imbalances between trials confirmed non-significant differences between stent type and stent thrombosis rates. The trend for a higher definite stent thrombosis rate in the BES group was by multivariate analysis less prominent (HR 2.05 [CI95% 0.75-5.60]; p=0.16).
Conclusions: At 1-year follow-up the biodegradable polymer-coated BES has similar stent thrombosis rates as the durable polymer-coated EES. However, incidence of definite stent thrombosis is numerically higher in the BES group without reaching statistical significance. Longer follow-up is needed to determine the safety profile of biodegradable polymer-coated BES in real world clinical practice.

Events at 1 years	EES (n=2,530)	BES (n=3,412)	p-value
Definite Stent Thrombosis			
All Stent Thrombosis	0.2% (5)	0.5% (17)	0.08
Early Stent Thrombosis	0.2% (4)	0.4% (13)	0.14
Late Stent Thrombosis	0.04% (1)	0.1% (4)	0.40
Definite or Probable Stent Thrombosis			
All Stent Thrombosis	0.4% (10)	0.5% (18)	0.57
Early Stent Thrombosis	0.3% (8)	0.4% (13)	0.83
Late Stent Thrombosis	0.1% (2)	0.2% (5)	0.71

TCT-645

Optical coherence tomography findings in bioresorbable scaffold thrombosis

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Background: Bioresorbable scaffolds (BVS) are a new treatment for coronary artery disease with promising results in first-in-man studies. As their use is extending in more complex lesions and populations, several cases of BVS thrombosis have been reported. We present optical coherence tomography findings from the culprit lesion of patients with BVS thrombosis.
Methods: Up to 1/5/2014, 442 patients received BVS in our center. Among those, 14 patients that developed definite BVS thrombosis, according to the ARC criteria, were readmitted to our cathlab. Eight of them were imaged by optical coherence tomography (OCT) at the time of the event. OCT images were reviewed offline and the presence of thrombus, underexpansion, neointimal hyperplasia >50%, incomplete scaffold apposition, and scaffold discontinuity were assessed. The current status of dual antiplatelet therapy at the time of the event was also recorded.
Results: Thrombus was visualized in 7/8 cases, underexpansion in 1/8, neointimal hyperplasia >50% in 2/8, incomplete scaffold apposition in 4/8, and scaffold discontinuity in 2/8 cases. In 3 cases, dual antiplatelet therapy had been discontinued at the time of the event. A summary of the most prominent OCT findings is presented in the Table.

Case	Type/ timing	Baseline OCT findings	Prominent OCT findings at event	Dual antiplatelet therapy
1	Acute/ same day		Thrombus at proximal stent edge, deriving from an adjacent fibroatheroma	Yes
2	Subacute/ 2 days		Thrombus overlying extensive overlap region (7.6mm)	Yes
3	Late/ 40 days	Undersizing/residual thrombus/plaque prolapse	Incomplete scaffold apposition with thrombus	Yes
4	Late/ 4 months		Occlusive edge restenosis	Yes
5	Late/ 4 months		Uncovered struts at the carina of a bifurcation treated with T-stenting	No
6	Late/ 4 months	Scaffold fracture	Thrombus overlying overlap region with underexpansion/ scaffold fracture	No
7	Late/ 7 months		Incomplete scaffold apposition/ occlusive restenosis	Yes
8	Very late/ 2 years	Optimal scaffold expansion	Late scaffold discontinuity/ incomplete scaffold apposition	No

Conclusions: Discontinuation of antiplatelet therapy was identified in some patients as a reason for BVS thrombosis, however, in the majority of the cases mechanical factors were identified by OCT as a substrate. OCT can provide useful insights on the pathomechanisms of this complication.

TCT-646

IVUS findings and clinical outcomes of angiographic late and very-late definite stent thrombosis treated with additional stent implantation versus balloon angioplasty

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Background: Incidence of late stent thrombosis (ST) is increasing due to the persistent risk of thrombosis after implantation. Most of the cases are treated with percutaneous coronary intervention (PCI). PCI of late-ST with additional stent implantation has been associated with worse outcomes. Intravascular ultrasound (IVUS) imaging is able to assess the pathological causes of late-ST and guide the best treatment. The objectives of this study are to describe the IVUS findings of late-ST and compare outcomes between patients treated without and with additional stent implantation.
Methods: All patients with late-ST (>1 month) undergoing IVUS-guided PCI were included in 7 Spanish institutions. The operators were left to decide the PCI treatment: balloon angioplasty (POBA) vs. stent implantation. Four IVUS findings were assessed: late incomplete stent apposition (LISA), aneurysm, stent underexpansion and excessive neointimal proliferation.
Results: 117 patients were included (54.4% drug-eluting stents). The median time after implantation was 3.5 years. ST was presented as ST-elevation myocardial infarction in 99 (84.1%) patients. Additional stent implantation was used in 54 patients (46.2%). Prior to intervention, there were no differences in LISA (71.4% vs. 63.0%; p=0.33), aneurysm (11.1% vs. 11.1%; p=1.0), underexpansion (31.7% vs. 18.5%; p=0.10) or excessive neointimal proliferation (11.1% vs. 22.2%; p=0.10) between patients treated with POBA vs. additional stent implantation. After PCI, persistent LISA was observed in 25.4% vs. 51.9% of patients (p=0.01), respectively. Persistent underexpansion was observed in 6.3% and 14.8% (p=0.05). Follow-up was obtained at 2.0 years. Cardiac death was observed in 3.4% vs. 5.8% of patients treated without and with additional stent (p=0.55). Definite or probable re-thrombosis was observed in 1.7% vs. 7.7% (p=0.13), respectively.
Conclusions: The most frequent IVUS findings of late-ST are LISA and underexpansion. POBA seems to improve these IVUS-findings with respect to additional stent implantation. IVUS-guided treatment of definite ST is associated with favorable outcomes independently of the use of additional stent implantation.

TCT-647

Predictors of Stent Thrombosis up to 12 Years Follow-up After Drug-Eluting Stent Implantation in Daily Clinical Practice

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Background: Stent thrombosis (ST) has been described as a rare event in current drug-eluting stent (DES) era; however, its occurrence has been associated with high morbimortality, including fatality rates up to 50%. Previous studies have shown ST could be increased in complex subsets; however, the incidence and predictors of ST after DES overtime are still no fully understood
Methods: A total of 5,408 pts with >8,000 coronary lesions undergoing routine or emergency PCI were prospectively (and consecutively) enrolled in the DESIRE (Drug-Eluting Stent In the REal World) registry at single institution between May/2002 and May/2012 (enrollment ongoing). By protocol, clinical follow-up was performed at 1 and 6 months, and yearly up to 12 years post-index procedure (97%). Stent thrombosis (ST) was defined according to the propositions of the Academic Research Consortium.
Results: Mean age was 65 years, 32% had diabetes, and 16% had clinical presentation of recent myocardial infarction (MI) (< 30 days). Overall, patients were treated with approximately 8,500 DES and angiographic success was high (>99%) despite relatively high complexity in the majority of lesions (67% type B2/C). Up to 12 years (median 4.9 years) FU, cumulative incidence of ST was 2.4%, given that 95.1% of patients were ST-free at 10 years (Kaplan-Meier survival curve). Of the 113 ST reported, 13% occured up to 30 days, 55% were definite ST (ARC), and >60% occured 12 months. Independent predictors of ST are shown in the Table.

Predictors of Overall ST	HR	95% CI	p value
Recent MI up to 72 hours	2.66	1.52-4.66	0.001
Recent MI >72 hours	1.89	1.08-3.29	0.03
Multiple DES implanted	1.89	1.28-2.80	0.002
SVG	2.21	1.29-3.78	0.004
Residual stenosis (QCA analysis)	1.03	1.00-1.05	0.03
Predictors of Definite ST			
Recent MI up to 72 hours	3.68	1.87-7.23	<0.001
Multiple DES implanted	2.24	1.30-3.86	0.004
SVG	2.62	1.32-5.22	0.006
Predictors of Early ST (up to 30 days)			
	OR	**95% CI**	**p value**
Diabetes	2.45		0.014
Recent MI up to 72 hours	3.65		<0.001

Conclusions: In this study, pts had relatively low cumulative incidence of ST (2.4%), given that around 95% of patients were ST-free up to 12 yrs. Significant predictors of overall ST were recent MI, multiple stent implantation, SVG and stent underexpansion; as for definite ST only, predictors were recent MI, multiple stent implantation and SVG; considering early ST occuring up to 30 days, predictors were diabetes and recent MI.

Coronary Lesions - In-stent Restenosis

Washington Convention Center, Lower Level, Hall A

Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 648-663

TCT-648

The Optimal Strategy for Restenosis With Stent Fracture After Drug-Eluting Stent Implantation: Plain Old Balloon Angioplasty vs. Paclitaxel-Coated Balloon vs. Drug-Eluting Stent

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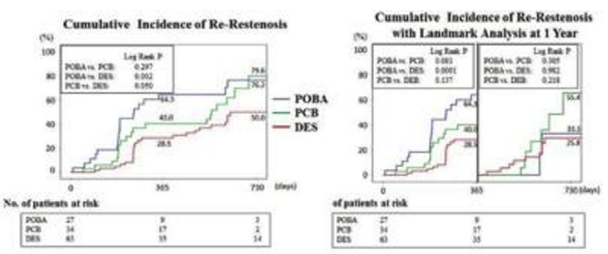
Background: Stent fracture is related to restenosis after drug-eluting stent (DES) implantation. As percutaneous coronary intervention (PCI) cases for complex lesions increased, those for stent fracture-related restenosis also increased. However, the optimal PCI strategy for such restenosis remains unclear. We compared the results of PCI with plain old balloon angioplasty (POBA), paclitaxel-coated balloon (PCB), and DES (sirolimus-eluting stent, paclitaxel-eluting stent, zotarolimus-eluting stent, everolimus-eluting stent, and biolimus-eluting stent) for restenosis with stent fracture after DES implantation.
Methods: From November 2002 to December 2012, 9357 patients with 15894 lesions underwent DES implantation successfully. Of these, 12918 lesions were angiographically followed up after 6 to 8 months (midterm f/u) and 9989 were followed up at 12 months after midterm f/u. Stent fracture occurred in 576 (4.5%) of the 12918 lesions and restenosis with stent fracture occurred in 206 lesions. Restenosis with stent fracture was defined as a restenosis lesion within 5 mm from a stent fracture site. Of the 206 lesions, target lesion revascularization by PCI with POBA, PCB, or DES was performed on 124 lesions.
Results: Data are shown in the figure. At 2-year f/u, the cumulative incidence of restenosis was significantly lower after retreatment with DES than that with POBA and PCB. In addition, late catch-up phenomenon was found after retreatment with PCB.



Conclusions: Retreatment with DES could be an acceptable treatment for restenosis with stent fracture after DES implantation.

TCT-649

Outcomes After Repeat Intervention With Everolimus-eluting Stent For Sirolimus-eluting Stent Restenosis Lesion With Stent Fracture

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Background: Presence of stent fracture (SF) after sirolimus-eluting stent (SES) implantation has reported to be associated with an increased risk of adverse events and those are previously reported. But little is known about the outcomes after re-intervention for SES restenosis lesion with SF.
Methods: From April 2007 to August 2011, total 2059 lesions implanted SES during PCI at our hospital. Total 228 lesions, 11.1% had restenosis (defined as %diameter stenosis >50%) in follow-up angiogram until March 2013. Subjects of the study were 49 lesions 42 patients those implanted SES for denovo coronary artery stenosis and in-stent restenosis with SF was documented in follow-up angiogram. SF was defined as complete or partial separation of the stent as assessed by plain fluoroscopy. During the target lesion revascularization procedure, 14 lesions implanted everolimus-eluting stent (EES group), 20 lesions implanted sirolimus- and paclitaxel-eluting stent, stainless steel stent with durable polymer (SS group). And also 15 lesions were dilated with balloon angioplasty alone (POBA group). We compared the outcomes of 3 groups retrospectively.
Results: Baseline characteristics were similar. One-year cumulative incidence of restenosis after repeat intervention those calculated by Kaplan-Meier methods were EES group 22%, SS group 66% and POBA group 76%, respectively. EES group significantly reduced the cumulative incidence of restenosis after repeat intervention (versus SS group; p=0.0471 and POBA group; p=0.0085).
Conclusions: For reduction in incidence of re-restenosis for the SES restenosis lesion with SF during 1-year after repeat intervention, cobalt chromium EES implantations were superior to stainless steel stent with durable polymer or balloon angioplasty alone.

TCT-650

Incidence and Clinical Impact of Stent Fracture after the PROMUS Element Platinum Chromium Everolimus-Eluting Stent Implantation

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Background: Stent fracture (SF) is an unresolved, clinically relevant issue, even in the newer-generation drug-eluting stent era. The PROMUS Element platinum-chromium everolimus-eluting stent (PtCr-EES; Boston Scientific, Natick, Massachusetts) is designed to provide the improved fracture resistance, whereas the incidence and clinical impact of SF after PtCr-EES implantation remains unclear. The aim of this study was to assess the incidence and clinical impact of SF after PtCr-EES implantation.
Methods: Between March 2012 and June 2013, a total of 676 patients with 839 lesions undergoing PtCr-EES implantation and follow-up angiography within 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 the follow-up. We assessed the rate of SF and the cumulative incidence of clinically-driven target lesion revascularization and definite stent thrombosis within 9 months.
Results: SF was observed in 12 of 839 lesions (1.4%) and 12 of 676 patients (1.7%). Cumulative incidence of clinically-driven target lesion revascularization within 9 months was numerically higher in the SF group than that in the non-SF group (25.0% versus 2.4%). Cumulative incidence of definite early and late stent thrombosis within 9-month was similar between the SF and non-SF groups (0.0% versus 0.2%).
Conclusions: SF after PtCr-EES occurs in 1.4% of lesions and appears to be associated with clinically-driven target lesion revascularization.

TCT-651

The Relevance to Clinical Outcomes of Stent Fracture after Second Generation DES deployment

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