

Long-Term Outcomes in Treating Left Main Trifurcation Coronary Artery Disease with the Paclitaxel-Eluting Stent

Nicolas W. Shammass, MD, MS, Eric J. Dippel, MD, Amber Avila, BSc, Lauren Gehbauer, BSc, Leslie Farland, Stephanie Brosius, Michael Jerin, PhD, Matthew Winter, Penny Stoakes, RN, Jeannette Byrd, RN, Lynne Majetic, RN, Gail Shammass, RN, Peter Sharis, MD, Jon Robken, MD

ABSTRACT: Background. Left main trifurcation coronary artery disease stenting is a challenging and complex percutaneous procedure that has been infrequently reported. We present our own experience with left main trifurcation stenting using the Taxus® paclitaxel-eluting stent (*Boston Scientific*). **Methods.** Twenty consecutive left main trifurcation stenting procedures were performed in 2005 at our institution. The primary endpoint of the study was the combined endpoints of death, acute stent thrombosis and target lesion revascularization (TLR). Conditional logistic regression analysis was performed to determine the predictors of the primary endpoint using a number of variable combinations. **Results.** The mean patient age was 71.7 ± 8.9 years. The procedure was urgent in 10%, and the left main artery was unprotected in 95% of cases. Follow up was achieved in 17/20 (85%) patients, either from medical records or by phone calls. The follow-up median duration was 272 days (range 30–534 days). The primary endpoint was met in 5/17 (29.4%) patients. One of 19 patients (5.3%) had a sudden cardiac death 1 month after the procedure, 2/20 patients (10%) experienced an acute in-hospital stent thrombosis, and 2/17 (11.8%) patients underwent TLR. Conditional logistic regression analysis could not identify a relationship between the stenting method and the primary endpoint. The 2 patients who experienced in-hospital thrombosis were the only patients who received a clopidogrel load (600 mg) postprocedure after arrival to the floor, and were not on a glycoprotein IIb/IIIa inhibitor. All others received their clopidogrel either during the procedure ($n = 7$) or were on it chronically ($n = 11$). One patient with acute stent thrombosis did not have a kissing balloon performed post-stent deployment. **Conclusion.** Left main trifurcation stenting carries an overall high rate of adverse events and may need to be reserved for patients who are at high risk or who refuse bypass surgery. Overall TLR is low, but stent thrombosis remains a concern. Although we suspect that thrombosis could be related to failure to perform kissing balloon post-stent deployment and/or not receiving a clopidogrel load until after the procedure, the small number of patients in this study prevents us from making definite statistical conclusions about this observation.

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Left main (LM) trifurcation coronary stenting is a challenging and complex percutaneous procedure that has been reported

in small series and case reports.^{1–5} Typically, this disease is treated surgically, but with the advent of drug-eluting stents (DES), interventionalists are increasingly tackling more complex coronary artery disease (CAD), including trifurcation disease. The outcome of DES in the treatment of LM trifurcation disease remains unknown. In this study, we report on our experience with patients who underwent trifurcation LM stenting using paclitaxel-eluting stents and present their long-term outcomes. To our knowledge, this is the largest reported experience in the literature describing in-hospital and long-term outcomes for LM trifurcation treatment using paclitaxel-eluting stents.

Methods

Twenty consecutive patients who underwent LM trifurcation stenting at our institution from January 1, 2005 to December 31, 2005, were included. This retrospective study was approved by our center's Institutional Review Board. All vessels were evaluated by an experienced interventional cardiologist for their size, presence of calcium, the number of stents deployed, type of disease (A or B), stenting technique, the use of double or triple kissing balloons, pre- and post-treatment lesion severity, presence of dissection and embolization or slow-flow. These angiographic variables were estimated by reviewing the actual angiograms, but no quantitative analysis was performed. Procedural success was defined as obtaining a residual narrowing of $\leq 30\%$ in all branches treated. The Taxus® paclitaxel-eluting stent was exclusively used in all patients (*Boston Scientific Corp., Natick, Massachusetts*).

Charts were reviewed for clinical and demographic variables as well as the use of antiplatelet and anticoagulant agents during the procedure. Dilatation pressures were recorded from the cardiac catheterization laboratory procedure log sheet. Patients with the admission diagnosis of myocardial infarction were diagnosed by serial cardiac enzymes prior to the procedure. A rise in creatinine kinase (CK) with abnormal MB fractions or a rise in troponin I was considered diagnostic. CK and troponin I were not measured routinely postprocedure, thus the incidence of non-ST-elevation myocardial infarction (NSTEMI) postprocedure could not be accurately assessed. Only those patients with acute ST-elevation myocardial infarction (STEMI) secondary to acute stent thrombosis were able to be diagnosed using electrocardiographic and enzymatic criteria.

The primary endpoint of the study was the combined endpoint of death, acute stent thrombosis and target lesion

From the Midwest Cardiovascular Research Foundation, Davenport, Iowa.

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Address for Correspondence: Nicolas W. Shammass, MD, MS, Research Director, Midwest Cardiovascular Research Foundation, Cardiovascular Medicine, PC, 1236 East Rusholme, Suite 300, Davenport, IA 52803. E-mail: shammass@mchsi.com

Table 1. Demographics and clinical variables.

Male (%)	95.0
Age (years)	71.7 ± 8.94
Body mass index	29.55 ± 6.67
Prior bypass surgery (%)	30.0
Unprotected left main artery (%)	95.0
Previous myocardial infarction (%)	30.0
Family history of coronary disease (%)	20.0
New York Heart Classification (%)	
Class I	20
Class II	70
Class III	10
Chronic lung disease (%)	40.0
Peripheral vascular disease (%)	30.0
Hypertension (%)	100.0
Cerebrovascular disease (%)	25.0
Diabetes mellitus (%)	40.0
Hyperlipidemia (%)	90.0
Past or current smoker (%)	80.0
Procedure status (%)	
Elective	90.0
Urgent	10.0
Presentation (%)	
Stable	85.0
Unstable angina	5.0
Non-ST-elevation myocardial infarction	10.0

All continuous variables are expressed as mean ± SD

revascularization (TLR). Follow-up data were obtained on 17 (85%) patients from medical records and phone interviews (2 patients were alive and were contacted but refused to provide further information; 1 patient was unable to be reached. All 3 patients had no available follow-up records at our institution). Descriptive analysis was performed on all variables included. Patients were divided into two groups: those who met the primary endpoint and those who did not. The two groups were compared for all angiographic, clinical and procedural variables. A conditional logistic regression analysis was performed by entering two variables at a time because of the limited number of cases in this cohort. The following variables were considered: ejection fraction, lesion severity, age, presence of calcification, clopidogrel use (before and during the procedure versus after the procedure), smoking history, family history of CAD, congestive heart failure, number of stents utilized, weight and stenting technique (VT, YV2/YV and VB/V2).

Results

Patients' demographics are included in Table 1. The procedure was performed urgently in 10% of patients. Patients had multiple comorbidities including hypertension (100%), diabetes mellitus (40%), past or current smoking history (80%), hyperlipidemia (90%) and prior bypass surgery (30%). The mean age was 71.7 ± 8.9 years. The majority of patients were males (95%). The left main artery was unprotected in 90% of cases.

A summary of the angiographic and procedural variables is provided in Table 2. Disease involving the trifurcation was

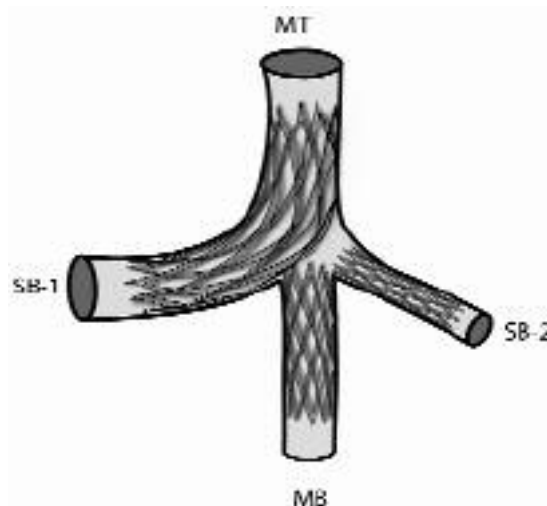


Figure 1. VT-stenting for trifurcation disease. A 9 Fr guide is utilized. The 3 branches are wired. Kissing balloon (KB) dilatation is done as needed. Stents are first positioned into SB1, MB and SB2. The SB1 stent extends into the MT to cover the area of disease. MB and SB2 stents are positioned to cover the ostium of these vessels in the V-stenting position. V-stenting on SB2 and MB is performed first. Wires and balloons are then removed from SB2 and MB, and the SB1 stent is deployed, spanning the ostium of SB2 and MB and into the MT. SB2 and MB stents are then rewired and KB dilatation is done across the struts at high pressure (18–20 atm), with 2 balloons inflated at a time (SB1 and MB, SB2 and MB). A low-pressure (10–12 atm) triple KB is then performed on all stents, assuming the MT size allows for it.

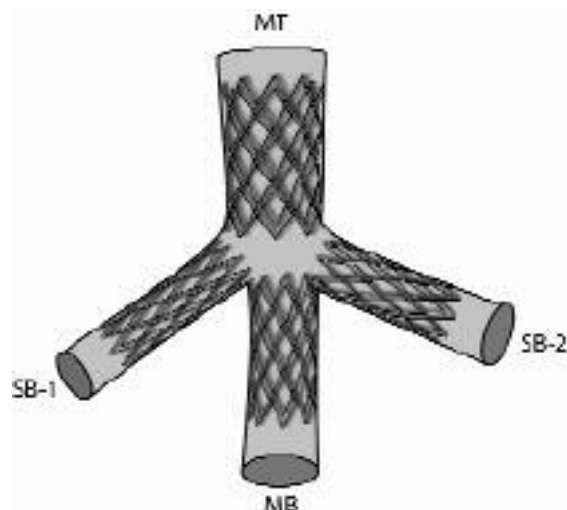


Figure 2. YV2-stenting for trifurcation disease. A 9 Fr guide is utilized. The 3 branches are wired. Kissing balloon (KB) dilatation is done as needed. The MT is first stented as close to the trifurcation as possible without jeopardizing the side branches and with the wire placed in the largest branch. Following this, the 2 remaining branches are rewired and KB is performed in the 3 branches. V-stenting is then carried out for SB1 and MB and with an uninflated stent positioned in SB2. This is followed by KB in the MB and stent inflation in SB2. Following this, the 3 branches are dilated simultaneously with the KB at a low pressure of 10 atm. A modification of this technique is the YV (culotte-V-stenting), where only SB1 and MB are stented, and SB2 is treated with balloon only.

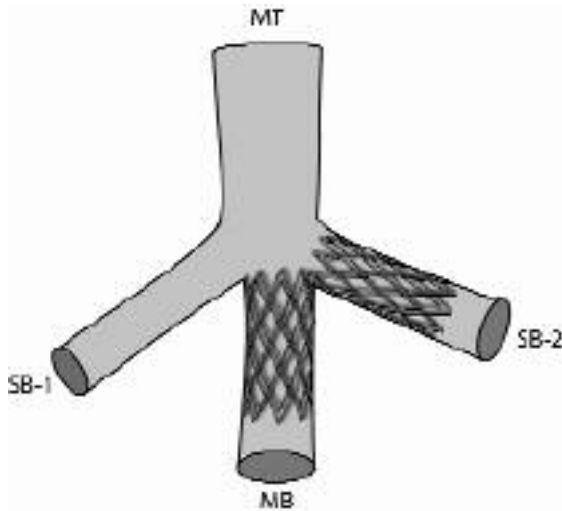


Figure 3. VB-stenting for trifurcation disease. A 9 Fr guide is utilized. After wiring the 3 branches, kissing balloon (KB) dilatation is done as needed. The MB and SB1 are stented using the V-stenting technique. KB is then performed on all 3 branches as needed.

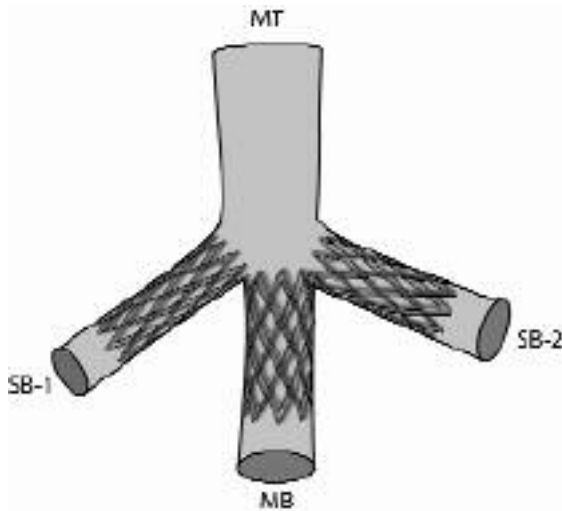


Figure 4. V2-stenting for trifurcation disease. A 9 Fr guide is utilized. After wiring the 3 branches, kissing balloon (KB) dilatation is performed as needed. Stents are then positioned to cover the origin of all branches. The MB and SB1 are stented first using the V-stenting technique. Next, the balloon in the MB and stent in SB2 are deployed using the stent/balloon kissing technique. KB is then performed on all 3 branches simultaneously using low-pressure inflation (10 atm).

classified into two main classes that have been previously published⁶: *Type A* (50%), involving the distal main trunk with or without extension to one or more of the branches; and *Type B* (50%), involving the origin of one or more of the main branches without extension to the main trunk (MT). LM trifurcation stenting was also classified according to a previously-published classification⁶:

1. VT-stenting (10.0%) (Figure 1)
2. YV2- and YV-stenting (40.0%) (Figure 2)
3. VB-stenting (25%) (Figure 3)
4. V2-stenting (25%) (Figure 4)

Table 2. Patient demographics and clinical variables.

Type A lesions (involving left main) (%)	50.0
Type B lesions (left main not involved) (%)	50.0
Ejection fraction (%)	47.75 ± 13.52
Glycoprotein IIb/IIIa inhibitor use (%)	10.0
IVUS-guided procedure (%)	5.0
Simultaneous 3 kissing balloons (%)	55.0
Simultaneous 2 kissing balloons (%)	40.0
No kissing balloon performed (%)	5.0
Mean number of stents used per case	3.0 ± 1.34
Embolization or slow-flow (%)	0.0
On chronic clopidogrel use preprocedure (%)	55.0
Loaded with clopidogrel in the cath lab (%)	35.0
Loaded with clopidogrel after procedure on the floor (%)	10.0
Loading dose of 600 mg (%)	100.0
Side branch 1 (SB1) treatment variables:	
SB1 size (mm)	2.85 ± 0.29
SB1 restenotic lesions (%)	40.0
SB1 calcified lesion (%)	65.0
SB1 pretreatment lesion severity (%)	57.0 ± 27.50
SB1 post-treatment lesion severity (%)	0.5 ± 2.24
SB1 pressure dilatation (mmHg)	15.45 ± 2.89
SB1 stent number used	0.95 ± 0.51
SB1 stent size used (mm)	3.0 ± 0.56
Side branch 2 (SB2) treatment variables:	
SB2 size (mm)	2.79 ± 0.39
SB2 restenotic lesions (%)	30.0
SB2 calcified lesion (%)	55.0
SB2 pretreatment lesion severity (%)	52.0 ± 37.68
SB2 post-treatment lesion severity (%)	0.25 ± 1.12
SB2 pressure dilatation (mmHg)	14.60 ± 1.60
SB2 stent number used	0.95 ± 0.60
SB2 stent size used (mm)	2.88 ± 0.42
Middle branch (MB) treatment variables:	
MB size (mm)	2.48 ± 0.33
MB restenotic lesions (%)	0.0
MB calcified lesion (%)	50.0
MB pretreatment lesion severity (%)	56.40 ± 35.68
MB post-treatment lesion severity (%)	2.5 ± 7.86
MB pressure dilatation (mmHg)	14.74 ± 1.79
MB stent number used	0.70 ± 0.47
MB stent size used (mm)	2.71 ± 0.26
Main trunk (MT) treatment variables:	
MT size (mm)	3.65 ± 0.33
MT restenotic lesions (%)	0
MT calcified lesion (%)	50.0
MT pretreatment lesion severity (%)	41.75 ± 33.88
MT post-treatment lesion severity (%)	5.75 ± 10.42
MT pressure dilatation (mmHg)	18.09 ± 3.59
MT stent number used	0.40 ± 0.50
MT stent size used (mm)	4.45 ± 1.20

IVUS = intravascular ultrasound; SB1 = left anterior descending artery; SB2 = left circumflex; MB = ramus intermedius; MT = left main. All continuous variables are expressed as mean ± SD.

Table 3. Presentation and angiographic variables.

Pt #	Presentation	Status	Preload with Clopidogrel	Loading Dose (mg)	GP IIb/IIIa	IVUS	Total Stents	AT Vessels	VT	V2Y	VB	V2	KB	KBP
1	Stable	Elective	No (given in the lab)	600	0	0	3	NA	0	0	0	1	3	14
2	Stable	Elective	No (given after PCI)	600	0	0	2	LM and Trifurcation	0	0	1	0	2	14
3	Stable	Elective	Yes (chronic use)	None	0	0	2	NA	0	0	0	1	2	14
4	Stable	Elective	No (given in the lab)	600	0	0	4	NA	0	1	0	0	2	14
5	NSTEMI	Urgent*	Yes (chronic use)	None	1	0	4	NA	0	1	0	0	3	14
6	Stable	Elective	No (given in the lab)	600	1	0	5	NA	0	1	0	0	3	14
7	Stable	Elective	Yes (chronic use)	None	0	1	1	NA	0	0	1	0	2	14
8	Stable	Elective	No (given in the lab)	600	0	0	4	NA	1	0	0	0	2	14
9	Stable	Elective	No (given in the lab)	600	0	0	2	NA	0	0	1	0	2	14
10	Stable	Elective	Yes (chronic use)	None	0	0	1	NA	0	1	0	0	3	20
11	Stable	Elective	Yes (chronic use)	None	0	0	2	NA	0	0	1	0	2	14
12	Stable	Elective	Yes (chronic use)	None	0	0	4	NA	0	1	0	0	3	14
13	Stable	Elective	No (given in the lab)	600	0	0	3	NA	0	0	0	1	3	14
14	Stable	Elective	Yes (chronic use)	None	0	0	1	NA	0	1	0	0	3	14
15	Stable	Elective	No (given in the lab)	600	0	0	5	LCX and RI	0	1	0	0	0	NA
16	Stable	Elective	Yes (chronic use)	None	0	0	3	NA	0	0	0	1	3	10
17	Stable	Elective	Yes (chronic use)	None	0	0	2	NA	0	0	1	0	3	14
18	UA	Elective	Yes (chronic use)	None	0	0	4	NA	1	0	0	0	3	12
19	NSTEMI	Urgent	No (given in the lab)	600	0	0	5	NA	0	1	0	0	2	14
20	Stable	Elective	Yes (chronic use)	None	0	0	3	NA	0	0	0	1	3	14

IVUS = intravascular ultrasound; AT = acute thrombosis; KB = kissing balloon (2 or 3 simultaneous balloons used); NA = not applicable; LM = left main; LAD = left anterior descending artery; LCX = left circumflex; RI = ramus intermedius; Pt = patient; Pt #7: only 1 stent placed in a trifurcating branch, with subsequent simultaneous 2 kissing balloons performed; Pts #10 and #14: only 1 stent placed in the LM, with subsequent simultaneous 3 kissing balloons performed in previously stented trifurcating branches. *Urgent was defined as the need to perform the procedure before discharge; KBP = kissing balloon pressure; UA = unstable angina.

Individual patient presentations, angiographic variables and follow-up data are described in Tables 3 and 4. All patients received unfractionated heparin during the procedure. The acute procedural success was 100% in all vessels treated, including the main trunk (MT) and side branches (SB). Review of actual angiograms showed no distal embolization, slow-flow or dissections. Kissing balloon (KB) dilatation was performed in all patients except 1 in the YV2 stent group. The same patient developed acute stent thrombosis.

The follow-up median duration was 272 days (range 30–534 days). The primary endpoint was met in 5/17 (29.4%) patients. One of 19 patients (5.3%) experienced sudden cardiac death 1 month after the procedure, with no autopsy performed, 2/20 (10%) patients experienced in-hospital acute stent thrombosis and 2/17 (11.8%) patients underwent TLR. Target vessel revascularization (TVR) occurred in 3/17 (17.6%) patients. There were no strokes. All patients who had a myocardial infarction secondary to acute stent thrombosis required transient intra-aortic balloon pump insertion. All were discharged from the hospital alive. Two patients developed in-hospital thrombosis prior to discharge following the index procedure. The following is a brief description of these patients:

Case 1. The patient was an elective admission with stable but advanced symptoms. The angiogram revealed type B (no LM involved) disease. He underwent stenting using the VB technique (Figure 3). Kissing balloon was performed at 14 atm following stent deployment. He received a clopidogrel 600 mg po load after

his transfer from the cardiac catheterization laboratory to the floor. No GP IIb/IIIa inhibitor was administered to the patient during the procedure. Shortly after arrival to the floor, he developed sudden chest pain and hypotension. Emergency angiography was performed, revealing thrombosis of the LM and all trifurcation vessels which were treated successfully. Abciximab was administered during the salvage procedure, and an intra-aortic balloon pump was placed. The patient did well and was discharged from the hospital.

Case 2. The patient was an elective admission with stable but advanced symptoms. The angiogram revealed type A (LM involved) disease. He underwent stenting using the YV2 technique (Figure 2). Kissing balloon was not performed following stent deployment. He received a 600 mg po clopidogrel load after his transfer from the cardiac catheterization laboratory to the floor. The patient was not given a GP IIb/IIIa inhibitor during the procedure. After arrival to the floor, he developed sudden chest pain and hypotension. Emergency angiography was performed, revealing thrombosis of the LCX and RI vessels, which were successfully treated. Abciximab was administered during the salvage procedure, and an intra-aortic balloon pump was placed. The patient did well and was discharged from the hospital.

Of interest, both of these patients with thrombotic occlusions were treated with clopidogrel after the procedure and after they left the cardiac catheterization laboratory. In contrast, all other patients received their clopidogrel load of 600 mg during the percutaneous intervention ($n = 7$), or were on chronic clopidogrel prior to their admission to the hospital ($n = 11$).

Table 4. Follow-up data on trifurcation stenting.

Pt #	F/U (days)	TLR	TVR	Angiographic Restenosis	Time to Re-Angio	Indication for Angiography	Disease Location	Death	Cardiac Death*	F/U Call	F/U Records
1	534	0	0	0	93	Routine post-LM	None		0	0	1
2	214	1	1	0 (de novo lesion)	214	CP	Ostial LM 70% (de novo)	0	0	0	1
3	68	0	0	0	68	Abnormal stress	None	0	0	1	
4	467	0	0	NA	NA	NA	NA	0	0	1	
5	520	0	0	NA	NA	NA	NA	0	0	1	
6	512	0	0	NA	NA	NA	NA	0	0	1	
7	214	1	1	1	214	Abnormal stress	LAD (restenosis)	0	0	0	1
8	272	0	0	NA	NA	NA	NA	0	0	1	
9	239	0	0	NA	NA	NA	NA	0	0	1	
10	242	0	0	0	163	Routine post-LM	None	0	0	1	
11	87	0	0	NA	NA	NA	NA	0	0	0	1
12	320	1	1	1	168	CP	LAD, LCX and RI (restenosis)	0	0	0	1
13	30	0	0	NA	NA	NA	NA	1	1	0	1
14	267	0	0	NA	NA	NA	NA	0	0	0	1
15	*	*	*	*	*	*	0	0	0		
16	397	0	0	NA	NA	NA	NA	0	0	1	
17	*	*	*	*	*	*	0	0	0		
18	290	0	0	NA	NA	NA	NA	0	0	0	1
19	*	*	*	*	*	*	*	*	0		
20	350	0	0	NA	NA	NA	NA	0	0	0	1

Pt = patient; F/U = follow up; Re-Angio = re-angiography; NA = not applicable; LM = left main artery; LAD = left anterior descending artery; LCX = left circumflex artery; RI = ramus intermedius; TLR = target lesion revascularization; TVR = target vessel revascularization; cardiac death was sudden (etiology unknown, whether primary arrhythmia or acute vessel closure); CP = chest pain.

Six patients underwent follow-up angiography at a median of 165.5 days (range 68–214 days). The angiogram was performed for the following reasons: (1) Routine test to check the stented LM artery in 2 patients, both had no restenosis; (2) chest pain in 2 patients, 1 had restenosis and 1 had a de novo lesion; (3) abnormal stress test in 2 patients, 1 with documented restenosis.

Regression results indicated no statistically significant relationships in the data. Two of the models tested (clopidogrel and family history of CAD; clopidogrel and congestive heart failure), however, correctly predicted 80% of the patients who met the primary endpoint criteria.

Discussion

Left main trifurcating lesions are generally treated with bypass surgery. With the advent of DES, complex lesions, including LM trifurcating disease, are now treated percutaneously. To our knowledge, this is the largest series of LM trifurcation stenting procedures reported using the paclitaxel-eluting stent with long-term follow up.

In this retrospective series, the combined endpoint of death, acute stent thrombosis and TLR occurred in 29.4% of patients. TLR was favorable at 11.8%, and the median duration was 272 days (range 30–534 days). However, in-hospital acute stent thrombosis occurred in 10% of patients. Of interest, this occurred in 2 out of 2 patients who were not given clopidogrel until after arrival to the floor postprocedure

(and both were not on a GP IIb/IIIa inhibitor), and in 1 patient who did not undergo kissing balloon dilatation post-stent placement. All other patients in this study were either preloaded with clopidogrel during the procedure, or were on it chronically prior to their index procedure. Based on these observations, all patients should receive a 600 mg po clopidogrel load as early as possible prior to or during their index procedure if they have not been on it. Also, kissing balloon treatment post-stenting should be performed, preferably with the triple-balloon method when feasible. The benefit of using GP IIb/IIIa inhibitors is not clear from our data, but is probably advisable.

It is not possible to attribute stent thrombosis to the paclitaxel-eluting stent in this study, since there was no bare-metal stent (BMS) control. Also, the acute presentation makes thrombosis less likely to be related to the stent itself and more likely to be due to technique or adequate antiplatelet coverage before or during the treatment. Although logistic regression analysis did not reveal a relationship between the method of stenting and outcome, the number of patients in this study precludes us from making definite conclusions.

LM trifurcation disease is more complex than LM bifurcation disease, and therefore its percutaneous treatment is expected to have a higher rate of adverse events. Treatment of complex bifurcation disease with DES has been acceptable

overall, but continues to have a significant incidence of myocardial infarction (4%),⁷ TLR (8.2–12.2%),^{8,9} acute stent thrombosis (3.5%)⁸ and major cardiac events (20%).⁵ Kissing balloon following stenting is a critical step in treating bifurcation lesions¹⁰ to improve overall outcomes, and we believe that the same applies to the treatment of trifurcation lesions. In fact, the only patient who did not receive kissing balloon treatment in our study developed acute stent thrombosis.

In conclusion, trifurcation stenting carries a high rate of adverse events overall, and may need to be reserved for patients who are at high risk for bypass surgery or who refuse surgery. Data are needed to elucidate the relationships between stenting techniques and overall outcomes, including stent thrombosis. We believe, based on the above findings, that administration of clopidogrel preprocedure and kissing balloon dilatation post-stenting are important measures to reduce the incidence of acute stent thrombosis in LM trifurcation stenting.

Study limitations. This study is limited by its retrospective design. However, all patients with LM trifurcation disease were included, and angiograms were reviewed by an experienced angiographer. Also, CK and troponin I were not measured routinely postprocedure, and the incidence of non-Q-wave myocardial infarctions postprocedure could not be accurately assessed. Only those patients with acute STEMI secondary to acute stent thrombosis were diagnosed with a nonfatal myocardial infarction. Furthermore, angiographic restenosis cannot be accurately determined from this study, as only 6 patients underwent follow-up angiography. Finally,

this study has a small number of patients and is nonrandomized. Therefore, no conclusions can be made on how the results would compare with BMS or bypass surgery for trifurcation LM disease. Data, however, suggest that DES have superior outcomes to BMS in complex bifurcating lesions, and this is likely to be the case in trifurcation disease.

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