Effects of drug-eluting stents used in combination with bare metal stents for treating multivessel disease

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[Purpose] To evaluate the effectiveness and safety of combination of drug eluting stents (DES) and bare metal stents (BMS) in treating multivessel coronary diseases.

[Methods] Between January 2002 and December 2004, a total of 801 consecutive patients with multivessel coronary disease who treated by multivessel stenting and achieved complete revascularization were studied. Among whom, 206 were treated entirely by DES, 158 were by DES combined with BMS and 437 were by BMS alone. Acute and long-term outcome were compared between the three groups.

[Results] Baseline clinical characteristics and procedure outcomes in the three groups were comparable. Mean follow-up duration was 18.6 \pm 13.9 months. Rates of total follow-up and angiographic follow-up were comparable in three groups. In DES combined with BMS group, BMSs were implanted in 31.3% of all lesions located in left anterior descending(fully A/B1 type lesions), and 81.6% of all lesions located in left circumflex and 69.9% located in right coronary artery. Compared with BMS group, the angiographic restenosis rates of DES group and DES combined with BMS group were significantly lower (20.3% vs 7.3% and 8.8%, respectively, P<0.05), and major adverse cardiac events rates of latter two groups were significantly lower (18.4% vs 6.5% and 9.9%, respectively, P<0.05), too. However, those outcomes were not significantly different between DES group and DES combined with BMS group.

[Conclusion] The combination of DES and BMS implantation might be a promise and cost saving strategy for treatment of multivessel diseases.

Early experience and initial results 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 in patients who received complex coronary intervention using Cypher. Methods: Cypher stents were implanted in 52 patients (63 lesions) with symptomatic ischemic heart disease 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 complex coronary diseases

Mean age	72 ±7.3 years
Men	73%
Diabetes	44%
ACS and CTO	26%
Mutiple vessel diseases	67%
In stent restenosis	24%
ACC type B2JC	78%
Left main trunk	1636
Mean lesion length	34.4 &plusmr,26.5mm
Procedural and clinical success	100%
MACE at 90 days	
Q MI	0%
Non Q MI	3.8%
CABG	0%
Death	1.3%
Acute thrombosis	036
Sub acute thrombosis	0%
TLR	1.9%
Mean stent size	3.146plusmn;0. 29 mm
Mean number of stent	2.16plusmn; 1.2
Mean stent total length	46.66plusmn; 28.1 mm
Mean pressure	21.16plusmn; 2.52 alm

Acute and mid-term clinical and angiographic outcomes between sirolimus and paclitaxel stents---- the Taiwan Experience

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[Purpose]To investigate the immediate and 9-month clinical and angiographic outcomes in patients undergoing sirolimus-eluting stents (SES) or paclitaxel-eluting stents (PES).

[Methods] There were 156 SES implantations on 143 lesions in 122 patients (group A) and 207 PES implantations on 189 lesions in 160 patients (group B) between May 2004 and June 2005.

[Results] The baseline demographics and lesion characteristics were similar in the two groups. Both groups had a high rate of complex lesions (B2 or C) (84% and 77%). Two patients in group B developed Q-wave myocardial infarction, one due to acute thrombosis during the procedure and the other subacute stent thrombosis 4 days after stenting. Thirty-six patients with 37 lesions in group A and 55 patients with 66 lesions in group B underwent a 9-month follow-up coronary angiography. Group A had larger follow-up minimal luminal diameter (MLD) (2.92 ± 0.63 vs. 2.60 ± 0.65 , p=0.022), less late loss (0.11 ± 0.51 vs. 0.39 ± 0.55 , p=0.019), less loss index (0.04 ± 0.22 vs. 0.17 ± 0.23 , p=0.013), and larger net gain (2.40 ± 0.68 vs. 2.07 ± 0.79 , p=0.047) than those of group B. There was no difference in restenosis rate between the two groups (5% vs. 4%, p=0.377). During a mean follow-up period of 7±6 months, one patient in each group developed late stent thrombosis about 9 and 7 months later. There was no difference in cardiac event free survival rate (6% vs. 4%, p=0.637)

[Conclusion]]SES and PES groups have similar immediate and mid-term clinical and angiographic outcomes; however, SES group appears to have larger follow-up MLD and less late loss.

Case of PCI treatment strategy for a diffuse RCA lesion decided from Virtual Histology[™] IVUS.

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 $\langle Background \rangle VH-IVUS$ is believed useful in the assessment of coronary plaque activity. This reports our experience of a case where treatment strategy for PCI was decided by using VH-IVUS. $\langle Subject \rangle$ 57 year old male; POBA performed on LAD #7 with 75% stenosis, LCx#11with 90% stenosis in the year 2000. Restenosis of the LCx was observed in February 2001 and POBA was performed. Following this, the patient's, condition was stable and he was undergoing outpatient treatment. However, due to chest pains upon exertion from around May 2005, repeat angiography was performed on June 2. A significant diffuse stenosis was seen in RCA # 1-3. PCI was performed on June 22. Considering the possibility of distal embolization from conventional stent implantation due to the length of the lesion and the large size of the RCA, VH-IVUS was performed before the procedure to assess lesion properties. However, upon confirmation that much of the lesion was fibrous, it was believed that there would be little possibility of distal embolization during PCI. Thus, using no distal protection, balloon pre-dilatation was performed and 3 Cypher stents were overlapped for implantation from # 3-1. No flow complications such as slow flow or no-reflow were observed at this time. $\langle Conclusion \rangle Examination of plaque morphology using VH-IVUS was useful in deciding$ treatment strategy for PCI.

Early and mid-term experience with the multiple overlapping sirolimus-eluting stents (SES) for diffuse lesions

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<Purpose>We report our initial experience and middle term outcome with the multiple overlapping SES for the diffuse lesion.

<Methods> Between August 2004 and Jun 2005, consecutive 168 patients (age 67±14y.o, 142 male) 175 diffuse type lesions (ACC/AHA type B2 30 lesions (17%), type C 133 lesion (76%) including 39 CTO cases and 62 in-stent restenosis (ISR) of the bare metal stent) which were implanted multiple SES (cypher stent). We examined the initial and middle term (6 months after procedure) results by QCA and IVUS images. <Results>Procedural success rate was 100%. The number of stents implanted per vessel were 2.4±0.7. Total

length of the stents were 43.5 ± 18.2 mm. Reference Diameter was 2.65 ± 0.45 mm. MLD (pre-procedure, post-procedure and after 6 months) were 0.46 ± 0.52 mm, 2.45 ± 0.49 mm, 1.91 ± 0.68 mm. %DS were 85 ± 18 %, 14 ± 9 %, 27 ± 17 %. Acute gain was 1.98 ± 0.4 mm, Late loss was 0.54 ± 0.82 mm in QCA. And there was no neo-intimal hyperplasia by 2D IVUS at 6 month follow up. There were 7(4%) restenotic lesions (2 lesions were in-stent type, 5 lesions were in-segment type), but all of them were de-novo cases. There was major complication (SAT 0%, TLR was observed in 2 lesions(1%), TVR was observed in 7 lesions(4%), death, MI and CABG 0%). <Conclusion>Multiple overlapping Cypher stent implantation for diffuse lesion is safe and the clinical outcome is acceptable.

Early outcomes after sirolimus-eluting stent implantation in patients with small artery disease ¹Cardiovascular Disease Center, Tokyo Metropolitan Police Hospital

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Percutaneous coronary revascularization of small vessels is associated with a high restenosis rate. We compared the early outcome of sirolimus-eluting stents (Cypher) between patients with untreated lesions of small and large coronary arteries. The study group was consisted of 5patients with small coronary arteries (group S) and 17 patients with large one. The patients in group S had a previously treated or untreated atherosclerotic lesion located in a small segment with a diameter of 2.75mm or less and a large segment with a diameter of 3mm or more in group L. The elective implantation with 2.5mm diameter Cypher stents in group S and 3 or 3.5mm in group L was performed under intravascular ultrasound guidance and previous ticlopidine intake in all patients. The angiographic restenosis rate and late loss at 3 months were compared 2 groups. The 3 month binary in-stent and in-segment restenosis rates were 0% in both groups. There was no significant difference of in-segment late loss at 3 months (-0.30 \pm 0.27 mm in group S and -0.01±0.48mm in group L), and similary no significant difference in both stent proximal and distal segment late loss at 3 months (proximal site -0.21±0.28mm in group S and 0.22±0.40mm in group L, distal site -0.26±0.22 in group S and 0.04±0.39 in group L). The 3 month binary rate of major adverse cardiac and cerebrovascular events were 0% in both groups. The early outcome of sirolimus-eluting stents for the treatment of atherosclerotic lesions in small coronary arteries is favorable similar to those seen in large coronary atherosclerotic lesions.

Efficacy of Sirolimus-eluting stents in small coronary arteries

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Purpose: The benefits of bare-metal stenting in small coronary diseases remains quetionable. The purpose of this study was to assess the clinical and angiographic benefits of Sirolimus-eluting stents (SES) in small coronary arteries. Methods and Results: 155 lesions in 134 consequtive patients treated by SES from June 2004 to March 2005 by way of intravascular ultrasound. Of the 155 lesions, 39 lesions (30 patients) treated with 2.5mm SES. Important patient and lesion characteristics were: age 66.5 ± 8.7 years, 70% men, 53% diabetes melitus, 10% chronic total occlusion, 10% in stent restenosis and 66% ACC/AHA type B2/C lesion. At pre-procedure, the mean lesion length was 16.7 \pm 8.1mm, reference diameter 2.29 ± 0.48 mm and minimal lumen diameter (MLD) 0.64 ± 0.46 mm. Assessed by IVUS, the minimal lumen vessel area (VA) was 10.1±4.5mm², minimal lumen area (LA) 1.7±0.7mm² and % plaque area (%PA) 81.2±9.2 %. At post-procedure, MLD was 2.46±0.30mm, VA 11.2±3.0mm², LA 4.8±1.3mm² and %PA 55.2±10.8%. Mean number of stents per lesion was 1.15 ± 0.36 , average stent length 21.5 ± 6.1 mm. Rotational atherectomy was performed before stenting in 9 lesions. Procedual success was obtained in 100% of patients, without a major adverse cardiac event. 6 months follow-up angiography was performed in 17 lesions. At 6 months follow-up, The mean MLD was 2.17 \pm 0.31mm, late loss 0.24 \pm 0.38mm and loss index 0.15 \pm 0.24. Binary restenosis rate was 6%. There was no target lesion revascularization in all lesions. Conclusion: The treatment of small coronary diseases with Sirolimus-eluting stent is safe and has good acute and mid-term results.

Sirolimus-eluting versus thin strut bare metal stents for small vessel disease

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 $\langle Purpose \rangle$ To assess follow up results of PCI for small vessel disease (<2.5mm) with Sirolimus eluting stent, thin strut and thick strut bare metal stent. $\langle Methods \rangle$ Between August 1999 to April 2005, 59 patients with small vessel disease (<2.5mm) underwent coronary intervention. 31 patients were treated with Sirolimus eluting stent (Cypher stent), 11 patients were with thin strut bare metal stent (Tsunami stent), and 17 patients were with thick strut bare metal stent (Bx Velocity stent). We investigated restenosis and Target Lesion Revascularization (TLR) rate of these groups at 6-month angiographic follow-up. $\langle Results \rangle$ Restenosis rate (3.2% versus 29.1%, p=0.03) and TLR rate (0% versus 29.4%, p=0.008) of Cypher stent were significantly lower than that of Bx Velocity stent. There was no significant difference in restenosis rate (18.2%, p=0.03) and TLR rate (18.2%, p=0.11) between Cypher and Tsunami. Tsunami stent could be delivered in all 10 complex small lesions that Cypher stent could not be delivered. $\langle Conclusion \rangle$ These results suggested that thin strut bare metal stent was very useful for small vessel disease where sirolimus eluting stent could not be delivered.

Percutaneous Coronary Intervention (PCI) with TORNUS in a patient with a severely calcified coronary lesion

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Rotablator is effective for a calcified lesion, but we cannot yet use it in many institutions. Using TORNUS, we experienced a successful PCI for a severely calcified lesion. In this paper we would discuss about detailed teqnique of using TORNUS in severely calcified lesion. 73 years old male with heart failure was admitted to our institution. We tried PCI for a chronic total occlusion in LCx Seg. 11. The guide wire was crossed, but 1.25mm-balloon catheter could not pass by. In the other day, we approached from right radial artery, and used Heartrail IL4.0-guiding catheter. The calcified lesion was crossed with Magic S guidewire. Then we tried to penetrate using TORNUS 88Flex and TORNUS. But TORNUS was trapped in proximal lesion in two places of calcified department. After dilatation by 1.25mm-Ryujin Plus-baloon, we used 5F in 8F catheter technique and tried to cross TORNUS again. Then TORNUS was successfully passed in the calcified lesion. After predilatation by 1.5mm-Ottimo-balloon and 2.5mm-Ryujin-balloon, we detained Cypher2.5/18mm and Cypher3.0/18mm. It was thought that TORNUS was able to pass the calcified stenosis by torque reached to the tip by 5F in 8F technique. We experienced a case that we were able to treat the severely calcified lesion using TORNUS.

Clinical experience of Sirolimus-eluting stent without lesion-debulking in hemodialysis patients ¹Cardiology Department, Iwatsuki-minami Hospital, Saitama, Japan

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[Purpose] The clinical efficacy of sirolimus-eluting stent (SES) has been well documented, however the strategy and safety to some particular clinical subsets such as calcified lesion in hemodialysis (HD) patients has not been well known. [Methods] We examined 17 HD cases which underwent percutaneous coronary intervention without lesion debulking prior to SES deployment in our hospiral. [Results] Mean age was 69.9 years old and mean duration of HD was 6.6 years. SESs were used 1.5/case and 19% of SESs was directly deployed without pre-dilatation. Debulking devices such as rotablator were not used in all cases. Mean diameter of SES was 2.81 mm and length was 22.0 mm. Maximum diamter of post-dilatation balloon was 3.04 mm, maximum pressure was 16.6 atm and mean post -minimum stent area was 5.01 mm2. Intravascular ultrasound (IVUS) was used in 82% and complete stent apposition was confirmed in all IVUS used cases. Procedure success rate was 94%. There was no stent thrombosis occurred in follow-up period after PCI. [Conclusion] Although complete stent expansion was not obtained because of lesion calcification, SES without debulking devices seems to be safe and effective in HD patients when high-pressure post-dilatation was attempted and complete stent apposition was confirmed by IVUS. More accumulated numbers will be presented in the meeting.