cause serious long-term complications. It has been proposed that the bioabsorbable polymer may reduce such late-stage adverse
effects. The purpose of this registry was to evaluate clinical outcomes of an ultra-thin (60μm) biodegradable polymer-coated sirolimus-eluting Supraflex (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) stent for the treatment of coronary artery disease across a wide range of unsel ected patients treated in routine clinical practice, including those with high-risk characteristics and complex lesions.

METHODS The FLEX-Registry was a retrospective, multicenter, all-comers, observational registry of patients implanted with the Supraflex sirolimus-eluting stent (SES). A total of 995 patients with 1,184 lesions were included, spread from 9 different tertiary care centers in India between July-2013 to May-2014. Patients were included if their index procedures were completed using only the Supraflex SES. The primary endpoint was 9-month major adverse cardiac events (MACE, defined as the composite of cardiac death, myocardial infarction [MI], target lesion revascularization [TLR], and target vessel revascularization [TVR]). We also evaluated stent thrombosis rate through 9-month; as defined by the Academic Research Consortium (ARC) criteria.

RESULTS The FLEX-Registry evaluated clinical outcomes in high risk patients, including 441 (44.3%) hypertensive patients, 231 (23.2%) diabetic patients, 775 (65.5%) type B2/C lesions, and 185 (15.6%) totally occluded lesions. The average number of stents per patient was 1.41±0.56; and mean stent length was 26.6±9.3 mm. Clinical follow-up at 9-month was completed in 99.1% of patients (986/995). MACE rates at in-hospital, 30-day and 6-month were 0.4% (4/995), 1.1% (11/995) and 2.2% (22/986). At 9-month, the primary endpoint occurred in 26 (2.6%) of 986 patients, consisting of 1.1% (11/995) cardiac deaths, 16.1% (6/37) MI, and 6.0% (60) TLR. Cumulative MACE-free survival at the 9-month clinical follow-up determined by Kaplan-Meier method was 97.4%. According to the ARC definition, definite and probable stent thrombosis occurred in 1.1% (10/986) patients, until the 9-month follow up.

CONCLUSIONS The FLEX-Registry evaluated clinical outcomes in real-world and more complex cohorts and thereby provides evidence to the clinicians for safe and routine extended use of Supraflex SES to a broader percutaneous coronary intervention population.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Biodegradable polymer, Coronary artery disease, Sirolimus-eluting stent

TCT-484 Impact of Left Main Percutaneous Coronary Intervention Operator’s Experience and Volume on Outcomes after Left Main Percutaneous Coronary Intervention (PCI): Insight from a Cohort of 1,948 Patients

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BACKGROUND The impact of operator experience and volume of left main (LM) percutaneous coronary intervention (PCI) performed yearly on outcomes after LM PCI is unknown. To characterize the impact of LM-PCI operator’s experience and volume on the occurrence of adverse events after LM-PCI.

METHODS High volume LM-PCI operators were defined as performing at least 15 LM PCI cases per year, for at least 3 consecutive years. Thirty day and 5-year outcomes were reported and compared between high-volume and low-volume operators.

RESULTS From January 2004 to December 2011, 25 operators performed 1,948 LM-PCI in a single center. Among them, 7 were considered high-volume and performed 1,422 (73%) LM-PCI and 18 operators were considered low-volume and performed 526 (27%) procedures. The number of LM-PCI performed by each operator was 25±18 and 4±3 in the high-volume and low-volume group, respectively. Patients treated within the high-volume operator group were in general more complex, with higher SYNTAX score, higher SYNTAX score II, more often 3-vessel disease, and with more frequently LM lesions involving the distal segment (bifurcation) requiring two stents implantation. Intravascular ultrasound was more often used by the high-volume operators compared to the other group (39.2% vs. 31.7%). Thirty-day outcomes demonstrated significantly lower rates of death and cardiac death, with trend toward lower rate of myocardial infarction and stent thrombosis (Figure). At 3 years of follow-up, patients treated with high-volume operators showed significantly lower rate of cardiac death (2.5% vs. 4.6%, p=0.02), with no significant difference in rate of ischemia driven target vessel revascularization (6.8% vs. 5.1%, p=0.20) when compared with the low-volume operators. After multivariate analysis, high-volume LM operator patients were associated with freedom of 3-year cardiac death (adjusted HR 1.90 95% CI = [1.10, 3.30] p = 0.02).

CONCLUSIONS Despite treating more complex and higher-risk patients, high-volume operators had better short and long-term prognostic compared with low-volume operators when performing LM-PCI. These findings could be important when considering minimal operator’s volume requirements for the treatment of high-risk lesion subset.

CATEGORIES CORONARY: PCI Outcomes

KEYWORDS Left main coronary artery, Outcomes, Percutaneous coronary intervention

TCT-485 Effect of Gender on Clinical Outcomes in Patients With or Without Myocardial Infarction Undergoing Percutaneous Coronary Intervention: Results from a Large Single Center Registry

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BACKGROUND Women with coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI) are at higher risk of early and late major adverse cardiac events (MACE) compared with male subjects. Moreover, previous studies suggest a differential prognostic impact of clinical presentation between genders. In this study, we sought to investigate the effect of gender according to clinical presentation on clinical outcomes.

METHODS We retrospectively analyzed patients from a large single-center PCI registry treated between January 2009 and December 2013. Study population was categorized according to gender and presence or not of myocardial infarction (MI) at time of PCI. Endpoints of interest were all-cause mortality, MI and cerebrovascular events (CVEs) at 1 year after the index procedure.

RESULTS Out of 15,988 patients included in the present analysis, 10,764 (67%) were males and 5224 (33%) were females. Of them, 1,198 (7%) and 672 (4%) presented with an MI in the male and female group, respectively. In both groups, women were older, more commonly affected by multiple comorbidities but had lower CAD complexity compared with men. A stepwise increase in the rates of mortality, MI and CVE was observed in the transition from male with no MI, to female with MI (Figure 1). Following multivariable adjustment for baseline confounders, women with MI had similar risk of all-cause mortality (HR: 1.02; 95% CI: 0.81–1.28), MI (HR: 1.55; 95% CI: 0.93–2.59) and CVE (HR: 2.44; 95% CI: 0.64–9.36) to that of the male counterpart. The effect of gender across clinical presentation was uniform, without evidence for interaction for the investigated outcomes.
CONCLUSIONS After PCI, most of the risk associated with female gender is attributable to the presence of concomitant clinical comorbidities. The adjusted effect of gender on outcomes was uniform between clinical presentations.

KEYWORDS Acute coronary syndromes, Women

TCT-486
Long-Term Comparison of Percutaneous Coronary Intervention Using Drug-Eluting Stents and Coronary Artery Bypass Grafting for Chronic Total Occlusion Revascularization

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BACKGROUND There is limited information of clinical outcomes after chronic total occlusion (CTO) revascularization by drug-eluting stent (DES) compared to coronary artery bypass grafting (CABG). We performed the long-term (5-year) follow-up of patients who underwent percutaneous coronary intervention (PCI) using DES or CABG for CTO revascularization.

METHODS We identified 883 patients with CTO who underwent PCI using DES (n=484) or CABG (n=399) in Asan Medical Center between January 2005 and May 2010. The primary end point was a major adverse cardiac event (MACE), which was composite of death from any cause, myocardial infarction or target vessel revascularization.

RESULTS After adjustment for difference in baseline characteristics, the 5-year incidence of MACE was similar between two groups (hazard ratio [HR]: 0.80; 95% confidence interval [CI]: 0.51-1.27, p=0.35). In addition, individual component of the primary endpoint, including death (HR: 0.67; 95% CI: 0.40-1.14, p=0.33), myocardial infarction (HR: 0.57; 95% CI: 0.31-2.99, p=0.51), and target vessel revascularization (HR: 1.43; 95% CI: 0.47-4.37, p=0.53) were not significantly different between two groups. However, the risk of new lesion revascularization was significantly higher (HR: 19.79; 95% CI: 2.04-192.37, p=0.01) and risk of cerebrovascular event was lower (HR: 0.12; 95% CI: 0.02-0.7, p=0.02) in the DES group.

Table 1. Adjusted Hazard Ratio for Clinical Outcomes at 5 Year After PCI using DES as Compared With After CABG in the Overall Population

<table>
<thead>
<tr>
<th>Clinical outcomes</th>
<th>Adjusted HR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD</td>
<td>0.80 (0.51-1.27)</td>
<td>0.35</td>
</tr>
<tr>
<td>Death</td>
<td>0.67 (0.40-1.14)</td>
<td>0.14</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0.56 (0.30-1.06)</td>
<td>0.08</td>
</tr>
<tr>
<td>Death or MI</td>
<td>0.70 (0.42-1.15)</td>
<td>0.16</td>
</tr>
<tr>
<td>Repeat Revascularization</td>
<td>1.43 (0.47-4.37)</td>
<td>0.53</td>
</tr>
<tr>
<td>Target Vessel Revascularization</td>
<td>3.41 (0.60-19.33)</td>
<td>0.17</td>
</tr>
<tr>
<td>CTO Vessel Revascularization</td>
<td>19.79 (2.04-192.37)</td>
<td>0.01</td>
</tr>
<tr>
<td>New Lesion Revascularization</td>
<td>0.12 (0.02-0.7)</td>
<td>0.02</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>0.57 (0.22-1.48)</td>
<td>0.24</td>
</tr>
</tbody>
</table>

The composite of death from any cause, myocardial infarction and target vessel revascularization

CONCLUSIONS Patients with CTO, DES treatment, compared with CABG, showed similar rates of mortality and the combined end point of MACE up to 5 years.

KEYWORDS Chronic total occlusion, Coronary artery bypass grafting, Drug-eluting stent

TCT-487
Temporal Associations Between Myocardial Infarction, Major Bleeding and Mortality Risk in ACS Patients Undergoing PCI: Insights from the PROMETHEUS Cohort

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BACKGROUND Dual antiplatelet therapy (DAPT) prevents myocardial infarction (MI), yet increases bleeding complications after percutaneous coronary intervention (PCI). Whether or not the mortality risks after each type of adverse event are comparable, both in magnitude and over time, to one another is unclear.

METHODS We examined associations between MI, bleeding requiring hospitalization (BRH) and one-year mortality in the PROMETHEUS cohort, a multicenter observational study (n=19,914) of acute coronary syndrome (ACS) patients treated with PCI. Hazard ratios for MI and BRH were generated using Cox regression with each adverse event entered as a time-updated covariate.

RESULTS One-year rates of all-cause mortality, MI and BRH were 5.6% (n=963), 5.5% (n=977) and 4.4% (n=776), respectively. Patients with BRH were older, more often female with a higher frequency of renal dysfunction compared to those with MI. In contrast, diabetes mellitus, current smoking and prior PCI were more commonly observed in those with MI. Adjusted HRs for mortality associated with MI and BRH were 2.3 (95% CI 1.9-2.8) and 2.3 (95% CI 1.8-2.8), respectively. Mortality risk was highest up to 30 days after either event, and remained significantly increased, beyond 30 days post event (Figure).