Frequency of Coronary Arterial Late Angiographic Stent Thrombosis (LAST) in the First Six Months: Outcomes With Drug-Eluting Stents Versus Bare Metal Stents

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Concerns have been raised about the long-term safety of drug-eluting stent (DES) implantation due to late angiographic stent thrombosis (LAST). We investigated the incidence and 6-month clinical and angiographic outcomes of LAST after DES versus bare metal stent (BMS) implantation. This study comprised 6,551 patients treated with BMSs (n = 4,104) or DESs (n = 2,447). LAST was defined as angiographically proved stent thrombotic occlusion with acute ischemic symptoms >30 days after stenting. Major adverse cardiac events were defined as death, Q-wave myocardial infarction, and target lesion revascularization. Patients treated with DESs had a significantly higher risk profile than did patients treated with BMSs. There were 8 cases (0.33%) of LAST in the DES group and 7 (0.17%) in the BMS group, showing similar event rates after risk adjustment (adjusted hazard ratio 1.2, 95% confidence interval 0.1 to 18.4, p = 0.9). Four patients with LAST treated with DESs (50%) and 1 treated with BMSs (14%) were associated with discontinuation of antiplatelet therapy. Two cases (25%) of LAST with DESs occurred in patients on aspirin monotherapy and another 2 cases (25%) occurred in patients on dual antiplatelet therapy. There was no case of in-hospital death associated with LAST events. At 6-month follow-up after LAST events, major adverse cardiac events occurred in only 3 patients (43%) in the BMS group. In conclusion, the incidence of LAST was similar after DES and BMS implantations. LAST treated with DESs was associated with antiplatelet therapy discontinuation in a significant number of patients, and LAST events also developed on dual antiplatelet therapy. Patients with LAST and DESs showed favorable outcomes during follow-up. **(Am J Cardiol 2007;99:774–778)**

Although the efficacy and safety of drug-eluting stents (DESs) have been well demonstrated, concerns about late angiographic stent thrombosis (LAST) events have been raised after DES implantation,[1,2] which had been regarded as a very uncommon phenomenon with bare metal stents (BMSs) except after coronary brachytherapy.[3] Recent reports have shown that rates of stent thrombosis for DESs in clinical trials and registries are similar to those for BMSs.[4,5] However, data comparing the incidence and characteristics of patients with LAST after DES versus BMS implantation are lacking. We compared the incidence, characteristics, and outcomes of LAST events between DES and BMS populations.

Methods

Study population: We identified 2,447 consecutive patients who underwent DES implantation at Asan Medical Center (Seoul, Korea) from February 2003 to February 2005 (DES group). Sirolimus-eluting stents and paclitaxel-eluting stents were used in 1,948 and 499 patients, respectively. During this period, use of DESs was the default strategy of coronary intervention except in patients with anticipated major surgery necessitating antiplatelet therapy interruption within 3 months after stenting, lesions in a large vessel without an available DES size, and a patient's refusal. A control group was composed of 4,104 consecutive patients treated with BMSs from March 1997 to January 2003 before introduction of the DES (BMS group). All interventions were performed according to current standard techniques, with the selection of DES type left to the discretion of the operator. Standard qualitative and quantitative analyses and definitions were used for angiographic analyses.[6]

Antithrombotic and antiplatelet regimens: During the procedure, patients received heparin to maintain an activated clotting time of ≥250 seconds. Use of glycoprotein IIb/IIIa inhibitors was at the operator's discretion. All patients who underwent stenting were pretreated with aspirin plus ticlopidine or clopidogrel. A loading dose of 300 mg of clopidogrel (or 500 mg of ticlopidine) was given to patients not previously taking these antiplatelet agents. After the procedure, aspirin was continued indefinitely. Clopidogrel (75 mg/day) was prescribed for ≥6 months in the DES

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Table 1
Baseline clinical, procedural, and angiographic characteristics

Variable	BMS (n = 4,104)	p Value*	DES			p Value†
			Overall (n = 2,447)	SES (n = 1,948)	PES (n = 499)	
Age (yrs)	59 ± 10	<0.001	60 ± 10	60 ± 10	61 ± 10	0.2
Men	2,955 (72%)	0.3	1,734 (71%)	1391 (71%)	343 (69%)	0.2
Hypertension	1,659 (40%)	<0.001	1,255 (51%)	988 (51%)	267 (54%)	0.3
Diabetes mellitus	885 (22%)	<0.001	699 (29%)	546 (28%)	153 (31%)	0.2
Hypercholesterolemia (total cholesterol >200 mg/dl)	1,496 (36%)	<0.001	595 (24%)	478 (25%)	117 (23%)	0.6
Current smoking	1,620 (40%)	<0.001	742 (30%)	585 (30%)	157 (32%)	0.5
Clinical presentation		<0.001				0.3
Stable angina pectoris	1,113 (27%)		1,244 (51%)	1,001 (51%)	243 (49%)	
Unstable angina pectoris	2,121 (52%)		885 (36%)	689 (35%)	196 (39%)	
Acute myocardial infarction	870 (21%)		318 (13%)	258 (13%)	60 (12%)	
Previous myocardial infarction	310 (8%)	<0.001	259 (11%)	216 (11%)	43 (9%)	0.1
Previous percutaneous coronary intervention	369 (9%)	<0.001	528 (22%)	435 (22%)	93 (19%)	0.1
Previous coronary bypass surgery	66 (2%)	0.006	63 (3%)	48 (3%)	15 (3%)	0.5
Left ventricular ejection fraction (%)	59 ± 10	0.049	58 ± 9	59 ± 9	58 ± 9	0.3
Multivessel coronary disease	1,514 (37%)	<0.001	1,427 (58%)	1,123 (58%)	304 (61%)	0.2
Treated coronary artery		<0.001				<0.001
Left main	209 (5%)		229 (9%)	224 (12%)	5 (1%)	
Left anterior descending	2,110 (52%)		1,358 (56%)	1,076 (55%)	282 (57%)	
Left circumflex	612 (15%)		273 (11%)	216 (11%)	57 (11%)	
Right	1,139 (28%)		577 (24%)	428 (22%)	149 (30%)	
B2 or C type‡	2,249 (55%)	<0.001	1,962 (80%)	1,593 (81%)	382 (77%)	0.008
Chronic total occlusion	205 (5%)	0.010	159 (7%)	132 (7%)	27 (5%)	0.3
Ostial lesion	413 (10%)	0.036	286 (12%)	248 (13%)	38 (8%)	0.001
Bifurcation lesion	388 (10%)	<0.001	506 (21%)	440 (23%)	66 (13%)	<0.001
In-stent restenosis	150 (4%)	<0.001	246 (10%)	222 (11%)	24 (5%)	<0.001
Maximal balloon diameter (mm)	3.7 ± 0.6	<0.001	3.6 ± 0.5	3.6 ± 0.5	3.6 ± 0.4	0.3
Maximal inflation pressure (atm)	12.9 ± 3.1	<0.001	16.1 ± 3.9	16.7 ± 3.7	13.8 ± 3.9	<0.001
Stents per lesion (no.)	1.0 ± 0.2	<0.001	1.5 ± 0.7	1.5 ± 0.7	1.4 ± 0.6	0.2
Total stent length (mm)	19.5 ± 7.5	<0.001	35.6 ± 19.2	35.7 ± 19.4	34.9 ± 18.4	0.4
Lesion length (mm)	17.1 ± 9.6	<0.001	27.8 ± 15.6	27.7 ± 15.8	28.4 ± 15.1	0.4
Reference vessel diameter (mm)	3.3 ± 0.6	<0.001	2.9 ± 0.6	2.9 ± 0.7	2.9 ± 0.5	0.3
Minimal luminal diameter (mm)						
Before intervention	0.8 ± 0.5	<0.001	0.9 ± 0.6	0.9 ± 0.6	0.9 ± 0.5	0.4
After intervention	3.2 ± 0.6	<0.001	2.9 ± 0.5	2.9 ± 0.5	2.9 ± 0.4	0.5

Values represent numbers of patients (percentages) or means ± SDs.
* Comparisons between the BMS and DES groups.
† Comparisons between the SES and PES groups in the DES population.
‡ Based on American College of Cardiology/American Heart Association classification.
PES = paclitaxel-eluting stent; SES = sirolimus-eluting stent.

group without difference according to DES type, and clopidogrel (75 mg/day) or ticlopidine (500 mg/day) was prescribed for ≥1 month in the BMS group.

Follow-up and definitions: Clinical follow-up was performed by telephone contact or office visit at 1, 3, 6, and 12 months and then every 6 months after the index procedure. Patients who had not developed any major adverse cardiac events (MACEs) in the first month and who had not presented any medical contraindication for angiographic restudy were requested to have a 6-month follow-up angiogram. All patients with LAST were clinically followed for ≥6.0 months (range 6.1 to 30.7) after the index events, except for 1 case of sudden cardiac death. These patients were also recommended to have a 6-month follow-up angiogram. A MACE was defined as death (all cause), Q-wave myocardial infarction, and target lesion revascularization. LAST was defined, as in a previous study,[7] as angiographically documented partial or total thrombotic occlusion of the stent (Thrombolysis In Myocardial Infarction grade 0 or 1 flow) or as the presence of flow-limiting thrombus (Thrombolysis In Myocardial Infarction grade 1 or 2 flow) that occurred >30 days after stent implantation. Acute cardiac ischemic events in addition to angiographic documentation had to be present for a diagnosis of LAST. All events were adjudicated by a local clinical events committee in our institution.

Statistical analysis: Categorical data are presented as frequencies and were compared using chi-square statistics or Fisher's exact test. Continuous variables are presented as mean ± SD or median (range) and were analyzed using Student's *t* test or the Mann-Whitney U test, as appropriate. Risk of LAST incidence during follow-up after DES versus BMS implantation was compared by Cox proportional hazard regression after adjustment of baseline clinical, procedural, and

Table 2
Clinical and procedural characteristics of patients with late angiographic stent thrombosis

Patient	Age (yrs)/ Sex	Stent Type	Coronary Artery	No. of Stents	Total Stent Length (mm)	Stent Diameter (mm)	Final MLD (mm)	Clinical Presentation	Months to LAST
1	55M	SES	LAD	1	33	3.5	3.2	STEMI	14.3
2	65F	SES	LAD	1	33	3.5	2.9	Unstable angina	7.0
3	46M	SES	Right	4	132	3.0–3.5	2.8	NSTEMI	1.9
4	48M	SES	LC	1	23	3.0	3.0	NSTEMI	32.6
5	36M	PES	LAD	1	28	3.5	3.1	NSTEMI	8.5
6	54M	PES	LAD	1	28	3.0	2.7	STEMI	1.6
7	43M	PES	Right	1	16	3.0	3.1	STEMI	20.4
8	44M	PES	Right	1	24	3.5	3.5	STEMI	5.2
9	52M	BMS	LAD	1	24	4.0	3.4	STEMI	17.1
10	57M	BMS	LAD	1	24	3.5	2.9	STEMI	1.3
11	59F	BMS	LAD	1	40	3.0	3.0	Unstable angina	2.6
12	32M	BMS	Right	1	15	3.5	3.5	NSTEMI	1.3
13	47M	BMS	Right	5	74	3.0–3.5	3.1	Unstable angina	4.2
14	54M	BMS	Right	1	18	4.0	4.4	STEMI	36.1
15	63F	BMS	LCx	1	18	3.0	2.8	STEMI	4.3

LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; MLD = minimal luminal diameter; NSTEMI = non–ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction. Other abbreviations as in Table 1.

angiographic characteristics between the 2 groups. All statistical tests were 2-sided, and differences were considered statistically significant at a p value <0.05. Analyses were performed with SPSS 12.0 (SPSS, Inc., Chicago, Illinois).

Results

Baseline characteristics and incidence of LAST: Long-term (≥1 year) follow-up was completed in 98.7% of the DES group and 98.3% of the BMS group (p = 0.2). Mean follow-up durations were 24.3 ± 7.3 months in the DES group and 27.5 ± 8.7 months in the BMS group. Patients treated with DESs had a significantly higher risk profile than patients treated with BMSs, except that hypercholesterolemia, smoking, unstable angina, and acute myocardial infarction were more common in the BMS group (Table 1). Of patients treated with DESs, sirolimus-eluting stents were more frequently used in complex lesion subsets than paclitaxel-eluting stents.

In the DES group, 8 patients (0.33%, 95% confidence interval [CI] 0.17 to 0.64) developed LAST events, 4 (0.21%, 95% CI 0.08 to 0.52) in the sirolimus group and 4 (0.80%, 95% CI 0.33 to 2.03) in the paclitaxel group (p = 0.06). The only difference between patients with and without LAST after DES implantation was younger age (49 ± 9 vs 60 ± 10 years, p = 0.002) in the LAST group. There were 58 deaths (2.4%) in the DES group during the follow-up period: cardiac death in 19 patients (0.8%) and noncardiac death in 38 patients (1.6%). In the BMS population, there were 7 cases of LAST (0.17%, 95% CI 0.08 to 0.35). Patients with LAST had a trend of younger age (52 ± 10 vs 59 ± 10 years, p = 0.085) and longer stents (30 ± 21 vs 20 ± 8 mm, p = 0.080) compared with those without LAST after BMS implantation. After risk adjustment (listed in Table 1), treatment with DES was not associated with an increased risk of LAST compared with the BMS group (adjusted hazard ratio 1.2, 95% CI 0.1 to 18.4, p = 0.9). The incidence of angiographically proved acute/subacute stent thrombosis was significantly higher in patients treated with BMSs than in those treated with DESs (0.5%, n = 22, vs 0.2%, n = 5, p = 0.046).

Patient characteristics of LAST: Baseline characteristics of patients with LAST (Tables 1 and 2) did not differ significantly between DES and BMS implantations, except that the BMS group had a larger reference diameter (3.6 ± 0.6 vs 2.9 ± 0.2 mm, p = 0.027) and maximal balloon diameters (4.0 ± 0.4 vs 3.5 ± 0.2 mm, p = 0.017). No patient with LAST had received previous coronary brachytherapy. Time to LAST events after the procedure was a median of 7.7 months (range 1.6 to 32.6) in the DES group and a median of 4.2 months in the BMS group (range 1.3 to 36.1, p = 0.4). Figure 1 shows a representative case of LAST after DES implantation; the patient received 1 sirolimus-eluting stent and 1 BMS. Aspirin was stopped at 963 days after stenting because of noncompliance. The patient presented with acute myocardial infarction 1 month later, and an angiogram displayed total thrombotic occlusion of the sirolimus-eluting stent but a widely patent BMS.

Antiplatelet therapy, management, and outcomes of LAST: In the DES group, 4 events (50%) were associated with antiplatelet therapy discontinuation; 2 patients had stopped aspirin monotherapy during long-term follow-up (963 and 567 days after stenting) and 2 had premature discontinuation (<6 months) of all antiplatelet therapy (36 and 51 days after stenting). Two patients developed LAST during aspirin monotherapy after completion of a 6-month course of clopidogrel; in 1 of these patients LAST occurred 30 days after stopping clopidogrel. The other 2 cases occurred while the patients were on dual antiplatelet therapy. In the BMS group, 1 event (14%) was related to cessation of antiplatelet therapy (stopping aspirin and ticlopidine 15 days after the procedure due to noncompliance).

Of patients with LAST and DESs, balloon angioplasty was done in 6 (75%), and 3 of these (38%) received additional DES implantation. Of the remaining 2 patients, 1 underwent intravenous thrombolysis and 1 received only

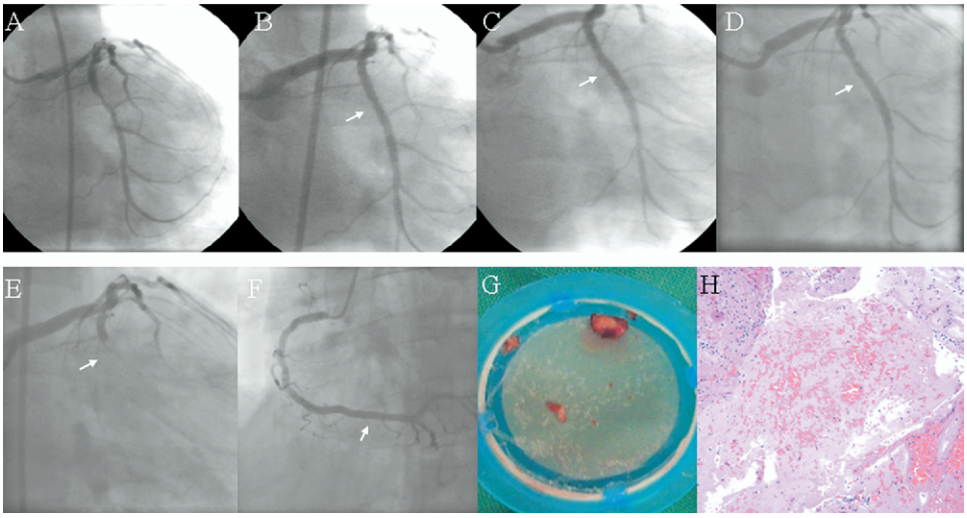

Figure 1. Representative case of very LAST in a patient who underwent successful implantation of 1 sirolimus-eluting stent in the proximal circumflex artery and 1 BMS in the distal right coronary artery *(A)* before and *(B)* after sirolimus-eluting stent implantation *(arrows, stents)*. *(C)* Six-month and *(D)* 2-year follow-up angiograms show a patent stent. *(E)* Late thrombotic total occlusion was present in the sirolimus-eluting stent, *(F)* but the BMS was widely patent. *(G)* Huge thrombi were aspirated after mechanical thrombectomy. *(H)* Microscopic findings (hematoxylin and eosin stain, 200×) showed that the thrombus was fresh with the formation of fibrin layers separated from blood cells; in other areas, early signs of organization consisting of incipient ingrowth of capillaries were present.

medical treatment due to passage failure of the guidewire. In the BMS group, balloon angioplasty was performed in all patients followed by additional BMS implantation in 2 (29%). After LAST events, we empirically prescribed dual antiplatelet therapy for ≥1 year in the DES group and ≥2 months in the BMS group.

All patients with LAST and DESs were clinically stable at 6-month follow-up after thrombotic events. Seven patients (88%) underwent 6-month follow-up angiography after LAST events, which showed patent stents in 6 and a persistent total occlusion in 1. Of patients with LAST and BMSs, sudden cardiac death occurred in 1 patient at 5 months after a LAST event. Excluding this 1 death, follow-up angiography was performed in 4 patients (67% in eligible patients). Diffuse in-stent restenosis developed in 2 patients, 1 of whom had bypass surgery and 1 underwent repeat intervention. Two patients without follow-up angiograms were clinically stable. MACEs at 6-month follow-up after LAST events occurred in no patients (0%) in the DES group and 3 (43%) in the BMS group ($p = 0.077$).

Discussion

In a large cohort of 6,551 patients undergoing coronary stenting, we found that, although DES was unrestrictedly used in complex and high-risk patients, the incidence of LAST after DES implantation was similar to rates in the BMS population (adjusted hazard ratio 1.2, 95% CI 0.1 to 18.4, $p = 0.9$). Previous studies have reported an incidence of LAST of 0.39% to 0.76% in patients after insertion of BMSs.[8,9] A meta-analysis of clinical trials has shown that rates of late stent thrombosis were similar for DESs and BMSs (0.23% vs 0.25%, respectively, $p = 1.000$).[4] Recent studies of a large unselected population have reported an incidence of LAST after DES implantation from 0.19% to 0.35%,[7,10,11] similar to our findings. However, because the duration of dual antiplatelet therapy was much longer in the DES than in the BMS group, we cannot exclude the possibility that patients treated with DES might be more vulnerable to late thrombotic events. In addition, recent reports have raised concerns about late thrombotic events by showing that the incidence of death/myocardial infarction was significantly higher in patients treated with DESs than in those treated with BMSs.[12] Longer term evaluations and assessment of all-cause mortality in patients treated with DES are needed to clearly determine the long-term safety of DESs.

After DES implantation, premature discontinuation of antiplatelet therapy was the most important determinant of stent thrombosis development.[13–15] We previously reported on the incidence of stent thrombosis (0.8%) in 1,911 consecutive patients, similar to historical data of BMSs.[15] Premature discontinuation of antiplatelet therapy was most significantly associated with thrombotic events. In the present study, some cases of LAST occurred even while patients were on dual antiplatelet therapy. Such an observation indicates the critical need for further investigations to determine other predictive factors, such as resistance to antiplatelet therapy and to identify adjunctive pharmacologic therapies for high-risk patients. In addition, our data indicate that very late stent thrombosis up to 2 to 3 years after stent placement can occur with DES and BMS implantations, which has also been found in previous studies.[1,8] However, cessation of antiplatelet therapy was strongly related to development of very late thrombosis with DESs but not with BMSs. These findings indicate the paramount significance of antiplatelet therapy maintenance for preventing LAST after DES implantation.

In the present study, cases of LAST in the BMS group were associated with a high morbidity after index events, as reported in a previous study.[8] Although MACE rates were

not statistically different between the 2 groups due to the small number of events, LAST cases after DES implantation showed favorable clinical and angiographic outcomes in the first 6 months after the index LAST events.

This was a nonrandomized observational study in a single center. This study was confined to patients who had angiographic confirmation of stent thrombosis except patients who presented with sudden cardiac death or myocardial infarction without undergoing angiography. Moreover, long-term follow-up was not completed in 1.3% and 1.7% of patients treated with DESs and BMSs, respectively. The low frequency of LAST events may underestimate or preclude an accurate assessment of the true frequency of late stent thrombosis. Sirolimus-eluting stents were used more frequently and implanted in more complex subsets than paclitaxel-eluting stents. The small number of LAST events does not allow for formal statistical assessment of interaction between covariates.

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