Results: Population consisted of 78% of males, mean age: 66 yrs ± 11 yrs. Indications were 55.9 % stable angina or silent ischemia and 33.1% ACS. Risk factors were well balanced between the 2 populations: hypertension (68.0% P vs. 68.6% X), hypercholesterolemia (63.0% P vs. 63.4% X), diabetes (30.1% P vs. 28.1% X), insulin-treated diabetes (7.8% P vs. 7.1% X), current smoking (22.0% P vs. 20.9% X). Mean number of stents implanted per patient was 1.7 ±1.1. Procedural success was very high in both groups: 97.6% in recipients of PROMUS Element™ stents and 97.8 % for XIENCE PRIME™. At 30 days, clinical events were TVF 1.2% in P vs. 0.8% in X (p=0.56) including all death 0.6% in P vs.0.5% in X (p=0.99), MI 0.7% in P vs. 0.5% in X (p=0.74) and TVR 0.1 % in P vs. 0.1 in X (p=0.85), Stent Thrombosis (definite and probable) was 0.6% in P vs. 0.2% in X (p=0.21).
Conclusions: Non inferiority in 30-day outcome was observed between the 2 stents; the primary endpoint (12-month outcome) will be available for the meeting.

TCT-16

Incidence, mechanisms and outcome of longitudinal stent deformation (LSD) associated with Element, Resolute, Biomatrix and Xience stents: angiographic and case-by-case review of 1,800 cases.

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Background: The incidence of LSD is unknown. The aims of this study were to estimate the incidence of LSD associated with 4 commonly used DES platforms; to compare the mechanism of LSD across platforms; to estimate the incidence of major complications and assess angiographic procedural factors associated with LSD.
Methods: Angiographic and case details for 1,800 PCI cases were examined individually by a panel 3 experienced interventional cardiologists. This cohort included 450 consecutive PCI procedures associated with the use of Promus Element, Xience V, Biomatrix Flex and Resolute Integrity stents respectively. We classified cases as: no LSD, LSD, and stent not visible. Cases of LSD were classified according to mechanism (guide catheter or secondary device related). Treatment, subsequent clinical outcome and cases in which re-entry of the stent following LSD was difficult were recorded.
Results: LSD was detected in a higher proportion with the Promus Element (3.1%) compared to other platforms (Xience V 0.9%, Biomatrix 0.7%, Resolute 0.7%; p=0.002). Guide catheter related LSD occurred equally in all 4 platforms; Promus Element 1.1%, Xience V 0.9%, Biomatrix 0.7%, Resolute 0.7%; p=0.85. However, 9/24 cases were caused by a secondary device, all of which occurred in the Promus Element stent (p<0.0001). Stent thrombosis occurred in 1 of the 3 cases in which LSD was not identified at the time of procedure. Difficulty re-entering the deformed stent was encountered in 6 cases, all of which were in cases of secondary device impact on Promus Element stents. Univariate predictors of LSD were previous CABG, culprit vessel, ostial involvement and lesion tortuosity. Multivariate predictors of LSD were the Promus Element stent, Guideliner use, post-dilation balloons and number of stents deployed.
Conclusions: LSD is more common than previously reported.LSD in ostial lesions caused by guide catheter or guide catheter extension occurred equally with all platforms. LSD associated with secondary devices only occurred with the Element stent, complicating >3% of procedures where it was frequently associated with difficulty re-entering the deformed stent. However, no sequelae were detected when LSD was recognised and treated.

TCT-17

Current Perspectives On Stent Fractures: Trends, Characteristics And Outcomes From The Food And Drug Administration Manufacturer And User Facility Device Experience Database

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Background: Stent fracture (SF) is associated with restenosis and thrombosis. The contemporary incidence and clinical implications of SF remain uncertain in view of newer drug-eluting stents (DES). The FDA Manufacturer and User Facility Experience Database (MAUDE) is an electronic system that aims to capture voluntarily reported device-related safety issues.
Methods: The MAUDE database was searched from January 2008 through March 2013 for "stent fractures" and "coronary fractures". Data were extracted with respect to types of DES, lesion characteristics, presence of overlapping DES, time from index procedure to SF presentation, clinical presentation of SF, treatments and outcomes of SF.
Results: A total of 126 patients were identified with coronary SF. The median time from index procedure, when available, to SF was 17 months [IQR 6-33]. The majority of patients with SF presented with chest pains and 15.1% had documented acute coronary syndrome. Most of the SF occurred in lesions with at least moderate tortuosity (66%) and calcifications (70%). More than half (57.1%) of the reported SF involved overlapping stents. The observed SF was 41.3% in the LAD, 40.5% in the RCA, 9% in the LCX and 4% in the vein grafts. There were 29 overlapping stents in the left anterior descending (LAD) artery (26.9%), 25 in RCA (23.2%) and 4 in LCX (3.7%), respectively. SF was reported more frequently with Cypher (61.1%), followed by Xience (16.7%), Promus (9.5%), Endeavor (5.6%), Taxus (4.8%) and BMS (2.4%). Almost half of reported SF were treated with another DES (54%), 15% had balloon angioplasty only, 7% underwent CABG, 5% had bare metal stent and another 5% with medical therapy.
Conclusions: Throughout the DES platform evolution, there are continued SF reported. However, Cypher remained the most commonly reported SF in the MAUDE database. In accordance with previous reports, Cypher, LAD, RCA, moderate tortuosity and calcifications, and overlapping stents were a recurrent observation seen with SF.

TCT-18

Clinical and Procedural Predictors and Consequences of Stent Thrombosis Following Drug-eluting Stents for Acute Coronary Syndromes: Results From the ADAPT-DES Study

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Background: Stent thrombosis (ST) remains a major concern in patients with acute coronary syndromes (ACS) treated with drug-eluting stents (DES).
Methods: ADAPT-DES was a multicenter prospective study evaluating outcomes in 8,583 patients treated with DES, aspirin, and clopidogrel, and evaluated with platelet reactivity testing. The frequency and consequences of 1-year ST (definite/probable) were evaluated in the subset of 4,436 patients with ACS (STEMI [n=813], NSTEMI [n=1,250], unstable angina [UA; n=2,373]).
Results: ST within 1 year occurred in 50 patients (1.1%) and was associated with high 1-year rates of mortality (30.4%) and myocardial infarction (82.6%). ST occurred more frequently in patients with PAD (2.3% vs 1.0%, p=0.026), hypertension (1.4% vs 0.4%, p=0.008), STEMI vs NSTEMI/UA (1.9% vs 1.0%, p=0.033), ejection fraction ≤40% (2.4% vs 1.0%, p=0.005), no intravascular ultrasound (IVUS)-guidance (1.4% vs 0.8%, p=0.049), stent size ≤3.0 mm (1.5% vs 0.8%, p=0.049), early versus later generation DES (1.5% vs 0.9%, p=0.043), high platelet reactivity post clopidogrel (PRU >208) (1.8% vs 0.6%, p<0.001), and premature dual antiplatelet therapy (DAPT) discontinuation (4.6% vs 1.0%, p=0.008). Independent predictors of ST by Cox regression are shown in the Table.