Comparison of Dual Drug-Eluting Cilotax Stent and *Paclitaxel*-Eluting Taxus Liberte Stent in Native Coronary Artery Lesions

Cheol Whan Lee, MD[a], Duk-Woo Park, MD[a], Ki Bae Seung, MD, PhD[b], Pum Joon Kim, MD[b], Hun Joon Park, MD[b], Won-Jang Kim, MD[a], Jong Young Lee, MD[a], Soo-Jin Kang, MD[a], Seung-Hwan Lee, MD[a], Young-Hak Kim, MD[a], Seong-Wook Park, MD, PhD[a], and Seung-Jung Park, MD, PhD[b,*]

Cilotax stent is a new type of drug-eluting stent (DES) designed to increase the antirestenotic performance of the paclitaxel-eluting stent and decrease the risk of stent thrombosis by the incorporation of cilostazol. Therefore, we investigated the safety and efficacy of Cilotax dual DESs and compared their performance to that of paclitaxel-eluting Taxus Liberte. Patients undergoing percutaneous coronary intervention for de novo coronary artery lesions at 2 centers in Korea were randomized to receive Cilotax (n = 55) or Taxus Liberte (n = 56) stents. The primary end point was in-segment late loss at 8 months. The 2 groups had similar baseline characteristics. Cilotax stent was not inferior to Taxus Liberte stent as determined by in-segment late loss (0.28 ± 0.30 vs 0.42 ± 0.45 mm, difference −0.14, 95% confidence interval −0.27 to −0.01, 1-sided p = 0.028 for noninferiority). In-stent late loss was significantly lower in the Cilotax than in the Taxus Liberte group (0.22 ± 0.31 vs 0.50 ± 0.55 mm, p = 0.002). Although in-segment restenosis rate did not differ significantly between the 2 groups (3.8% vs 10.9%, respectively, p = 0.271), in-stent restenosis rate was significantly lower in the Cilotax stent group (0% vs 10.9%, p = 0.027). There was no stent thrombosis at 8 months in either group. Rates of death, myocardial infarction, and any target lesion revascularization at 8 months were 0%, 0%, and 1.9%, respectively, in the Cilotax group and 1.8%, 0% and 3.6%, respectively, in the Taxus Liberte group. In conclusion, the Cilotax stent was safe and effective in decreasing late loss, indicating that this stent represents a promising new type of DES system. **(Am J Cardiol 2011;xx:xxx)**

Drug-eluting stents (DESs) have been widely adopted as the most effective antirestenotic strategy in coronary intervention. Despite their remarkable success, restenosis remains a significant problem for high-risk patients.[1] Although DESs prevent restenosis by inhibiting neointimal hyperplasia, they also delay endothelialization, resulting in a more prolonged risk of stent thrombosis.[2,3] In current DES systems, stents are coated with rapamycin derivatives or paclitaxel as the primary antirestenotic agents. However, restenosis results from multiple mechanisms, and late stent thrombosis remains a serious complication of current DES therapies. Dual DESs may allow differential targeting of restenosis and thrombosis with potential synergy and less toxicity. Cilostazol is a potent inhibitor of phosphodiesterase that has an antiplatelet effect similar to that of ticlopidine.[4–8] Moreover, cilostazol has antiproliferative activity against cultured vascular smooth muscle cells and has been demonstrated to decrease restenosis after placement of bare metal stents or DESs.[9–13] The Cilotax stent was designed to increase the antirestenotic performance of paclitaxel and decrease the risk of stent thrombosis by incorporating cilostazol. We have compared the safety and efficacy of the dual DES Cilotax with a commercially available standard paclitaxel-eluting stent in native coronary artery lesions.

Methods

From February 2008 through October 2009, 111 consecutive patients ≥18 years of age with documented ischemia at 2 centers in Korea were deemed eligible (Figure 1). All patients had de novo native coronary artery lesions with target lesion diameter stenosis >50%, reference vessel 2.5 to 3.5 mm, and lesion length <20 mm by visual estimation. Exclusion criteria included left main coronary artery disease (diameter stenosis >50%), ostial lesion, planned bifurcation stenting in the side branch, acute myocardial infarction, left ventricular ejection fraction <30%, contraindication to aspirin and clopidogrel, and inability to follow the protocol. The trial protocol was approved by the ethics committee or institutional review board at each site, and all participants provided written informed consent.

Eligible patients were randomized to receive Cilotax stents (Cardiotec Co. Ltd, Seoul, Korea) or Taxus Liberte stents (Boston Scientific Corporation, Natick, Massachusetts) with randomization concealed using a central interac-

[a]Division of Cardiology, Heart Institute, Asan Medical Center, University of Ulsan, Seoul, Korea; [b]Catholic University of Korea, St. Mary's Hospital, Gangnam, Seoul, Korea. Manuscript received September 10, 2010; revised manuscript received and accepted November 12, 2010.

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*Corresponding author: Tel: 82-2-3010-3150; fax: 82-2-486-5918.

E-mail address: sjpark@amc.seoul.kr (S.-J. Park).

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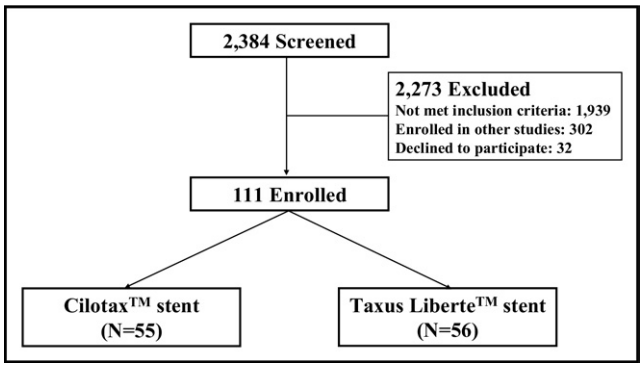

Figure 1. Study flow chart of patient enrollment.

tive Web response service. Patients, but not investigators, were unaware of treatment assignment.

Stents were implanted according to standard techniques. Patients were pretreated with aspirin (100 to 200 mg) and clopidogrel (300 mg). During the procedure, patients received a bolus of heparin 100 U/kg, with a repeat bolus of 2,000 U to maintain an activated clotting time ≥300 seconds. Patients were discharged when clinically stable according to local practice.

Patients were prescribed aspirin (100 to 200 mg/day) indefinitely and clopidogrel (75 mg/day) for ≥12 months. Clinical evaluations were performed at time of hospital discharge and at office visits after 1, 4, 6, and 8 months with routine angiographic follow-up recommended at 8 months. All demographic, clinical, and procedural characteristics were prospectively entered into the Web-based database, and all adverse cardiac events including death, myocardial infarction, repeat revascularization, and stent thrombosis were recorded.

Coronary angiograms were sent to the core laboratory at the CardioVascular Research Foundation and were independently analyzed by experienced angiographers unaware of treatment assignment and study goal. Percent diameter stenosis, minimal lumen diameter, and reference diameter were measured using an on-line quantitative angiographic analysis system (CASS 5.7, Pie Medical Imaging, Maastricht, The Netherlands) before predilation, after the stenting procedure, and at follow-up. Angiographic measurements were made during diastole after intracoronary nitroglycerin administration using a guiding catheter to calibrate magnification. Single matched views with worst diameter stenosis were compared.

Primary end point was in-segment late loss at 8 months. Secondary end points included in-stent late loss, diameter stenosis, binary restenosis, target lesion revascularization, stent thrombosis, and major adverse cardiac events. Deaths that could not be classified were considered cardiac. Myocardial infarction was defined as clinical symptoms or occurrence of electrocardiographic changes accompanied by a new increase of creatine kinase-MB to >3 times the upper limit of normal. Stent thrombosis was classified by the Academic Research Consortium[14] definition as definite (presence of an acute coronary syndrome with angiographic or autopsy evidence of thrombus or occlusion) or probable (unexplained deaths within 30 days after the procedure or acute myocardial infarction involving the target vessel territory without angiographic confirmation) and as acute (<24 hours after procedure), subacute (1 to 30 days after procedure), or late (>30 days after procedure). Procedural success was defined as residual diameter stenosis <30% and a final Thrombolysis in Myocardial Infarction flow of grade 3.

Table 1
Baseline characteristics

Characteristics	Cilotax (n = 55)	Taxus Liberte (n = 56)	p Value
Age (years)	61.31 ± 8.68	60.54 ± 8.86	0.643
Men/women	39/16	39/17	0.884
Body mass index (kg/m^2)	25.1 ± 2.6	25.2 ± 2.7	0.862
Current smoker	17 (31%)	14 (25%)	0.488
Diabetes mellitus	16 (29%)	16 (29%)	0.952
Hypercholesterolemia (>200 mg/dl)	28 (51%)	29 (52%)	0.926
Hypertension	33 (60%)	34 (61%)	0.940
Clinical presentation			
Stable angina pectoris	30 (55%)	34 (61%)	0.789
Unstable angina pectoris	18 (33%)	15 (27%)	
Recent myocardial infarction	1 (2%)	0 (0%)	
Silent myocardial ischemia	6 (11%)	7 (13%)	
Previous myocardial infarction	2 (4%)	4 (7%)	0.679
Previous percutaneous intervention	7 (13%)	3 (5%)	0.203
Left ventricular ejection fraction (%)	60.1 ± 5.5	60.9 ± 4.5	0.396
Target coronary artery			
Left anterior descending	20 (36%)	23 (41%)	0.842
Left circumflex	15 (27%)	13 (23%)	
Right	20 (36%)	20 (36%)	
Type of lesions			0.097
A/B1	44 (80%)	51 (91%)	
B2/C	11 (20%)	5 (9%)	
Procedural characteristics			
Balloon-to-artery ratio	1.13 ± 0.17	1.10 ± 0.10	0.454
Maximum balloon pressure (atm)	17.91 ± 3.58	17.62 ± 3.92	0.769
Stents per lesion			1.000
1	54 (98.2%)	54 (96.4%)	
2	1 (1.8%)	2 (3.6%)	
Stented length per lesion (mm)	20.42 ± 3.27	22.14 ± 3.57	0.009
Multivessel coronary disease	16 (29.1%)	12 (21.4%)	0.353

The clinical events committee independently reviewed and adjudicated all major clinical events without information on the treatment assignment of individual patients.

Continuous variables are expressed as mean ± SD, and categorical variables are presented as frequencies. The study protocol was designed to assess the noninferiority of Cilotax stents compared to Taxus Liberte stents for the primary end point of in-segment late loss. Sample size calculation was based on a margin of noninferiority for in-segment late loss of 0.2 mm and SD of comparator of 0.5 mm. We calculated that 50 patients per group were needed to demonstrate noninferiority of the Cilotax stent with a statistical power of 80%. Expecting that up to 10% of patients would not return for follow-up coronary angiography, we sought to enroll ≥110 patients (55 patients in each arm).

Table 2
Quantitative coronary angiographic analysis

Characteristics	Cilotax (n = 55)	Taxus Liberte (n = 56)	p Value
Lesion length (mm)	13.08 ± 3.93	13.99 ± 4.81	0.281
Reference vessel diameter (mm)			
Before procedure	2.96 ± 0.31	3.05 ± 0.32	0.158
After procedure	2.99 ± 0.31	3.06 ± 0.31	0.279
At follow-up	2.96 ± 0.30	3.05 ± 0.32	0.144
Minimal lumen diameter (mm)			
In segment			
Before procedure	0.96 ± 0.38	0.96 ± 0.32	0.990
After procedure	2.38 ± 0.41	2.51 ± 0.43	0.120
At follow-up	2.12 ± 0.48	2.09 ± 0.58	0.819
In stent			
After procedure	2.69 ± 0.38	2.78 ± 0.36	0.205
At follow-up	2.48 ± 0.42	2.29 ± 0.64	0.068
Diameter stenosis (%)			
In segment			
Before procedure	67.7 ± 11.7	68.4 ± 9.8	0.745
After procedure	20.7 ± 7.7	18.2 ± 8.9	0.120
At follow-up	28.9 ± 11.3	31.7 ± 16.0	0.295
In stent			
After procedure	10.2 ± 7.0	9.1 ± 6.2	0.365
At follow-up	16.5 ± 9.8	25.3 ± 19.0	0.003
Acute gain (mm)			
In segment	1.42 ± 0.45	1.54 ± 0.43	0.140
In stent	1.73 ± 0.45	1.82 ± 0.39	0.269
Late loss (mm)			
In segment	0.28 ± 0.30	0.42 ± 0.45	0.056
In stent	0.22 ± 0.31	0.50 ± 0.55	0.002
Proximal edge	0.35 ± 0.49	0.43 ± 0.43	0.338
Distal edge	0.18 ± 0.30	0.17 ± 0.27	0.799
Restenosis			
In segment	2 (3.8%)	6 (10.9%)	0.271
In stent	0 (0%)	6 (10.9%)	0.027
Proximal edge	2 (3.8%)	1 (1.8%)	0.615
Distal edge	1 (1.9%)	0 (0%)	0.491
Pattern of restenosis			
Focal edge	2 (3.6%)	1 (1.8%)	0.175
Multifocal	0 (0%)	1 (1.8%)	
Diffuse proliferative	0 (0%)	4 (7.1%)	

All analyses were performed according to the intention-to-treat principle. Continuous variables were compared using the 2-sample *t* test. Categorical variables were compared using chi-square test or Fisher's exact test. Noninferiority for in-segment late loss would be declared if the upper limit of the 1-sided 95% confidence interval of the difference was ≤0.2 mm. Superiority testing was performed after demonstration of noninferiority for the primary end points and for all other secondary end points using a 2-sided alpha value equal to 0.05. All p values are 2-sided apart from noninferiority testing of the primary end point for comparison between groups.

Results

Baseline clinical and angiographic characteristics were similar in the 2 study groups (Table 1). Median patient age was 63 years (range 34 to 85), 70.3% of patients were men, and 28.8% had diabetes mellitus. Lesion characteristics and treated vessel distribution were also similar in the 2 groups (Table 1). More than 80% of target lesions were type A/B1 with a mean lesion length of 13.54 ± 4.40 mm. Stent lengths per lesion were significantly longer in the Cilotax than in the Taxus Liberte stent group (20.42 ± 3.27 vs 22.14 ± 3.57 mm, p = 0.009). Stent implantation was successful in all patients.

Table 3
Clinical outcomes at eight months

All events	Cilotax (n = 55)	Taxus Liberte (n = 56)	p Value
Death	0 (0%)	1 (18%)	1.000
Cardiac	0 (0%)	0 (0%)	
Noncardiac	0 (0%)	1 (18%)	
Myocardial infarction	0 (0%)	0 (0%)	
Stent thrombosis	0 (0%)	0 (0%)	
Target lesion revascularization	1 (1.9%)	2 (3.6%)	1.000
Target vessel revascularization	1 (1.9%)	2 (3.6%)	1.000
Death, myocardial infarction, or target lesion revascularization	1 (1.9%)	3 (5.4%)	0.619

Quantitative coronary angiographic results are presented in Table 2. Angiographic follow-up was performed in 96.4% of patients (53 of 55) in the Cilotax group and 98.2% (55 of 56) in the Taxus Liberte group. At baseline, reference vessel diameter and pre- and postintervention minimal lumen diameters and acute gain were similar in the 2 groups. At 8-month follow-up, in-segment late loss tended to be lower for Cilotax than for Taxus Liberte stents, reaching the primary end point of noninferiority (0.28 ± 0.30 vs 0.42 ± 0.45 mm, difference, −0.14, 95% confidence interval −0.27 to −0.01, 1-sided p = 0.028 for noninferiority). Late loss within the stent was significantly lower in the Cilotax than in the Taxus Liberte stent group (0.22 ± 0.31 vs 0.50 ± 0.55 mm, p = 0.002), but late loss at the proximal and distal edges did not differ significantly between the 2 groups. Rates of in-segment restenosis did not differ significantly between the Cilotax and Taxus Liberte groups (3.8% vs 10.9%, p = 0.271), and target lesion revascularization was required in 3 patients (2.7%) overall. In-stent restenosis rate was significantly lower in the Cilotax than in the Taxus Liberte group (0% vs 10.9%, p = 0.027).

All patients were clinically followed up at 8 months (Table 3). One patient in the Taxus Liberte stent group died from sepsis at 1 month, but there was no stent thrombosis or nonfatal myocardial infarction in any patient. Rates of death, myocardial infarction, and target lesion revascularization at 8 months were 0%, 0% and 1.9%, respectively, in the Cilotax stent group and 1.8%, 0% and 3.6%, respectively, in the Taxus Liberte stent group.

Discussion

This study met the primary end point of late loss by showing the noninferiority of Cilotax compared to Taxus

Liberte stents. In addition, the 2 stent types showed a good safety profile, with no incidence of cardiac death, myocardial infarction, or stent thrombosis in either group for up to 8 months. Despite the small number of patients, these findings suggest that a dual DES may improve the efficacy and safety of the paclitaxel-eluting stent.

Cilostazol is an antiplatelet agent with similar effects as ticlopidine and clopidogrel.[5–8] Cilostazol selectively inhibits phosphodiesterase III with a wide therapeutic window, and its mechanism of action is different from that of adenosine diphosphate receptor antagonists. Adding cilostazol to aspirin plus clopidogrel has been shown to prevent stent thrombosis after stent implantation.[8] In addition, cilostazol has antiproliferative effects against vascular smooth muscle cells.[9] Cilostazol also inhibits stent-induced P-selectin expression on platelets and upregulation of leukocyte macrophage-1 antigen and upregulates the expression of the antioncogenes p53 and p21 in vascular smooth muscle cells, thus preventing neointimal hyperplasia and restenosis after stent implantation.[11] In addition, cilostazol has been shown to significantly decrease the risks of restenosis after placement of bare metal stents[10] or DESs.[12,13]

DESs are a revolutionary approach to prevent the risk of restenosis after percutaneous coronary intervention. Despite the complexity of restenosis, current DES systems use single agents, rapamycin derivatives or paclitaxel, which primarily inhibit vascular smooth muscle cell proliferation. Recently, the intercoronary stenting and anti-thrombotic regimen-TEST-2 trial[15] compared the efficacy and safety of dual DESs (sirolimus and probucol) and single DESs (sirolimus or zotarolimus). Their dual DES consisted of a quick-release polymer-free platform that incorporated 2 drugs targeting different steps of the restenotic response cascade. At 2 years, the safety profiles of the 3 stent platforms were the same, whereas the antirestenotic efficacy of dual DESs remained durable from 1 year through 2 years, suggesting that dual DESs may have advantages over conventional DES systems.

The Cilotax stent was developed to increase the efficacy and safety of paclitaxel-eluting stents by including cilostazol. The stent platform consists of a thin-strut tube stent (77 μm) made of L605 cobalt chromium, and the drug-carrying polymers consist of a mixture of hydrophilic biocompatible cellulose acetate butyrate and bioabsorbable resomer (coating thickness 10 μm). Most of the incorporated paclitaxel (1 $\mu g/mm^2$) is released within 1 month and most of the cilostazol (6 $\mu g/mm^2$) within 3 months. Slow release of cilostazol may hinder local thrombus formation around the stent strut, helping to prevent stent thrombosis during the early hazard period. The efficacy and safety of this device were demonstrated in a porcine coronary model (unpublished data). To our knowledge, this study is the first clinical experience with Cilotax stent, showing promising efficacy with less late loss compared to Taxus Liberte stent. The 2 DESs were safe with no difference in clinical outcomes, but in-stent late loss was lower in the Cilotax stent group. Late loss, which reflects degree of neointimal hyperplasia, is a useful measurement of DES efficacy.[16,17] In general, risks of DES failure are higher in high-risk patients with complex lesions, and use of the Cilotax stent, with less late loss, may provide better clinical outcomes in these patients. Further studies in larger patient populations with less restrictive eligibility criteria are planned to confirm the findings of this pilot study.

Several potential limitations must be addressed. First, the number of study patients was small and not sufficient to allow the drawing of any safety conclusions. Second, because this trial included only those patients with relatively simple lesions, our findings cannot be extrapolated to patients with different clinical characteristics. Third, angiographic outcome was used as the primary end point, requiring additional studies using clinical end points. Nevertheless, we found that Cilotax stent was safe and effective in decreasing late lumen loss after coronary intervention, suggesting that these stents may overcome the drawbacks of current DES systems.

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