# Early experience and initial results for unprotected left-main coronary artery revascularization with Sirolimus-eluting stents (Cypher)

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Background: Sirolimus-eluting Stents (Cypher) are now widely used, and their efficacy has been reliably documented in several randomized trials. The purpose of this study was to identify the efficacy and safety of treat unprotected left main coronary artery stenosis. Methods: Cypher stents were implanted in 13 patients with unprotected left main coronary artery stenosis between August 2004 and December 2004. We investigated clinical outcomes at 1, 3, 6 months. Results: Results are shown in the Table below. Conclusion: Cypher was efficacious in the treatment of unprotected left main coronary artery stenosis.

Mean age	69 ±8.8 years
Men	63%
Diabetes	55%
EF	60%
IABP use	36%
Mean lesion length	24.4 ±16.5mm
Procedural and clinical success	100%
LMCA alone	0%
LMCA and bifurcation	
crush	27%
single stent spanning LAD	55%
single stent spanning LCX	3%
T stanting	3%
MACE at 90 days	
CABG	0%
Death	0%
Acute thrombosis	0%
Sub acute thrombosis	0%
TLR	0%
Mean stent size	3.446plusmn;0. 29 mm
Mean number of stent	2.18plusmn; 1.2
Mean stent total length	26.66plusmn; 18.1 mm
Mean pressure	21.18plusmn; 1.64 atm

#### Usefulness of paclitaxel-eluting stents in the unprotected left-main

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[Purpose] To evaluate the effectiveness and safety of paclitaxel eluting stents (Taxus) for treatment of unprotected left main coronary artery (LMCA) stenosis.

[Methods] Between April 2003 and April 2005, a total of 71 patients had undergone Taxus implantation on LMCA lesions. The angiographic restenosis at 6 months and major adverse cardiac events (MACE) including death, myocardial infarction (MI) or any target lesion revascularization were evaluated.

**[Results]** Of all patients, 22(31%) had diabetes, 26(36.6%) had a low ejection fraction  $\leq 0.4$  and 44 (62%) had multi-vessel disease. The site of LMCA lesions were ostial in 13(18.3%), shaft in 7(9.9%), and distal in 51(71.8%) patients. Reference lumen diameter was  $3.3\pm0.3$  mm and lesion length was  $19.8\pm6.1$  mm. All lesions were successfully treated by Taxus stenting. Bifurcation techniques included crossover stenting in 40, T stenting in 1, provisional T stenting in 5, kissing stenting in 1 and stent crush in 4 patients. Procedure success was achieved in all patients. During hospital stay, no death, MI, stent thrombosis or emergent CABG occurred. Angiographic follow-up was obtained in 20(47.6%) of 42 patients eligible for 6-month angiography. Binary in-stent restenosis occurred in 1(5%) patient. Mean clinical follow-up time was 378.9 $\pm$ 121.9 days. There was no death or MI during follow-up. MACE developed only in 1(1.4%) patient who underwent repeat intervention of lesion on distal LMCA due to in-stent restenosis.

**[Conclusion]** In this preliminary experience, Taxus implantation for LMCA lesions is safe and feasible, with low incidences of restenosis and MACE.

#### Usefulness of the guidewire as a landmark for identifying CTOs in the LMT

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A 76-year-old man with a history of coronary bypass graft surgery in 2001 admitted to our hospital for coronary angioplasty. The coronary angiogram in September 2004 showed severe stenosis in the anastomosis of the LIMA bypass graft to left anterior descending artery (LAD), a 90% stenosis in the proximal LAD and chronic total occlusion in the left main trunk (LMT). The myocardial scintigraphy showed ischemia of the LAD area. We performed bilateral coronary angiogram, using guiding catheter, 7F VL 3.5 for the LCA and 6F ALISTSH for the RA graft. The LAD was visualized by contrast media circulating in the PL via the RA graft. The severe stenosis was shown in the bifurcation of the LCX and the LAD. First, we negotiated the guide wire, Universal to LAD via RA-PL-CX. Next, we penetrated the lesion with the guide wire, Miracle 3g to the LAD from the LMT. We used the radiopaque site of the guide wire inserted in the RA graft as a landmark. With the parallel wire technique using the Miracle 12g, we succeeded in penetrating the lesion. After crossing CTO, we performed balloon dilatation and stent implantation from the LMT to the LAD. And we also performed kissing balloon tequnique to the LAD and the LCX. To penetrate the CTO lesion, using a guide wire in the distal artery accessed via a graft as a landmark is a useful technique.

#### DES for chronic total occlusions in LMT ostial lesions

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Chronic total occlusion(CTO) of LMT ostial lesion is not common. We have experienced a case of CTO of LMT ostial lesion. 74 years old man who has had chronic obstructive lung disease admitted with effort angina. Coronary risk factors were hypertension and smoking. Left coronary angiogram showed CTO at ostium of LMT, and LAD and LCX were not visible. Right coronary angiogram showed significant stenosis of #4PD, and good collateral from #4PD to LAD and from SN branch to LCX. 8F guiding catheter with transfemoral approach was used to have good back up. It was difficult to penetrate one Conquest pro wire, so parallel wire technique was used. Then the wire crossed CTO site. But 1.5mm balloon did not cross the lesion, Tornus was used. Finally 1.5mm balloon crossed the lesion. After that, IVUS showed that the ostium of LCX was not stenotic. Cypher 3.5\*23 was implanted LMT-LAD. Final CAG showed #5-6 0%, #11 0%. 3 days later, stent was implanted at #4PD. After these two PCIs, symptom disappeared. In the era of DES, not only usual lesion but also CTO at ostial LMT were thought as good candidate for PCI.

#### Analysis of long term follow-up after Palmaz-Schatz stenting (CTOs vs. non-CTOs)

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Object: The long term follow up of restenosis after percutaneous coronary intervention (PCI) for chronic total occlusions(CTO) is not clear. Then, we investigated the long term follow up of restenosis after Palmaz-Schatz(P-S stent) stent for CTO. Methods:Between March 1993 and May 1995, 127 patients, 163 lesions who were performed the implantation of P-S stent. 45% of the lesions were CTO lesions. The necessary of TVR(target lesion revascularization) in CTO and non CTO was 62.1% and 45.9%(p=0.047) 36.4% and 23.8%(p=0.094) after 6 months, then the necessary of TVR with more than 3 times was 19.7% and 9.6%(p=0.076). Conclusion: CTO lesions were higher rate of TVR and more carefully watching the prognosis of after intervention.



#### Reduced restenosis rate with DES compared to BMS in PCI for CTOs

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Background: DES had shown remarkable reduction in binary restenosis in recent trials. However the efficacy are not completely understood in complex lesion subsets. In this report we retrospectively estimated the MACE and restenosis rate in PCI of CTO with DES compared to BMS. Material & Method: Since May. 2002 to Dec. 2004, 38 CTO lesions were successfully treated with stent implantation and were performed 6 month follow-up study. Twenty one lesions were treated with BMS (group B) in the first half period and 15 lesions were treated with DES (group D) in the second half period. MACE and binary restenosis rate were compared between 2 groups. **Results**: The mean stent diameter was 3.2±0.4mm in group B v.s. 3.0±0.1 in Group D (p=n.s.), and the mean length of stented segment was  $26.5 \pm 14.5$  mm in Group B v.s.  $35.9 \pm 19.8$  mm in Group D (p=n.s.). Mean dilatation pressure was significantly higher in Group D. (13.0 $\pm$ 2.7 atm in Group B and 16.8 $\pm$ 4.1 atm in Group D, p<0.002). No MACE has found in both groups. Binary restenosis were found only in one case (6.7%) in Group D, which were significantly lower than 8cases (34.8%) in Group B. Four cases (50%) of focal restenosis (2 cases in edge and 2 cases in stent) and 4 cases (50%) of diffuse type restenosis (including 2 re-occlusion cases) were seen in Group B, while edge restenosis was the type of one DES Conclusion: DES implantation in CTO lesions is considered to be safe and reduce restenosis case. restenosis rate, especially diffuse type restenosis including reocclusion.

#### Late clinical outcomes for PCI in CTOs

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[Purpose] With recent advances in technology and experience, the primary success rate of percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) is much improved. The aim of this study is to review the outcomes of PCI of CTO in Dongsan medical center.

[Methods] Since January 2002 to December 2004, 113 patients (male64, 56.6%) with CTO intervention were analyzed. Patients with totally occluded coronary artery were included if the event causative for the occlusion occurred at least 3 months earlier, and excluded with acute myocardial infarction.

**[Results]** The patient's age was  $62.2 \pm 8.8$  years. Diabetes was in 27.4%, hypertension in 51.3%, hypercholesterolemia in 29.2%, smoking in 48.7%. 97 (85.8%) patients were successfully recanalized. Clinical follow-up data was available in 109 patients (96.5%). Mean follow-up duration was 13.8 months. Major cardiac adverse event (MACE) was observed in 10.6%. When the implanted stent size was bigger than 2.75mm, MACE was observed in 6.9%. However, in the cases below 2.75mm, MACE was developed in 20% (p value: 0.99).

[Conclusion] In our data, Immediate success rate of PCI of CTO was relatively high (85.8%). In spite of no statistical value (maybe due to small cases in patients below 2.75mm used: 20patients), implanted stent size or reference vessel diameter might be predictor for MACE in CTO intervention.

#### Acute results and one-year clinical outcomes after drug-eluting stenting for CTOs

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[Purpose] DES may be effective in CTO intervention. However, there are less data about CTO intervention with DES. This study was performed to assess the outcome of DES in CTO intervention.

[Methods] Seventy four patients underwent PCI for CTO were enrolled in this study from July 2002 to May 2005. Among them, thirty nine consecutive patients were treated in DES (Cypher in 18 patients, Taxus in 20 patients and both in 1 patient). Patients underwent an follow-up angiography after 6 months and were followed clinically for 12months. We evaluated the immediate and one-year clinical outcome.

[Results] No patients experienced in-hospital major adverse cardiac events(MACE) including death, MI, TLR. The one-year MACE occurred in 2.5% of patients. 66% of patients underwent an follow-up angiography. The angiographic restenosis occurred in 7.7% of patients.

[Conclusion] The immediate result and one-year clinical outcome after the use of DES for CTO is favorable. The subsequent angiographic and clinical outcome will be presented.

#### Usefulness of sirolimus-eluting stents for treating CTOs

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[Purpose] To evaluate the effectiveness and safety of sirolimus-eluting stents (SES) for treatment of chronic total coronary occlusions(CTOs).

[Methods] Between January 2003 and April 2005, a total of 75 patients with 94 CTOs had undergone SES implantation. CTO was defined as TIMI grade 0 flow, and the age of occlusions was >3 months. The angiographic restenosis at 6 months and major adverse cardiac events (MACE) including death, myocardial infarction (MI) or any target lesion revascularization were evaluated.

**[Results]** Of all patients, 23 (30.7%) had diabetes and 30(40%) had old MI. The mean age of CTOs was 3.6  $\pm 2.1$  years. Locations of CTOs were left anterior descending coronary artery, 54.3%; left circumflex coronary artery, 14.8%; right coronary artery, 30.9%. Bridging collateral was presented in 24 (32%) CTOs. SES were successfully deployed in all CTOs. The number of implanted SES was 1.4 $\pm$ 0.7 per lesion. Stent diameter was 2.9 $\pm$ 0.3 mm. The length of stent segment was 30.2 $\pm$ 17.1mm. During hospital stay, no death, MI, stent thrombosis or repeat intervention has occurred. Angiographic follow-up was obtained in 25 (51%) of 49 patients eligible for 6-month angiography. Binary restenses occurred in 2 (8%) patients. Mean clinical follow-up time was 12.6 $\pm$ 6.3 months. One patient suffered from MI and no death or stent thrombosis developed during follow-up. The incidence of MACE was 4% (2 patients of target lesion revascularization and 1 patient of MI).

[Conclusion] The use of SES for treatment of CTOs is safe and efficient with low rates of restenosis and MACE during average 1 year follow-up.

#### Angiographic and clinical outcomes for PCI in chronic total occlusions

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[Purpose] Recent clinical trials reveal that successful CTO revascularization reduce adverse cardiac events and improve overall survival. This study was undertaken to assess the technique and outcomes of CTO intervention.

[Methods] 2917 consecutive patients taken coronary angiography from July 2002 to May 2005 were analyzed retrospectively. There were 104 CTO lesions in 74 patients. Procedural success and in-hospital complication were analyzed.

**[Results]** procedural success rates of patients and lesions were 91.8%(68/74) and 88.4%(92/104). Procedural failure were occurred in 12 lesions in 6 patients. In 5 lesions that failed, the guidewire passed through the proximal cap of occlusion. Occlusion characteristics with stump missing, lesion length >15mm, presence of side branch were associated with procedural failure. No major events occurred during in-hospital period. But acute pericardial effusion by vessel perforation occurred in 1 patient.

[Conclusion] In CTO intervention, the success rate of recanalization was very high with a low incidence of complication and satisfactory result. The subsequent angiographic and clinical outcome will be presented.

### **Two cases of chronic total occlusion evaluated by multislice computed tomography** <sup>1</sup>Tokorozawa Heart Clinic, Saitama, Japan

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Multislice computed tomography (MSCT) may contribute to the decision of the strategies of percutaneous coronary interventions (PCI). We report 2 ambivalent cases of PCI for totally occluded coronary arteries evaluared by MSCT. Case 1: A 67-year-old man was admitted to our hospital with effort angina pectoris. MSCT showed severe stenosis and calcifications in all coronary arteries. It was highly possible that there was the total occlusion lesion in the segment 2 of the RCA. Coronary angiography showed almost same result of MSCT images. We selected the right femoral approach promising powerful backup of 7Fr system. We succeeded in crossing the lesion by using Tornus catheter. Adjunctive balloon angioplasty was performed and we finally deployed three stents. Case 2: A 64-year-old man was admitted to our hospital with effort angina pectoris. MSCT performed at our out-patient clinic showed 90% stenosis with vulnerable plaque in the segment 6 of the LAD. We performed PCI from the right radial artry. Differing from MSCT images, coronary angiography showed 75% mild lesion in the segment 6, and more total occlusion in the segment 7. The distal LAD was sorced from bridge collateral flow. After we managed to deploy stnet for the total occlusion at the segment 7, we deployed an additional stent to cover the vulnerable lesion at the segment 6.

### Clinical efficacy of 16-slice computed tomography in CTOs: Impact on the crossability of the CTO lesion. <sup>1</sup>Division of Cardiology, Teikyo University, School of Medicine, Tokyo, Japan

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Background: The main reason for failure of percutaneous coronary intervention (PCI) of CTO is inability to cross the occlusion with a guide wire because of the occlusive calcified plaque. Objectives: We aimed to evaluate the visibility of chronic total occlusion (CTO) and characterization of plaque components within CTO by 16-slice computed tomography (MSCT). Methods: Sixteen angiographic CTO (7 in LAD, 5 in LCX and 4 in RCA) of 15 patients were included. All patients had undergone MSCT prior to PCI. MSCT data sets were evaluated by 3D volume rendered, thin-slab maximum intensity projections and multiplanar reformatted images. Images were analyzed regarding lesion visibility and plaque characteristics of CTO. Procedural failure was defined as inability to cross a guide wire. Results: All coronary routes of CTO were visualized. MSCT revealed 2 markedly bended CTO segment. Calcified plaques were detected in 21 lesions of 12 CTO vessels. Location of calcified plaque was proximal site of CTO in 3 vessels, mid in 2, both proximal and distal in 6, and both proximal and mid in 2. Nine of 21 calcified lesions (42.9%) were exclusive calcified plaques. Procedural success was obtained in 13 vessels (81.5%). Locations of calcified plaque in 2 of 3 failure cases were both proximal and distal with exclusively calcified plaques. Conclusions: The results indicate the potential of MSCT to detect CTO. The benefit of evaluating plaque characterization by MSCT may lead to predict the procedural difficulty in patients undergoing PCI of CTO.

# Diagnostic accuracy with 16-row multi-detector computed tomography coronary angiography (16-MDCT-CA) in hemodialysis (HD) patients

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Purpose: Our aim was to evaluate the accuracy of coronary artery disease (CAD) by 16-MDCT-CA in HD patients. Methods: We retrospectively examined consecutive 52 HD patients (31 men, mean age 63.7, 21 diabetes, mean HD duration 5.9 years) suspected CAD, who received both 16-MDCT-CA and CAG. 48 patients (92.3%) received additional beta-blockade before MDCT-CA. 36 patients (69.2%) had coronary disease (13 in 1 vessel, 15 in 2 vessels, and 8 in 3 vessels) on the basis of CAG. Results: 713 of 731 segments (97.5%) were assessable (mean heart rate 63.2). Sensitivity, specificity, positive and negative predictive value were 94%, 94%, 71%, and 99% respectively. Severe calcification (27 of 32 segments) and motion artifacts (5 of 32) were the causes of false positive. Conclusion: We concluded that noninvasive MDCT-CA in HD patients was useful diagnostic modality.

Table 1. Diagnostic Performance of MDCT CA of Detect ≥50% Stenosis

	#1	#2	#3	4PD	4AV	#5	#6	Ħ7	#8	#9	#10	#11	#12	#13	#14	HL	TOTAL
ICA (n of sgts)	52	50	48	46	43	52	52	51	51	47	35	52	48	52	42	10	731
MDCT (n of sgts)	51	50	41	32	31	51	49	48	49	43	28	51	35	47	24	10	713
average of IQS	1.81	2.71	2.83	3.41	3.30	1.62	2.29	2.61	2.80	3.00	3.26	2.10	2.98	2.94	3,60	2.20	2.72
Stenosis $\geq 50\%$	3	19	4	2	3	3	14	21	5	12	1	-8	3	11	0	2	111
True positive (n)	3	13	3	1	2	2	11	16	3	6	0	6	2	6	0	2	77
True negative (n)	48	31	37	29	28	48	34	26	44	31	27	43	32	35	24	6	494
False positive (n)	0	6	1	1	1	1	3	5	2	4	1	2	1	5	0	0	32
False negative (n)	0	0	0	1	0	0	1	1	0	0	0	-0	0	1	0	2	5
Sensitivity (%)	100%	100%	100%	50%	100%	100%	92%	94%	100%	100%	2	100%	100%	86%	?	50%	94%
Specificity 00	100%	84%	97%	97%	97%	98%	92%	84%	96%	89%	96%	96%	97%	88%	100%	100%	94%
PPV (%)	1.00%	68%	75%	50%	67%	67%	79%	76%	60%	67%	0%	7.9%	67%	55%	?	100%	71%
NPV (%)	100%	84%	100%	97%	100%	100%	97%	96%	100%	100%	100%	100%	100%	97%	100%	79%	99%

\* IQS : Image quality score: visually classified (1=excellent, 2=good, 3=moderate, 4=heavy calcified, 5=blurred)

Initial clinical experience with an IVUS-guided transmembrane puncture device to facilitate recanalization of total femoral artery occlusions

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[Purpose] Failure to recanalize chronic superficial femoral artery (SFA) occlusions is frequently caused by subintimal passage of the occlusion with inability to re-enter the true lumen with the guide-wire. The present study details our initial experience with the Pioneer catheter (Medtronic, Menlo Park, CA, USA) to facilitate recanalization of total femoral artery occlusions.

[Methods] 25 consecutive patients (18 male, mean age 63 years) who failed recanalization attempts of chronic SFA occlusions (mean occlusion length 12.7 cm) with standard techniques were re-scheduled for a secondary recanalization procedure. The Pioneer catheter is a 6.2F rapid exchange catheter, which tracks over an 0.014"-wire. A 20MHz phased array IVUS transducer is integrated into the tip of the catheter allowing visualization of the vessel morphology. Using the guidance of the IVUS crossectional image supported by colour-flow imaging the true lumen is punctured with an integrated 24G needle allowing delivery of a second 0.014"-wire.

[Results] Re-entry into the true lumen was successfully accomplished in all cases without complications. In 8 cases with severe calcification predilatation of the false channel was necessary to allow advancement of the Pioneer catheter. Furthermore, in 7 patients with severe calcification multiple puncture attempts were necessary to penetrate the dissection membrane. A procedural success (<25% residual stenosis) could be achieved in all cases after predilatation and stenting of the occlusion with selfexpanding nitinol stents.

[Conclusion] The Pioneer catheter is an effective and save tool to facilitate true lumen re-entry during recanalization of total SFA occlusions.