Ng and Lundstrom. Int J Clin Cardiol 2015, 2:1
ISSN: 2378-2951

International Journal of Clinical Cardiology

Research Article: Open Access

Double-Stenting of the Left Main Coronary Artery lesions: Safety, Clinical Outcome and Long Term Follow-up

William Ng* and Robert Lundstrom

Division of Cardiology, Kaiser Permanente Medical Center, USA

***Corresponding author:** *William Ng, MBBS, FACC, Division of Cardiology, Kaiser Permanente Medical Center, Modesto, 4601, Dale Road, 4/floor, 4A5, Modesto, CA 95356, USA, Tel: (209) 735-4282, Fax: (209) 735-4283, E-mail: ngwlsrc@gmail.com*

Abstract

This study aimed to assess the safety & medium/long-term outcome of using double-stenting strategy on left main (LM) stem for the treatment of significant suboptimal angiographic result after initial left main coronary artery (LMCA) stent implantation. Between August 2005 & June 2010, patients undergoing PCI with double-stenting of LMCA lesions comprised the study cohort. Baseline characteristics, EuroSCORE (I), lesions & stent characteristics and outcomes were analyzed. Thirty-eight patients were included in the study. Sixty-three percent were male, mean age of 73 years old, 37% were diabetic & 74% had unprotected LMCA stenting. Majority presented with acute coronary syndrome (57%) in which 7 (18%) had STEMI. They represented a high risk cohort with high EuroSCORE (I) (logistic 17.7 ± 19.1%, additive 8.2 ± 4.7). In addition, 32 (84%) patients had multi-vessels disease. Estimated left ventricular ejection fraction in the series was 54 ± 13%. Drug eluting stents were placed in all cases as the first stent (mean size 3.55 ± 0.28mm), 34 (89%) patients had bare metal stent as the second stent (mean size 4.15 ± 0.43mm). All stents were placed successfully. There was no in-hospital death. At one year, for those who survived, no patient required repeat PCI to LMCA lesion and non-target lesion revascularization was 16%. One-year survival was 87% & 82% by the end of second year. In conclusion, favorable outcomes were seen in this unselected series of patients undergoing double-stenting of LM stem lesions. The technique is safe and feasible, provides another option for treatment of severe LMCA disease with suboptimal initial stenting result.

Keywords

Percutaneous coronary intervention, Double stenting, Left main, outcomes

Introduction

With current clinical environment, percutaneous coronary intervention (PCI) on protected or unprotected left main coronary artery (LMCA) using bare metal stent (BMS) or more frequently drug eluting stent (DES) are not uncommon practice [1-6]. However, stenting to LMCA is still challenging, partly related to the possible hemodynamic instability during stent deployment with transient occlusion of LMCA, more importantly, there exists limited success in the treatment of aorto-ostial LMCA disease which often resulted in suboptimal long term result [7-10]. The limited success in PCI on LMCA can be explained by early elastic recoil in dilating aorto-ostial lesions which is usually rich in elastic media. In addition, high plaque burden with inadequate scaffolding with current stent platform often leads to suboptimal angiographic result. Lastly but not the least, there is high rate of restenosis in treating these lesions. Introduction of DES helps to reduce restenosis, but it is still unable to tackle suboptimal angiographic result following initial stenting caused by plaque prolapse or undersizing of the DES. There are early reports with placement of 2 overlapping stents, mostly DES, onto the same target lesion in the LMCA—the stent 'sandwich' technique or 'double-barrel' stenting—to improve angiographic result, either for treatment of instent restenosis, reconstruction of LMCA or to provide better scaffolding [11-14]. Of note, there is neither adequate information on the safety of this new double-stenting technique nor data on long term outcome. Thus, we aimed to evaluate the safety and feasibility of the above technique. In addition, short & medium term outcomes of patients receiving this treatment were also reported.

Methods

This protocol was approved by the institutional review board of Northern California Kaiser Permanente. Electronic Medical Records (EMR) were reviewed retrospectively to identify all patients between August 2005 & June 2010 at Kaiser Permanente Medical Center, San Francisco, who underwent double-stenting of LMCA for the treatment of suboptimal result after initial stent implantation in the LMCA. The various reasons leading to placement of the second stent at the same target lesion were noted in Table 1, they are namely under sizing of the drug coated stent being use, recoils, better scaffolding required for plaque prolapse and lastly, aiming at better drug coverage with double drug eluting stents. The inflation pressure

Table 1: Indications for placement of double stents: in decreasing order

Undersize of DES
Recoil & to improve radial strength
Better scaffolding for plaque prolapse
Better drug coverage with double DES

DES: Drug-Eluting Stent

ClinMed International Library

Citation: Ng W, Lundstrom R (2015) Double-Stenting of the Left Main Coronary Artery lesions: Safety, Clinical Outcome and Long Term Follow-up. Int J Clin Cardiol 2:022

Received: January 28, 2015: **Accepted:** February 27, 2015: **Published:** February 28, 2015

Table 2: Demographics and clinical characteristics

Age (yr)	73 ± 17	
Male (%)	63%	
DM (%)	37%	
Hypertension (%)	89%	
Extracardiac arteriopathy	8 (21%)	
Serum Cr>200mcg/dL	3(8%)	
neurodysfunction	5 (13%)	
Prior CABG	10 (26%)	
Stable angina	16 (42%)	
NSTEMI/UAP	15 (39%)	
STEMI	7 (18%)	
Shock	2 (5%)	
EuroSCORE (l)	Logistics	17.7 ± 19.1% (range0.88-85.8%)
	Additive	8.2 ± 4.7 (range 0-19)
LVEF (%)	54 ± 13%	(25-75%)
IABP use	4 (11%)	

DM: Diabetic Mellitus, Cr: Creatinine; CABG: Coronary Bypass Surgery, NSTEMI: Non-ST Segment Elevation Myocardial Infarct, UAP: Unstable Angina, STEMI: ST Segment Elevation Myocardial Infarction, LVEF: Left Ventricular Ejection Fraction, IABP: Intra-Aortic Balloon Counterpulsation.

Table 3: Angiographic, lesions and stents characteristics

Multi-vessels disease	32 (84%)	
Left main- site involved	ostial	26 (68%)
	body	1 (3%)
	distal	3 (8%)
	whole length	8 (21%)
1st stent	DES use	100%
	mean size (mm)	3.55 ± 0.28
	mean length (mm)	15.5 ± 6.2
2nd stent	BMS/DES use	34 (89%)/4 (11%)
	mean size (mm)	4.25 ± 0.43
	mean length (mm)	11.8 ± 3.7
2nd stent larger than 1st stent by	0.5-1.5mm	35 (92%)
	Equal size	3 (8%)
	>0.5mm	21 (55%)
	>1mm	10 (26%)
	>1.5mm	4 (11%)

BMS: Bare-Metal Stent, DES: Drug-Eluting Stent, mm: Millimeter

of the first stent has a mean of 18 atmospheres (atm) (range 12-24, mode of 20 atm), whereas that of the second stent at mean of 15.4 atmospheres (range 12-20, mode of 14 atm). As described by most operators, after deployment of the first stent at high pressure, there existed suboptimal angiographic result leading to placement of the second stent. In some scenarios, the operators decided to use a drug eluting stent, oftenly, a smaller stent-size available in market at that period, with the aim to deploy a second larger bare metal stent to improve the angiographic result, hoping that there still exists some treatment effect from the use of coated stent.

The choice of stenting strategy, type of drug eluting stent (DES) or bare metal stent (BMS) used, use of intravascular ultrasound (IVUS), balloon inflation pressure and the decision to perform final kissing balloon inflations were left to the discretion of the individual operator. The use of IVUS to guide stenting procedure is uncommon, and occurred in four patients only. In addition, there existed no standard classification/definition of plaque prolapsed as described by the operators, the decisions to use the second stent was per operator discretion. All patents were treated for at least 12 months with dual antiplatelet therapy following PCI. Beyond 12 months, decision to continue clopidogrel therapy or not was left to the operator's discretion depending on the complexity of the lesion and procedure.

Baseline characteristics, clinical presentation, EuroSCORE (l) [15,16] and angiographic data were recorded. Endpoints of the study include: 1) data captured for safety and feasibility of the technique; 2) 1-year target lesion revascularization (TLR); 3) overall major adverse cardiac events (MACE) at one year defined as cardiac death, myocardial infarction (MI), stroke or any repeat PCI procedure; 4) short term (6 months) and medium & long term survival (1- & 2-year) data were also recorded. The study concluded by the end of the second year of follow-up.

Results

From August 2005 until June 2010, there were 38 patients in our center that received double-stenting to the left main stem lesions. No one lost to follow-up. Twenty-four of them (63%) were male, mean age of 73 years old, 14 (37%) were diabetic, 34 (89%) had hypertension, 8 (21%) with extracardiac arteriopathy, 3 (8%) with chronic kidney disease (with serum creatinine> 200 mcg/dL, one on dialysis), 5 (13%) with neurodysfunction. Ten patients (26%) had prior coronary bypass surgery (CABG). Clinically, 16 (42%) presented with stable angina, 15 (39%) with non-ST segment elevation myocardial infarction (NSTEMI) or unstable angina. Seven patients had ST-segment elevation myocardial infarction (STEMI) on presentation. The patients in the present cohort had relatively preserved left ventricular systolic function as the measured mean ejection fraction (LVEF) was 54 ± 13% (with the range between 25-75%). We did have 2 patients with cardiogenic shock on presentation and 4 patients (11%) required intra-aortic balloon counterpulsation (IABP) support during the procedure. In addition, the patients in the present study did suggest a high risk cohort as reflected by the high EuroSCORE (l) (mean: logistic 17.7%, additive 8.2) calculated (Table 2).

Eighty-four percent of the patients had multi-vessels disease in addition to the severe LMCA. With regard to LMCA lesions, 26 (68%) had ostial disease, 1 (3%) with mid-shaft lesion, 3 (8%) with distal narrowing and 8 (21%) with diffuse disease affecting the LM stem. DES was placed in all cases as the first stent with their mean size of 3.55 ± 0.28mm & length of 15.5 ± 6.2mm. Regarding the second stent onto the same target lesion, 34 (89%) patients had bare metal stent as the second stent with mean size of 4.15 ± 0.43mm & length of 11.8 ± 3.7mm. The second stents were very often larger than the initially deployed stent in 92% of the cases, with 21 stents (55%) larger by 0.5mm, 10 (26%) larger by 1mm & 4 (11%) by >1.5mm (Table 3). All stents were placed successfully. No patient received bifurcation stenting for distal LMCA disease.

There was no in-hospital death. Scanning the robust EMR system, there was neither reported acute stent thrombus (AT) nor subacute stent thrombosis (SAT). Surveillance angiography was performed in 34% of the cases. At one year, for those who survived, no patient required repeat PCI to LM lesion and non-TLR rate was 16%. There was one patient who required open heart surgery for resection of aortic valve fibroelastoma and CABG. Six months survival was 92%, 1-year survival was 87% & 82% by the end of second year. Cumulative one-year MACE (any death, MI, stroke, any repeat PCI) occurred in 10 patients (26%), mainly contributed by non-TLR 6 (16%) & two non-cardiac death. There was no other report on patient with stroke or MI by the end of one year. Nevertheless, there were 7 patients that had passed away by the end of the study in which there were four cardiovascular deaths, one patient suffered from peri-procedural stroke & died in skilled nursing facility a month later. One patient died suddenly 10 months post-PCI. One died from cerebral hemorrhage after receiving thrombolytic therapy for acute inferior STEMI in outside facility. One died in hospice from end-stage heart failure. There were 3 other deaths, 1 patient died of terminal lung cancer, one from abdominal sepsis and the last one died from C Diff. colitis (Table 4).

Discussion

After initial stent placement in the LMCA, there exist the occasional suboptimal result due to plaque prolapse, undersize stent use and elastic recoil after bare metal stenting, which necessitate alternate treatment, one of which is the application of double-stenting technique [12,13]. The present study is by far the largest reported cohort of patients receiving double-stenting (stent sandwich) of the LMCA. Overlapping stents were deployed successfully in all 38

Table 4: Outcomes on follow-up

In-hospital death AT/SAT	0 0
Surveillance angiogram	13 (34%)
1-year TLR	0
1-year non-TLR	6 (16%)
Cross-over to surgery	1 (3%) *
6-months survival	35 (92%)
1-year survival	33 (87%)
2-year survival	31 (82%)
Cardiovascular death	4 (16%)
1-year MACE (death, MI, stroke, repeat PCI)	10 (26%)

*One patient requires CABG and resection of aortic valve fibroelastoma

CVS deaths: One patient suffered from periprocedural stroke & died in skilled nursing facility a month later. One died suddenly 10 months post-PCI. One died from cerebral hemorrhage after receiving thrombolytic therapy for acute inferior STEMI in outside facility. One died in hospice from end-stage heart failure.

Other deaths: one patient died of terminal lung cancer, one died from abdominal sepsis and one died from C Diff colitis.

AT: Acute Stent Thrombus; SAT: Subacute Stent Thrombus; TLR: Target Lesion Revascularization, MACE: Major Adverse Cardiac Event, MI: Myocardial Infarction, PCI: Percutaneous Coronary Intervention

patients in the study. There was no in-hospital death. There was no reported case of AT/SAT as well. The technique is believed to be safe and feasible procedure for the treatment of suboptimal angiographic result after initial stenting to LMCA disease. Despite being a high risk cohort of patients with high EuroSCORE(l) (mean; logistic 17.7, additive 8.2), these patients who received the double-stenting turned out to have quite favorable procedure outcome. No patient required repeat PCI to LMCA in one year. Short-term (6 months) survival was 92%. Medium & long term survival at 1-year & 2-year were 87% and 82% respectively.

Use of DES in the LMCA has the unique advantage in the reduction of instent restenosis in comparison to BMS [17,18], however, the former came with a limited size when it was first marketed in early 2000s, and available sizes were often smaller than the diameter of LM stem. This undersizing certainly contributed to suboptimal angiographic result after initial stenting to LMCA. On the other hand, BMS are often available in larger size and can alleviate the problem of undersizing. This was exemplified in our current study in which the DES used for initial deployment was smaller than the second stent (mostly BMS) placed (mean size 3.55 ± 0.28mm versus 4.25 ± 0.43mm). Nevertheless, with the new bigger size DES available in the market, the problem of undersize may resolve, but double-stenting might still be required to handle the problem of elastic recoil and plaque prolapsed.

The use of 'stent sandwich' raised another concern of having excessive metal in close proximity to each other, leading to higher incidence of ST/SAT and/or high rate of restenosis. However, in the present series, there was no patient suffering from ST/SAT and no patient required repeat PCI to LMCA in one year. This again demonstrated that the double-stenting technique is safe and able to provide lasting result. The reasons for these favorable outcomes might related to, firstly, a relatively large luminal diameter of the second stent used (4.25 ± 0.43mm), frequently with high pressure post-dilatation performed, achieving a relatively large final lumen diameter, a 'bigger the better' scenario. Secondly, the actual length of the overlapping stented segment required to achieve good angiographic result was shorter, as shown by the length of the 2nd stent used was shorter than the first stent (11.8 ± 3.7mm versus 15.5 ± 6.2mm); basically the function of the 2nd stent was used to target a focal problem like the elastic recoil at the ostium of the LMCA (68% in the present cohort) or focal area of plaque prolapsed.

As mentioned at the beginning, the current study is the largest cohort of patients receiving 'stent sandwich', comparing to other short reports or smaller series, we were able to show the safety & feasibility of the technique in the LMCA, as well as showing the medium & long term results [11-14]. Again, there is no patient requiring TLR. Obviously with a cohort of patients with high percentage of multivessels disease (84%) in addition to LMCA stenosis, the non-TLR rate of 16% was not too unexpected.

There are several limitations on the present study. Firstly, it is a retrospective, nonrandomized analysis of a small cohort of patients. However, the robust EMR system in the Kaiser system allows very accurate data capturing. Information like clinical presentation, angiographic data and follow-up events could be retrieved adequately. In addition, no patient was lost to follow-up in the current series. Secondly, we did not include a control group with single stent placement in LMCA for comparison; certainly, there has been plentiful outcome data of PCI to LMCA in the literature [1-6]. Thirdly, surveillance angiogram was only performed in 34% of the patients, all of them showed widely patent stents, and again no patient required repeat PCI to LMCA after surveillance angiography or on clinical follow-up. One can argue that without routine surveillance angiogram, the actual incidence of instent restenosis or other local angiographic complication in the LMCA like aneurysmal dilatation could not be accurately documented [19]. However, the absence of the need for repeat PCI in the LMCA, in which 74% was unprotected LMCA stenting, argued against significant angiographic restenosis or local complication necessitate further intervention. Besides, we have stopped performing surveillance angiography for patients receiving LMCA stenting as the former is no longer recommended.

In conclusion, favorable outcomes were seen in this unselected cohort of high risk patients undergoing double-stenting of LMCA. The technique is thought to be safe and feasible, provides another option for treatment of severe LMCA disease with suboptimal initial stenting result.

Disclosures

Dr. Lundstrom receives grant support from the Kaiser Foundation Research Institute. Drs. Ng and Lundstrom are employees of the The Permanente Medical Group, Inc.

References

1. Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, et al. (2006) ACC/AHA/SCAI Writing Committee to Update 2001 Guidelines for Percutaneous Coronary Intervention. J Am Coll Cardiol 47: e1-e121.

2. Park DW, Hong MK, Suh IW, Hwang ES, Lee SW, et al. (2007) Results and predictors of angiographic restenosis and long-term adverse cardiac events after drug-eluting stent implantation for aorto-ostial coronary artery disease. Am J Cardiol 99: 760-765.

3. Kim YH, Park DW, Kim WJ, Lee JY, Yun SC, et al. (2010) Impact of the extent of coronary artery disease on outcomes after revascularization for unprotected left main coronary artery stenosis. J Am Coll Cardiol 55: 2544-2552.

4. Park DW, Seung KB, Kim YH, Kim WJ, Kang SJ, et al. (2010) Long-term safety and efficacy of stenting versus coronary artery bypass grafting for unprotected left main coronary artery disease: 5-year results from the MAINCOMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) registry. J Am Coll Cardiol 56: 117-124.

5. Serruys PW, Morice MC, Kappetein AP, Colombo A, Holmes DR, et al. (2009) Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. N Engl J Med 360: 961-972.

6. Morice MC, Serruys PW, Kappetein AP, Feldman TE, Ståhle E, et al. (2010) Outcomes in patients with de novo left main disease treated with either percutaneous coronary intervention using paclitaxel-eluting stents or coronary artery bypass graft treatment in the Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery (SYNTAX) trial. Circulation 121: 2645-2653.

7. Iakovou I, Ge L, Michev I, Sangiorgi GM, Montorfano M, et al. (2004) Clinical and angiographic outcome after sirolimus-eluting stent implantation in aorto-ostial lesions. J Am Coll Cardiol 44: 967-971.

8. Kurbaan AS, Kelly PA, Sigwart U (1997) Cutting balloon angioplasty and stenting for aorto-ostial lesions. Heart 77: 350-352.

9. Nassar H, Gotsman I, Gerganski P, Moseri M, Lotan C, et al. (2009) Cutting balloon angioplasty and stent implantation for aorto-ostial lesions: clinical outcome and 1-year follow-up. Clin Cardiol 32: 183-186.

10. Topol EJ, Ellis SG, Fishman J, Leimgruber P, Myler RK, et al. (1987) Multicenter study of percutaneous transluminal angioplasty for right coronary artery ostial stenosis. J Am Coll Cardiol 9: 1214-1218.

11. Meliga E, De Benedictis M, Gagnor A, Scrocca I, Lombardi P, et al. (2011) New drug-eluting stent implantation for recalcitrant in-stent restenosis treated with drug-eluting stents. the Stent-in-Stent Cube (SIS³) registry. J Invasive Cardiol 23: 365-368.

12. Ratib K, Doshi SN, Townend JN (2005) Double-stenting of an ostial left main-stem lesion for elastic recoil. Int J Cardiol 102: 357-358.

13. Damelou A, Davlouros P, Karantalis V, Alexopoulos D (2010) Double-barrel stenting of distal left main stenosis in a patient with acute coronary syndrome: intravascular ultrasound and optical coherence tomography follow-up at six months. Can J Cardiol 26: e282-285.

14. Cosgrave J, Melzi G, Corbett S, Biondi-Zoccai GG, Babic R, et al. (2007) Repeated drug-eluting stent implantation for drug-eluting stent restenosis: the same or a different stent. Am Heart J 153: 354-359.

15. Nashef SA, Roques F, Hammill BG, Peterson ED, Michel P, et al. (2002) Validation of European System for Cardiac Operative Risk Evaluation (EuroSCORE) in North American cardiac surgery. Eur J Cardiothorac Surg 22: 101-105.

16. Roques F, Nashef SA, Michel P, Gauducheau E, de Vincentiis C, et al. (1999) Risk factors and outcome in European cardiac surgery: analysis of the EuroSCORE multinational database of 19030 patients. Eur J Cardiothorac Surg 15: 816-822.

17. Hsueh SK, Wu CJ, Fang HY, Hsieh YK, Fang CY, et al. (2011) Comparison of drug-eluting stent with bare metal stent for distal de novo unprotected left main coronary artery stenosis. A propensity score-matched cohort study. Circ J 75: 290-298.

18. Pandya SB, Kim YH, Meyers SN, Davidson CJ, Flaherty JD, et al. (2010) Drug-eluting versus bare-metal stents in unprotected left main coronary artery stenosis a meta-analysis. JACC Cardiovasc Interv 3: 602-611.

19. Morici N, Cosgrave J, Iakovou I, Zoccai GB, Tassanawiwat W, et al. (2006) Sandwich drug-eluting stenting: a novel method to treat high-risk coronary lesions. J Invasive Cardiol 18: 2-5.