Comparison of Acute and Long-term Outcomes of Drug-eluting Stents for Aorto-ostial Lesions at the Left Main and Right Coronary Arteries

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Abstract

Background: An aorto-ostial lesion (AOL) is a challenge for interventional cardiologists because it exhibits poorer clinical outcomes compared with non-ostial lesions. Several differences in the characteristics of the ostia of right coronary artery (RCA) and left main (LM) have been pointed out. The aim of this study was to compare acute and long-term outcomes of stenting with DESs for AOLs at the LM with those at the RCA.

Method: From July 2004 to January 2018, a total of 155 patients treated with DESs at LM or RCA AOLs were enrolled: 109 in the RCA group and 46 in the LM group. Acute and long-term clinical follow-up results were evaluated.

Results: The RCA group had more patients with hypertension, multi-vessel disease, type C lesions, longer lesions, or chronic total occlusion than did the LM group. The in-hospital major adverse cardiac events between the two groups were similar. Follow-up angiography showed that the RCA group had greater late loss (1.10 ± 1.03 mm vs. 0.53 ± 0.54 mm, $p < 0.01$), loss index (0.43 ± 0.38 vs. 0.22 ± 0.23, $p < 0.01$), and restenosis rate (25% vs. 8%, $p = 0.04$) than did the LM group. During long-term follow-up (47 ± 37 months), Kaplan-Meier analysis showed that the two groups had similar cardiac event-free survival rates ($p = 0.44$).

Conclusions: This study revealed higher restenosis rate when stenting with DESs for AOLs at the RCA than at the LM. However, the acute and long-term clinical outcomes of stenting with DESs for patients with AOLs at the LM coronary artery and those with AOLs at the RCA were similar.

Keywords: aorto-ostial lesions, percutaneous coronary intervention, drug eluting stent

Introduction

Aorto-ostial lesion (AOL) is a unique manifestation of coronary artery disease.[1,2] Percutaneous coronary intervention (PCI) for AOL remains challenging for interventional cardiologists. Several different characteristics of the right coronary artery (RCA) and left main

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(LM) have been pointed out.[3,4] Furthermore, the diameters of the RCA and LM also differ.[5,6] The diameter of a coronary artery has been shown to be a predictor of the severity of coronary artery disease.[7] High degrees of rigidity and elastic recoil of the AOLs lead to poorer outcomes after conventional balloon angioplasty.[8] Intracoronary bare-metal stent can provide adequate scaffolding, thus preventing recoil.[8,9] However, bare metal stents (BMSs) have been reported to be associated with high restenosis rates due to neointimal hyperplasia. Drug-eluting stents (DESs), compared with BMSs, have shown lower restenosis rates and favorable results in a broad range of lesions.[10-15] Several studies have described the safety and efficacy of DESs in treating AOLs.[12,16-19] However, thus far, the academic literature has lacked information regarding the clinical outcomes for AOLs treated with DESs at the LM and the RCA. The aim of this study was to compare the acute and long-term outcomes of stenting with DESs in patients with AOLs at the LM coronary artery and those with AOLs at the RCA.

Materials and methods

Study population

The CAPTAIN (Cardiovascular Atherosclerosis and Percutaneous TrAnsluminal INterventions) registry is a prospective observational database in a single medical center. This ongoing registry contains data from 9,300 patients who underwent elective or emergency PCI at our hospital starting from November 1995. From this registry, we enrolled 155 consecutive patients with AOLs treated with DESs from July 2004 to January 2018. An AOL was defined as a lesion > 50% stenosis and located within 3 mm from the aortic orifices. The exclusion criteria were multi-vessel disease requiring coronary bypass surgery; contraindications for aspirin, clopidogrel, or ticagrelor; and refusal to undergo the procedure. We divided the patients into two groups, the RCA group and the LM group, depending on where the stents were implanted. The DESs used in this study included TAXUS (Boston, Massachusetts, USA), Endeavor (Medtronic, Minnesota, USA), Cypher (Johnson & Johnson, New Jersey, USA), Xience (Abbott, Illinois, USA), Resolute (Medtronic, Minnesota, USA), Biomatrix (Biosensor, Singapore), Promus (Boston, Massachusetts, USA), Nobori (TERUMO, Tokyo, Japan), SYNERGY (Boston, Massachusetts, USA) and Ultimaster (TERUMO, Tokyo, Japan). Dual antiplatelet therapy with aspirin plus clopidogrel or aspirin plus ticagrelor was administered after coronary stenting.

Intervention techniques and follow-up

The procedures were performed through the femoral or radial approach according to the operator's preference. The stents were implanted to allow approximately 1 mm protrusion into the aorta. Depending on the available stent size and patients' preference, the operator decided the type of stent to be implanted. Intravascular ultrasound (IVUS) was used routinely for LM lesions only. For RCA lesions, the use of IVUS was at the discretion of the operator. Cardiac isoenzymes were measured immediately and 6 hours after the procedure in all patients. Clinical follow-up was performed by outpatient visits or telephone contact at 1, 2, and 3 months and every 3 months thereafter.

Angiographic analysis

Quantitative angiographic analysis was performed with a selective end-diastolic frame showing the stenosis in its most severe angiographic projection. Quantitative measurements included the diameter of reference vessel (RVD), minimal luminal diameter (MLD), percentage (%) of diameter stenosis, and balloon diameter. Binary restenosis was defined as stenosis more than 50% of the minimal luminal diameter in the target lesion at angiographic follow-up. Acute gain was calculated as the difference between the initial and final MLD in the index procedure. Late loss was calculated as the difference between the MLD at the end of the index procedure and the MLD at

follow-up. Net gain was defined as the difference between acute gain and late loss, and loss index as the ratio of late loss to acute gain.

Definition

Adverse events were assessed in the index hospitalization and during follow-up periods. The in-hospital major adverse cardiac events (MACE) were defined as a composite of death, non-fatal myocardial infarction, and need for emergency coronary bypass surgery. The long-term cardiovascular events were defined as cardiac death, nonfatal myocardial infarction, target lesion revascularization (TLR), a new lesion requiring stenting, coronary bypass surgery, and a cerebrovascular accident. Mortality was classified as being of cardiac or non-cardiac cause. All deaths were regarded as those of cardiac cause unless a non-cardiac cause was proven. Nonfatal myocardial infarction was diagnosed when the patient experienced prolonged chest pain for more than 30 minutes which could not be relieved by nitroglycerin, elevated troponin I levels or creatine kinase-MB (CK-MB) fraction > 3 times upper limit of normal.

Statistical analysis

All statistical analyses were performed using SPSS 25 (SPSS Corp., Chicago, IL) statistical software. Continuous variables are presented as mean ± SD and compared using the Student-t test. Categorical variables are presented as frequencies and analyzed using the χ^2 test or Fisher's exact test where applicable. The cardiac event-free survival rates during the follow-up period were estimated using Kaplan-Meier method and compared using Log rank test. A p value < 0.05 was considered statistically significant.

Result

Patient characteristics

A total of 155 patients with AOLs were enrolled: 109 patients treated at the RCA and 46 patients at the LM coronary artery. The baseline characteristics are presented in Table 1.

Table 1. Patient Characteristics

	Total	RCA	LM	p value
Patients number, *n*	155	109	46	
Age (years)	65±12	65±12	66±10	0.52
Male, *n* (%)	115(74)	78(72)	37(80)	0.25
Hypertension, *n* (%)	98(63)	75(69)	23(50)	0.03
Diabetes mellitus, *n* (%)	66(43)	45(40)	21(46)	0.62
Smoking, *n* (%)	37(24)	26(24)	11(24)	0.99
Dyslipidemia, *n* (%)	57(37)	40(37)	17(37)	0.98
Multi-vessel disease, *n* (%)	125(81)	93(85)	32(70)	0.02
Previous PTCA, *n* (%)	3(2)	3(3)	0(0)	0.56
Recent infarction, *n* (%)	31(20)	21(19)	10(22)	0.73
Unstable angina, *n* (%)	102(66)	72(66)	30(65)	0.92
LVEF (%)	59±13	60±13	58±15	0.46

RCA: Right coronary artery; LM: left main coronary artery; PTCA: percutaneous transluminal coronary angioplasty; LVEF: Left ventricular ejection fraction.

The RCA group had more patients with hypertension and multi-vessel disease than did the LM group. No difference was observed between the two groups in age, gender, diabetes mellitus, current smoking habit, dyslipidemia, previous history of PCI, recent infarction, unstable angina, and left ventricular function.

Lesion characteristics

Of the 155 lesions considered in this study, 109 were at the RCA and 46 were at the LM coronary artery. Most of the lesions were complex (Type B_2, 39%; type C, 58%), including 28 chronic total occlusion lesions. (Table 2)

The RCA group had more type C lesions than did the LM group (69% vs. 35%, $p < 0.01$). The mean length was longer in the RCA group than in the LM group (34 ± 22 mm vs. 17 ± 9 mm, $p < 0.01$). Furthermore, more chronic total occlusion was observed in the RCA group than in the LM group (24% vs. 7%, $p = 0.02$). The LM group had more eccentric lesions than the RCA group (50% vs. 24%, $p < 0.01$). No difference was observed between the two groups in restenotic lesions, segmental lesions, calcification, or thrombus-containing lesions.

Procedure results and in-hospital events

Table 3 shows the in-hospital events of patients in the two groups. One patient died in the hospital due to STEMI with cardiogenic shock. Three patients developed nonfatal myocardial infarction: of these patients, two were in the RCA group and one was in the LM group.

The procedure results are presented in Table 4. A total of 155 stents were implanted successfully: 109 in the RCA group and 46 in the LM group. The RCA group had a larger percentage of diameter stenosis (83% ± 14% vs. 73% ± 14%, $p < 0.01$), smaller MLD (0.62 ± 0.58 mm vs. 1.04 ± 0.59 mm, $p < 0.01$) and smaller RVD (3.44 ± 0.52 mm vs. 3.82 ± 0.49 mm, $p < 0.01$) before stenting. No difference was observed in the percentage of diameter stenosis between the two groups after stenting. However, the MLD (3.22 ± 0.43 mm vs. 3.56 ± 0.50 mm, $p < 0.01$)

Table 2. Lesion Characteristics

	Total (n=155)	RCA (n=109)	LM (n=46)	p value
Type				<0.01
A, *n* (%)	0(0)	0(0)	0(0)	
B1, *n* (%)	4(3)	3(3)	1(2)	
B2, *n* (%)	60(39)	31(28)	29(63)	
C, *n* (%)	91(58)	75(69)	16(35)	
Restenosis lesion, *n* (%)	9(6)	7(6)	2(4)	>0.99
Lesion length (mm)	29±20	34±22	17±9	<0.01
Lesion morphology				
Segmental, *n* (%)	133(86)	97(89)	36(78)	0.08
Eccentric, *n* (%)	49(32)	26(24)	23(50)	<0.01
Calcification, *n* (%)	53(34)	38(35)	15(33)	0.79
Thrombus, *n* (%)	2(1)	2(2)	0(0)	>0.99
Chronic total occlusion, *n* (%)	28(18)	25(24)	3(7)	0.02

RCA: Right coronary artery; LM: left main coronary artery

Table 3. In-Hospital Events

	Total (n=155)	RCA (n=109)	LM (n=46)	p value
Procedural death, n (%)	1(1)	1(1)	0(0)	>0.99
Myocardial infarction, n (%)	3(2)	2(2)	1(2)	>0.99
Emergent bypass surgery, n (%)	0(0)	0(0)	0(0)	N/A
Pseudoaneurym at access site requiring surgical repair, n (%)	0(0)	0(0)	0(0)	N/A
Major adverse cardiac events, n (%)	4(3)	3(3)	1(2)	>0.99
Acute stent thrombosis, n (%)	0(0)	0(0)	0(0)	N/A
Subacute stent thrombosis, n (%)	0(0)	0(0)	0(0)	N/A

RCA: Right coronary artery; LM: left main coronary artery

Table 4. Quantitative Angiographic Measurements

	Total (n=155)	RCA (n=109)	LM (n=46)	p value
Before-stenting				
% diameter stenosis	80±15	83±14	73±14	<0.01
MLD (mm)	0.74±0.61	0.62±0.58	1.04±0.59	<0.01
RVD (mm)	3.55±0.54	3.44±0.52	3.82±0.49	<0.01
After-stenting				
% diameter stenosis	7±5	7±5	7±6	0.78
MLD (mm)	3.33±0.48	3.22±0.43	3.56±0.50	<0.01
RVD (mm)	3.57±0.53	3.46±0.50	3.85±0.50	<0.01
Follow-up				
Number of patients, *n*	95	59	36	
Days to follow-up	294±87	285±82	309±95	0.19
% diameter stenosis	32±25	39±28	22±15	<0.01
MLD (mm)	2.46±1.03	2.12±1.03	3.02±0.77	<0.01
RVD (mm)	3.60±0.53	3.46±0.49	3.83±0.50	<0.01
Maximal balloon size (mm)	3.98±0.54	3.87±0.51	4.24±0.51	<0.01
Balloon/artery ratio	1.14±0.24	1.15±0.29	1.11±0.04	0.43
Maximal inflation pressure (atm)	18±3	19±3	18±3	0.08
Stent length (mm)	26±10	28±10	20±8	<0.01
Acute gain (mm)	2.60±0.58	2.62±0.55	2.53±0.61	0.34
Late loss (mm)	0.89±0.91	1.10±1.03	0.53±0.54	<0.01
Net gain (mm)	1.70±1.00	1.49±1.07	2.05±0.77	<0.01
Loss index	0.35±0.35	0.43±0.38	0.22±0.23	<0.01
Restenosis rate (lesion number)	19% (18)	25% (15)	8% (3)	0.04

RCA: Right coronary artery; LM: left main coronary artery; MLD: minimal luminal diameter; RVD: reference vessel diameter.

and RVD (3.46 ± 0.50 mm vs. 3.85 ± 0.50 mm, $p < 0.01$) were smaller in the RCA group than they were in the LM group after stenting. The LM group had a larger diameter of maximal balloon size than did the RCA group (4.24 ± 0.51 mm vs. 3.87 ± 0.51 mm, $p < 0.01$). The stents implanted in the RCA group were longer than those implanted in the LM group (28 ± 10 mm vs. 20 ± 8 mm, $p < 0.01$). No differences were observed between the two groups in balloon-artery ratio, maximal inflation pressure, and acute gain. Moreover, 59 patients in the RCA group and 36 patients in the LM group received 9-month follow-up coronary angiography. Relative to the LM group, the RCA group had a higher percentage of stenosis (39 ± 28% vs. 22 ± 15%, $p <0.01$), smaller MLD (2.12 ± 1.03 mm vs. 3.02 ± 0.77 mm, $p < 0.01$), and smaller RVD (3.46 ± 0.49 mm vs. 3.83 ± 0.50 mm, $p < 0.01$) at follow-up coronary angiography. The RCA group had greater late loss (1.10 ± 1.03 mm vs. 0.53 ± 0.54 mm, $p < 0.01$) and loss index (0.43 ± 0.38 vs. 0.22 ± 0.23, $p < 0.01$) but less net gain (1.49 ± 1.07 vs. 2.05 ± 0.77 mm, $p < 0.01$) than did the LM group. The restenosis rate was higher in the RCA group (25% vs. 8%, $p = 0.04$) than in the LM group. The in-hospital MACE (3% vs. 2%, $p > 0.99$) was not significantly different between the two groups.

Long-term clinical outcomes

All patients received long-term clinical follow-up (47 ± 37 months). Table 5 shows the long-term outcomes of patients in the two groups. Nine patients died of cardiac causes, and 10 patients died of non-cardiac causes. Six patients (4%) had nonfatal myocardial infarction. In addition, 20 patients (13%) required TLR and 19 patients (12%) had new lesions requiring stenting. Ten patients (7%) underwent coronary artery bypass surgery. Five patients (3%) had nonfatal stroke. The overall cardiac event-free survival was 69%.

No significant differences were observed between the RCA group and the LM group with regard to mortality rate, nonfatal myocardial infarction, new lesions requiring stenting, nonfatal stroke, and elective coronary artery bypass surgery during the follow-up periods. The two groups had similar cardiac event-free survival rates (68% vs. 72%, $p = 0.64$). The cardiac event-free survival rates determined in our Kaplan-Meier analysis were also similar between the two groups ($p = 0.44$) (Figure 1).

Table 5. Clinical Events during Follow-Up

	Total (n=155)	RCA (n=109)	LM (n=46)	p value
Mortality, *n* (%)	19(12)	14(13)	5(11)	0.73
Cardiac, *n* (%)	9(6)	7(6)	2(4)	
Non-cardiac, *n* (%)	10(7)	7(6)	3(7)	
Nonfatal myocardial infarction, *n* (%)	6(4)	5(5)	1(2)	0.67
Target lesion revascularization, *n* (%)	20(13)	17(16)	3(7)	0.12
New lesion requiring stenting, *n* (%)	19(12)	13(12)	6(13)	0.85
Coronary bypass surgery, *n* (%)	10(7)	6(6)	4(9)	0.48
Nonfatal stroke, *n* (%)	5(3)	2(2)	3(7)	0.16
Cardiac event-free survival, *n* (%)	107(69)	74(68)	33(72)	0.64

RCA: right coronary artery; LM: left main coronary artery

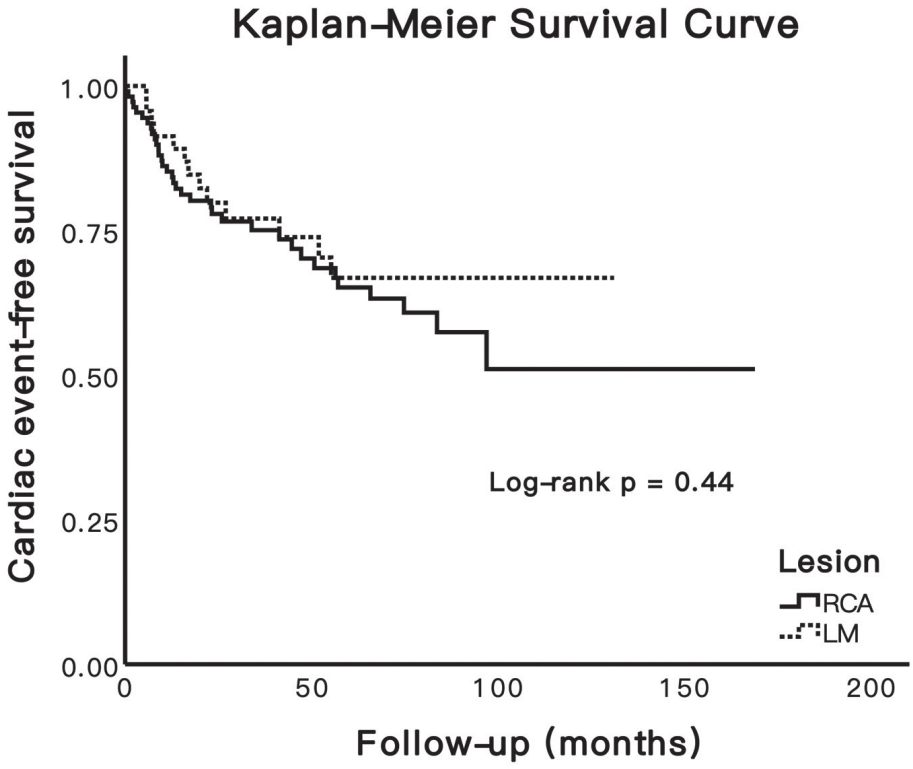

Figure 1. Kaplan-Meier survival curve
The cardiac event-free survival rates determined in our Kaplan-Meier analysis were similar in the RCA group and the LM group.

Discussion

The results of this study revealed similar acute and long-term outcomes in the LM and the RCA groups for AOLs treated with DESs. The restenosis rate was higher in the RCA group than in the LM group. The mortality rate and cardiac events were similar between the two groups. Additionally, the Kaplan-Meier analysis showed similar cardiac event-free survival rates between the two groups.

An AOL is an uncommon manifestation of coronary artery disease, with an approximate incidence of 2.6%.[4] AOLs could be the cause of fatal MI and sudden cardiac death due to large myocardial territories.[20] Previous pathological studies have shown that ostial lesions are characterized by more elastic recoil due to a considerably higher degree of fibrosis, sclerosis, and calcification.[9] The IVUS study showed that the coronary ostia may be associated with tissue proliferation from the aortic wall and chronic recoil after stenting.[21]

The properties of the RCA ostium and the LM ostium are different. In a cohort study, higher incidence rates of acute myocardial infarction, sudden death, and violent death were observed in patients with RCA AOLs.[20,22] Some physical properties have been suggested to explain this difference. Boucek et al. suggested that the muscle in the aortic wall surrounding the coronary orifice influenced the resistance and blood flow of the coronary artery, which may result in more atherosclerotic plaques at the RCA ostium compared with those at the LM ostium.[20]

Several studies have reported that the

coronary vessel diameter is a major predictor of in-stent restenosis, regardless of the implanted stent type.[23,24] The diameter of the RCA ostium is smaller than that of the LM ostium.[5,6] Zhou et al, reported that the diameter of the coronary artery was inversely associated with the severity of coronary artery disease.[7] Elezi et al. have furthermore shown that the vessel size influences the long-term results of coronary stenting.[23] Several studies have demonstrated higher angiographic restenosis rates at the RCA ostium than at the LM ostium.[4,21]

Our study revealed similar in-hospital and long-term outcomes for AOLs treated with DESs, at the RCA and at the LM. The performed angiographic analysis also showed that the RCA group had a higher restenosis rate, greater late loss and loss index at follow-up. Though no significant differences were observed between the two groups regarding TLR, the RCA group had a higher incidence of these events than did the LM group. This statement should be supported with additional evidence.

Limitations

This observational study has some limitations. First, because it was not a randomized study, the patient population, lesion characteristics and therapeutic strategies may differ between the two groups. Second, the angiographic follow-up was not performed for all the patients. These may result in selection bias. Third, medical treatment is imperative for patients with coronary artery disease, including anti-platelet agents, beta-blockers, statins and oral hypoglycemic agents, and all would influence the outcomes. However, this study did not collect information on these medications and related follow-up data such as blood pressure change, glycohemoglobin, and lipid profile of each patient. Fourth, the limited number of patients may limit the statistical power to compare angiographic and clinical outcomes.

Conclusion

This study revealed higher restenosis rate when stenting with DESs at AOLs of the RCA than of the LM. But the acute and long-term clinical outcomes of stenting with DESs for patients with AOLs at the LM coronary artery and those with AOLs at the RCA are similar.

Acknowledgments

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