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Clinical Outcome of Patients Undergoing Endoluminal Coronary Artery Reconstruction With Three or More Stents

VERGHESE MATHEW, MD, DAVID HASDAI, MD, DAVID R. HOLMES, JR., MD, FACC, KIRK N. GARRATT, MD, FACC, MALCOLM R. BELL, MBBS, FACC, AMIR LERMAN, MD, FACC, STEVEN MELBY, RN, DIANE E. GRILL, MS, PETER B. BERGER, MD, FACC

Rochester, Minnesota

Objectives. **We sought to evaluate the outcome of patients undergoing multiple (three or more), contiguous stent implantation within a single native coronary artery.**

Background. **The implantation of multiple stents within a single coronary artery is increasing in frequency, although the outcome of such patients is not well described.**

Methods. **Forty-five patients without previous coronary artery bypass graft surgery (CABG) undergoing multiple, contiguous stent implantation in a single coronary artery were identified. Clinical and angiographic characteristics and outcomes were analyzed.**

Results. **The angiographic success rate was 97.8%. The procedural success rate was 91.1%; stent occlusion during the initial hospital period occurred in four patients (8.9%). Death, myocardial infarction (MI), CABG, repeat target vessel intervention or severe angina occurred in 10 (23.3%) of 43 hospital survivors at 6-month follow-up. The indication for stent placement was threatened or abrupt closure in 30 patients (66.7%). Of the 25 patients with abrupt or threatened closure whose clinical and angiographic data would have indicated emergent CABG had stents not been available, the frequency of in-hospital death and Q wave MI was similar to that of a matched consecutive series of patients at our institution who underwent emergent CABG after failed angioplasty. At 1 year, the frequency of death, Q wave MI, CABG and severe angina at 1 year was similar in the two groups; the need for repeat percutaneous intervention was more common in the stent group (25% vs. 0%, p = 0.01).**

Conclusions. **Implantation of multiple, contiguous intracoronary stents was associated with a high initial success rate, although the incidence of early stent closure was relatively high. Adverse events at 6 months of follow-up were more frequent than previously reported for elective single-stent implantation; however, adverse angiographic characteristics such as dissection and thrombus were frequent in this group. In addition, the strategy of multiple stent implantation in the setting of failed angioplasty is a reasonable alternative to emergent CABG, although the need for further percutaneous intervention must be anticipated.**

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Intracoronary stent implantation has added an important dimension to percutaneous revascularization strategies. Stents have been shown to reduce the incidence of restenosis in simple de novo lesions (1–3). Stents are also an effective means of treating the acute complications associated with balloon angioplasty, specifically coronary artery dissection and abrupt or threatened vessel closure (4,5). Before the availability of stents, these patients typically required emergent coronary artery bypass graft surgery (CABG) or sustained a myocardial infarction (MI), or both. Although early stent thrombosis had been a major problem, with early series reporting a striking incidence of this complication (6–8), improved implantation techniques and adjunctive anticoagulant regimens have reduced its incidence substantially (9). Placement of multiple coronary stents, however, particularly when overlapping or contiguous within the same coronary artery or segment, has been associated with a poorer outcome than single-stent placement (10), although there is a relative paucity of data on this issue. Despite this, the frequency with which multiple coronary stents are implanted in a single native vessel is increasing. In addition, multiple stent implantation performed in the setting of severe dissection and acute or threatened closure may reduce the need for emergent CABG and may be reasonable if it is associated with at least a comparable outcome to emergent CABG, which carries significant morbidity and mortality (11). To further examine these issues, we

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Address for correspondence: Dr. Peter Berger, Division of Cardiovascular Diseases, Mayo Clinic, 200 First Street SW, Rochester, Minnesota 55905. E-mail: berger.peter@mayo.edu.

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Abbreviations and Acronyms

CABG = coronary artery bypass graft surgery
INR = international normalized ratio
MI = myocardial infarction
TIMI = Thrombolysis in Myocardial Infarction

reviewed the clinical outcomes of all patients at our institution undergoing implantation of multiple (≥3) stents in a single native coronary artery.

Methods

We performed a retrospective analysis of the Mayo Clinic cardiac catheterization data base from January 1990 through December 1995, and identified 45 patients who had undergone implantation of three or more contiguous stents in a single native coronary artery; stents within major branch vessels were included if they were contiguous with stents placed within the adjacent major epicardial artery. Patients with previous CABG were excluded from the study. The medical records of all patients were reviewed. For all patients, baseline demographic information, vessel(s) treated, types and nominal sizes of stents, indication for stent placement and post-stent anticoagulation regimen were recorded. Angiographic data acquired during stent placement were reviewed, including target vessel, extent of coronary artery disease, percent diameter stenosis before and after stent deployment (assessed visually or by hand-held calipers by two or more operators using orthogonal views), Thrombolysis in Myocardial Infarction (TIMI) (12) flow grade before and after stent placement and presence of dissection or thrombus before and after the procedure. Indications for stent deployment were categorized as either elective (due to recurrent restenosis or complexity of lesion), treatment of abrupt closure after coronary angioplasty (worsening stenosis with TIMI flow grade 0, 1 or 2 [6,13]), suboptimal angioplasty result or dissection or threatened closure; patients may have undergone stent implantation for more than one of these indications. The study protocol was approved by the Mayo Clinic Institutional Review Board.

Definitions. *Angiographic success* was defined as ≥20% reduction in lumen diameter stenosis with <50% final residual diameter stenosis. *Procedural success* was defined as the achievement of angiographic success without the occurrence of death, CABG or Q wave MI during the initial hospital period. *Acute MI* was considered to have occurred when at least two of the following three criteria were met (14): 1) chest pain >30 min; 2) persistent electrocardiographic changes suggestive of ischemia; or 3) characteristic elevations in serum creatine kinase levels with a corresponding rise in the MB isoform. *Q wave MI* was defined as two of the above criteria with pathologic Q waves in the coronary distribution of the stented artery. *Thrombus* was considered to be present when one or more lumen filling defects in the coronary artery were visualized with contrast agent on three sides (13). *Dissection* was considered to have occurred when contrast staining was apparent within the vessel wall (6,13). In patients without angiographic confirmation of stent occlusion, *subacute stent occlusion* was defined clinically as the sudden onset of chest pain associated with electrocardiographic changes in the distribution of the target vessel, suggestive of acute ischemia or infarction, occurring within 30 days of stent placement. *Multivessel disease* was defined as ≥70% stenosis of the lumen diameter in a major epicardial coronary artery with ≥50% stenosis in a second major epicardial vessel (two-vessel disease) or both of the other epicardial vessels (three-vessel disease). *Complete revascularization* was defined as successful treatment of the index vessel with no residual stenosis ≥70% in any other coronary artery. *Severe angina* was defined as Canadian Cardiovascular Society class III or IV angina.

Angioplasty technique for stent implantation. All angioplasty procedures were performed using standard techniques (15) through the femoral artery. Intracoronary stent implantation techniques evolved over the study period. Gianturco-Roubin (Cook Inc.) and Wiktor (Medtronic Inc.) stents were generally placed across target lesions using 0.046-cm (0.018-in.) extra support guide wires for delivery, as described previously (16,17). Coronary Palmaz-Schatz stents (SDS, Johnson & Johnson Interventional Systems) were positioned within the delivery sheath over 0.036-cm (0.014-in.) extra support guide wires according to standard techniques (18). Delivery balloons were inflated to nominal pressure. As of 1994, stent delivery has been routinely followed by high pressure (≥14 atm) balloon inflations using noncompliant or minimally compliant balloons at sizes equivalent to or slightly larger than nominal stent size with the goal of achieving 0% residual diameter stenosis. Intravascular ultrasound was used to guide stent deployment at the discretion of the operator.

Anticoagulation. All patients received preprocedural oral aspirin (325 mg) and intraprocedural heparin to achieve an activated clotting time >300 s. Until 1994, patients received dextran immediately before the procedure, in accordance with the stent manufacturer's instructions. Our protocol for stent implantation until late 1994 included warfarin (target international normalized ratio [INR] of 2.0 to 4.0), dipyridamole (75 mg three times a day) and aspirin (81 to 325 mg/day) indefinitely; in these patients, heparin was discontinued after the procedure and sheaths were removed when the activated clotting time was <180 to 200 s, and then heparin was resumed after sheath removal and continued until the target INR was achieved. Between late 1994 and early 1995, warfarin was administered only to patients with suboptimal stent deployment, as assessed by coronary angiography or intravascular ultrasound, with standard post-stent therapy consisting of ticlopidine (250 mg twice daily for 4 to 6 weeks) and aspirin (81 to 325 mg/day); in patients treated only with antiplatelet agents after stent implantation, no further heparin was administered after the procedure. Later, warfarin was completely eliminated and patients believed to be at increased risk for subacute stent occlusion received subcutaneous injections of low molecular

weight heparin (30 or 60 mg twice daily for 10 to 14 days) in addition to aspirin and ticlopidine. Dipyridamole was eliminated in late 1994. Abciximab, available since 1995, was used in only two patients in this series.

Adverse events. In-hospital events, including death, Q wave MI, CABG, stent occlusion and repeat angioplasty of the target vessel, were recorded. Events in the 30 days after the index procedure, including the occurrence of any MI (Q wave or non–Q wave), were available for all patients. The occurrence of these events, including any MI, in the 6 months after the procedure were also analyzed. Follow-up angiography was generally only performed at the discretion of the referring physician for clinical indications such as the recurrence of severe angina or an early positive functional test, or to satisfy the requirements of clinical stent protocols. For all patients receiving multiple stents for the indication of dissection and threatened or abrupt closure, we reviewed the procedural angiograms and clinical histories, thereby identifying 25 patients (without chronically occluded arteries) with angiographic and clinical considerations that would have warranted emergent CABG had stents not been available. In a separate analysis, these patients were matched by age, gender and target vessel to patients who had been referred for emergent CABG after failed angioplasty. Patients with chronic total occlusions were excluded from this analysis, because severe dissection rarely requires emergent CABG in such patients.

Follow-up. The mean duration of follow-up was 19.2 ± 11.6 months; no patient was lost to follow-up. Patients were contacted by telephone by the nurse stent coordinator weekly for the first 8 weeks after the procedure. Patients were also contacted 6 and 12 months after the procedure. The case records of all patients followed at this institution were reviewed. Documentation of adverse events that occurred at other institutions during the follow-up period was obtained from the physicians at those institutions.

Statistical analysis. Descriptive statistics for the patients undergoing multiple stent implantation are presented as either mean value ± SD or percentage. Thirty-day follow-up was available for all patients, and the 30-day event rates presented include only posthospital discharge events. Six-month follow-up was available for all hospital survivors. Kaplan-Meier event-free survival curves were used to obtain estimates of 1-year event-free survival. In the subgroup analyses, comparisons between groups were done using the Student *t* test, Pearson chi-square test or log-rank test.

Results

Patient characteristics. The clinical and angiographic characteristics of the 45 patients in the study group are described in Table 1. The mean age of the patients was 60.5 years. Diabetes mellitus was present in 8 patients (17.8%). Previous MI had occurred in 22 patients (48.9%). The indication for stent placement was treatment of dissection in 26 patients (57.8%), abrupt closure in 6 patients (13.3%), suboptimal angioplasty result in 5 patients (11.1%) and elective in 10 patients (22.2%). Patients may have been classified as having more than one of these indications. A total of 158 stents were implanted in these patients (mean 3.5 stents per patient [range 3 to 6]).

Table 1. Baseline Characteristics of 45 Study Patients

Total stents	158
Stents/patient	
Mean	3.5
Range	3–6
Male	35 (77.8)
Mean (±SD) age (yr)	60.5 ± 10.8
1 vessel disease	18 (40.0)
2 vessel disease	17 (37.8)
3 vessel disease	9 (20)
Unstable angina	27 (60)
Diabetes	8 (17.8)
Hypertension	21 (46.7)
Active smoker	13 (28.9)
Previous smoker	18 (40)
Cholesterol >250 mg/dl	22 (48.9)
History of CHF	5 (11.1)
Previous MI	22 (48.9)
MI ≤24 h	2 (4.4)
Indications for stent placement	
Abrupt closure	6 (13.3)
Suboptimal result	5 (11.1)
Dissection	26 (57.8)
Elective	10 (22.2)

Data presented are number (%) of patients, except where otherwise indicated. CHF = congestive heart failure; MI = myocardial infarction.

Angiographic and procedural characteristics. De novo lesions were treated in 69% of patients, and restenotic lesions were treated in 31.1%; a second vessel was treated during the same procedure in six patients (13.3%). Complete revascularization was achieved in 66.7% of patients. The mean diameter stenosis before intervention was 82.5 ± 17.7%; the mean residual diameter stenosis was 11.3 ± 16%. The mean nominal stent size was 3.4 ± 0.4 mm. High pressure inflations (≥14 atm) were performed in 31 patients (68.9%). The right coronary artery was the most frequently treated vessel in this group, comprising 34 patients (75.6%). TIMI flow grade 3 was present in 32 patients (74.4%) immediately before stent implantation and in 40 patients (93.0%) after implantation. Angiographic evidence of thrombus in the treated segment was present in eight patients (17.8%) before implantation and in four patients (8.9%) after implantation. Branch vessel (≥2 mm diameter) occlusion occurred in two patients (4.4%). The Palmaz-Schatz stent was used in 29 patients, the Gianturco-Rubin stent in 30 and the Wiktor stent in 3; patients may have received more than one stent design.

Postprocedure anticoagulation regimen. Twelve patients were placed on antiplatelet therapy alone; 25 patients received warfarin; and six patients received low molecular weight heparin.

In-hospital events. Table 2 shows the in-hospital event rate of the study group. The angiographic and procedural success

Table 2. Adverse In-Hospital Events in Study Group

Death	2 (4.4)
Q wave MI	1 (2.2)
CABG	2 (4.4)
Stent occlusion	4 (8.9)
Repeat angioplasty of target vessel	2 (4.4)
Any of above	7 (15.6)

Data presented are number (%) of patients. CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

rates were 97.8% and 91.1%, respectively. Death occurred in two patients (4.4%); one of these deaths was due to acute stent occlusion on the day of the procedure in a patient who did not receive high pressure postdeployment inflations. The other death occurred in a patient returning to the catheterization laboratory with electromechanical dissociation, who had initially been referred for primary angioplasty in the setting of a large anterior wall MI; the stents were found to be widely patent on repeat angiography immediately before the patient's demise. One patient (2.2%) sustained a Q wave MI, and two patients (4.4%) required CABG during the initial hospital period. In total, four patients (8.9%) had stent occlusion, two of whom (4.4%) had repeat angioplasty of the stented segment. Any of these events occurred in seven patients (15.6%). Multivariate analysis revealed that angiographic evidence of thrombus before or after the procedure, TIMI flow grade before or after the procedure and stent type did not predict adverse events during the initial hospital period.

Adverse events at 30-day follow-up. No patient died, sustained an MI or stent closure, developed severe angina or required CABG or repeat angioplasty after discharge from the hospital within 30 days after the procedure.

Adverse events at 6-month follow-up. Table 3 shows the additional event rates occurring in 43 hospital survivors at 6 months. Death occurred in one patient (2.3%); MI in two patients (4.7%); CABG in three patients (7.0%); severe angina in seven patients (16.3%); repeat intervention of the target vessel in six patients (14.0%); and one or more of these events in 10 patients (23.3%). Eight patients (18.6%) required any intervention (angioplasty or CABG). No additional cases of stent occlusion were identified in this period. Multivariate analysis revealed that angiographic evidence of thrombus before or after the procedure, TIMI flow grade before or after the procedure, stent type or warfarin use did not predict adverse events at 6 months.

Table 3. Adverse Events at 6 Months for 43 Hospital Survivors

Death	1 (2.3)
Any MI	2 (4.7)
CABG	3 (7.0)
Stent occlusion	0
Repeat angioplasty of target vessel	6 (14.0)
Severe angina	7 (16.3)
Any of above	10 (23.3)

Data presented are number (%) of patients. Abbreviations as in Table 2.

Table 4. Patients Undergoing Rescue Stent Placement Versus Emergent Coronary Artery Bypass Graft Surgery for Failed Percutaneous Transluminal Coronary Angioplasty

	CABG (n = 25)	Stent (n = 25)	p Value
Men	19 (76)	19 (76)	1.00
Mean (±SEM) age (yr)	63.8 ± 11.2	62.6 ± 10.8	0.70
Active smoker	10 (40)	6 (24)	0.46
Diabetes	1 (4)	4 (16)	0.16
Hypertension	11 (44)	10 (40)	0.96
Multivessel disease	17 (68)	17 (68)	1.00
Cholesterol >250 mg/dl	10 (40)	11 (44)	0.95
Previous MI	14 (56)	12 (48)	0.47
ST segment elevation in catheterization laboratory	3 (12)	4 (16)	0.93
Shock in catheterization laboratory	4 (16)	3 (12)	0.36
In-hospital death	2 (8.0)	1 (4.0)	0.55
In-hospital Q wave MI	0	0	0.66
In-hospital CABG	0	1 (4.0)	0.31
In-hospital repeat angioplasty	0	1 (4.8)	0.31
Adverse events at 1 year			
Death	2 (8.9)	1 (4.2)	0.46
MI	1 (4.8)	2 (8.3)	0.95
CABG	0	1 (4.8)	0.31
Angioplasty	0	6 (25)	0.01
Severe angina	2 (13.7)	7 (29.4)	0.11

Data presented are number (%) of patients, except where otherwise indicated. Abbreviations as in Table 2.

In-hospital and 6-month event rates for patients receiving high pressure inflations. In the 31 patients receiving high pressure (≥14 atm) postdeployment inflations, the procedural success rate was 93.5%, and the in-hospital occurrence of death, Q wave MI, CABG, repeat intervention of target vessel, severe angina or any combination of these events was 1 (3.2%), 0, 1 (3.2%), 1 (3.2%) and 3 (9.7%), respectively. Death, any MI, CABG, repeat intervention of target vessel, severe angina or any combination of these events in hospital survivors (n = 30) in this group were 1 (3.3%), 2 (6.7%), 3 (10%), 5 (16.7%), 6 (20%) and 9 (30%), respectively, at 6 months.

In a Kaplan-Meier analysis of event-free survival (freedom from death, CABG, any MI, repeat intervention of target vessel or severe angina) comparing the subgroup of 13 hospital survivors not receiving high pressure postdeployment inflations with the subgroup of 30 hospital survivors receiving high pressure postdeployment inflations, 6-month and 12-month event-free survival rates were not influenced by the use of high pressure postdeployment inflations in this small series ($p = 0.07$).

Comparison of multiple stents and emergent CABG in patients with severe dissection and abrupt or threatened vessel closure. These two groups of 25 patients each were similar with respect to baseline characteristics as well as the presence of ST segment elevation and shock in the catheterization laboratory (Table 4). All procedures were successful. In-hospital rates of death, Q wave MI, subsequent CABG and repeat percutaneous interventions were similar between the

groups; Kaplan-Meier analysis of 12-month event-free survival demonstrated equivalence in the occurrence of the end points of death and MI between the stent and CABG groups. Although there was a trend toward an increased frequency of severe angina in patients who had stented arteries, this was not statistically significant. The need for repeat interventional procedures was greater in the patients who had received stents (25% vs. 0%, p = 0.01).

Discussion

The clinical outcome of patients undergoing multiple stent implantation in a single native coronary artery has not been well delineated; however, a potential concern has been the possibility of adverse outcomes associated with a greater burden of metal within the vasculature (10). The concern that adverse outcomes are more frequent in patients undergoing multiple stent implantation has not been well demonstrated. The question is relevant in that the implantation of multiple stents in a single coronary artery is becoming more frequent.

Based on this review of our early experience, it is apparent that multiple, contiguous or overlapping stents, even in the setting of severe dissections and abrupt vessel closure, may be placed with a high degree of procedural success; in this series, 41 (91.1%) of 45 patients were discharged from the hospital without sustaining a Q wave MI or requiring CABG. However, acute and subacute stent occlusion was a significant problem in this series; 4 (8.9%) of 45 patients had stent occlusion during the initial hospital period, and one of these patients died. This is consistent with previously published data showing that stent implantation in the setting of failed angioplasty is associated with a greater frequency of stent thrombosis and restenosis (19–21), despite the achievement of a satisfactory angiographic result (22). Also notable is the fact that patients undergoing multiple stent implantation in our series were likely to have angiographic evidence of thrombus within the target vessel at the end of the procedure (8.9%), perhaps contributing to the higher rate of stent thrombosis. Additional measures to reduce acute or subacute closure, such as the combined use of aspirin and ticlopidine, as well as abciximab and low molecular weight heparin in selected patients, may improve clinical outcome. Additionally in this series, the adverse event rate at 6 months was 23.3%, whereas 18.6% of patients required further revascularization. Although not case-controlled, this is higher than the rates reported for single stent implantation for discrete de novo lesions (2,3). However, such comparisons may not be appropriate, because a significant proportion of these patients received stents in the setting of adverse lesion characteristics, including dissection and the presence of thrombus, which were exclusion criteria for the randomized trials comparing stents with angioplasty.

The current standard of stent deployment includes the use of high pressure postdeployment inflations (23); as this series included our early stent experience, 14 patients (31.1%) did not receive high pressure inflations. However, in this small series, an improvement in clinical outcome could not be demonstrated with high pressure inflations, suggesting that factors other than implantation techniques may have been involved. One such factor may be that a substantial proportion of our patients received warfarin as part of their postprocedure anticoagulation regimen. Although the use of warfarin did not predict adverse events in this series, it has been previously suggested that the use of warfarin may in fact be detrimental after stent implantation (24). Similarly, angiographic evidence of thrombus, reduced TIMI flow grade and stent type did not predict in-hospital or 6-month outcome, although the small number of patients precludes definitive conclusions in this regard.

In this series, the implantation of multiple stents was often performed because of complications related to angioplasty or failed angioplasty; before the availability of intracoronary stents, such patients would have often been referred for emergent CABG or would have had an MI. In such instances, it appears that implanting multiple stents in an attempt to avoid emergent CABG is a reasonable strategy. The occurrence of death, MI, CABG and severe angina was similar between the two groups, although the patients who had stents placed were more likely to require repeat intervention during follow-up.

Study limitations. The present study was a retrospective analysis that included different stent types as well as varying implantation techniques and postprocedure anticoagulation regimens. High pressure inflations were not routinely used in our early experience, and warfarin was used in a significant portion of patients in this series; such factors may skew this series toward an increased adverse event rate. Only a prospective, randomized trial can determine with certainty the relative merits of multiple, contiguous stent placement compared with emergent CABG; such a study is not likely to be performed given the current enthusiasm for stent placement.

Conclusions. Multiple, contiguous intracoronary stents may be placed with a high procedural success rate, although subacute stent occlusion was a significant problem. The rate of adverse events at 6 months is likely higher than that reported after single stent implantation for discrete de novo lesions, although dissection and abrupt or threatened vessel closure were frequently the indication for stent placement in this series. In addition, the utilization of a strategy of multiple stent implantation in the setting of failed angioplasty is an effective alternative to emergent CABG in certain patients, although the need for further intervention must be anticipated.

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