). One patient died 2 months after stent placement, after having undergone surgery for a penetrating duodenal ulcer followed by refractory respiratory failure. There was no antemortem indication of myocardial ischemia. Another patient had an acute closure of the left main and left anterior descending artery and underwent >10 minutes of cardiopulmonary resuscitation for asystole before balloon angioplasty and stent placement. Although the left main coronary was successfully opened, the distal runoff was slow, and he did not regain a cardiac rhythm. Stent-related deaths were evident in one patient who had a presumed intracranial bleed while on continuous intravenous heparin and in another patient who successfully had two right coronary artery stents placed followed by CABG and apparent acute closure evident by right ventricular infarction after heparin reversal. Another patient suffered acute respiratory arrest followed by asystole shortly after pulmonary aspiration at 4 AM the day after stent implantation. By postmortem angiogram, angioscopy, and histology, there was no thrombus or closure at the stent site.

Q-wave myocardial infarction. Five patients suffered Q-wave myocardial infarctions after stenting while in the hospital. One patient had acute closure of the stent site when his partial thromboplastin time fell to 39 seconds; he underwent repeat PTCA. Another patient developed a Q-MI with the acute closure event despite good angiographic success with the stent. Another patient had only partial crossing of the distal RCA site with the stent and no recanalization of the posterolateral left ventricular branch; he underwent emergency CABG. One patient presented with an acute inferoposterior infarction and had unsuccessful balloon PTCA followed by successful stenting. She had thrombotic reoclusion and was treated medically. Last, one patient had a directional atherectomy of a mid LAD stenosis and developed acute closure several hours later. He underwent successful stent placement, then developed acute closure of the proximal stent site and underwent emergency CABG.

Revascularization procedures. There were nine repeat in-hospital acute closures at the stent sites (Table 3). Six patients underwent repeat PTCA and the remainder underwent CABG. A total of 29 patients underwent CABG either because of enrollment in the phase I protocol (9 patients), potential for future myocardial ischemia (9 patients), or for ongoing ischemia poststent implantation (11 patients).

In-hospital complications. Femoral hematomas were the most common complication, occurring in 30 patients

Fig 2. Bar graph of learning curve for angiographically successful coronary artery stenting.

Fig 3. Bar graph shows effect of coronary artery stenting on angina and ECG changes.

Fig 4. Bar graph of percent stenosis changes with coronary artery stenting as measured by digital electronic calipers.
TABLE 4. In-Hospital Complications After 105 Procedures

<table>
<thead>
<tr>
<th>No.</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral hematoma</td>
<td>30</td>
</tr>
<tr>
<td>Femoral pseudoaneurysm repair</td>
<td>7</td>
</tr>
<tr>
<td>Hematuria</td>
<td>7</td>
</tr>
<tr>
<td>Fever</td>
<td>5</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>2</td>
</tr>
<tr>
<td>Gastrointestinal bleeding</td>
<td>4</td>
</tr>
<tr>
<td>Ventricular fibrillation</td>
<td>4</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>4</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>2</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>2</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>2</td>
</tr>
<tr>
<td>Vein graft rupture</td>
<td>1</td>
</tr>
<tr>
<td>Postpericardiotomy pericarditis</td>
<td>1</td>
</tr>
<tr>
<td>Complete heart block</td>
<td>1</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td>Cerebral contusion</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary aspiration</td>
<td>1</td>
</tr>
<tr>
<td>Pneumonitis</td>
<td>1</td>
</tr>
<tr>
<td>Adult respiratory distress syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>1</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>1</td>
</tr>
<tr>
<td>Lower extremity amputation</td>
<td>1</td>
</tr>
<tr>
<td>Acute abdomen</td>
<td>1</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>1</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>1</td>
</tr>
</tbody>
</table>

Hematologic changes

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission hematocrit, % (n=104)</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>Hematocrit nadir, % (n=101)</td>
<td>28</td>
<td>6</td>
</tr>
<tr>
<td>Hematocrit decrease, % (n=101)</td>
<td>12</td>
<td>6</td>
</tr>
</tbody>
</table>

(28.6%) (any size) (Table 4). Seven (6.7%) were pseudoaneurysms that required surgical repair. Transient hematuria occurred in 7 patients (6.7%). This commonly resolved spontaneously despite continued heparin therapy in some cases. In one patient an unsuspected urinary malignancy was discovered during evaluation.

Fever occurred in 5 patients, most commonly with no source, although 2 patients did have transient bacteremia. A number of other complications occurred and are listed in Table 4. Of note was the finding that ventricular fibrillation (4 patients) occurred most commonly at the time of acute occlusion or just before CABG, whereas atrial fibrillation (4 patients) occurred after CABG. One patient developed an interstitial pulmonary edema along with a low grade fever, without evident myocardial ischemia, pneumonia, or elevated left ventricular filling pressures. Diuresis failed to improve her chest radiograph until 5 days later, when it began to resolve. One patient fell in his room while on heparin and developed a cerebral contusion, which resolved. Another patient with diabetes who initially presented with a large inferoposterior MI developed occlusion of the femoral artery at the site of an intra-aortic balloon pump insertion and ultimately required amputation.

Postdischarge Outcomes

Three patients died after discharge from the hospital (Table 5). One with steroid-dependent chronic obstructive pulmonary disease died approximately 1 week after an asthmatic attack while still in hospital. There was no clinical suggestion of myocardial ischemia (no ECG changes, angina, or congestive heart failure). Another patient with severely compromised left ventricular function died suddenly. Finally, a patient who had repeat CABG at another hospital died early in the postoperative course.

There were two new postdischarge Q-wave MIs, one in a patient who had a suboptimal prothrombin time of 14 seconds. Fifteen patients underwent CABG, and 16 patients had a repeat PTCA. Class 3 or 4 angina was present in 1 and 5 patients, respectively.

Combined Outcomes

Fig 5 shows the cumulative survival curves derived from the Kaplan-Meier method. This curve contains the initial 9 phase 1 patients and therefore may, artificially, lower the CABG-free and repeat PTCA–free curves. As summarized from the totals expressed above, most of the events occurred in-hospital. In Fig 6, the cumulative event-free survival for 69 patients having a clinically successful in-hospital stent procedure is shown. By 6 months, most of the events have occurred. The risk of clinical events was significantly increased if the patient had hypertension, diabetes mellitus, or suffered a non-Q-wave MI periprocedurally (Fig 7). The majority of follow-up events were revascularization procedures. A trend toward fewer events was seen in the larger stent cases despite small numbers (n=12).

Table 6 shows the acute and postdischarge clinical outcomes grouped according to whether stenting was
used alone or followed by CABG. Neither death or Q-MI were different between these groups except when combined (5.3% for stent alone versus 20.7% for stent and CABG, \( P=.016 \)). Non-Q-wave MI occurred more often when stenting was followed by CABG. The transfusion rate was higher in the surgical group (1.4 units for stent group versus 7.1 units for the stent and CABG group, \( P=.002 \)). With a median follow-up of 14 months, the postdischarge clinical outcomes of death, Q-wave MI, and need for CABG were not different for the two groups. Repeat PTCA was necessary in 21.9% of patients in the stent group compared with zero in the stent and CABG group (\( P=.008 \)).

**Clinical Outcomes With Respect to Indication**

The threatened closure group had 3 in-hospital deaths (5.2%) compared with 2 in the acute closure group (4.4%) (\( P=NS \)). In addition, the threatened closure group had 2 Q-wave MIs (3.4%) compared with 3 in the acute closure group (6.5%) (\( P=NS \)). Repeat PTCA was required in 3 in the threatened closure group (5.1%) and 3 in the acute closure group (6.5%) (\( P=NS \)). However, CABG was performed after 9 procedures in the threatened closure group (15.2%) and after 20 procedures in the acute closure group (43.5%) (\( P=.0013 \)). The frequency of emergency CABG after stenting for acute closure showed a trend toward decreasing over consecutive terciles of procedures: 66.7%, 26.7%, and 37.5%, respectively (\( P=.07 \)). However, 46% of the first tercile went to CABG as mandated by the phase one protocol.

Follow-up death, Q-wave MI, CABG, and repeat PTCA were 3.6%, 1.8%, 12.5%, and 17.8% in the threatened closure group and 2.3%, 2.3%, 18.2%, and 13.6%, in the acute closure group, respectively (\( P>.10 \) for all).

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**Fig 5.** Graph of cumulative freedom from clinical events in entire stent group. QMI indicates Q-wave myocardial infarction; CABG, coronary artery bypass graft; and PTCA, percutaneous transluminal coronary angioplasty.

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**Fig 6.** Graph of cumulative freedom from clinical events in 69 patients having a clinically successful in-hospital stent placement. QMI indicates Q-wave myocardial infarction; CABG, coronary artery bypass graft; and PTCA, percutaneous transluminal coronary angioplasty.
Fig 7. Graphs show effects of clinical variables and stent size on cumulative freedom from events in successful stent procedures (n=69). HTN indicates hypertension; DM, diabetes mellitus; and NQMI, non-Q-wave myocardial infarction.

Angiographic Restenosis

Restenosis occurred in 30 of the 57 patients undergoing follow-up catheterization (52.6%). These 57 patients constituted a 92% follow-up catheterization rate of those surviving patients eligible for restudy (no in-hospital CABG), at a median of 4 months. There was no change in the restenosis rate during the period of these observations. Correlates of restenosis were looked

### TABLE 6. Outcomes in Stent and Stent/CABG Groups

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Stent Alone</th>
<th></th>
<th></th>
<th>Stent/CABG</th>
<th></th>
<th></th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Total</td>
<td>Percent</td>
<td>No.</td>
<td>Total</td>
<td>Percent</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>3</td>
<td>74</td>
<td>4.0</td>
<td>2</td>
<td>29</td>
<td>6.9</td>
<td>NS</td>
</tr>
<tr>
<td>QMI</td>
<td>2</td>
<td>76</td>
<td>2.6</td>
<td>3</td>
<td>29</td>
<td>10.3</td>
<td>NS</td>
</tr>
<tr>
<td>Death and/or QMI</td>
<td>4</td>
<td>76</td>
<td>5.3</td>
<td>6</td>
<td>29</td>
<td>20.7</td>
<td>.016</td>
</tr>
<tr>
<td>NQMI</td>
<td>13</td>
<td>72</td>
<td>18.0</td>
<td>15</td>
<td>29</td>
<td>51.7</td>
<td>.0006</td>
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<tr>
<td></td>
<td>No.</td>
<td>Mean</td>
<td>SD</td>
<td>No.</td>
<td>Mean</td>
<td>SD</td>
<td></td>
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<tr>
<td>Peak CK, IU/L</td>
<td>73</td>
<td>376</td>
<td>766</td>
<td>28</td>
<td>1,034</td>
<td>754</td>
<td>.0002</td>
</tr>
<tr>
<td>CK-MB, %</td>
<td>72</td>
<td>8.4</td>
<td>7.7</td>
<td>28</td>
<td>9.4</td>
<td>5.0</td>
<td>NS</td>
</tr>
<tr>
<td>CK-MB, IU/L</td>
<td>72</td>
<td>51</td>
<td>120</td>
<td>28</td>
<td>135</td>
<td>158</td>
<td>.005</td>
</tr>
<tr>
<td>Hematocrit decrease, %</td>
<td>72</td>
<td>10.8</td>
<td>5.0</td>
<td>29</td>
<td>14.6</td>
<td>7.8</td>
<td>.021</td>
</tr>
<tr>
<td>RBC transfusions, units</td>
<td>75</td>
<td>1.4</td>
<td>3.8</td>
<td>29</td>
<td>7.1</td>
<td>9.0</td>
<td>.002</td>
</tr>
<tr>
<td>After discharge</td>
<td>No.</td>
<td>Total</td>
<td>Percent</td>
<td>No.</td>
<td>Total</td>
<td>Percent</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>71</td>
<td>2.8</td>
<td>1</td>
<td>27</td>
<td>3.7</td>
<td>NS</td>
</tr>
<tr>
<td>QMI</td>
<td>2</td>
<td>73</td>
<td>2.7</td>
<td>0</td>
<td>27</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>CABG</td>
<td>13</td>
<td>73</td>
<td>17.8</td>
<td>2</td>
<td>27</td>
<td>7.4</td>
<td>NS</td>
</tr>
<tr>
<td>Repeat PTCA</td>
<td>16</td>
<td>73</td>
<td>21.9</td>
<td>0</td>
<td>27</td>
<td>0</td>
<td>.008</td>
</tr>
<tr>
<td>Angina pectoris</td>
<td>15</td>
<td>69</td>
<td>21.7</td>
<td>4</td>
<td>26</td>
<td>15.4</td>
<td>NS</td>
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</tbody>
</table>

CABG indicates coronary artery bypass grafting; QMI, Q-wave myocardial infarction; NQMI, non-Q-wave myocardial infarction, defined as CK-MB (IU/L) >50 in acute closure patient without subsequent development of Q waves; RBC, red blood cell; and PTCA, percutaneous transluminal coronary angioplasty.
the time course of the study. For example, the initial patients in the phase 2 part of the study did not receive chronic anticoagulation with coumadin. Full use of soluble aspirin, dipyridamole, and dextran was only adopted as the study progressed. Similarly, the technique for successful placement including the correct choice of guiding catheters and guide wires, correct sizing, and deployment strategies were developed during the early part of this study. Accordingly, the deployment success rate was lower and complication rates were higher than those being achieved in current experiences.\textsuperscript{17}

In a significant number of cases, the stent was used only after prolonged attempts at stabilizing the vessel with alternative techniques including autoperfusion balloons and laser balloon angioplasty. Because the late outcome from stent placement was unknown, the device was frequently only used in the most severe cases of dissection and acute closure refractory to conventional balloon or other methods.

Acute closure refractory to repeat balloon inflations has traditionally been an indication for emergency coronary artery bypass surgery. In acute closure patients, this stent served to reduce myocardial ischemia before emergency CABG and functioned as an alternative to CABG. This device had a high degree of success in reducing myocardial ischemia (84%).

A consideration in the use of this or any other metallic intracoronary stent is the need to avoid implantation in patients who are at risk for significant hemorrhage. The most common hemorrhagic site was the femoral artery. However, despite selection of patients at low risk for hemorrhage, there were a number of episodes of genitourinary and/or gastrointestinal bleeding.

Five deaths occurred during hospitalization. Although these patients were clearly at greater risk than routine angioplasty patients, the stent placement and anticoagulant therapy played a role in two deaths.

The rate of Q-wave myocardial infarction is low in this group of patients in comparison with other reports of patients with acute closure. However, it should be recognized that comparisons of this nature are subject to inappropriate interpretations because of the nature of historical controls and entry criteria used to select these patients. It is hoped that one of the benefits of this device is to convert infarcts that are destined to be Q-wave or transmural MIs into either no infarction or, at most, small non-Q-wave MIs.

The decision for CABG after stenting is made either because the stent placement is unsuccessful or because even though successful, the amount of circulatory compromise should stent thrombosis occur would have a significant chance of being life threatening. In this series, the utilization of poststenting bypass surgery was probably inflated because 9 patients had surgery mandated by protocol (phase 1), and the threshold for referring to surgery in the early experience of the trial was low until confidence in stent placement was established.

The long-term follow-up presented cannot be fairly compared with other stent data because the other major stent observational studies have been in patients not undergoing acute closure. Acute closure studies of unstented patients also fail to provide a good frame of

### Table 7. Correlates of Restenosis in All Stented Vessels With Angiographic Follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>No.</th>
<th>%</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NQMI (n=9)</td>
<td>8</td>
<td>89</td>
<td>.017</td>
</tr>
<tr>
<td>Vein graft site (n=6)</td>
<td>6</td>
<td>100</td>
<td>.014</td>
</tr>
<tr>
<td>Diabetes mellitus (n=11)</td>
<td>9</td>
<td>82</td>
<td>.026</td>
</tr>
<tr>
<td>Left circumflex artery (n=14)</td>
<td>11</td>
<td>78</td>
<td>.025</td>
</tr>
<tr>
<td>B:A ratio &gt;0.98 (n=27)</td>
<td>19</td>
<td>70</td>
<td>.019</td>
</tr>
<tr>
<td>Artery diameter &lt;3.2 mm (n=38)</td>
<td>24</td>
<td>63</td>
<td>.024</td>
</tr>
<tr>
<td>Maximum inflation time &lt;215 s</td>
<td>20</td>
<td>67</td>
<td>.025</td>
</tr>
<tr>
<td>Re cath &lt;4 months (n=30)</td>
<td>20</td>
<td>67</td>
<td>.025</td>
</tr>
<tr>
<td>Diabetes or vein graft (n=23)</td>
<td>18</td>
<td>78</td>
<td>.001</td>
</tr>
</tbody>
</table>

NQMI indicates non-Q-wave myocardial infarction and B:A, balloon to artery.

for including coronary artery risk factors, angiographic features, procedural features, and acute events. Table 7 shows the univariate correlates of restenosis and the respective restenosis rates. Non-Q MIs, vein graft sites, presence of diabetes, left circumflex artery stent placement, balloon to artery ratio of >0.98, native artery diameters <3.2 mm, a shorter maximal inflation time used either before the acute closure or after, and a short time to angiographic restudy were all correlated with restenosis. All 6 vein graft sites had restenosis. If the site was not a vein graft and the patient did not have diabetes, then the restenosis rate was 35% (n=34 patients). Table 8 shows the independent multivariate factors related to restenosis: saphenous vein graft sites and small native artery size.

### Discussion

The purpose of this report is to describe the initial single center experience of a balloon-expandable stent used in patients suffering acute closure after PTCA. This experience represents the developmental clinical phase in the application of this device. Successful placement techniques, anticoagulation regimens, and correct patient management procedures evolved over

### Table 8. Multivariate Predictors of Restenosis and Cardiac Events in the Clinically Successful Group (No In-Hospital Death, Q-Wave Myocardial Infarction, or CABG)

<table>
<thead>
<tr>
<th></th>
<th>Coefficient</th>
<th>Improvement in $\chi^2$</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restenosis (n=51)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saphenous vein vs native artery</td>
<td>5.4234</td>
<td>8.177</td>
<td>.010</td>
</tr>
<tr>
<td>Native artery diameter</td>
<td>-1.5070</td>
<td>8.135</td>
<td>.036</td>
</tr>
<tr>
<td>Clinical events: death, QMI, PTCA, CABG (n=67)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent size</td>
<td>-1.6932</td>
<td>4.770</td>
<td>.035</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>0.6008</td>
<td>6.337</td>
<td>.043</td>
</tr>
</tbody>
</table>

QMI indicates Q-wave myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; and CABG, coronary artery bypass graft.
reference, since many of the usual therapies for solving acute closure were tried before stenting. In follow-up, 2% had MI and 3% died. One MI was associated with noncompliance with coumadin therapy, and one death was a result of a well-documented respiratory failure in a patient with chronic lung disease. Revascularization procedures were common, with repeat PTCA being more frequent in the nonoperated patients. It is our impression that repeat PTCA in the stented segment is an easily performed procedure that yields excellent initial results, perhaps related to the reinforcement provided by the stent wires, thereby eliminating elastic recoil. However, restenosis occurs in approximately half of these patients. Restenosis was correlated with saphenous vein graft sites and small native artery size using multivariate analysis (Table 8). Factors not correlated with restenosis included age, serum cholesterol, smoking history, length of the lesion, maximum atmospheres of inflation, number of inflations, pre- or postballoon percent stenosis, pre- or poststen percent stenosis, proximal LAD location, angina class, hypertension, threatened versus actual acute closure, multivessel disease, reclosure of stented segment, presence of dissection or thrombus, TIMI flow, prior PTCA at site, and medications including mevacor, short-course glucocorticoids, and/or colchicine. In six patients, the use of glucocorticoids and colchicine was associated with late coronary aneurysm formation.11 In a few asymptomatic patients the restenotic but nontarget lesions were not reloaded, and a second follow-up angiogram showed regression of the intimal hyperplasia. The restenosis process may be exuberant in some patients, but, owing to the large poststen lumen diameter, an adequate lumen is maintained, making repeat PTCA unnecessary. This is supported by our experimental work in animals.18,19

Clinical events were more common in patients with diabetes mellitus, hypertension, and non-Q wave myocardial infarction. While the mechanisms for these are unclear, these are the subsets of patients who historically have incurred excessive risk of events in follow-up after treatment.

Limitations of the Current Study

This experience represents the initial, single-center experience with this device for these indications. As such, the investigators had to work out refinements in patient/artery selection and improvements in deployment techniques and poststen care (eg, anticoagulation and activity). In addition, patients with three-vessel disease were excluded by protocol, and this data would not be applicable to such patients. Also, patients with angiographically evident thrombus were excluded from entry, although careful cinefilm analysis later revealed filling defects in many of these arteries. This was not a clinical trial comparing different techniques of interventional arterial repair after injury, and little can be said regarding the present devices (eg, prolonged inflations, perfusion balloons, laser balloons) except that they were deemed failures in individual cases. Diligent attempts were made to repair the artery with other means before resorting to the stent.

Finally, one must assess the overall value of any new therapy after a period of study. This stent provided an alternate means of treatment in 71 of 96 phase 2 procedures (74%). Most of these patients would have gone to emergency coronary artery bypass surgery had the stent been unavailable. In addition, when placed, it provided relief from myocardial ischemia in 84% of patients. Also, the rate of Q wave MI in both the stent alone group (2.6%) and the stent followed by CAGB group (10.3%) was low in comparison with data previously reported from this institution (21%). Despite this, the stent has the potential to expand the indications for balloon PTCA by providing a safety net for patients with multivessel disease. It also provides a means for predictability restoring adequate flow when unexpected acute closure occurs. Significant complications related to stent thrombosis and anticoagulant-induced hemorrhage remain a problem. The greatest need is for systems producing a nonthrombogenic stent site, thereby obviating the need for aggressive systemic anticoagulation. In this setting, restenosis has certainly not been eliminated. However, in addition to relieving acute myocardial ischemia, intra-arterial prostheses provide an opportunity to deliver local drug therapy over a prolonged period of time and thereby may contribute to the control of restenosis.

We conclude that this balloon-expandable stent can stabilize most patients with arterial dissection and acute or threatened closure and avoid the need for emergency CAGB surgery or provide a bridge to CAGB after a failed PTCA. However, an aggressive anticoagulation program is needed and often results in bleeding and repeat revascularization. Modification of stent prototypes, improvements in anticoagulants, development of arterial plugs, and refinement of poststen protocols may increase the safety and effectiveness of these devices in the future. These results will be further clarified by the ongoing multicenter experience.

References


Clinical and angiographic outcomes after coronary artery stenting for acute or threatened closure after percutaneous transluminal coronary angioplasty. Initial results with a balloon-expandable, stainless steel design.


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