M-10

Clinical and angiographical results of Cypher ™ stent: Comparison with Bx Velocity™

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Objective

The purpose of this study was to estimate the safety and efficacy of Cypher™ compared to Bx Velocity™.

Methods

We evaluated stent implantation success, complications and MACE(death, CABG, TLR and myocardial infarction) in 167 patients(76.4% male), 195 lesions with Cypher™ stenting from September 2004 to February 2005(Group A), compared to 110 patients(73.6% male), 115 lesions with Bx Velocity™ stenting from January 2003 to November 2003(Group B).

Results

The target vessels were shown that:70 vs. 38 in RCA, 82 vs. 58 in LAD, 37 vs. 10 in LCx, 6 vs. 8 in LMT, and 0 vs. 1 lesion in SVG in group A and B, and 118 and 74 lesions were typed to B2 or C of ACC/AHA classification. All stents were successfully implanted, and the revascularization success(defined as DS<50% and TIMI 3) was 98.4% and 99.1%(NS). There was no difference about the number of used stents, but the stents in group A were smaller(3.11 vs 3.55mm, $p<0.0001$) and longer(21.5 vs 17.2mm, $p<0.0001$) than ones in group B. Reference diameters were similar in each group. There was no difference in MLD and %DS before and after stent procedure. Lumen CSA in IVUS was 6.73±1.81 vs. 8.65±4.12mm^2($P<0.0001$). SAT occurred in 1 vs. 2 patients(NS), and MACE in 2 vs.7 patients($P=0.0318$) at 1 month.

Conclusion

In spite of small stent CSA after Cypher™ implantation, there was no increase in clinical complications, compared to Bx Velocity™. The long-term results will be presented.

M-11

3-6 month angiographic follow-up of Sirolimus-eluting stents (Cypher)

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Sirolimus-eluting stent has been shown to be highly effective for prevention of post-PCI restenosis. However, we do not have enough follow-up data of angioplasty with sirolimus-eluting stent. So in this study, we evaluated 3-6 month angiographic results of angioplasty with sirolimus-eluting stent. Between April 2004 and January 2005, 186 lesions in 119 patients(mean age 68.2&plusmn10.2)were treated with sirolimus-eluting stent, Cypher in our hospital. Of these lesions, 41 (22.0%) were in-stent restenotic lesions, 27(14.5%) were chronic total occlusion, 27(14.5%) were ostial lesions, and 69(38.3%) were bifurcation lesions. We needed rotational ablation with 7 calcified lesions. Mean reference diameter was 2.80&plusmn0.67mm and mean lesion length was 16.2&plusmn11.5mm. Primary success rate was 98.9%. We observed one subacute thrombosis and one slow flow phenomenon in two patients. 3-6 month (mean118.3&plusmn40.5days) angiographic follow-up was performed in 55 patients with 88 lesions. Mean late loss was 0.23&plusmn0.75mm and overall restenosis rate was 12.5% (11/88 lesions). Restenosis pattern was focal(mean5.73&plusmn2.25mm) in 9 patients and total occlusion in 2 patients. Restenosis rate was significantly higher in HD patients than in non-HD patients: 38.5 % (5/13 lesions) vs. 8.0 % (6/75 lesions)($p<0.01$). In addition, we observed interesting findings of intra-vascular ultrasound in 2 HD patients.

M-12

Initial clinical outcomes for the Cypher drug-eluting stent

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Background: Drug eluting stent "Cypher" have been demonstrated to be highly effective for treatment of angina pectoris.We investigated initial clinical outcome of Cypher stent.Method:We enrolled 225 consecutive patients(170 male,67±10 years)with 249 lesions who had been treated by Cypher stent between July 2004 and August 2005.Patients characteristics and intervention procedural findings including lesion type,stent size and quantitative coronary angiography (QCA) analysis were investigated.Lesion and clinical success ratio and 3 months MACE were also investigated.Results:Among 225 patients,those without ACS.Mean stent size,stent length and maximal inflation pressure were 3.1±0.4,19.2±4.7mm,13.7±3.2atm.Minimum lumen diameter (MLD) was increased from 0.6±0.4mm (at baseline) to 2.9±0.7mm(after the procedure).Angiographic and clinical success had been achieved in all patients.No patients had been undergone acute occlusion (within 24 hours after procedure)but one patient had sub-acute thrombosis (SAT).Also, we experienced points such as liver dysfunction(five patients,2.2%),eruption(four patients,1.7%)and granulocytopenia(three patients,1.3%).These points had effects on long term(three months) medication of tycropidine,and have to be care generalcondition after procedure.Conclusion: Cypher stent showed good procedural results.And previously saying,we expected the points effect of tycropidine same as former bare metal stents procedure.

M-13

Early and mid-term outcomes of SES implantation and restenosis cases in our hospital

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[Background] It is expected that silorimus-eluting stent (SES) is an epoch making stent which prevents restenosis after stent implantation. In the era of DES, there are several statements that show what kinds of lesion would be appropriate for SES and for BMS. Now, I would like to show how we implanted SES in our hospital. [Methods] Since July 2004, we were permmitted to use SES in our nation, Japanese Red Cross Nagoya 1st. Hospital also implanted SES in 248 pts. (296 vessels) from June 2004 to June 2005.Diagnosis and patient characteristics are shown. Also angiographical characteristics and the consequence of QCA analysis are shown. We note the techniques and procedures how we implanted SES. We scheduled follow-up angiography on 6 months after PCI for each case. Incidence of MACE and QCA are evaluated.[Results and Conclusions] Forty seven percent of all patients have diabetes mellitus, 54 percent of all patients have hypertension. There was one overall death (1.5%), no cardiac death, one SAT (1.5%).The late-loss after 6 months was 0.10±0.3mm. TLR rate was 4.7%(2pts) and TVR rate was 9.3%(4 pts) One case is RCA ostial lesion (SES was implanted in ISR) and the other case is highly calcificated long lesion of mid segment of LAD, where is the overlap part of two SESs.SES is safe and efficient for coronary artery disease but we still have the risk of SES-instent restenosis.

M-14

Predictors of proximal-edge restenosis with the Sirolimus-eluting stent in proximal LAD lesions -IVUS analysis-

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Background: Stenting at the proximal LAD has been known for more restenosis than that at the other coronary vessels.To reduce restenosis, Sirolimus Eluting stent(SES) implantation strategy for the proximal LAD stenosis have to be confined.**Methods**: From July 2004 to November 2004,SESs were implanted for 24 patients(63±10y,male23) with de novo proximal LAD stenosis.SES were implanted at proximal LAD , not protruding mid LMCA(left main coronary artery).We devided two groups;proximal edge restenosis(PR group , 4cases) and no restenosis(NR group,20cases).All patients had pre and postprocedure IVUS.Quantitative IVUS analysis was performed in 5-mm vessel segments immediatery proximal to the stent. **Results**: The 2 groups had similar baseline characteristics. IVUS data showed that %plaque area(mm^2) at minimal lumen area and plaque volume in proximal segment(mm^3) in PR group were higher than that in NR group(%PA: 68 ±4vs50±10:$p<0.05$,PV: 604±55vs376±148 ;$p<0.05$).**Conclusions**: Strategy of "lesion full coverage " may be applied even at proximal LAD lesion. We have to deploy LMCA stenting if the lesion is extented to LMCA by using IVUS .

	PR group (4 cases)	NR group(20 cases)	
Stent size(mm)	3.4±0.3	3.3±0.3	n.s.
Minimal Lumen Diameter(mm) at proximal edge	2.87±0.41	2.9±0.64	n.s.
IVUS analysis			
Minimal Lumen area(MLA,mm^2)at proximal edge	6.0±1.1	9.1±2.8	p<0.05
Pre Vessel area at MLA site(mm^2)	18.6±2.0	17.8±4.0	n.s.
Pre %Plaque are at MLA site(%)	68±4	50±10	p<0.01
Stent Edge Injury	2/4(50%)	4/20(20%)	n.s.
Postprocedure MLA(mm^2)at proximal edge	6.7±1.1	9.8±3.2	n.s.
Postprocedure Vessel area at MLA site(mm^2)	18.3±1.8	18.2±4.5	n.s.
Postprocedure %Plaque are at MLA site(%)	64±3	46±10	p<0.05
3D-IVUS analysis			
Pre Lumen Volume (mm^3)	395±103	491±191	n.s.
Pre Plaque Volume (mm^3)	604±55	378±148	p<0.05
Postprocedure Lumen Volume (mm^3)	419±108	536±203	n.s.
Postprocedure Plaque Volume (mm^3)	609±55	388±147	p<0.05

M-15

The Sirolimus-eluting stent for the treatment of in-stent restenosis: a comparison with cutting balloon angioplasty

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[Purpose] The use of drug-eluting stent implantation for in-stent restenosis (ISR) has shown promising results. This study investigated the clinical and angiographic results of sirolimus-eluting stent (SES) implantation for the treatment of patients with ISR compared with cutting balloon angioplasty (CBA).

[Methods] Thirty six patients with ISR (38 lesions) were treated with SES implantation and retrospectively compared with a group of patient with matched lesions treated with CBA (51 patients and 55 lesions). Routine angiographic follow up was obtained at about 6 months and the incidence of major adverse cardiovascular event was evaluated.

[Results] Baseline clinical characteristics and patterns of ISR and minimal luminal diameters(MLD) were not different between the two groups. There was no procedural failure and immediate major cardivascular adverse event (MACE) in the two groups. There were two target lesion revascularization during the clinical follow up in CBA group and no MACE was found in SES group (4% vs. 0%, $p<0.001$). On the follow up angiogram, the MLD and the diameter stenosis were significantly lower in SES group than CBA group (2.82 ± 0.33 vs. 1.80 ± 0.82 mm, $p<0.001$; and 11.3 ± 9.6 vs. 41.2 ± 24.8%, $p<0.001$, respectively). The acute gain and late loss were also significantly lower in SES group than CBA group (2.64 ± 0.38 vs. 2.02 ± 0.44 mm, $p<0.001$; and 0.21 ± 0.28 vs. 0.71 ± 0.73, $p<0.001$, respectively).

[Conclusion] Sirolimus-eluting stent was safe, feasible and highly effective in patients with in-stent restenosis compared with cutting balloon angioplasty.

M-16

Safety of the Cypher stent when used with ticlopidine

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[Purpose] We examined the safety of the Cypher stent combined with ticlopidine for patients including acute coronary syndrome.[Methods] We performed 112 PCI procedures using the Cypher stents and ticlopidine in 104 pts from June 2004 to November 2004, including 17 pts with AMI and 24 pts with UAP (age 67&plusmn12, 33-89 year old). 200mg of ticlopidine was administered for 6months in all pts after PCI, which was decreased to 100mg afterwards. If side effects of ticlopidine were suspected, we changed ticlopidine to cilostazol. Follow-up CAG was done at 6 month after PCI in 75 pts (81 procedures) and side effects of ticlopidine were examined by means of our hospital medical records in 88 pts (16 pts were dropped out or followed by another hospitals).[Results] MASE were observed 11 pts; 1 in-hospital death (agranulocytosis and pneumonia degenerated into MOF at 1 day after PCI, 11 days after ticlopidine administration), 5 ISR, 5 TLR (5 re-PCI) and 5 TVR (3 re-PCI and 2CABG). Ticlopidine was discontinued in 24 pts; 14 side effects (8 liver dysfunctions, 2 skin rushes, 1 agranulocytosis, 1 leukocytepenia and 2 bleedings (gastric ulcer and chronic subdural hematoma), 4 major surgeries and 2 biopsies (stomach and prostate) and 4 unknowns. No SAT was observed in those 24 pts.[Conclusion] Lower MASE were observed in pts with the Cypher stent implantation including 41pts with ACS and 24 pts in whom ticlopidine was discontinued.

M-17

Incidence and time-course of the adverse effects of ticlopidine after PCI - from the BMS era to the DES era -

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Background and Aim: Ticlopidine is an essential medication after coronary stent implantation as an adjunctive antiplatelet therapy, which has been key treatment strategy both in the bare metal stent (BMS) era and the drug-eluting stent era. The aim of this study is to clarify the incidence of the adverse effects and to validate the methodology of routine blood testing (every 2 weeks).**Methods:** Three hundred and three patients underwent BMS implantation from April 2001 to May 2002, and 69 patients underwent Cypher stent implantation from August 2004 to January 2005. Blood count, laboratory data and any symptoms due to side effects were examined by means of medical records in all of them. **Results:** In BMS, side effects were observed in forty patients (13.2%), of whom liver dysfunction (8.3%), WBC reduction (1.3%), and skin rush (2.7%) were presented. In Cypher stent, side effects were in 6 patients, (8.7%), of whom liver dysfunction (4.3%), WBC reduction (2.9%),and skin rash (1.4%) were presented. Average duration until the occurrence of liver injury was 14±11 days in BMS, and 17±7 days in Cypher. All patients recovered after discontinuation of the drug at the mean of 54±41 days from the initial medication in BMS, and 16±11 days in Cypher.**Conclusions:** The incidence of the side effects such as liver injury was higher than that described in the instruction for use. Side effects occurred within 8 weeks and were able to be found at early stage by the frequent blood testing.

M-18

The sirolimus-eluting stent should be implanted after a two month course of ticlopidine hydrochloride

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[Purpose] Recently, the sirolimus-eluting stents (SES) have been used in Japan. However, the problem concerning the adverse effects of ticlopidine hydrochloride after the SES stenting is not yet resolved. Therefore, we use the SES for the patient with stable angina pectoris after taking ticlopidine for two months without any adverse event. We evaluated the safety of this procedure from the evaluation of the adverse effects.

[Methods] Twenty patients with coronary artery stenosis, who had been planed to be treated by the SES from August 2004 to June 2005, had been checked the occurrence of adverse effects once in two weeks for two months. After two months, the patients without the adverse effect were treated by the SES, and the patients with the adverse effect were treated by the bare metal stent.

[Results] Six patients (20%) suffered from adverse effects of ticlopidine, liver dysfunction in 3, leucopenia in 1, renal dysfunction in 1, and drug eruption in 1. It was difficult to expect the occurrence of adverse effects before taking drugs because of no significant difference of patient's characteristics in two groups. The adverse effects were detected from 9th day to 54th day (mean=29±19 days) after taking ticlopidine. Moreover, the patients treated by the SES have not been suffered from any adverse effect after PCI.

[Conclusion] The adverse effect of ticlopidine often occurs within two months after taking drugs. Therefore, when using the SES, we had better check the adverse effect of ticlopidine at least for two months before PCI.

M-19

Is cilostazol safe for the prevention of sub-acute thrombosis (SAT), when ticlopidine has to be discontinued after DES implantation?

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Background: Early reports have showed more risk of SAT after DES implantation than BMS. Therefore, Ticropidine administration is recommended at least 3 months after DES implantation in Japan. However in some cases discontinuance of Ticlopidine is required, because of the side effects.

Purpose: This study was to compare the relative risk of SAT between two groups, group of patients who continued Ticropidine over 3 months(GroupT) and who had to exchange to Cilostazole due to the side effects of Ticropidine(GroupC).

Material & Method:97 serial cases implanted Cypher stent at our cath-labo since June 2004 to March 2005 were retrospectively analyzed. Aspirin(100mg/day) had been administered peri-procedual period, and Ticropidin(200mg/day) were administrated after the PCI procedure in all cases. Cilostazole were administered at a dose of 200mg/day. 84 cases(86.6%) were enrolled in GroupT, and 13 cases(13.4%) were in GroupC.

Results: There were no significant differences in patiant characteristics between two groups. The mean stent diameter(3.0±0.2 in GroupT v.s. 3.1±0.3mm in GroupC), the mean length of stented segment(27.4±12.7mm in GroupT v.s. 34.4±17.9mm in GroupC), and mean implantation pressure(14.9±2.8atm. in GroupT and 16.1±2.2atm. in GroupC) showed no significant difference. The mean administrated period of Ticropidine in GroupC was 19days, and the reasons of discontinuance were eczema(n=8), mild to moderate liver dysfunction(n=4), and agranulocytosis(n=1). All these abnormalities were improved after discontinuance of Ticlopidine. And SAT was not found in both groups.

Conclusion: This study suggests that Cilostazole is safe for the prevention of SAT, only in case of Ticlopidine has to be discontinued after implantation of DES.

M-20

Cilostazol improves long-term outcomes after coronary stent implantation

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[Purpose] To investigate effects of cilostazol on long-term outcomes after coronary stenting.

[Methods] One hundred patients who underwent coronary stent implantation were randomly assigned to receive cilostazol 200 mg/d for 6 months (n=50) or ticlopidine 500 mg/d for 1 month (n=50). Primary endpoints were major adverse cardiac and cerebral events (MACCE) at 3-year follow-up, including death, myocardial infarction, stent thrombosis, any revascularization and stroke. The second endpoints were angiographic restenosis at 6 month.

[Results] Angiographic restenosis occurred in 5 of 34 patients (14.7 %) in cilostazol group and 10 of 37 patients (27%) in ticlopidine group (P = 0.20). At the end of follow-up, cilostazol group was associated with a lower incidence of MACCE compared to ticlopidine group (16 % vs 36 %, p = 0.02). According to Seattle Angina Questionnaire, the improvement of physical limitation score in cilostazol group was greater than but not statistically different from that of ticlopidine group (21.8 ± 12.3 vs 16.8 ± 15.9, p = 0.09). The improvement of angina frequency score was significantly greater in cilostazol group (22.6 ± 12.7 vs 16.1 ± 13.3, p = 0.02). Rate of recurrent angina was slightly lower in cilostazol group but not statistically significant. (38 % vs 54 %, p = 0.11). Readmission due to cardiac and cerebral vascular diseases was significantly reduced in cilostazol group as compared to ticlopidine group (20 % vs 40 %, p = 0.03).

[Conclusion] Cilostazol significantly reduces MACCE and markedly improves the quality of life in patients after coronary stenting.

M-21

Angioscopic observation into whether neo-intimal formation occurs 3-months after Cypher placement.

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In bare metal stent, it is known that stent surface neointimal formation occurred one month after stent implantation. This phenomenon is the evidence to stop the administration of ticlopidine in Japan. In drug eluting stent era, there is no observation when neointimal formation over the stent ocurr. So we have to administrate ticlopidine three to six months to prevent stent thrombosis. Recent angioscopic technique can visualize stent surface clearly and observe the process of stent strut neointimal formation. So the aim of this study is to observe Cypher stent surface by angioscopy whether or not stent surface neointimal formation occur three month after stent implantation. We performed angioscopy to 15 patients three months after Cypher stent implantation subsequently. 4 males, one female, mean age was 65+/-6 years old. All patients received asprin (100mg/day) and ticlopidine (200mg/day) orally before stent implantation. Angioscopy we used was coronary angioscopy system supplied by Intertec Medicals. Three patients did not observe neointima over Cypher stent surface. Two patients had thin neointima over Cypher stent surface. There were no thrombus at stented lesions .This observation indicated that we have to administrate ticlopidine at least three months or longer.

M-22

Do we need more large-sized drug-eluting stents?

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[Purpose] The largest size of DES available during procedure is 3.5mm. When you meet more large reference vessel diameter (RVD) in QCA, you might think over which type of stent should be deployed. The aim of this study is to clarify the incidence of major adverse cardiac event (MACE) after 4.0mm sized bare metal stent (BMS) implantation compared with 3.5mm DES.

[Methods] This retrospective study included 164 patients (180 lesions) since June 2002 to August 2004, who underwent coronary stent (RVD within 3.5~4.0mm, BMS 4.0mm, DES 3.5mm). The clinical outcomes and follow-up coronary angiographic result were analyzed.

[Results] 12months clinical follow-up was available in 93.9%, 6 months angiographic follow up in 51.1%. Other data are in the following table.

[Conclusion] Although ISR rate was more frequent in BMD, MACE was not statistically different. Until now, we recommend BMS in large coronary artery with confidence, which could not be deployed with 3.5mm sized DES.

% (n)	Group1 (BMS)	Group2 (DES)	P value
Patient/Lesion	73/80	91/100	
Nonfatal MI	0(0)	0(0)	1.0
Death	1.3(1)	1.9(2)	1.0
TLR	3.8(3)	3.3(3)	1.0
MACE	5.1(4)	5.6(5)	1.0
ISR	21.3(10)	6.7(3)	0.07

M-23

Coronary risk factors are likely to be higher in patients presenting less initial stenosis reduction after DES implantation

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Purpose: Certain risk factors contribute to a high incidence of restenosis after coronary stenting, and drug-eluting stents are increasingly being used in complex patients and lesions. This study investigated how risk variables affect initial stenosis reduction, which may affect subsequent restenosis.

Methods: The BEACON study is a prospective multicenter observational registry evaluating the BioMatrix Biolimus A9-Eluting Stent (Biosensors International, Singapore) in a diverse patient population. The BioMatrix stent was used exclusively in 168 primary lesions. Univariate analysis identified lesion and patient variables that correlated with acute stenosis reduction, which was calculated as [(Pre % Diameter Stenosis (DS) - Post %DS)/Pre %DS]*100.

Results: Overall (n=168), preoperative and postoperative %DS was 74.3±15.8 and 6.1±8.1, respectively, and mean acute stenosis reduction was 90.7%±12.9 (range, 30.4% to 100%). Differences in acute stenosis reduction were found in ostial lesions (81.8%±16.3 vs. 91.4%±12.3, p=.009), TIMI flow <2 (86.8%±14.6 vs. 95.8%±7.6, p<.001), severe calcification (84.8%±17.4 vs. 91.2%±12.3 p=.076), vessel diameter <2.25 (80.1%±14.7 vs. 93.2%±11.1, p<.001), AHA lesion class B2 or C (87.9%±13.7 vs. 95.4%±9.8, p<.001), patient age ≥70 (85.6%±16.1 vs. 92.2%±10.8, p=.002), and prior cardiac intervention (87.7%±12.3 vs. 92.4%±13.0, p=.021). Except for TIMI flow <2, patients with these risk factors had significantly higher residual stenosis. Diabetes and lesion length were among variables that did not affect acute stenosis reduction.

Conclusion: Several risk factors are associated with less immediate stenosis reduction. Later restenosis may be related to lower initial stenosis reduction and higher residual stenosis. Further study is warranted to determine the clinical importance of this finding.