POSTERS

In-stent Restenosis and Stent Thrombosis

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TCT-447

Predictors and clinical implications of stent thrombosis in patients with ST-segment elevation myocardial infarction. Insights from the EXAMINATION trial

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Background: few data are available about safety of second generation drug eluting stents in an all-comer ST elevation myocardial infarction (STEMI) population. We sough to investigate the predictors and clinical implications of 1-year stent thrombosis (ST) in patients with STEMI, included the EXAMINATION trial.
Methods: The EXAMINATION trial is an all-comer prospective, randomized 1:1 controlled trial, testing everolimus-eluting stent (EES) vs. cobalt chromium bare metal stent (BMS) in STEMI patients. It included 1498 patients, randomized to EES (n=751) or BMS (n=747).
Results: At 1-year, definite/probable stent thrombosis, defined according to ARC criteria, occurred in 26 patients (1.73%), including 18 definite and 8 probable events. The incidence of ST was lower in patients treated with EES than in those treated with BMS (HR 0.16, 95% CI 0.03 – 0.29, p=0.017). Patients with ST have higher 1-year rates of cardiac death (30.8% vs. 2.5%, p<0.001), myocardial infarction (30.8% vs. 0.5%, p<0.001) and target vessel revascularization (65.4% vs. 4.2%, p<0.001) compared with those without. Independent predictors of 1-year definite/probable ST were BMS implantation at the index procedure (HR 3.41,95% CI 1.35–8.60), ST segment resolution of at least 70% in the EKG post-PCI (HR 0.30,95% CI 0.13–0.70) and Killip class on admission (HR 2.57,95% CI 1.70–3.90).
Conclusions: ST had low frequency in the first year after implantation of EES/BMS in STEMI patients, but it is associated with adverse events. BMS implantation, lack of ST-segment resolution and high Killip class on admission were independent predictors of 1-year ST.

TCT-448

Long-Term Clinical Results Of SeQuent Please Paclitaxel-Coated Balloon Angioplasty For The Treatment Of In-Stent Restenosis

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Background: Paclitaxel-coated balloons (PCB) have been proven to be effective for the treatment of coronary in-stent restenosis (ISR) after bare-metal stent (BMS) or drug-eluting stent (DES) implantation. This study aims to evaluate the long-term safety and efficacy of the second-generation SeQuent Please PCB in coronary ISR in routine real-world practice.
Methods: Between May 2009 and April 2011, all consecutive patients with ISR lesions treated with the SeQuent Please PCB at our institution were prospectively included. Patients were followed up for 24 months by clinical observation. The primary endpoint was the clinically driven target lesion revascularization (TLR) rate at 24 months. The secondary endpoint was the rate of major adverse cardiac events (MACE: defined as a composite of cardiac death, myocardial infarction, and TLR) at 24 months.
Results: 48 patients with 52 ISR lesions (30 BMS, 22 DES) were included. Mean age was 66.2±12.3 years. 75 % were male and 50 % were diabetics. The majority of patients presented with stable angina (63.5%). The target lesion was mainly located in the right coronary artery (46.1%) and the left anterior descending coronary artery (42.3%). The mean reference vessel diameter was 3.0±0.5 mm and the mean target lesion length was 21.4±6.8 mm.Procedural success was 100 %. Coronary dissection occurred in 1 patient (1.9 %), requiring additional stent implantation. Follow-up rate was 94.2 %. The TLR rate was 5.8 % after 24 months. Cumulative MACE at 24 months was 9.6 %, with 1.9 % cardiac death and 1.9 % myocardial infarction. No vessel thrombosis was documented. The TLR rate did not differ for PCB angioplasty for BMS-ISR compared with DES-ISR (3.3% vs. 9.1%, p=0.38). Baseline lesion characteristics and procedural data did not differ except for a longer lesion length for BMS-ISR compared with DES-ISR (25.4 ±5.1 mm vs. 19.7±6.9 mm, p=0.008).
Conclusions: Treatment of coronary ISR with the second-generation SeQuent Please PCB provides good clinical outcomes demonstrated by the low TLR rate and low MACE rates at long-term follow-up.

TCT-449

COMPARISON OF PACLITAXEL-ELUTING BALLOONS WITH DRUG-ELUTING STENTS FOR TREATMENT OF IN-STENT RESTENOSIS: A RETROSPECTIVE ANALYSIS OF AN ALL-COMERS COHORT

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Background: The optimal treatment strategy for coronary in-stent restenosis (ISR) is unclear. Drug-eluting balloons (DEB) offer an alternative to drug-eluting stents (DES) by avoiding risks of stent thrombosis, and by lowering the risks of restenosis associated with standard balloon angioplasty and bare-metal stents. The objectives were to compare clinical outcomes of DEB versus second-generation DES for the treatment of ISR. The hypothesis was that DEB and DES would provide similar outcomes.
Methods: From December 2009 to November 2012, 102 coronary ISR were treated with a paclitaxel-eluting balloon in all-comer patients in a Canadian tertiary center. The comparator group consisted of a random sample of 100 patients with ISR treated with a second-generation DES in the same time period. Data was collected from medical files and telephone interviews. Mean follow-up was 16±9 months (222 patient-years). Baseline characteristics were similar between both groups (mean age: 65±11 [p=0.91]; 28% women [p=0.69]). Diabetes was present in 45% of patients (p=0.79). Indication for revascularization was non-ST-elevation acute coronary syndrome in 71% of cases in the DEB group as compared to 73% in the DES group (p=0.37).
Results: The composite clinical outcome of MACE (death from any cause, non-fatal myocardial infarction, or clinically-driven target-lesion revascularization) occurred in 26% of patients in the DEB group, compared to 24% in the DES group (p=0.80). Freedom from MACE was similar between both groups after adjustment for confounding factors. Secondary outcomes are shown in the Table.
Conclusions: DEB appears as a safe and effective treatment for ISR as compared to second-generation DES. Our data suggest that clinical outcomes following revascularization with both devices are similar. Long-term clinical outcomes following ISR treatment with a DEB compared to second-generation DES remain to be prospectively studied.

Outcomes following treatment of in-stent restenosis

	DEB	DES	Total	*p*
MACE	25 (26%)	21 (24%)	46 (25%)	0.80
Death	15 (16%)	6 (7%)	21 (12%)	0.06
Non-fatal MI	8 (9%)	10 (13%)	18 (11%)	0.43
TLR	7 (8%)	10 (13%)	17 (10%)	0.26
Restenosis ≥ 50%	10 (11%)	10 (13%)	20 (12%)	0.72
Thrombosis	1 (1%)	1 (1%)	2 (1%)	0.93
Stroke/TIA	1 (1%)	1 (1%)	2 (1%)	0.96

TCT-450

PREDICTORS OF ANGIOGRAPHIC OUTCOMES FOLLOWING IN-STENT RESTENOSIS TREATMENT WITH PACLITAXEL-ELUTING BALLOONS AND SECOND-GENERATION DRUG-ELUTING STENTS.

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Background: Success of in-stent restenosis (ISR) treatment depends on angiographic lesion characteristics and co-morbidities. The optimal treatment option for ISR between drug-eluting balloons (DEB) or drug-eluting stents (DES) is not well known. The objectives were to assess risk factors for adverse outcomes following ISR treatment, and to evaluate the use of DEB in this setting.
Methods: Multivariate binary logistic regression was performed to assess predictors of treatment success following ISR treatment in a cohort including 102 patients treated with paclitaxel-eluting balloons and 100 random patients treated with a second-generation DES between December 2009 and November 2012 in a Canadian tertiary center (mean follow-up: 16±9 months; mean age: 65±11 years). The effect of using a DEB was adjusted for angiographic and clinical confounders. Indication for revascularization was non-ST-elevation acute coronary syndrome in 145 cases (72%). Lesion localization was similar in both groups (p=0.45): 4% left main, 33% LAD, 27% circumflex, and 37% RCA. ISR pattern was focal in 62% of patients in the DEB group, compared to 46% in the DES group (p=0.02).
Results: Compared to diffuse, proliferative or occlusive lesions, a focal ISR was a protective factor against death (OR=0.2; p=0.01), and target-lesion revascularization (TLR) (OR=0.3; p=0.04), but not against MACE (death, non-fatal myocardial infarction [MI], and TLR) (p=0.29), MI (p=0.95), or ≥50% restenosis (p=0.19). DEB/DES length was associated with MACE (OR=1.0; p=0.03), and death (OR=0.9; p=0.001), but not with TLR, MI, and ≥50% restenosis (p>0.05 each). DEB/DES diameter was associated with none of these outcomes (p>0.05 each). Presence of chronic kidney disease (CKD) was the only identified independent risk

factor for MACE (OR=2.4; p=0.04), and death (OR=6.8; p=0.001). Upon multivariate logistic regression adjusting for CKD, DEB/DES length, and focal ISR, DEB was not associated with MACE (OR=0.9; p=0.71) or death (OR=1.7; p=0.44).
Conclusions: Chronic kidney disease is an independent predictor of adverse outcomes following percutaneous treatment of ISR. When adjusted for confounders, DEB and DES are associated with similar outcomes in this setting.

TCT-451

Impact of Stent Recoil and Fracture in RCA Ostium Restenosis Following Stainless Steel or Cobalt Chromium Drug-Eluting Stent Implantation: A Serial Angiographic and IVUS Study

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Background: PCI procedure of RCA ostium stenosis is still a challenging issue due to high stent restenosis rate, possibly due to mechanical stress. However, mechanisms of restenosis following cobalt-chromium everolimus-eluting stent (EES) or stainless steel biolimus-eluting stent (BES) implantation have not been well clarified.
Methods: Sixty-four RCA ostium restenosis cases after 2nd generation DES (40 EES and 24 BES) were retrospectively analyzed. Serial (post initial stent and follow-up as revascularization) angiographic and IVUS evaluation were performed. In quantitative angiographic analysis (QCA), incidence of stent fracture (defined as complete separation of the stent segments and/or the absence of a stent strut on magnified fluoroscopic image), and partial (only one of the inner or outer struts was separated) and complete (both the inner and outer struts were disconnected) fracture type were evaluated. In IVUS, serial changes of minimum lumen and stent area (SA), and degree of stent recoil at minimum lumen area, defined as (follow-up SA - baseline SA / baseline SA*100), were also measured.
Results: Average follow-up phase was 14±10-months. Angiographic and IVUS morphometric parameters were similar in both groups at baseline. Significant lumen narrowing was observed from baseline to follow-up in both groups (10.2±4.6 to 2.5±2.0, 10.7±5.4 to 2.4±2.3 mm2 in minimum lumen area, EES vs. BES, p<0.01 from baseline to follow-up for all). Stent fracture was more frequently observed in BES than EES (85 vs. 8%, p<0.01). In addition, complete fracture was highly observed in BES (29%) compared to EES (2%, p<0.05). In contrast, significant stent recoil was observed in EES only (11.8±5.7 to 9.0±5.4 mm2, p<0.01 from baseline to follow-up for EES, 11.6±4.8 to 11.3±3.4 mm2, p=ns for BES, and degree of stent recoil was significantly larger in EES than BES (23.8 vs. 2.6%, p<0.05). Additionally, there was only 1 BES and no EES case that both stent fracture and significant recoil, resulting in stent restenosis, was observed.
Conclusions: Stent fracture appears to be the major cause of RCA ostium restenosis after stainless steel BES, whereas stent recoil seem to be associated with restenosis after cobalt-chromium EES.

TCT-452

A retrospective analysis of the incidence and predictors of new generation drug-eluting stent fracture following percutaneous coronary intervention

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Background: Stent fracture (SF) is one of the complications after percutaneous coronary intervention (PCI), although it is not often. To date many data on first generation drug-eluting stent (DES) fracture were published. However study on second generation DES fracture is rare. The aim of this study was to assess the predictors of second generation DES fracture.
Methods: From March 2010 to August 2012, a total of 1032 patients with 1283 lesions who underwent successful implantation with second generation DES at Inje University Haeundae Paik Hospital were followed prospectively. Among them, 369 patients (35.7%) with 476 (37.1%) lesions who underwent follow-up coronary angiography (CAG) 6 to 12 months after initial procedure, irrespective of clinical symptoms, were performed.
Results: SF was identified in 45 of 1032 patients (4.36%) and 51 of 1283 lesions (3.82%). The patients were divided into SF group and non-SF group. The most prevalent vessel of SF was the left anterior descending artery (24 lesions, 47.1%), followed by the right coronary artery (16 lesions, 31.4%). Most lesions were classified as type B2 (15 lesions, 29.4%) or type C (22 lesions, 43.2%). All implanted stents were the second generation DES such as everolimus-eluting stents (17 stents, 33.3%), zotarolimus-eluting stents (12 stents, 23.5%) and biolimus-eluting stents (10 stents, 19.7%). Compared with non-SF group, SF group was more likely to have stent overlap (52.4% vs. 22.4%; p<0.001) and peri-procedural myocardial infarction (32.6% vs. 12.1%; p<0.001). On multivariate logistic regression analysis, stent overlap (odds ratio 3.45, 95% confidence interval 1.66-7.17, p<0.001), Biolimus-eluting stents (odds ratio 6.17, 95% confidence interval 2.19, p<0.001), stent length (odds ratio 1.07, 95% confidence interval 1.02-1.13, p=0.009), and peri-procedural MI (odds ratio 3.14, 95% confidence interval 1.36-7.23, p =0.007), were identified as independent predictors for fracture of second generation stent.
Conclusions: The incidence of stent fracture in the second generation DES was 3.82%. The biolimus-eluting stent, overlapping stent, peri-procedural MI, and long stent length are significant determinants of stent fracture in the second generation.

TCT-453

Multiple Predictors of In-Stent Restenosis with Clinical Presentation of Acute Coronary Syndrome After Drug-Eluting Stent Implantation

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Background: Although in-stent restenosis (ISR) after drug-eluting stent (DES) is perceived to be a benign phenomenon, some patients with ISR showed clinical presentation of acute coronary syndrome (ACS). We sought to identify parameters influencing the likelihood of restenosis with clinical presentation of ACS after DES implantation.
Methods: Stented patients (n=3,817) with DESs were retrospectively reviewed for inclusion in the study from the Korea University PCI Database Registry. From this database, age and sex-matched 302 patients (7.9%) with ISR were assigned to either the Stable ISR group (n=156) or the ACS ISR group (n=146). Predictors of coronary restenosis with clinical presentation of ACS were identified with Cox regression analyses.
Results: The rate of risk factors such smoking, hypertension, and diabetes were similar between the 2 groups; moreover, the use of medications at baseline did not differ significantly between the 2 groups. More patients in the ACS ISR group showed two vessel diseases (n=70 [47.9%] vs. n=44 [28.2%], P=0.028, respectively). No significant differences in ISR pattern were noted between the 2 groups during the follow-up angiogram. Follow-up MMP-2 level was significantly higher in the ACS ISR group when compared to the Stable ISR group (66,639+/-12,519 vs. 57,386+/-2,423, P=0.011, respectively). Age (Hazard ratio [HR], 1.13; 95% confidence interval [CI], 1.02 to 1.26; P=0.024), diabetes (HR, 6.80; 95% CI, 1.16 to 39.9; P=0.034), the use of aspirin (HR, 0.005; 95% CI, 0.001 to 0.760; P=0.039), clopidogrel (HR, 0.010; 95% CI, 0.001 to 0.162; P=0.001), ACE inhibitor (HR, 0.210; 95% CI, 0.003 to 0.515; P<0.001), the use of first generation DES (HR, 1.130; 95% CI, 1.030 to 1.260; P=0.001), and MMP-2 level (HR, 1.120; 95% CI, 1.001 to 1.190; P=0.004) during follow-up were significant predictors of ISR with clinical presentation of ACS during the 3-year follow-up.
Conclusions: In the era of DES, older age, diabetes, the use of first generation DES, and increased MMP-2 levels were significant predictors of ISR with clinical presentation of ACS. In contrast, the use of aspirin, clopidogrel, high-dose statin, and ACE inhibitor prevented ISR with clinical presentation of ACS.

TCT-454

Incidence and Clinical Impact of Stent Fracture After the Nobori Biolimus-Eluting Stent Implantation

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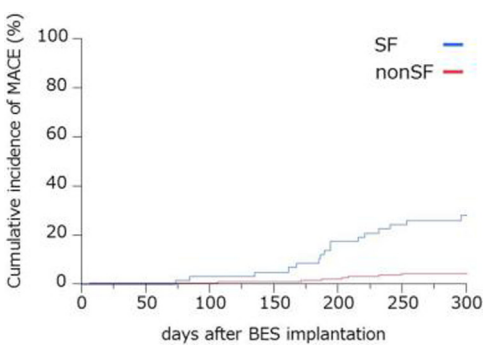
Background: Stent fracture (SF) after drug-eluting stent implantation has recently became an important concern. However, the incidence and clinical impact of SF after the Nobori biolimus-eluting stent (BES) remains unclear.
Methods: A total of 1031 patients with 1407 lesions undergoing BES implantation and follow-up angiography 6 to 9 months after index procedure were analyzed. SF was defined as complete or partial separation of the stent, as assessed by plain fluoroscopy, intravascular ultrasound, or optical coherence tomography during follow-up. We assessed the rate of SF and major adverse cardiac events (MACE), defined as cardiac death, myocardial infarction, stent thrombosis, and clinically driven target lesion revascularization (TLR) within 9 months.
Results: SF was observed in 58 of 1407 lesions (4.1%) and 57 of 1031 patients (5.5%). Lesions with hinge motion (odd ratio [OR], 6.15; 95% confidence interval [CI], 3.40-11.46; p<0.001), tortuosity (OR, 3.12; 95% CI, 1.46-7.31; p=0.003), or overlapping stents (OR, 2.66; 95% CI, 1.23-5.81; p=0.013) were independent predictors of SF. The MACE rate within 9 months were significantly higher in the SF group than in the non-SF group (28.1% vs. 4.6%, p<0.001). The rate of TLR was significantly higher in the SF group than in the non-SF group (28.0% vs. 4.1%, p<0.001), whereas the rate of myocardial infarction and stent thrombosis were not different between the 2 groups (1.8% vs. 1.0%, p=0.61; 1.8% vs. 0.9%, p=0.53, respectively).



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