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# Bifurcation Lesions: Two Stents Versus One Stent—Immediate and Follow-up Results

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OBJECTIVES	The purpose of this study was to evaluate two different techniques of stent placement in bifurcation lesions.
BACKGROUND	Although stent placement with dedicated techniques has been suggested to be a useful therapeutic modality for bifurcation lesions, limited information is available if stent placement on the side branch and on the parent branch provides any advantage over a simpler strategy of stenting the parent vessel and balloon angioplasty of the side branch.
METHODS	Between March 1993 and April 1999, we treated a total of 92 patients with bifurcation lesions with two strategies: stenting both vessels (group B, $n = 53$ ) or stenting the parent vessel and balloon angioplasty of the side branch (group P, $n = 39$ ). Paired angiograms were analyzed by quantitative angiography, and clinical follow-up was obtained.
RESULTS	Stent placement on both branches resulted in a lower residual stenosis (7.4 $\pm$ 10.9% vs. 23.4% $\pm$ 18.7%, p < 0.001) in the side branch. Acute procedural success was similar in the two groups (group B: 87% vs. Group P: 92%). In-hospital major adverse cardiac events (MACE) occurred only in group B (13% vs. 0%, p < 0.05). At the six-month follow-up, the angiographic restenosis rate (group B: 62% vs. Group P: 48%) and the target lesion revascularization rate (38% vs. 36%, respectively) were similar in the two groups. There was no difference in the incidence of six-month total MACE (51% vs. 38%).
CONCLUSIONS	For the treatment of true bifurcation lesions, a complex strategy of stenting both vessels provided no advantage in terms of procedural success and late outcome versus a simpler strategy of stenting only the parent vessel. (J Am Coll Cardiol 2000;35:1145–51) $©$ 2000 by the American College of Cardiology

The treatment of stenoses at a bifurcation remains one of the most challenging lesion subsets in coronary angioplasty. Bifurcation lesions carry a risk of side branch occlusion because of plaque redistribution or so-called "plaque shift" across the carina of the bifurcation. The risk is increased if there is an eccentric lesion at the bifurcation site and a stenosis in the ostium of the side branch (1). To lower the risk of plaque shift, the "kissing" balloon technique was developed (2). However, the results after balloon dilatation of bifurcation lesions are frequently subotpimal with a high incidence of complications and restenosis (1,3-5). Treatment of bifurcations with directional atherectomy was shown to improve the immediate procedural outcome compared with balloon dilatation alone, but the incidence of restenosis remained high (6). Recently, it has been reported that debulking (either directional atherectomy or rotational

atherectomy) with adjunctive balloon angioplasty not only improved acute angiographic results but also decreased target vessel revascularization compared with balloon angioplasty alone (7). It has also been pointed out that optimal results and low complication rates could not necessarily be anticipated by all operators (8). The use of coronary stents has improved the treatment of bifurcation lesions, but it is technically challenging and there is still a high incidence of compromising the branch vessel (9–11). Stent implantation on both the parent vessel and the side branch, which is called "kissing stents," is a useful technique for maintaining maximum expansion of both vessels. The use of two stents minimizes lumen loss of one side during expansion of the other vessel (12). The four main techniques used for bifurcation stenting (the "T" stent, the "V" stent, the "Y" stent and the "Culotte" technique) have been described with their advantages and disadvantages (13,14). Although these dedicated techniques have evolved along with new stent designs, it is not clear if the strategy of stenting both vessels provides better outcome than that of stenting only the parent vessel. So far, only case reports or limited series are

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Abbreviations and Acronyms				
CABG	= coronary artery bypass grafting			
DCA	= directional coronary atherectomy			
MACE	= major adverse cardiac events			
MI	= myocardial infarction			
MLD	= minimum luminal diameter			
NQMI	= Non-Q wave myocardial infarction			
QCA	= quantitative coronary angiography			
QMI	= Q wave myocardial infarction			
TIMI	= thrombolysis in myocardial infarction			
TLR	= target lesion revascularization			

available to understand the results of these different techniques (12,15-17).

For this reason, we analyzed in-hospital results and long-term outcomes for 92 consecutive patients with true bifurcation lesions treated with either stenting both vessels or stenting the parent vessel plus balloon angioplasty for the branch.

### **METHODS**

**Study population.** Between March 1993 and April 1999, a total of 92 patients underwent coronary stenting at our institute for the treatment of symptomatic bifurcation lesions that had a >50% diameter stenosis in both the parent vessel and the ostium of the contiguous side branch. Informed consent for coronary angiography and stent implantation was obtained from all patients.

Interventional procedures. Before angioplasty, oral aspirin and intravenous bolus of heparin (100/kg until the end of 1997 then 70 U/kg) were administered to all patients. Angiograms in multiple views were obtained using the transfemoral approach. Some lesions were pretreated by debulking devices, such as directional atherectomy, if the vessels had a large reference vessel diameter and a large plaque mass or by rotational atherectomy when extensive calcifications were present or the balloon did not expand at high pressure. After placement of the guiding catheter, two wires were inserted in the distal bed of the two branches. Balloon angioplasty was conducted by sequential inflation of a semicompliant balloon in each branch. Two strategies for bifurcations were available: a less complicated angioplasty strategy that used stenting in only the parent vessel of the bifurcation lesions (group P) and a more complicated angioplasty treatment strategy that included stenting of both branches of bifurcation lesion (group B). As a general rule, both lesions were stented when the reference vessel size of the side branch was greater than 2.5 mm. Group B was comprised of 53 patients and group P was comprised of 39 patients. For group B, stent placement for both vessels was performed using one of the previously reported techniques (13,14). For group P, the stent was implanted in the parent vessel and then balloon dilatation was performed through

the stent struts into the side branch. Simultaneous kissing balloon inflation was frequently performed on completion of the procedure. Postprocedure creatine kinase was measured for the patients:

- 1) who experienced transient or permanent vessel or branch occlusion during the procedure,
- 2) who had prolonged (more than 15 min) chest pain after the completion of a successful procedure,
- 3) who had ECG change with or without chest pain,
- 4) who had unsuccessful procedure.

Angiographic analysis and clinical follow-up. We used a computer-based QCA-CMS system version 4.0 (MEDIS Medical Imaging Systems Inc., Leiden, the Netherlands) for quantitative coronary angiography (QCA), with the dye-filled catheter as a reference. Reference diameter, lesion length and minimum luminal diameter (MLD) were measured before and after angioplasty, and at the time of follow-up angiography. The diameter of the normal segment proximal to the traced area in the parent vessel was used to determine the parent vessel diameter, and the side branch reference diameter was determined from the diameter of the traced segment in the normal segment distal to the lesion in the branch. Lesion length was defined as the distance from the proximal to the distal shoulder of the lesion. Angiographic success was defined as the achievement of a residual stenosis <50% with at least Thrombolysis in Myocardial Infarction (TIMI) (18) flow 3 in both the parent vessel and side branch. Procedural success was defined as the achievement of angiographic success in the absence of any in-hospital major adverse cardiac events (MACE), which include death, myocardial infarction (MI) or emergency percutaneous treatment or coronary artery bypass grafting (CABG). A diagnosis of Q wave myocardial infarction (QMI) was made when there was documentation of new pathologic Q waves (>0.04 s) on an electrocardiogram in conjunction with an elevation in creatine phosphokinase greater than twice the normal value. A diagnosis of non-Q wave myocardial infarction (NQMI) was made when an elevation of cardiac enzymes to greater than twice the normal value was documented without development of new pathologic Q waves. Emergency coronary bypass surgery was defined as bypass surgery involving immediate transfer of the patient from the catheterization laboratory to the operating room or within 24 h of the procedure. Follow-up angiography was planned for all patients at six months or earlier, if there was a clinical indication. Restenosis was defined as >50% diameter stenosis of the treated lesion.

Clinical follow-up was obtained around six months after treatment by telephone or direct patient interview. Target lesion revascularization (TLR) was defined as any repeat percutaneous intervention to the target lesion (parent or side branch) or any coronary bypass graft to the treated vessel during follow-up. Six-month total MACE was defined as

	Group B (n = 53)	Group P (n = 39)	p Value
Age (yr)	57.8 ± 12.4	$62.0 \pm 10.7$	0.11
Men (%)	50 (94)	33 (85)	0.12
Risk Factors			
Hypertension (%)	30 (57)	23 (59)	0.82
Hypercholesterolemia (%)	33 (62)	29 (74)	0.22
Smoker (%)	28 (53)	22 (56)	0.91
Diabetes (%)	5 (9)	5 (13)	0.51
Family history (%)	24 (45)	22 (56)	0.29
Prior MI (%)	29 (55)	19 (49)	0.57
Previous angioplasty (%)	15 (28)	9 (23)	0.57
Previous CABG (%)	5 (9)	2 (5)	0.44
LVEF (%)	$61 \pm 13$	$59 \pm 16$	0.57
Extent of CAD			0.037
One vessel (%)	13 (25)	19 (48)	
Two vessel (%)	25 (47)	10 (26)	
Three vessel (%)	15 (28)	10 (26)	
Bifurcation lesion location			0.030
LAD/LCx (%)	10 (19)	2 (5)	
LAD/diagonal (%)	19 (36)	24 (62)	
LCx/OM (%)	17 (32)	10 (26)	
RCA/PDA (%)	7 (13)	1 (3)	
LAD/septal (%)	0	1 (3)	
LAD/IM (%)	0	1 (3)	

### **Table 1.** Baseline Clinical Characteristics

CABG = coronary artery bypass grafting; CAD = coronary artery disease; IM = intermediate artery; LAD = left anterior descending artery; LCx = left circumflex artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; OM = obtuse marginal artery; PDA = posterior descending artery; RCA = right coronary artery.

death, MI or target lesion revascularization during the follow-up period plus in-hospital MACE.

**Statistical analysis.** Data are expressed as mean  $\pm$  SD for continuous variables, as numbers with percentage for categorical variables. Continuous data were compared using unpaired Student *t* test, and frequencies were compared using the chi-square or Fisher's exact test. A p value <0.05 was considered statistically significant.

### RESULTS

**Baseline clinical characteristics (Table 1).** Between group B and group P, there was no difference in baseline clinical characteristics except for the extent of coronary artery disease or the location of bifurcation lesion. More patients with two vessel disease were included in group B, more patients with one vessel disease in group P.

**Procedural characteristics (Table 2).** In group B, the T technique was used in 16 patients (30%), the Y technique in 14 (26%), the V technique in 15 (28%) and the culotte technique in 8 patients (15%). In this same group, more debulking procedures were done before stenting as compared with Group P (36% vs. 10%, p < 0.01), especially directional coronary atherectomy (DCA) (19% vs. 3%, p < 0.05). The procedure for Group B needed more stents (2.4 ± 0.7 vs. 1.4 ± 0.8, p < 0.001) and longer time (127 ±

52 vs. 98  $\pm$  45 min, p < 0.05) than Group P. The total stent length per patient was longer in Group B than Group P (38  $\pm$  16 vs. 25  $\pm$  21 mm, p < 0.001). Abciximab was used electively in 13 patients and in a bail-out mode in 3 patients. There was no difference in the usage of abciximab (21 vs. 13%, p = NS). The final balloon/vessel ratio was similar in two groups. Higher inflation pressure was applied in group B than in group P for both the parent vessel (15.0  $\pm$  3.0 vs. 13.3  $\pm$  3.9 atm, p < 0.05) and the side branch (13.3  $\pm$  3.7 vs. 9.3  $\pm$  3.4 atm, p < 0.001). Most procedures (92%) were completed with simultaneous kissing balloon inflation in group B, while it was applied less (56%) in group P (p < 0.001).

**Baseline angiographic characteristics (Table 3).** Baseline angiographic characteristics of the parent vessel were similar in both groups. For side branches, the vessel size and lesion length were greater in group B than Group P ( $2.84 \pm 0.69$  vs.  $2.31 \pm 0.43$  mm, p < 0.001;  $9.5 \pm 6.83$  vs.  $6.4 \pm 4.99$  mm, p < 0.05).

**Final angiographic results (Table 4).** Stenting the parent vessel resulted in similar final angiographic measurements in both groups. Side branches of group P showed smaller MLD ( $2.81 \pm 0.50$  vs.  $1.89 \pm 0.62$  mm, p < 0.001) and greater residual stenosis ( $7.4 \pm 10.9$  vs.  $23.4 \pm 18.7\%$ , p < 0.001) than Group B after the procedure.

	Group B $(n = 53)$	Group P $(n = 39)$	p Value
Antecedent debulking (%)	19 (36)	4 (10)	0.005
Directional atherectomy (%)	10 (19)	1 (3)	0.017
Rotational atherectomy (%)	10 (19)	3 (8)	0.13
Number of stents/patient	$2.4 \pm 0.7$	$1.4 \pm 0.8$	< 0.001
Total stent length/patient (mm)	$38 \pm 16$	$25 \pm 21$	< 0.001
Abciximab (%)	11 (21)	5 (13)	0.32
Final balloon/vessel ratio			
Parent vessel	$1.14\pm0.21$	$1.19\pm0.20$	0.24
Side branch	$1.19\pm0.23$	$1.19\pm0.20$	0.89
Maximal inflation pressure (atm)			
Parent vessel	$15.0 \pm 3.0$	$13.3 \pm 3.9$	0.021
Side branch	$13.3 \pm 3.7$	$9.3 \pm 3.4$	< 0.001
Simultaneous kissing balloon inflation (%)	49 (92)	22 (56)	< 0.001
Procedural time (min)	$127 \pm 52$	98 ± 45	0.028

 Table 2.
 Procedural Characteristics

Procedural and in-hospital outcome (Table 5). There was no significant difference in angiographic success rate (98% vs. 92%, p = NS) or procedural success rate (87% vs. 92%, p = NS) for both groups. However, in-hospital MACE, which include death, MI and emergency revascularization, occurred in seven patients of Group B and in none of Group P (13% vs. 0%, p < 0.05). Q wave myocardial infarction occurred in three patients: distal tertiary branch occlusion in one patient and distal embolization in another patient. A third patient who developed slow flow and QMI after rotational atherectomy with subsequent stent placement for left anterior descending artery-left circumflex artery bifurcation lesion sustained in-hospital cardiac arrest and died suddenly two days after the procedure. There was no need for emergency CABG in any patient.

 Table 3. Baseline Angiographic Characteristics

881				
	Group B (n = 53)	Group P (n = 39)	p Value	
Parent Vessel				
Reference vessel	$3.09\pm0.57$	$2.95 \pm 0.44$	0.22	
(mm)				
MLD (mm)	$0.85 \pm 0.51$	$0.80 \pm 0.40$	0.61	
%DS (%)	$72.6 \pm 15.4$	$73.1 \pm 12.8$	0.86	
Lesion length	$12.1 \pm 8.37$	$14.7 \pm 9.09$	0.17	
(mm)				
Side Branch				
Reference vessel (mm)	2.84 ± 0.69	2.31 ± 0.43	< 0.001	
MLD (mm)	$0.68 \pm 0.37$	$0.66 \pm 0.40$	0.83	
%DS (%)	$75.2 \pm 13.2$	$70.8 \pm 16.6$	0.16	
Lesion length (mm)	9.5 ± 6.83	6.4 ± 4.99	0.028	

MLD = minimum luminal diameter; %DS = percent diameter stenosis.

Angiographic and clinical follow-up (Tables 6 and 7). The angiographic follow-up rate for group B and group P were 74% and 69%, respectively (p = NS) with no difference in angiographic follow-up duration. Follow-up QCA measurements of the parent vessel were larger in group B ( $3.07 \pm 0.51$  vs.  $2.80 \pm 0.39$  mm, p < 0.05). Patients of group B had side branches with a larger reference vessel size compared with patients of group P ( $2.68 \pm 0.49$  vs.  $2.02 \pm 0.50$  mm, p < 0.001). There was no difference between the two groups in the MLD ( $1.37 \pm 0.62$  vs.  $1.13 \pm 0.49$ , p = NS) or percent diameter stenosis ( $48 \pm 22$  vs.  $42 \pm 22\%$ , p = NS) of the side branch.

The angiographic restenosis rate was 62% for patients in group B and 48% for the ones in Group P (p = NS). There was no difference regarding the location of the restenosis.

Clinical follow-up was accomplished in all patients. The TLR rate was similar in the two groups (38% vs. 36%, p = NS). Two patients were treated with CABG for restenosis of the target vessel in group B, while one patient underwent CABG in group P. Six-month total MACE, including TLR, were similar in the two groups (51% vs. 38%, p =

Table 4. Final Angiographic Results

	Group B (n = 53)	Group P (n = 39)	p Value
Parent Vessel			
Reference vessel (mm)	3.21 ± 0.50	3.21 ± 0.40	0.97
MLD (mm)	$3.00 \pm 0.54$	$3.01 \pm 0.49$	0.75
%DS (%)	$6.7 \pm 9.9$	$7.6 \pm 12.1$	0.71
Side Branch			
Reference vessel (mm)	$3.05 \pm 0.55$	2.43 ± 0.39	< 0.001
MLD (mm)	$2.81\pm0.50$	$1.89 \pm 0.62$	< 0.001
%DS (%)	$7.4\pm10.9$	$23.4 \pm 18.7$	< 0.001

Abbreviations as in Table 3.

### Table 5. Procedural and In-hospital Outcome

	Group B $(n = 53)$	Group P (n = 39)	p Value
Angiographic success (%)	52 (98)	36 (92)	0.31
Procedural success (%)	46 (87)	36 (92)	0.51
In-hospital MACE* (%)	7 (13)	0	0.039
Death	1	0	
MI	7	0	
QMI	3	0	
NQMI	4	0	
CABG	0	0	

\*One patient suffered from QMI and died.

 $MA\dot{CE}$  = major adverse cardiac events; NQMI = non-Q wave myocardial infarction; QMI = Q wave myocardial infarction. Other abbreviations as in Table 1.

NS). Four patients died during the six-month follow-up period. In group B, one patient died after elective CABG and another patient suffered from pulmonary embolism resulting in death. In group P one patient sustained cardiac death and another patient suffered from sudden death.

### DISCUSSION

The optimal management strategy for bifurcation lesions remains unclear. The main finding of this study is that full stent coverage of the parent vessel and the side branch provides no advantage in long-term outcome over a simpler strategy of stenting the parent vessel plus balloon angioplasty for the side branch.

**Procedural success.** Surprisingly, this study demonstrates that stent placement on the side branch and on the parent vessel was associated with more procedural complications compared with a more conservative approach of stenting

### Table 6. Follow-up QCA Results

1	-		
	Group B (n = 39)	Group P (n = 27)	p Value
Parent Vessel			
Reference vessel (mm)	3.07 ± 0.51	2.80 ± 0.39	0.028
MLD (mm)	$1.89 \pm 1.07$	$1.66 \pm 0.81$	0.38
%DS (%)	$41 \pm 30$	$42 \pm 26$	0.91
Lesion length (mm)	9.6 ± 6.7	11.9 ± 9.6	0.30
Side Branch			
Reference vessel (mm)	2.68 ± 0.49	$2.02\pm0.50$	< 0.001
MLD (mm)	$1.37\pm0.62$	$1.13 \pm 0.49$	0.13
%DS (%)	48 ± 22	$42 \pm 22$	0.31
Lesion length (mm)	7.6 ± 5.4	8.2 ± 6.8	0.72

QCA = quantitative coronary angiography. Other abbreviations as in Table 3.

Table	7.	Fol	low-u	рF	Results
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	Group B (n = 53)	Group P (n = 39)	p Value
Patients Underwent			
Angiographic FU			
n (%)	39 (74)	27 (69)	0.65
Angiographic FU duration (mo)	5.6 ± 1.7	5.9 ± 1.6	0.45
Angiographic restenosis (%)	24 (62)	13 (48)	0.32
Restenosis location			0.34
Both vessels	11	4	
Parent vessel only	4	5	
Side branch only	9	4	
Patients Underwent			
Clinical FU			
n (%)	53 (100)	39 (100)	
Clinical FU duration	$9.6 \pm 7.1$	$7.9 \pm 3.9$	0.15
(mo)			
TLR (%)	20 (38)	14 (36)	1.00
Re-PCI/CABG	18/2	13/1	
Six-month total MACE* (%)	27 (51)	15 (38)	0.29
In-hospital MACE	7	0	
Death	2	2	
MI	2	1	
TLR	20	14	

\*Some patients have more than one event.

Six-month total MACE include death, MI and TLR during the follow-up period and in-hospital MACE.

FU = follow-up; PCI = percutaneous coronary intervention; TLR = target lesion revascularization. All other abbreviations as in Tables 1 and 5.

only the parent vessel. It is of note that no in-hospital MACE occurred in group P though three patients (two had a residual stenosis larger than 50% and one suffered from TIMI 2 flow at final angiogram) were considered angiographic failure. In contrast, procedural complications were the reason for the procedure's lack of success in group B. It can be speculated that the different complication rate came from the procedural complexity in group B. It was pointed out that stenting both vessels using the dedicated techniques (13,14) can be achieved with approximately a 50% success rate even when performed by an expert operator (12,19). The improvement of the operators' experience and the availability of new stents can now bring the angiographic success of kissing stenting to 90% (20) or higher. Something that may explain the higher complication rate observed in patients treated with two stents could be the more frequent usage of debulking techniques in this group. A more liberal usage of abciximab could have lowered the in-hospital events in most of the cases associated with slow flow.

Late outcome. Patients in group B had side branches with a larger reference diameter than patients of group P; operators applied more debulking procedures before stent placement and implanted more stents. According to some of these characteristics, a better outcome was expected for

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patients of group B. Follow-up data did not confirm this assumption. The reason is unclear; however, several studies suggest a possible explanation. An animal study reported that there was a correlation between the density of the stent material and the degree of restenosis (21). In addition, the length of the implanted stent known to be an independent contributing factor to restenosis (22,23) was greater in patients with double stenting. These factors might offset the favorable baseline lesion characteristics of group B lesions.

Side branch stenting. Regarding the advantage of stent placement to the side branch, two conflicting results have been reported so far (19,20). Pan et al. (24) showed that a complex technique providing radical stent reconstruction of the bifurcation gave no advantages over stent placement on the parent vessel followed by ostial side branch balloon dilation. They compared the results of two groups treated with either a strategy of stenting the parent vessel and balloon angioplasty of the side branch (simple approach) or a strategy of stenting both vessels using one of the previously reported methods (12,16,17,25-27) (complex approach). Major adverse cardiac events were more frequent with complex approach at 18-month follow-up period (eventfree probability 44% vs. 75%, p < 0.05). On the other hand, Chevalier et al. (19) suggested that the strategy of stenting both vessels using the "culotte" technique was highly feasible and provided excellent short-term results. An acceptable TLR rate of 24% was reported. It is also important to point out that a number of patients with angiographic restenosis limited to the side branch may remain totally asymptomatic undermining the value of TLR to assess the long-term success of a specific technique. In our study of the 13 patients with restenosis of only the side branch, eight were asymptomatic. The overall higher TLR rate reported in our study is likely to be a reflection of the high angiographic follow-up rate (28).

Study limitations. The major limitation of our study was its retrospective design with a small cohort size owing to the limited indication for these techniques. The fact that the two groups have differences in relation to the reference vessel size of the side branch can be viewed as a "favorable" limitation. In fact the larger reference vessel size of the side branch in the group treated with two stents should have given these lesions some advantage in terms of restenosis compared with the lesions treated with one stent in the parent vessel. On the other hand, the higher number of patients with multivessel disease and the more proximal location of the stenosis in the group treated with two stents may set these patients in a higher risk category for restenosis. Although the two cohorts were biased, we think they might represent the real-world selection of the treatment procedure for bifurcation lesions with various sizes of side branches. Operators often have difficulty refraining from reconstructing big side branches with stents, especially when considerable stenosis remains at the side branch takeoff. In this context, our results may motivate a more conservative

approach to treat bifurcation lesions with stenting only the parent vessel while waiting for more confirmatory data from a randomized study or new techniques with more dedicated stents.

**Conclusions.** The outcome of treating coronary bifurcation lesions did not improve with double vessel stenting compared with single vessel stenting. These results were obtained despite more favorable baseline reference diameters of the side branch in the bifurcations treated with double vessel stenting.

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