Impact of Stenting Technique and Bifurcation Anatomy on Long-Term Outcomes of PCI for Distal Unprotected Left Main Coronary Disease

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ABSTRACT: Objectives. We aimed to assess the associations of stenting strategy and bifurcation anatomy with outcomes of percutaneous coronary intervention (PCI) for distal unprotected left main (ULM) coronary disease. **Background.** There are limited and conflicting data regarding long-term outcomes associated with stenting strategies for PCI of distal ULM coronary disease. **Methods.** Patients undergoing non-emergent PCI for distal ULM coronary disease comprised the study cohort. Baseline characteristics and outcomes including cardiac death, cardiac death or myocardial infarction (MI), and overall major adverse cardiac events (MACEs) were compared for patients undergoing single-vessel stenting (SVS) versus bifurcation stenting (BS). **Results.** Seventy patients underwent treatment of distal ULM coronary disease with PCI. Drug-eluting stents (DESs) were used in 96% and 32 (46%) had BS. Patients undergoing SVS vs BS had more severe disease involving the left circumflex artery. Patients with BS were more likely to experience cardiac death and MI (hazard ratio [HR] 3.5; 95% confidence interval [CI], 1.1-11.1; *P*=.04) or combined MACE (HR, 4.2; 95% CI, 1.8-10.2; *P*=.001). After adjusting for angiographic characteristics of the bifurcation in Cox proportional hazards models, BS remained a significant predictor of MACE. **Conclusions.** In this unselected series of patients undergoing PCI for distal left main disease, a single-vessel stenting strategy was associated with superior long-term outcomes after accounting for angiographic characteristics of the bifurcation. Future studies need to take into account additional factors to clarify the ideal treatment strategy for distal left main disease.

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Key words: distal left main disease, bifurcation stenting, single-vessel stenting

Outcomes following percutaneous coronary intervention (PCI) of distal unprotected left main (ULM) lesions are worse than those following PCI of disease confined to the ostium or mid shaft.[1-8] Various techniques have been used to treat distal ULM disease and can be categorized broadly as single-vessel stenting (SVS) if stents extend into only one of the left anterior descending (LAD) or left circumflex (LCX) arteries, or bifurcation stenting (BS) if both the adjacent LAD and LCX are treated with stents. Prior observational studies comparing these two strategies for distal ULM disease have yielded conflicting results, with some demonstrating worse outcomes for patients treated with BS[9-11] and others showing no difference.[12] The most common adverse outcome associated with BS has been the need for repeat revascularization, but reported rates of this have ranged widely, from less than 10% to nearly 40% at 1 year.[10,13] In addition, rates of more serious adverse events associated with BS have also varied markedly, with one study reporting no deaths or myocardial infarctions (MIs)[9] and others reporting increased rates of stent thrombosis,[14] MI,[10] or death and MI.[11] These studies have had important limitations, including employing default BS strategy for dual ostial disease,[9] having no angiographic data regarding the configuration of the bifurcation,[11] and stratifying patients per the dichotomous schema used in calculating the Syntax Score,[15] which precludes analyzing the independent impact of disease involving the ostial circumflex and/or LAD.[10] In addition, patients with type B and E lesions were included in the most recent study (disease involving only the ostia of the LAD or LCX), which do not represent true distal left main disease. Given these gaps in knowledge, we sought to determine the impact of stenting strategy on the long-term outcomes of an unselected cohort of patients with distal ULM disease and account for angiographic characteristics of the bifurcation.

Methods

Study population. This protocol was approved by the institutional review board of Northern California Kaiser Permanente and a waiver of individual informed consent was granted. Electronic medical records (EMR) were reviewed retrospectively to identify all patients undergoing unprotected left main PCI (patients with prior coronary artery bypass graft [CABG] were excluded) at Kaiser Permanente Medical Center, San Francisco following drug-eluting stent (DES) availability. Patients with distal left main stenosis >50% treated between January 2003 and December of 2009 were included in the analysis. All seven operators performed >200 PCI procedures per year, with an institutional volume of >1500 PCIs per year. As the aim of the study was to assess outcomes of two treatment strategies in otherwise similar patients, patients with cardiogenic shock and/or ST-segment elevation MI were excluded. Patients were referred for ULM PCI as a consequence of patient preference (43%) or not

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Table 1. Baseline characteristics. Comparison of patients undergoing bifurcation stenting or single-vessel stenting for the treatment of distal unprotected left main coronary disease.

	Bifurcation Stenting (N = 32)	Single-Vessel Stenting (N = 38)	*P*-Value
Male	23 (72%)	24 (63%)	.44
Age (years)*	73 ± 12	74 ± 11	.59
Diabetes	10 (31%)	17 (45%)	.25
Insulin therapy	0 (0%)	5 (13%)	.06
Hypertension	29 (91%)	33 (87%)	.72
Hyperlipidemia	31 (97%)	35 (92%)	.62
Tobacco history	13 (45%)	16 (46%)	.94
Peripheral vascular disease	8 (25%)	6 (16%)	.38
Prior PCI	4 (13%)	7 (18%)	.53
Prior myocardial infarction	11 (34%)	18 (47%)	.33
Heart failure history	9 (28%)	15 (39%)	.45
Renal insufficiency	5 (16%)	2 (5.3%)	.23
Ejection fraction (%)*	53 ± 14	47 ± 21	.12
Presentation of acute coronary syndrome	23 (72%)	25 (66%)	.62
Not a CABG candidate	19 (59%)	19 (50%)	.43
EuroScore (logistic)**	8.0 (3.4-15)	7.8 (2.8-17)	.82 WRS

*Data given as number (percentage), *mean ± standard deviation, or **median (interquartile range). PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft surgery; WRS = Wilcoxon Rank Sum.*

being considered surgical candidates (57%). The most common reasons for not being surgical candidates included advanced age, severe left ventricular (LV) dysfunction, inadequate conduits or poor targets, and other severe co-morbid conditions.[16]

Definitions. *Distal left main disease* was defined as a non-iatrogenic narrowing of the left main (LM) coronary artery with a diameter stenosis ≥50% involving the distal portion of the vessel, the treatment of which required stent placement across the entire origin of either the LAD or LCX arteries. *BS* was defined as any LM PCI that resulted in stent placement into both the proximal circumflex and LAD and included the culotte, crush, T, and V stenting techniques. *SVS strategy* was defined as any PCI that resulted in stent placement into only one of either the LAD or LCX. *Ostial disease* of either the LAD or LCX was considered to be present if there was ≥50% diameter stenosis. Bifurcation anatomy was classified according to the Medina classification,[17] with the LAD considered to be the continuation of the LM. Therefore, disease involving the distal LM and ostial LAD was classified as Medina (1,1,0), disease involving the distal LM and ostial circumflex as Medina (1,0,1) and disease involving the distal LM and both ostia as Medina (1,1,1). LM, LCX, and LAD diameter stenosis were determined by subjective assessment. The logistic EuroScore was calculated by the method outlined by Nashef et al.[18] Covariates such as renal insufficiency and peripheral vascular disease were defined as per version 3 of the American College of Cardiology Cath PCI National Cardiovascular Data Registry.

Procedures. The choice of stenting strategy, type of DES utilized, use of intravascular ultrasound, and the decision to perform final kissing balloon inflations were left to the discretion of the individual operator. All patents were treated for at least 6 months with dual antiplatelet therapy following PCI from 2003 until December 2006, after which 12 months of dual antiplatelet therapy was recommended. Surveillance angiography was not routinely performed.

Endpoints. *Endpoints* were compared for each group and included cardiac death, cardiac death or MI, and overall major adverse cardiac events (MACE) defined as cardiac death, MI or target lesion revascularization (TLR). *MI* was defined as per the definition of type 1 in the universal definition of MI (procedural myocardial infarctions were excluded).[19] The *target lesion* was considered the LM coronary, the stented portions of the contiguous LAD or LCX, and the 5 mm distal to the stented portions. *Definite and probable stent thromboses* were defined as per the Academic Research Consortium definitions.[20] Medical records were reviewed to determine endpoints and vital status confirmed using the California Automated Linkage System (CAMLIS).[21] Kaiser Permanente has a robust EMR with progress notes, operative reports, as well as records of diagnoses and procedures performed within and outside the Kaiser system.

Statistical analysis. Dichotomous variables are presented as mean/percentage and continuous variables as median/standard deviation or median/intraquartile range. Baseline and procedural characteristics were compared for patients with SVS or BS using the Fisher's exact or chi-square tests for dichotomous variables and the Student's t-test or Wilcoxon Rank Sum test for continuous variables. Time to event analyses were performed with the patient considered at risk until event occurrence or until the last documented encounter in the medical record. For the purposes of determining censoring or time to endpoint, the documented last physical contact in the medical record was used. Kaplan Meier curves were constructed to estimate event rates, which were then compared using the Log Rank test. Cox proportional hazards analyses were performed after verification of the proportional hazards assumption.[22] Given the long time period of the study, we also tested for any interaction of endpoints with study time. A two-sided *P*-value of .05 was considered significant for all tests. All statistical analyses were performed using STATA version 11 (StataCorp). All authors had full access to the data and attest to the integrity of the analysis.

Table 2. Procedural characteristics. Comparison of patients undergoing bifurcation stenting or single-vessel stenting for the treatment of distal unprotected left main coronary disease.

	Bifurcation Stenting (N = 32)	Single Vessel Stenting (N = 38)	*P*-Value
LAD disease	30 (94%)	37 (97%)	.59
LCX disease	29 (91%)	33 (87%)	.72
RCA disease	24 (75%)	26 (68%)	.6
3-vessel disease (excluding left main)	21 (66%)	23 (61%)	.66
RCA total occlusion	4 (13%)	6 (16%)	.75
Right dominant	30 (94%)	37 (97%)	.59
Right coronary artery PCI	17 (53%)	16 (42%)	.47
Left main diameter stenosis	62 ± 17	64 ± 14	.66
Left anterior descending artery diameter stenosis	64 ± 26	54 ± 32	.17
LCX diameter stenosis	57 ± 28	41 ± 38	.05
Ostial LAD disease	25 (78%)	30 (79%)	.98
Ostial LCX disease	28 (88%)	26 (68%)	.09
LAD and LCX ostial disease (Medina 1,1,1)	22 (69%)	22 (58%)	.46
Either LAD or LCX ostial disease (Medina 1,1,0 or 1,0,1)	31 (96%)	34 (89%)	.37
Distal bifurcation angle >70 degrees	13 (43%)	19 (48%)	.73
Intra-aortic balloon pump used	2 (6.3%)	2 (5.3%)	.91
Final kissing balloons	24 (77%)	14 (37%)	.001
Largest left main stent diameter (mm)	3.6 ± 0.50	3.7 ± 0.41	.5
Drug-eluting stent used	32 (100%)	35 (92%)	.25
Sirolimus	13 (41%)	15 (39%)	.92
Paclitaxel	8 (25%)	7 (18%)	.57
Everolimus	11 (34%)	12 (32%)	.8
Zotarolimus	0 (0%)	3 (7.9%)	.25
Culotte stenting	14 (44%)	—	—
Crush stenting	11 (34%)	—	—
T-stenting	4 (13%)	—	—
V-stenting	3 (9%)	—	—
Glycoprotein IIb/IIIa inhibitor used	5 (16%)	9 (24%)	.55
Bivalirudin used	26 (81%)	24 (63%)	.12
Rotational atherectomy	4 (13%)	1 (3%)	.21
Intravascular ultrasound	6 (19%)	10 (26%)	.57
Follow-up surveillance angiography performed	6 (19%)	10 (26%)	.57

LAD = left anterior descending; LCX = left circumflex; RCA = right coronary artery; PCI = percutaneous coronary intervention. Data given as number (percentage) or mean ± standard deviation.

Results

From June of 2003 until December of 2009, a total of 70 consecutive patients with distal ULM disease underwent non-emergent PCI at our institution. The median follow-up was 448 days (intraquartile range, 372-588 days). While censoring was based on last contact in the medical record, no additional deaths were detected by linking with death registries. DESs were used in 96% of patients. Thirty-eight patients underwent BS and 32 underwent SVS. Baseline characteristics are compared for patients with BS or SVS in Table 1 and procedural characteristics are compared in Table 2. There was no significant difference in the prevalence of dual ostial disease in patients undergoing BS vs SVS, but patients undergoing BS did have more severe stenosis of the circumflex. There was a trend toward more insulin requiring diabetes in patients treated with SVS. Final kissing balloon inflations were more commonly performed in patients undergoing BS. Among patients undergoing BS, the culotte or crush techniques were used in 78% of procedures, with final kissing balloon inflations performed in 77%. Surveillance angiography was performed in 23% of patients over a period of 3 to 9 months.

Clinical outcomes are presented in Figure 1. There were 11 cardiac deaths (1 in-hospital and the remainder beyond 30 days), 7 non-fatal MIs and 10 TLRs (1 CABG and the remainder repeat PCIs). There was 1 case of definite stent thrombosis and 1 case of probable stent thrombosis (both in patients having BS). On univariate proportional hazards analysis, patients undergoing BS had similar cardiac mortality to patients undergoing SVS. However, BS was a significant predictor of cardiac death or MI (HR, 3.5; 95% CI, 1.1-11.1; *P*=.04) and overall MACE (HR, 4.2; 95% CI, 1.8-10.2; *P*=.001). After including the presence of disease involving the ostial LCX as a covariate along with BS, BS remained a strong predictor of overall MACE (HR, 4.5; 95% CI, 1.8 -11.4; *P*=.002). BS also remained a significant predictor of MACE after adjusting for LCX diameter stenosis (HR, 4.7; 95% CI, 1.9-11.7). Similarly, after adjusting for the presence of disease in both the ostial LAD and LCX (Medina 1,1,1) or for disease in either ostia (Medina 1,1,0 or 1,0,1), BS independently predicted MACE.

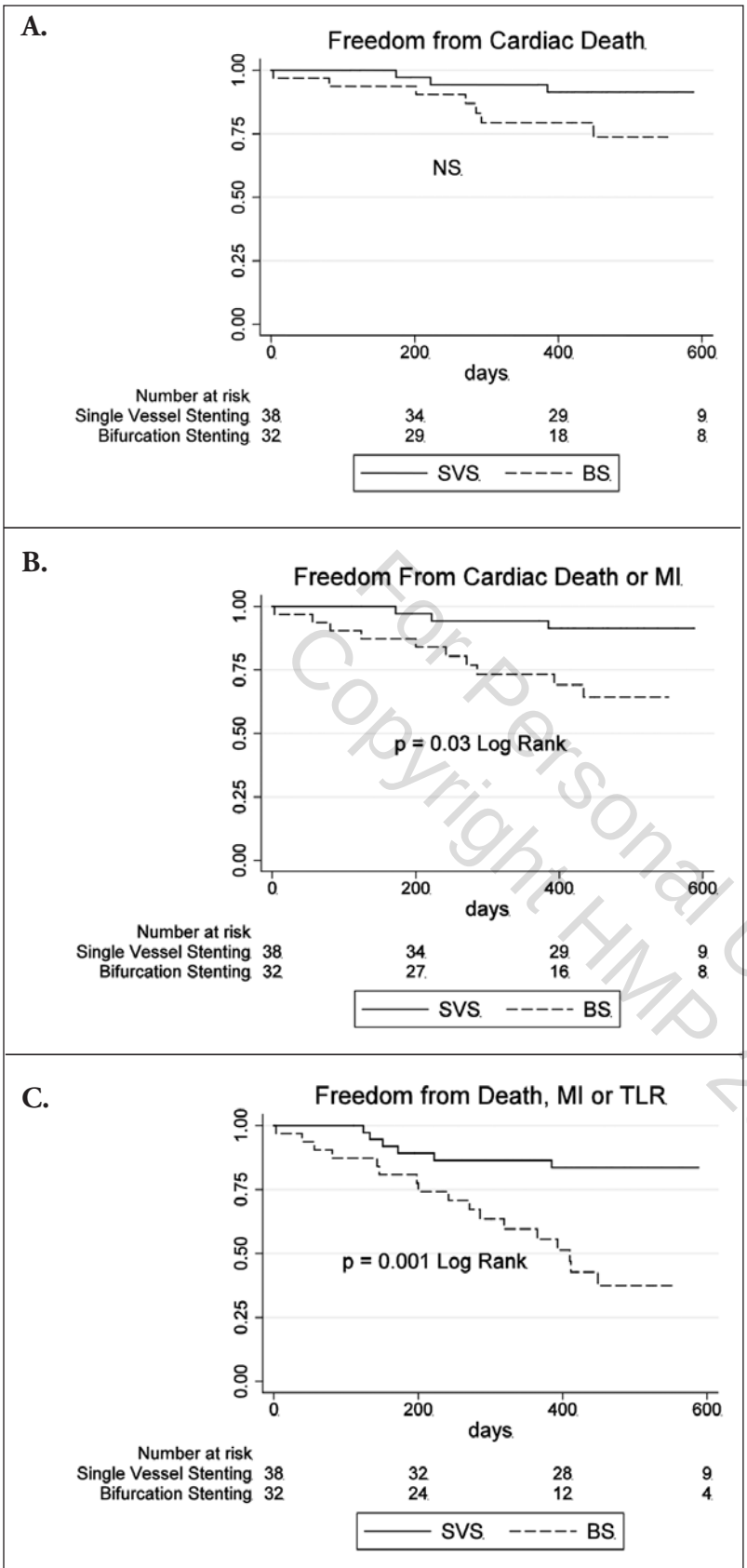

Figure 1. *Long-term outcomes. Kaplan Meier estimates of events for patients with bifurcation stenting (BS) or single-vessel stenting (SVS) of distal unprotected left main disease* **(A)**. *Freedom from cardiac death* **(B)**. *Freedom from cardiac death or myocardial Infarction* **(C)**. *Freedom from major adverse cardiac events (ie, cardiac death, myocardial infarction, or target lesion revascularization).*

The baseline complexity of bifurcation anatomy was not a predictor of outcomes. Finally, no interaction of study time with stenting strategy and outcomes was observed.

Discussion

The major findings of this study are that bifurcation stenting of distal unprotected LM disease is associated with increased rates of "hard" clinical endpoints and with overall MACE independent of bifurcation anatomy. While the prevalence of disease involving both ostia was similar between the two groups, we did observe a trend toward more disease involving the ostial circumflex in patients undergoing BS (88% vs 68%; *P*=.09) and mean circumflex diameter stenosis was more severe in patients undergoing BS (57 ± 27% vs 41 ± 38%; *P*=.05). However, BS remained a predictor of worse outcomes after adjusting for this or other characteristics of the bifurcation anatomy.

The outcomes we observed for patients undergoing BS for distal ULM disease were poor and substantially worse than in prior studies that compared BS with SVS for LM disease. This is likely due in part to the high incidence of co-morbid conditions in our population, as reflected by a median logistic EuroScore of 8.0 with the majority of patients being rejected for bypass surgery. The differences in outcomes could also be a consequence of more complete follow-up in the present series, differing BS techniques, and less frequent use of intravascular ultrasound. Of note, the rate of kissing balloon inflations for patients undergoing BS in this series was similar to that in prior studies.

Prior studies of BS in lesions outside the LM stem have generally demonstrated either worse outcomes or equivalent outcomes for patients with bifurcation lesions treated with a default two-stent technique as opposed to a provisional approach.[23-26] However, generalizing these trials to the LM stem is problematic. While the results of our study and prior studies could be interpreted as implying that an SVS strategy is the preferred strategy for distal ULM disease, additional confounders could be present. Although we adjusted for bifurcation anatomy, both the actual severity (as opposed to presence) of disease of the adjacent LAD and LCX as well as the size and distribution of the circumflex could interact with the choice of stenting strategy and outcome. Although this is a potential limitation, the presence of dual ostial disease at baseline did not predict outcomes (Table 2) and was equally prevalent in patients undergoing BS and SVS. This implies that additional factors may have influenced the decision to use BS, such as the desire to provide complete coverage of the carina or potentially to address intraprocedural

plaque shift. Given the retrospective nature of the study, we lacked reliable data on whether stenting strategies were "provisional" or planned. An adequately powered randomized trial that utilized a clearly defined default strategy taking into account the caliber and distribution of the circumflex as well as the physiologic significance of disease might be more definitive.

Study limitations. There are other important limitations to our analysis. The sample size precluded the use of full multivariable adjustment or the use of techniques utilizing inverse probability weighting, and there may have been other important differences between groups that we were underpowered to detect. Therefore, these results should be viewed as hypothesis generating and useful in planning appropriately powered studies. We were also unable to determine from the available data in the medical record why SVS was performed as opposed to BS. We lacked the capacity to perform formal quantitative coronary angiography (QCA) and determine reference vessel diameters. However, even QCA is not reliable in delineating plaque burden in patients with distal LM coronary disease and is not typically used in routine practice. As in all retrospective studies spanning longer time intervals, the evolution of contemporary practice is not captured, but rather the sum total of the experience. As an example, intravascular ultrasound guidance was used in a relatively small percent of patients in this series, but increased over time. While intravascular ultrasound more reliably documents plaque localization and improves outcomes for non-LM bifurcation lesions, the data on its use in improving LM outcomes are far from conclusive.[27]

Conclusions

In this unselected series of consecutive patients undergoing PCI using predominantly DESs and contemporary techniques for the treatment of distal ULM disease, BS was associated with worse outcomes even after adjusting for angiographic characteristics of the bifurcation. More definitive trials to clarify the ideal strategy for distal ULM disease should incorporate additional anatomic variables and/or physiologic assessment.

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