Algorithm for device choice using the perimeter and area derived diameters

| Watchman size (mm) | Area (mm2) | Area derived diameter (mm) | Perimeter (mm) | Perimeter derived diameter (mm) |
|---|---|---|---|---|
| **21** | 170-252 | 15 - 18 | 45 - 56 | 15 - 18 |
| **24** | 221-327 | 17 - 20 | 53 - 64 | 17 - 20 |
| **27** | 281-416 | 19 - 23 | 59 - 72 | 19 - 23 |
| **30** | 346-511 | 21 - 26 | 66 - 80 | 21 - 25 |
| **33** | 419-620 | 23 - 28 | 73 - 88 | 24 - 28 |

**CATEGORIES STRUCTURAL:** Left Atrial Appendage Exclusion

**KEYWORDS** Echocardiography transesophageal, 3-dimensional, Left atrial appendage closure

## TCT-57

### A Cost Analysis of Bleed Complications from Two Stroke Prevention Strategies in Non-valvular Atrial Fibrillation: Left Atrial Appendage Closure versus Warfarin

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**BACKGROUND** Warfarin is commonly used for stroke risk reduction in atrial fibrillation (AF). While effective at reducing the risk of ischemic stroke, it increases the risk of bleeding. Left atrial appendage closure (LAAC) provides embolic protection and enables most patients to discontinue lifelong oral anticoagulation (OAC). This analysis sought to quantify the cost to the US Centers for Medicare & Medicaid Services (CMS) of bleed-related complications with warfarin compared to LAAC with the WATCHMAN.

**METHODS** A Markov model was developed to assess cost of bleeding complications with LAAC versus warfarin from a CMS perspective over a 20-year time horizon. Probabilities for major bleeding events were determined from a pooled analysis of the PROTECT AF and PREVAIL trials. For costing purposes, LAAC patients were assumed to adhere to the OAC regimen in these study protocols. According to published data, bleeding history and age were modeled to increase bleeding risk. Bleed-related mortality risk was obtained from 2012 US HCUP data. Costs of bleeds included direct costs due to in-patient care as well as long-term disability costs. Cost data were taken from the literature and 2015 US DRGs/CPTs.

**RESULTS** The procedural-related bleeding event rate with LAAC was 4.9%, with an average cost to CMS of $176 per patient. Modeled post-procedural bleed event rates were 5.1% for LAAC compared to 11.5% for warfarin. Hemorrhagic stroke accounted for 18% and 24% of these bleed events for LAAC and warfarin, respectively. At 20 years, direct costs for non-procedural bleeds were $3,111 per LAAC patient and $9,244 per warfarin patient. On average, long-term disability costs accounted for an additional $3,440 per LAAC patient and $10,502 per warfarin patient. Total bleeding costs were $13,195 greater with warfarin than LAAC.

**CONCLUSIONS** This analysis suggests that among AF patients at risk for stroke, bleeding-related costs to CMS are nearly 3 times greater with chronic warfarin compared to LAAC with WATCHMAN. This should be considered when assessing the overall cost benefit for non-pharmacological, stroke risk reduction therapies in AF.

**CATEGORIES ENDOVASCULAR:** Stroke and Stroke Prevention

**KEYWORDS** Atrial appendage closure, Atrial fibrillation, Stroke

## TCT-58

### Immediate and long-term outcomes of ischemic versus non-ischemic functional mitral regurgitation in patients treated with MitraClip: insights from the 2011-12 Pilot European Sentinel Registry of Percutaneous Edge-to-Edge Mitral Valve Repair

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**BACKGROUND** Outcome data comparing ischemic functional mitral regurgitation (I-FMR) versus non-ischemic FMR (NI-FMR) following percutaneous repair are not currently available in the literature. We aimed to describe the early and 12-month results following MitraClip device implantation regarding the two etiologies.

**METHODS** Between January 2011 December 2012 the Transcatheter Valve Treatment Sentinel Pilot Registry included 452 patients with FMR who underwent MitraClip procedure in 25 centers of 8 European countries.

**RESULTS** The prevalent etiology was I-FMR (235 patients, 52.0%). I-FMR group had a significant higher proportion of men (74.9 vs 59.9%, $p<0.001$) and surgical risk (logistic EuroScore 24.8±18.2 vs 18.8±16.3, $p<0.001$). Acute procedural success was high (95.8%) and similar between groups ($p=0.48$). Patients with I-FMR required a higher, albeit not significant, number of clips to reduce MR ($p=0.08$). In-hospital mortality was low (2.0%) without significant differences between etiologies. Both I-FMR and NI-FMR showed a significant post-clip improvement in NYHA functional class with the majority of patients exhibiting a NYHA class<II (82.6 and 74.2%, respectively). EuroSCORE, an impaired ejection fraction (i.e. <30%), pre-procedural chronic kidney disease and the inability to reduce the mitral regurgitation represented the most important factors affecting both survival and re-hospitalization in FMR patients. Estimated overall 1-year mortality and re-hospitalization rates were 15.0 and 25.8% respectively, However, even though no significant differences in terms of long-term outcomes were demonstrated, the survival curve showed a trend toward a gradual decline in the I-FMR group versus a stabilization in the NI-FMR group after 6 months. Paired echocardiographic data, available for 264 consecutive patients, showed a persistent improvement of MR at 1 year in bothI-FMR and NI-FMR (6.6 and 5.4% of the patients with severe MR, respectively). Despite a significant overall reverse atrial remodeling after clip, suggestive for an effective correction of the volume overload, no significate changes in left ventricular volumes have been demonstrated. However, although both etiologies, showed a significant acute decrease in pulmonary pressure, only the I-FMR group demonstrated a concomitant significant acute decrement in atrial volume (ΔLAV 13.6 ml, $p=0.016$), while at the 1-year follow-up a significate reduction was detected in both groups.

**CONCLUSIONS** This independent large cohort showed that percutaneous "edge-to-edge" therapy is associated with early and long-term improvement of MR severity and functional status both in I-FMR and NI-FMR groups. However some, albeit not significant, differences detectable both in the echocardiographic patterns and long-term outcomes, suggest the possibility that the benefit of Mitraclip differ depending on the etiologies of mitral regurgitation prompting the need for further large controlled studies investigating the underlying pathogenetic mechanisms of FMR.

**CATEGORIES STRUCTURAL:** Valvular Disease: Mitral

**KEYWORDS** Mitraclip, Mitral regurgitation therapy, Mitral regurgitation, functional

# PCI OUTCOMES + DES

**Tuesday, October, 13, 2015, 2:00 PM-4:00 PM**

**Abstract nos: 59 - 66**

## TCT-59

### The Impact of Timing of Ischemic and Hemorrhagic Events on Mortality after DES: The ADAPT-DES study

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**BACKGROUND** Both ischemic and hemorrhagic events after percutaneous coronary intervention (PCI) with drug-eluting stents (DES) contribute to risk of subsequent death. Yet, the impact of the timing of these events on subsequent mortality is less well understood.

**METHODS** ADAPT-DES was a large, prospective, multicenter registry designed to identify the predictors of stent thrombosis. Patients with successful PCI had assessment of platelet function and were followed for 2 years. Events occurring after PCI - definite or probable stent thrombosis (ST), myocardial infarction (MI) not related to ST, and major bleeding (MB) were classified as early (≤30 days), late (31-365 days) or very late (>365 days). Death within 12 months of the events was analyzed by Kaplan-Meier techniques and a Cox regression multivariable model was constructed to analyze the relationship between each event - as a time-updated variable and mortality.

**RESULTS** Among 8,582 patients, 294 had MI not related to ST (3.4%), 75 had ST (0.9%), 691 had MB (8.1%) and 7,522 had no event (87.6%) during follow-up. Subsequent death within 2 years occurred in 12.4% 27.2%, 10.5%, and 2.7% of these patients respectively, P<0.0001. The independent predictors of death were: increasing age, male sex, insulin-requiring diabetes mellitus, MI before index PCI (>7 days), chronic kidney disease, cigarette smoking, higher white blood cell count, lower hemoglobin and lack of dual antiplatelet therapy (time-adjusted). The time-adjusted relationship between these events (corrected for the other events) and subsequent death, according to the time of their occurrence, appears in the Table (reference population is the group of patients without a particular event in the specified time frame). High-platelet reactivity (HPR) and presentation with acute coronary syndrome at index PCI were not independent predictors of death, but HPR was highly predictive of ST (P=0.001), MI (P=0.0006) and MB (P=0.002).

**CONCLUSIONS** In an all-comers patient population treated with DES, MI, ST and MB within 2 years are not uncommon (~1 in 8 patients). Early ST and early MI increased substantially the risk of death, while MB had a less pronounced effect, emphasizing the importance of improved devices, drugs and technique to prevent their occurrence.

| Event type | HR [95%CI] for death after event occurrence according to event timing | | | |
|---|---|---|---|---|
| | Any time | ≤30 days | 31 - 365 days | >365 days |
| ST | 12.03 [8.05, 17.97] | 569.60 [197.36, 1643.89] | 8.33 [4.12, 16.83] | 5.41 [2.39, 12.26] |
| MI (no-ST) | 2.00 [1.35, 2.94] | 12.65 [1.47, 108.93] | 2.51 [1.37, 4.60] | 3.22 [1.96, 5.28] |
| MB | 2.23 [1.71, 2.92] | 2.80 [0.90, 8.68] | 5.41 [3.75, 7.81] | 2.82 [1.91, 4.17] |

**CATEGORIES CORONARY:** PCI Outcomes

**KEYWORDS** Bleeding, Myocardial infarction, Stent thrombosis

## TCT-60

### Long Coronary Lesions Treated With Bioresorbable Polymer Drug Eluting Stent: Experience From eNOBORI Registry

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**BACKGROUND** Long coronary lesions have been associated with worse clinical outcomes. Our aim was to assess one-year clinical outcomes in real-world patients with different length of lesions after implantation of bioresorbable polymer drug eluting stent (DES).

**METHODS** We analyzed data of unselected patients who received Nobori® Biolimus A9 eluting stent within the large, prospective, single-arm, multicentre e-NOBORI registry. The primary endpoint was target lesion failure (TLF) defined as composite of cardiac death, target vessel related myocardial infarction (MI) and clinically driven target lesion revascularization at 1-year. An independent clinical events committee adjudicated all endpoint related adverse events.

**RESULTS** A total of 11919 patients were included in the analysis, of which 44.1%, 38.2%, 13.1% and 4.6% had stent lesion ≤ 20mm, 20-40mm, 40-60mm and >60mm, respectively. The mean age did not differ across four subgroups. There were more male patients with increased lesion length across groups (Table). The proportion of diabetic patients (33.2 %, 31.4%, 32.5%, 36.8%, P=0.036), hypertensive patients (71.0%, 70.5%, 73.3%, and 75.7, p=0.021) and current smokers (26.7%, 27.6%, 26.4% and 21.6%, P=0.038) were also different across subgroups. Other basic characteristics such as previous MI and pervious stroke did not differ (p≥0.21). LAD was the most frequent (45.2%) target vessel in stent lesion ≤ 20 mm group, while RCA was the most frequent (41.1%) target vessel in stent lesion > 60mm group. Complex lesion type (B2+C) were 45.4%, 59.6%, 62.6% and 65.7% across the groups. Total number of lesions treated per patient were 1.7±1.6, 2.0±1.3, 2.6±1.4 and 3.5±1.9 respectively (P<0.01). Number of stents per lesion were 1.1±0.3, 1.2±0.4, 1.3±0.5 and 1.5±0.8 (p<0.01) respectively. There were no differences in diameter stenosis at baseline (on average 84.8%, p=0.60) while after procedure they were 2.8%, 2.9%, 1.9% and 2.6% (P<0.01) respectively. At 1 year, there was no difference (P>0.35) in the rate of any death, cardiac death, and MI (Table). Composite endpoints TLF was slightly higher in long lesion subgroups (2.9%, 3.4%, 4.7% and 4.2% respectively, p=0.005). The rate of stent thrombosis was low and comparable across 4 subgroups (0.38%, 0.55%, 0.77% and 0.18%, p=0.16).

| | Stented lesion ≤ 20 mm | Stented lesion 20-40 mm | Stented lesion 40-60 mm | Stented lesion > 60 mm | P-value |
|---|---|---|---|---|---|
| Nr of patients | 5252 | 4558 | 1565 | 544 | |
| Basic characteristics | | | | | |
| Age, years | 63.6±12.1 | 63.1±11.9 | 63.0±11.9 | 64.0±11.5 | 0.07 |
| Male gender, % | 74.4 | 77.6 | 78.9 | 82.0 | <0.001 |
| Total stent lengths, mm | 15.4±2.9 | 27.6±4.3 | 48.4±5.7 | 82.0±18.7 | <0.001 |
| DAPT at baseline, % | 72.3 | 73.5 | 74.6 | 73.4 | 0.26 |
| 1-year outcome | | | | | |
| All death, % | 1.56% | 1.65% | 1.98% | 2.02% | 0.63 |
| Cardiac death, % | 0.97% | 1.10% | 1.34% | 1.29% | 0.61 |
| MI, % | 1.43% | 1.58% | 2.05% | 1.29% | 0.35 |
| CD-TLR, % | 1.26% | 1.27% | 2.30% | 1.65% | 0.01 |
| TVF, % | 3.66% | 3.73% | 5.50% | 5.33% | 0.003 |

**CONCLUSIONS** In a real-life practice registry, patients with long lesions showed favorable and similar clinical outcomes when treated with Nobori Biolimus A9 eluting stent. Although we cannot completely exclude the possibility of underreporting of events, especially of periprocedural MIs, the comparable and very low rate of stent thrombosis across different lesion length groups up to 1 year is encouraging.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**KEYWORDS** Bioabsorbable polymer, Drug-eluting stent, Long lesion

## TCT-61

### Non-invasive discrimination of coronary chronic total occlusion and subtotal occlusion by coronary computed tomography angiography

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**BACKGROUND** We investigated whether non-invasive discrimination of chronic total occlusion (CTO), a complete interruption of coronary artery flow, and subtotal occlusion (STO), a functional total occlusion, is feasible using coronary computed tomography angiography (CTA). CTO and STO may be different in pathophysiology and clinical treatment strategy.

**METHODS** We included 486 consecutive patients (median age 63 years, male gender 82%) who showed a total of 553 completely occluded coronary arteries in coronary CTA. The length of occlusion, side branches, the shape of proximal stump, and collateral vessels were measured as anatomical findings. Transluminal attenuation gradient (TAG), which reflects intraluminal contrast kinetics and functional extent of collateral flow, was measured as a physiological surrogate. All patients were followed by invasive coronary angiography (CAG).

**RESULTS** Coronary arteries with CTO showed longer occlusion length (cutoff ≥15 mm), higher TAG distal (cutoff ≥ -0.9 HU/10mm), more frequent side branches, blunted stump, cross-sectional