

Polymorphism	N (%)
FIA	
A1/A1	82 (89.1%)
A1/A2	10 (10.9%)
Glu29Basp	
Glu/Glu	81 (88.0%)
Glu/Asp	11 (12.0%)
_922a_g	
A/A	65 (70.7%)
A/G	22 (23.9%)
G/G	5 (5.4%)
Int	
420/420	76 (82.65)
420/393	16 (17.4%)
-786T>C	
TT	58 (63.0%)
CC	9 (9.8%)
TC	25 (27.25)

**Conclusions:** This study shows that the presence of PIA2 polymorphism is an independent risk factor for coronary in-stent restenosis and a marker for need of new revascularization. Its detection could have important implications in decision making.

#### TCT-474

##### Is Early Stent Thrombosis Reduced in Cobalt-Chromium Everolimus-Eluting Stent in Humans?

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**Background:** Published preclinical studies demonstrated that polymer-coated stents with thin struts exhibit less thrombogenicity as compared to uncoated or thick strut stents (Circulation 2011;123:1400-1409); however, no pathologic studies have been reported in man. We sought to evaluate the pathologic prevalence of early stent thrombosis (ST,  $\leq 30$  days) in cobalt-chromium everolimus-eluting stent (CoCr-EES) as compared to sirolimus-eluting (SES), paclitaxel-eluting (PES), and bare metal stents (BMS) in humans.

**Methods:** A total of 102 stented coronary lesions with duration of implant  $\leq 30$  days (CoCr-EES=17, SES=30, PES=39, and BMS=16 MULTI-LINK VISION® [ML VISION, Abbott Vascular, Santa Clara, CA]) from 77 autopsy cases were histopathologically evaluated for the prevalence of early ST and its etiology.

**Results:** Clinical and pathologic characteristics including duration of implant, indications for stenting, stent length, prevalence of bifurcation multistenting, incomplete stent apposition, and medial disruption were comparable among the groups, while the number of stents per lesion was greater in CoCr-EES as compared to SES ( $p=0.02$ ) (Table). Early ST was identified in 39 of 102 lesions (39%). The prevalence of early ST was the least in CoCr-EES (3 of 17 lesions, 18%), followed by PES (36%) and SES (43%), and was the highest in BMS (56%,  $p=0.02$  vs. CoCr-EES). Etiologies of early ST in the 3 lesions with CoCr-EES were septal thrombi, bifurcation multistenting, and long/overlapping stenting (stent length=70 mm), respectively. Other etiologies for SES, PES and BMS included medial disruption, necrotic core prolapse, strut malapposition, and stent fracture.

**Conclusions:** CoCr-EES had the lowest prevalence of early ST as compared to SES, PES, and BMS in human autopsy cases, and significant difference was identified between CoCr-EES and BMS (ML-VISION).

**Table. Clinical and pathologic characteristics and prevalence of early stent thrombosis in CoCr-EES versus SES, PES, and BMS (ML-VISION)**

	CoCr-EES (n=17)	SES (n=30)	PES (n=39)	ML VISION (n=16)	p value: CoCr-EES vs.		
					SES	PES	BMS
Duration of implant (days)	7 (1.5 - 11)	5 (1 - 7)	5 (3-7)	13 (1.3 - 20)	0.25	0.58	0.37
ACS as an indication for stenting	24%	50%	44%	38%	0.08	0.15	0.38
Stent length (mm)	27 (16 - 52)	21 (18 - 35)	22 (16 - 32)	23 (14 - 41)	0.39	0.34	0.41
Bifurcation multistenting	29%	20%	18%	6%	0.46	0.34	0.08
Number of stents per lesion	2.2 $\pm$ 1.8	1.4 $\pm$ 0.6	1.6 $\pm$ 0.8	1.5 $\pm$ 0.6	<u>0.02</u>	0.07	0.14
Incomplete stent apposition	12%	10%	15%	13%	0.85	0.72	0.95
Medial disruption	47%	67%	56%	53%	0.19	0.52	0.72
Prevalence of early ST	18%	43%	36%	56%	0.07	0.17	<u>0.02</u>

Values are expressed as mean  $\pm$  SD, median (interquartile range), or prevalence (%).

#### TCT-475

##### Is the Prevalence of Stent Fracture in MULTI-LINK VISION Everolimus-Eluting Stents Different from Bare Metal MULTI-LINK VISION Stents?

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**Background:** Stent fracture is associated with adverse cardiac events including thrombosis and restenosis where the underlying mechanisms of stent fracture have been considered to be multifactorial. It remains unknown whether drug-eluting and bare metal stents with similar platform exhibit difference in the prevalence of stent fracture in humans.

**Methods:** A total of 117 stented coronary lesions (70 cobalt chromium everolimus-eluting stents [CoCr-EES] and 47 bare metal MULTI-LINK VISION® stents [ML VISION, Abbott Vascular, Santa Clara, CA]) from 83 autopsy cases with matched duration of implant ( $\leq 3$  years; median=180 days) were analyzed. Of these, 18 (15%) had different type of stents in the same lesion (9 [13%] in CoCr-EES and 9 [19%] in ML VISION). Stented arteries were removed from the heart and high contrast radiography was performed to determine the presence and degree of stent fracture, followed by histologic assessment for patency, thrombosis and restenosis.

**Results:** There were no significant differences in clinical indications, duration of implant, prevalence of overlapping stents, and number of stent per lesion between the groups, while stent length limited for each stent type was longer in CoCr-EES as compared to ML VISION (Table). Stent fracture was identified in 8 of 70 lesions with CoCr-EES (11%), which did not differ from ML VISION (4 of 47 lesions [8.5%],  $p=0.61$ ). The prevalence of grade V fracture (acquired transection with gap in the stent body) was also comparable between CoCr-EES (1.4%) and ML VISION (2.1%,  $p=0.77$ ). Moreover, fracture-related adverse events did not differ between the groups (CoCr-EES=3 restenosis [4.3%] vs. ML VISION=1 restenosis [2.1%],  $p=0.53$ ).

**Conclusions:** The current pathologic study with high contrast radiography assessment showed similar prevalence of stent fracture in CoCr-EES and ML VISION in humans.

**Table. Clinical characteristics and prevalence of stent fracture in CoCr-EES versus ML VISION**

	CoCr-EES (n=70)	ML VISION (n=47)	p value
ACS as an indication for stenting	33 (47%)	14 (30%)	0.06
Duration of implant (days)	174 (30 - 360)	210 (14 - 540)	0.38
Stent length (mm): Only CoCr-EES or ML VISION	21 (15 - 29)	18 (12 - 24)	<u>0.045</u>
Stent length (mm): Including different type of stents	23 (15 - 38)	20 (12 - 35)	0.25
Overlapping stents: Only CoCr-EES or ML VISION	21 (30%)	10 (21%)	0.29
Overlapping stents: Including different type of stents	29 (41%)	17 (36%)	0.57
Number of stent (CoCr-EES or ML VISION) per lesion	1.5 $\pm$ 1.1	1.3 $\pm$ 0.6	0.12
Prevalence of stent fracture (all)	8 (11%)	4 (8.5%)	0.61
Grade I fracture	3 (4.3%)	2 (4.3%)	0.99
Grade II fracture	1 (1.4%)	1 (2.1%)	0.77
Grade III fracture	3 (4.3%)	0	0.15
Grade IV fracture	0	0	-
Grade V fracture	1 (1.4%)	1 (2.1%)	0.77
Fracture-related adverse events	3 restenosis (4.3%)	1 restenosis (2.1%)	0.53

Values are expressed as mean  $\pm$  SD, median (interquartile range), or n (%).

#### TCT-476

##### Angiographic and clinical analysis of 164 cases of longitudinal stent deformation: comparison of cases from a multicentre case series with cases identified from the MAUDE database

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**Background:** A dramatic increase in reports of longitudinal stent deformation (LSD) in the MAUDE database has recently been described. However, as a complications database these reports may not be representative of typical cases - possibly involving

the more extreme cases. Published reports of LSD have been small single centre series. We therefore sought to collect a large series of LSD cases from multiple centres to compare to the cases reported in the MAUDE database.

**Methods:** Two experienced interventional cardiologists analysed angiographic images and case histories of 59 LSD cases from 6 high volume European Centres (multicentre case series MCCS). These cases were compared to the 105 individual reports of cases identified from the MAUDE database (MAUDE series). The analysis included mechanism and location of LSD, stent type, and clinical outcome. Mechanism of LSD was divided into guide catheter induced LSD, and secondary device induced LSD.

**Results:** In both series, LSD occurred infrequently with circumflex interventions (7%), 2.25mm diameter stents (6%) and < 10mm length stents (3%). Lesion calcification (35% cases) and tortuosity (30% cases) were common. LSD occurred at the proximal edge alone in >80% cases. Guide catheter induced LSD was less common in the MAUDE series (17%) than the MCCS (62%,  $p<0.001$ ). Element-type stents were involved in guide catheter induced LSD in 75% cases and secondary device LSD in 82% cases. Major complications occurred more frequently in the MAUDE series (13%) than the MCCS (2%,  $p=0.04$ ), and were more frequent (33% MCCS, 67% MAUDE) if the LSD was untreated than if re-ballooning/stenting was performed (0% MCCS, 6% MAUDE;  $p<0.0001$ ).

**Conclusions:** LSD usually occurred at the proximal end of the stent, was associated with complex disease and occurred infrequently with small stents and circumflex interventions. The Element-type platform was the commonest stent involved in both guide catheter and secondary device LSD. In the MAUDE series guide catheter LSD was under-represented and cases involving major complications were over-represented. Major complications including stent thrombosis, emergency CABG and death were much commoner if the stent was not / could not be re-expanded.

#### TCT-477

##### Clinical characteristics, procedural and clinical outcome of patients treated with PCI for definitive stent thrombosis: a 12 years single centre experience

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**Background:** There are limited data on treatment and long-term clinical outcome after definitive (angiographically confirmed) stent thrombosis (ST).

**Methods:** Retrospective analysis of baseline characteristics and procedural and clinical outcomes in patients with angiographically confirmed ST (ARC classification) from a cohort of 8069 consecutive unselected patients treated by PCI in a single centre (June 2000-December 2012).

**Results:** One hundred thirty consecutive patients with definite ST were included in the analysis (1.6%). a) Main baseline characteristics: male sex 82.3%; age  $63\pm 13$ ; diabetes 38.5%; previous renal failure 23.1%; previous AMI 69.2%; peripheral arterial disease (PAD) 16.6%. Clinical presentation was ST-segment elevation myocardial infarction in 68% and cardiogenic shock in 13%. Mean time from stent implantation to ST was  $636\pm 1168$  days. According to ARC classification, 14.6% were acute; 35.4% subacute; 14.6% late and 35.4% very late. Previous implanted stent was DES in 39.2%. b) Main procedural characteristics: IIB/IIIa inhibitors were used in 66.2%; IVUS guidance in 44.6%; manual thrombectomy in 70.8%; new stent implantation in 74.6%. c) Main clinical outcomes: in-hospital mortality was 9.2% and one-year mortality was 12.3%. Two patients (1.5%) experienced recurrent ST on follow-up. Type of previously implanted stent (DES or BMS), time of ST (acute, subacute, late or very late), vessel treated and DES implantation for ST treatment were not related to mortality on follow-up. Independent predictors for one-year mortality were age, PAD, cardiogenic shock on admission and multivessel disease.

**Conclusions:** In a cohort of real-life consecutive patients, PCI for ST was relatively infrequent. Patients presenting with ST had high comorbidity levels. Up to one third of patients had very late ST. Nearly half of the PCI were IVUS-guided. One-year mortality and recurrent ST on follow-up was lower than previously reported; this may be explained by the high rate of IVUS-guided PCI.

#### TCT-478

##### Effect of different drug-eluting stent design on in-stent restenosis and stent thrombosis

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**Background:** Endeavor Resolute drug-eluting stent (ER-DES) has been used worldwide in many cath labs as standard DES during the last years. FDA used recently approved Resolute Integrity stent (RI-DES) which is based on different stent

platform. There is little clinical data in regard to safety and efficacy outcomes between these two stents after a direct comparison in unselected patients. Our aim was to compare ER-DES with RI-DES stent in regard to occurrence of in-stent restenosis and stent thrombosis in unselected consecutive patients.

**Methods:** Information was obtained from the SCAAR registry (Swedish Coronary Angiography and Angioplasty Registry) for the procedures performed in Västra Götaland County in Western Sweden. The database contains information about all consecutive procedures performed at five PCI centers with approximately 3000 PCI/year. ER-DES was used from 2008 with complete switch in the whole region to RI-DES in 2011. All procedures performed between 2008-2013 for stable angina, unstable angina, non-STEMI and STEMI were included in the analysis. The two stents were compared using propensity score-adjusted multilevel Cox proportional-hazards regression with stents as primary observation units. The following confounders were included in the calculation of propensity score: age, gender, indication for PCI, smoking habits, hypertension, diabetes, hyperlipidaemia, stent diameter, stent length, stenosis class and procedural success.

**Results:** Between 2008 and 2013, 614 ER-DES and 1858 RI-DES were implanted to 929 patients in 1327 procedures. There were 49 events in total of which 24 cases were in-stent restenosis and 25 cases were stent thrombosis. The use of RI-DES was associated with decreased risk for in-stent restenosis/stent thrombosis at one-year (HR 0.42; 95% CI 0.21 – 0.86;  $P=0.017$ ).

**Conclusions:** In this registry study RI-DES shows a lower frequency of in-stent restenosis and stent thrombosis compared to ER-DES. Improvement in DES stent design may provide substantial clinical benefit to the patients undergoing PCI. "Real world" registries are an important tool in continuous evaluation of new devices and interventions and for support in decision-making within health-care systems.

#### TCT-479

##### Impact of Angiographic Patterns (Focal vs. Diffuse) of Resistant In-stent Restenosis on Clinical Outcomes

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**Background:** Drug-eluting stents (DES) reduced restenosis. Though rare, in-stent restenosis (ISR) followed by a new ISR (resistant ISR, R-ISR) represents a challenging PCI complication. Whether angiographic patterns of R-ISR are indicative of clinical outcomes is unknown.

**Methods:** Resistant ISR (R-ISR) was defined as the 2nd episode of ISR after treatment of the 1st ISR. We reviewed 201 consecutive patients with DES presenting with R-ISR from 2003 to 2011. Angiograms were reviewed by a core lab for patterns of the 1st and 2nd ISR based on Mehran classification. We examined 1-year death, MI, revasc (TVR and TVF), and major adverse cardiac events (MACE).

**Results:** In 201 patients, 77% had focal and 23% diffuse R-ISR. Focal intrastent (IC) and diffuse intrastent (II) were prevalent patterns of focal and diffuse R-ISR (50% and 42% respectively). Groups were balanced with similar demography and angiography. Within groups original implanted stents were SES (44% vs 56%), PES (32% vs 22%), ZES (0% vs 8.5%), and EES (23% vs 14%) respectively. At 1 year, mortality was higher in diffuse R-ISR patients (9% vs 4.5%,  $p=0.06$ ), but MACE was comparable between groups (25% vs 29%,  $p=0.59$ , Figure 1). Correlates of revasc were R-ISR within 1-year of the index procedure (HR: 1.8, 95% CI 0.99-3.3,  $P=0.05$ ) and female sex (1.62 0.97-2.71,  $P=0.06$ ).

**Conclusions:** Resistant ISR is a rare complication of PCI even with newer DES. Though MI, TVR/TVF, and MACE did not differ significantly, those with diffuse R-ISR patterns had 2-fold the mortality rate than those with focal R-ISR. In the DES era, diffuse R-ISR still results in worse clinical outcomes.

