Immediate and Long-Term Outcome of Intracoronary Stent Implantation for True Bifurcation Lesions

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OBJECTIVES

The aim of this study was to evaluate the immediate and long-term outcome of intracoronary stent implantation for the treatment of coronary artery bifurcation lesions.

BACKGROUND

Balloon angioplasty of true coronary bifurcation lesions is associated with a lower success and higher complication rate than most other lesion types.

METHODS

We treated 131 patients with bifurcation lesions with ≥1 stent. Patients were divided into two groups; Group (Gp) 1 included 77 patients treated with a stent in one branch and percutaneous transluminal coronary angioplasty (PTCA) (with or without atherectomy) in the side branch, and Gp 2 included 54 patients who underwent stent deployment in both branches. The Gp 2 patients were subsequently divided into two subgroups depending on the technique of stent deployment. The Gp 2a included 19 patients who underwent Y-stenting, and Gp 2b included 33 patients who underwent T-stenting.

RESULTS

There were no significant differences between the groups in terms of age, gender, frequency of prior myocardial infarction (MI) or coronary artery bypass grafting (CABG), or vessels treated. Procedural success rates were excellent (89.5 to 97.4%). After one-year follow-up, no significant differences were seen in the frequency of major adverse events (death, MI, or repeat revascularization) between Gp 1 and Gp 2. Adverse cardiac events were higher with Y-stenting compared with T-stenting (86.3% vs. 30.4%, p = 0.004).

CONCLUSIONS

Stenting of bifurcation lesions can be achieved with a high success rate. However, stenting of both branches offers no advantage over stenting one branch and performing balloon angioplasty of the other branch. (J Am Coll Cardiol 2000;35:929–36) © 2000 by the American College of Cardiology

Coronary artery bifurcation lesions are difficult to treat with conventional balloon angioplasty and are associated with both a low success rate and relatively high incidence of procedural complications, including myocardial infarction (MI) and emergency coronary artery bypass grafting (CABG) (1,2). Various balloon and guide wire techniques have been applied, including “kissing” (simultaneous) and sequential balloon inflations (3–5). More recently, debulking techniques such as directional (6–11) and rotational atherectomy (12) have been evaluated for the treatment of these lesions. The practice of stent implantation for these lesions has evolved significantly in recent years, and different practical approaches have been suggested, including “T-stenting,” “reverse Y-stenting,” “trouser-leg stenting,” and stent implantation of the major branch with percutaneous transluminal coronary angioplasty (PTCA) or debulking of the side branch (13–22). To date, however, it is uncertain how these approaches compare with one another regarding in-hospital and long-term outcomes. Thus, the purpose of this study was to analyze the immediate and longer-term outcomes of patients treated with these different approaches involving intracoronary stent implantation in coronary artery bifurcation lesions at our institution.

METHODS

Patient population. We performed an analysis of the Mayo Clinic PTCA database and reviewed all coronary interventional procedures performed at our institution between October 1993 and November 1998. This prospectively coded registry includes baseline demographic, clinical, and angiographic data. Included were all patients with true bifurcation lesions, defined as lesions in which there was a
Atherectomy in the other branch. Group (Gp) 2 (n = 77) included patients who were treated with a stent in one branch and balloon angioplasty with or without atherectomy in the other branch. Group (Gp) 2 (n = 54) consisted of patients who underwent stent implantation in both branches. Group 2 was further divided into two subgroups depending on the stent deployment technique; Gp 2a (n = 19) consisted of patients in whom reverse angioplasty was used after 1994.

Beginning late 1995, warfarin was administered to patients only if clinically indicated for reasons unrelated to stent implantation. All other patients were treated with ticlopidine 250 mg twice daily (initially for four to six weeks and, from mid-1996, for two weeks). From March 1998 to the present, clopidogrel 300 mg oral load, followed by 75 mg daily for 14 days, was used in place of ticlopidine. Beginning late 1995, subcutaneous enoxaparin (30 to 60 mg twice daily) (Lovenox, Rhone-Poulenc, Rorer, Collegeville, Pennsylvania) was administered subcutaneously for 10 to 14 days to patients believed to be at increased risk of stent thrombosis; at the operator’s discretion, this was infrequently used.

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Angiography and ventriculography. The severity of coronary artery disease was assessed visually, generally by two observers, using two orthogonal views. Either sublingual nitroglycerin (0.4 mg), intracoronary nitroglycerin (100 to 200 µg) or both were given before the initial and final angiographic assessment. Single-vessel coronary artery disease was defined as luminal diameter stenosis of ≥70% of one major epicardial artery. Two- or three-vessel disease was diagnosed if there were one or two additional major epicardial arteries with at least a 70% luminal diameter stenosis, respectively.

The left ventricular ejection fraction was determined by ventriculography at the time of diagnostic angiography or during follow-up, as indicated clinically, by echocardiography, a radionuclide study, or left ventriculography.

Definitions. Procedural Q-wave MI was defined as the presence of new Q waves on the electrocardiogram (ECG) with either serum creatine kinase (CK), MB fraction concentrations that were at least three times higher than normal or positive tests for MB isoenzymes, an episode of prolonged angina, or new regional wall-motion abnormalities in the area of the treated vessel.

Complete revascularization was defined as successful dilation of all stenoses ≥70%. Incomplete revascularization was defined as a ≥70% diameter stenosis of one or more remaining arteries.

A successful procedure was defined as a ≥20% reduction in the stenosis of the lesions treated, resulting in a residual stenosis of <50% of the luminal diameter. Clinical success was defined as the achievement of angiographic success without in-hospital death, Q-wave MI, or referral for CABG.

Death from cardiac causes was defined as death due to MI, sudden death not proven to be noncardiac in nature, heart failure, or complications of cardiac surgery or transplantation.

Follow-up. Patients were contacted six and 12 months after the procedure and yearly thereafter by research technicians using a standardized questionnaire. In addition, if patients were rehospitalized during the follow-up period, the medical records of admissions and treatments at the Mayo Clinic and elsewhere were reviewed and data extracted, verified, and recorded. Follow-up angiography was generally only performed for clinical indications at the discretion of the attending physician, such as the recurrence of severe angina or for an early positive functional test.

Major adverse clinical events during the follow-up period included death, MI, (Q-wave and non-Q-wave), and severe angina (Canadian Cardiovascular Society [CCS] class III or IV). The frequency rates of repeat coronary angioplasty and coronary artery bypass surgery were also analyzed.

End points. The primary end point of this study was to evaluate procedural success and complication rates for the treatment of bifurcation lesions with one or more stents. We also sought the frequency of adverse cardiac events during one year of follow-up.

Statistical analysis. Comparisons of the baseline variables were done with the Student t test for continuous data or Pearson’s chi-square test for discrete data. Event-free survival curves were calculated using the Kaplan-Meier method; differences between the groups were tested with the log-rank test statistic. Univariate Cox proportional hazard survival models were fit to calculate the relative risk of an event for abciximab and debulking; other baseline variables were also looked at univariately. Multivariate models were constructed, but because of the low number of events we found nothing significant.

RESULTS

Of the 325 patients in our database who underwent coronary stenting of a major vessel and a branch arising from that vessel, 147 patients with true bifurcation lesions were identified. Sixteen patients were excluded because they had a MI ≤within 24 h of the procedure or had cardiogenic shock. The remaining 131 patients constitute the study group.

The outcome of the study group was initially compared to patients who underwent balloon angioplasty alone. Overall lesion success (98.1% vs. 89.5%, p < 0.05) and procedural success (93% vs. 80%, p < 0.05) were significantly higher in patients who underwent intracoronary stent implantation when compared to balloon angioplasty alone.

Patient characteristics. There were no significant differences in age, gender, risk factors, frequency of prior MI or previous CABG or the indications for revascularization between the various groups as shown in Table 1.

Angiographic characteristics and procedural performance. Among the 77 patients in Gp 1 who underwent stent deployment in one vessel, 55 (71%) underwent balloon angioplasty alone in the side branch and 22 (29%) underwent combination of balloon angioplasty with atherectomy. Among the 54 patients who underwent stent deployment in both branches, 47 (87%) underwent adjunctive balloon angioplasty and 7 (13%) underwent combination of balloon angioplasty with atherectomy prior to stent deployment. Of those patients who underwent stent deployment in both arms, 19 (37%) patients underwent Y-stenting and 33 (64%) underwent T-stenting (Fig. 2). There were no significant differences in the angiographic characteristics between the two study groups as shown in Table 2.

The mean maximum balloon sizes used for the main branches of the various groups were similar (3.4 ± 0.4 mm in Gp 1, 3.4 ± 0.4 mm in Gp 2, 3.3 ± 0.4 mm in Gp 2a, and 3.5 ± 0.5 mm in Gp 2b), and they were in the side branches as well (2.9 ± 0.4 in Gp 1, 3.0 ± 0.4 mm in Gp 2, 3.1 ± 0.5 mm in Gp 2a, and 3.0 ± 0.2 mm in Gp 2b). The mean stent sizes used for the treatment of the main branches were also similar (3.2 ± 0.4 mm in Gp 1, 3.0 ± 0.4 mm in Gp 2, 3.1 ± 0.5 mm in Gp 2a, and 3.0 ± 0.0 mm
in Gp 2b) and for the side branches as well (3.2 ± 0.4 in Gp 2, 3.3 ± 0.4 mm in Gp 2a, and 3.0 ± 0.3 mm in Gp 2b). The angiographic success rate was high in all the study groups, regardless of which approach was used (97.4% Gp 1 vs. 94.4% Gp 2, p = 0.38). When procedural complications were analyzed according to the approach used, the incidence of major complication rates was relatively low and no significant differences were seen between those who underwent stent implantation in one branch versus both branches with regards to death, Q-wave MI, or the need for emergency CABG.

Further analysis of the angiographic characteristics and complication rates in patients who underwent stent deployment in both arteries according to the stent approach are shown in Table 2. Procedural success rate tended to be greater in those who underwent T- rather than the Y-shaped stent design; however, this difference was not statistically significant (89.5% in Gp 2a vs. 97.0% in Gp 2b, p = 0.26). The frequency rates of death, QMI, and the need for emergency CABG were relatively low, and no significant differences existed among the various groups.

Multivariate analysis was performed to ascertain whether the selection of stenting technique was associated with certain variables including the clinical presentation of patients, angiographic characteristics including the severity of vessel tortuosity, straightness of the vessel, the presence of thrombus, calcification, eccentricity of the treated lesions, balloon and stent size, transient occlusion of the main or side branch, and the development of chest pain or hypotension during the procedure. None of these variables were associated with the use of a particular stenting technique.

Late clinical results. After one year of follow-up, no significant differences were noted in survival or the occurrence of MI, CABG, or need for repeat revascularization between those who underwent stent implantation in only one artery versus those who underwent stent implantation in both arteries (Table 3). Patients who underwent stent deployment in both arteries tended to develop more severe angina (19.4% in Gp 1 vs. 39.5% in Gp 2, p = 0.12) and require revascularization compared with those who underwent stent deployment in one arm only (17.4% in Gp 1 vs. 19.4% in Gp 2, p = 0.59 and CABG; 3.7% in Gp 1 vs. 7.5% in Gp 2, p = 0.41), although these differences did not reach statistical significance (Table 3). There was a trend toward better long-term outcome in Gp 1 versus Gp 2 (Fig. 3).

Further analysis of Gp 2 according to the treatment approach is shown in Table 3. No significant differences were seen between the two groups with regards to mortality or the occurrence of MI. However, at one year, the incidence of severe angina was 69% in patients who underwent Y-stent deployment versus 23.9% in the T-stent group.
Group 1 and Gp 2 patients who underwent target lesion revascularization all received treatment of the side branch, and 80% also received treatment of the main branch. In the Y-stent group, three side branches were completely occluded at follow-up. The cumulative occurrence of mortality, MI, severe angina, and need for repeat procedure was significantly greater in the Y-stent group than in the T-stent group, as shown in Figure 4.

The use of atherectomy or abciximab was not associated with a significant improvement in outcome (atherectomy RR 0.78 [CI 95%: 0.34, 1.81, p = 0.56], abciximab RR 0.86 [CI 95%: 0.43, 1.70, p = 0.67]).

DISCUSSION

This study demonstrates that percutaneous coronary interventions in bifurcation lesions with coronary stents overall are associated with high procedural success and low acute complication rates independent of whether stents were deployed in one or both vessels. In addition, after one year of follow-up, the frequency of death or MI was relatively low among the various groups. However, severe angina and revascularization tended to occur more frequently in the group that underwent stent deployment in both vessels, in particular in those who underwent Y-stenting. This study suggests that treatment of true bifurcation lesions with stents in both vessels may not offer any advantage over stenting of one vessel and balloon angioplasty and or atherectomy of the other.

The treatment of bifurcation lesions has posed a significant challenge to interventional cardiologists over the years and has been associated with relatively frequent procedural complications including MI and emergency coronary bypass surgery (1,2). Recently, however, considerable progress has been made in the field of percutaneous coronary revascular-
Procedural techniques other than balloon angioplasty have been developed. The feasibility of rotational atherectomy with adjunctive balloon angioplasty and stenting in the treatment of bifurcation lesions in 15 patients has recently been reported, with high procedural success rates and low complication rates (12). In addition, Dauerman et al. (7) reported their experience with atherectomy in the treatment of true bifurcation lesions. They compared conventional balloon angioplasty using a double-wire technique in which simultaneous (“kissing”) or sequential balloon inflations to debulking, primarily using directional atherectomy, followed by adjunctive balloon angioplasty. These investigators observed significantly lower postprocedural residual stenoses and a significantly lower target vessel revascularization rate at follow-up in the debulking group compared with the balloon angioplasty group. Whether these results can be reproduced by other centers remains to be determined (24).

Another recent advance in the treatment of bifurcation lesions is the use of coronary stents (25). The widespread use of stents is based on a number of randomized controlled trials confirming their superior long-term results compared with balloon angioplasty (26–28). However, none of these studies permitted treatment of bifurcation lesions. Intracoronary stent implantation across side branches is associated with an increased risk of side branch occlusion as well as restriction of future access to the side branch. These concerns have limited their use in bifurcation lesions (29,30).

Previous studies of stenting for true bifurcation lesions. Data on the role of stenting for the treatment of bifurcation lesions are limited to a number of case reports, small series (12–22), and preliminary studies (31–34) describing various techniques (T-stenting, reverse Y-stenting, and trouser-leg stenting). Carrie et al. (21) reported their experience of stenting bifurcation lesions in 54 patients using either T- or reverse Y-stenting techniques, and they demonstrated that the procedural success rate was high regardless of which approach was used. Our study and other preliminary studies suggest that stenting of bifurcation lesions can be achieved with a high success rate and an acceptable complication rate,

### Table 3. Adverse Cardiac Events at One Year

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1 (n = 75)</th>
<th>Group 2 (n = 51)</th>
<th>Group 2a (n = 17)</th>
<th>Group 2b (n = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe angina (CCS III–IV)</td>
<td>10 (19.4)</td>
<td>14 (27.5)</td>
<td>9 (69.1)</td>
<td>5 (23.9)</td>
</tr>
<tr>
<td>QMI</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Any MI</td>
<td>0 (0.0)</td>
<td>1 (2.4)</td>
<td>0 (0.0)</td>
<td>1 (4.2)</td>
</tr>
<tr>
<td>Repeat procedure</td>
<td>9 (17.4)</td>
<td>8 (19.4)</td>
<td>5 (33.3)</td>
<td>3 (12.5)</td>
</tr>
<tr>
<td>TLR</td>
<td>11 (20.5)</td>
<td>8 (19.4)</td>
<td>5 (33.3)</td>
<td>3 (12.5)</td>
</tr>
<tr>
<td>CABG</td>
<td>2 (3.7)</td>
<td>3 (7.5)</td>
<td>2 (14.3)</td>
<td>1 (3.8)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (2.1)</td>
<td>3 (8.8)</td>
<td>1 (14.3)</td>
<td>2 (8.2)</td>
</tr>
<tr>
<td>Any of these events</td>
<td>14 (26.8)</td>
<td>18 (47.7)</td>
<td>11 (86.3)</td>
<td>7 (47.7)</td>
</tr>
</tbody>
</table>

Data presented are numbers (%) of patients, unless otherwise indicated. CCS = Canadian Cardiovascular Society Classification; CABG = coronary artery bypass graft; MI = myocardial infarction; TLR = Target lesion revascularization. *p = 0.006 group 2a versus group 2b. †p = 0.004, group 2a versus group 2b.

![Figure 3](image3.png) **Figure 3.** Kaplan-Meier curves of the probability of survival and freedom from myocardial infarction (MI), bypass surgery, and repeat coronary angioplasty and severe angina (CCS class III or IV) in the two treatment groups.

![Figure 4](image4.png) **Figure 4.** Kaplan-Meier curves of the probability of survival and freedom from myocardial infarction (MI), bypass surgery, and repeat coronary angioplasty and severe angina (CCS class III or IV) in Gp 2a and Gp 2b.
but that stenting both limbs of bifurcation lesions offers no advantage over stenting of one arm and balloon angioplasty with or without atherectomy of the other vessel, and that stenting of both vessels may be associated with a higher restenosis rate and the need for more frequent revascularization (31–34). This worse clinical outcome may be hypothesized to be due to overlapped segments of stents and more trauma during stent deployment, possibly stimulating the formation of neointimal hyperplasia. Whether stents specifically designed to treat bifurcation lesions will result in higher success rates and lower complication rate is yet to be determined (25).

**Antiplatelet therapy.** Abciximab, a potent glycoprotein IIb/IIIa inhibitor of platelet aggregation, reduces ischemic complications in patients undergoing high and low risk balloon angioplasty (35–37) and stenting (28). Although the use of abciximab was shown to be beneficial in bifurcation lesions treated with balloon angioplasty (38), whether it is beneficial in combination with coronary stenting or other percutaneous interventions is unknown. In our study, abciximab use was not associated with a better short-term or long-term outcome. However, routine measurements of CK and CK-MB enzymes were not performed after uncomplicated procedures.

**Study limitations.** The major limitation of our study is its retrospective, observational design with possible confounding by baseline differences in patient characteristics. Our study was further limited by the lack of routine angiographic follow-up. Nonetheless, the ultimate goal of percutaneous revascularization is relief of angina and avoidance of additional procedures and cardiac events, and these were closely monitored in our study.

**SUMMARY**

This series demonstrates that stents can be deployed with high success and low complication rates in coronary bifurcation lesions. This study suggests that treatment of true bifurcation lesions with stents in both vessels may not offer any advantage over stenting of one vessel and balloon angioplasty and/or atherectomy of the other. Whether stents specifically designed to treat bifurcation lesions with or without other adjunctive therapies will result in higher success rates and lower complication rates has not yet been determined.

**References**

27. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of


