Methods: We used claims data from the Truven Health MarketScan Commercial and Medicare Supplemental Databases to identify adults with incident PCI (index event) from 2008-2011. We excluded patients who had less than 12 months of continuous medical and pharmacy benefits before or after the index procedure; patients were followed for 12 - 24 months after their index PCI. Baseline characteristics were defined in the 12-month pre-index period. Clinical outcomes were defined as an inpatient claim with a principal diagnosis of angina, chest pain, or acute coronary syndrome (ACS); new angina or chest pain were also defined by presence of an outpatient claim with an accompanying stress test or repeat PCI. Repeat PCI was defined as a PCI occurring at least 30 days post-index; PCIs < 30 days post-index were considered staged procedures.

Results: A total of 51,710 patients met the study criteria (mean age 61.8 [SD=11.3], 72.4% male). Of these, 33,197 (64.2%) had 24 months of follow-up. Cumulative incidence of post-index angina or chest pain was 24.8% in the first year and increased to 33.9% by the end of year 2. At two years, 4.1% of patients had undergone an ACS event. Repeat PCI occurred in 10.8% of patients by one year and 15.1% by two years.

Conclusions: Persistent or recurrent angina and chest pain remains a significant clinical challenge. Recurrent events, including angina, chest pain, and repeat-PCI, occurred in approximately one-quarter of patients in the first year post-procedure and increased in the second year of post-procedure follow-up, indicating substantial burden to patients and payers. Strategies that reduce these adverse events are needed.

TCT-103

Gender Impact on Clinical Characteristics and Outcomes In Patients Treated With Drug-Eluting Stents; Data From The IRIS DES registry

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Background: Previous studies have shown gender impact on clinical outcomes in patients presenting with coronary artery disease. However, exact role of gender impact in these studies still have not been fully investigated.

Methods: Gender differences were evaluated in the clinical outcomes of 9,674 patients with coronary artery disease from a large, 55 multicenter, contemporary percutaneous coronary intervention (PCI) registry enrolled between April 2008 and November 2011 in Korea; the IRIS DES registry. 3,097 women and 6,577 men were followed-up for more than 2 year. The primary end point was rates of major adverse cardiovascular events (MACE), defined as cardiac death, myocardial infarction (MI), and target vessel revascularization (TVR) at 2 year follow-up.

Results: At baseline, women, as compared with men, were older, more frequently had diabetes, hypertension, and previous congestive heart failure, less frequently had smoking habits, family history of coronary artery disease, previous MI, and previous PCI, and had a smaller average stent diameter of the target vessel. The unadjusted rates of death (2.2% vs 3.3%, P=0.32), MACE (6.0% vs 6.0%, P=0.946), and TVR (1.8% vs 1.6%, P=0.573) were comparable for women and men. MI (1.1% vs 0.9%, P=0.494) were similar between men and women. After adjustment for baseline characteristics in the multivariable analysis, women and men had a similar risk of MACE rates at 2 year follow up.

Conclusions: Although women had worse baseline characteristics, no differences in MACE and death were observed between men and women undergoing PCI with DES.

TCT-104

Does Direct Stenting with Drug-eluting Stents Improve Outcome? A Systematic Review with Meta-analysis of 10,513 Patients

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Background: Although direct stenting with drug-eluting stents (DES) has been adopted as standard of care, its safety and effectiveness in comparison to the formally recommended conventional pre-dilatation strategy remains not well established.

Methods: Medline/Pubmed, Cochrane Library, and EMBASE were searched from 2001 to 2014 for studies contrasting Direct DES with conventional pre-dilatation DES implantation. The primary outcome was major adverse cardiovascular events (MACE), Secondary outcomes included all-cause death or myocardial infarction (MI), and target lesion revascularization (TLR). Summarized estimates were obtained using a random-effects model. Heterogeneity across the studies was assessed through I2.

Results: Overall, 546 potentially relevant citations were screened with 407 excluded from the title. The remaining 139 abstracts were analyzed resulting in six studies that met the inclusion criteria enrolling a total of 10,513 participants. Of those, 3909 (37%) and 6004 (63%) underwent direct DES or pre-dilatation followed by DES implantation, respectively. Direct DES reduced the likelihood of MACE (odds ratio [OR]: 0.80 [95% confidence interval [CI]: 0.70-0.92] with no evidence of heterogeneity of effect (I2= 0%). Additionally, in comparison with pre-dilatation, Direct DES was also associated with reduced rates of death or MI (OR: 0.74 95% CI [0.60-0.91], I2= 0%), and TLR (OR: 0.60 95% CI [0.41-0.88],I2= 14%) Figure).

Conclusions: Our findings support the strategy of direct DES for selected patient and lesion population.
Clinical Outcomes of Percutaneous Coronary Intervention with Nobori, Biolimus A9 Eluting Stent and Everolimus Eluting Stent for High Age Patients

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Background: Clinical outcomes of percutaneous coronary intervention (PCI) for high age patients has not well investigated in real-world setting. The aim of this study is to examine clinical outcomes after PCI for high age patients.

Methods: This study was performed as a retrospective registry. Between February 2010 to June 2012, 1646 patients underwent PCI with NoboriTM biolimus-eluting stent (BES) or everolimus eluting stent (EES). A total of 679 patients were over 75 years old. The main endpoints were major adverse cardiac or cerebrovascular event (MACE; death, myocardial infarction (MI), percutaneous coronary intervention (PCI), stent thrombosis (ST), target vessel revascularization (TVR) and target lesion revascularization (TLR).

Results: Baseline characteristics were not significantly different between the 2 groups. At 2-year, the cumulative rate of MACE, TLR, TVR and ST were no significantly different between the two groups. The cumulative rate of freedom from any hemorrhagic complication was lower in over 75 years old group (96.1% vs 96.6%, p=0.0002). After correcting all end points with baseline variables, use of dual antiplatelet therapy for more than 2 years and use of clopidogrel were independent predictors for any hemorrhagic complication.

Conclusions: We might suggest that use of dual antiplatelet therapy with clopidogrel for more than 2 years is a risk factor of any hemorrhagic complication for high age patients.

TCT-107

Drug Eluting Stents Versus Coronary Artery Bypass Graft surgery for Isolated Proximal Left Anterior Descending Artery Stenosis: A Meta-analysis

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Background: Coronary Artery Bypass Graft surgery (CABG) involving Internal Mammary Artery (IMA) graft is considered superior to stenting for recanalization of Left Anterior Descending (LAD) artery. Current generation Drug Eluting Stents (DES) are associated with extremely low target vessel recanalization (TVR) rates. We sought to compare the outcomes of DES versus CABG for treatment of isolated stenosis of proximal LAD artery.

Methods: PubMed, Cochrane and Web of Science databases were searched for relevant articles in English language through April 30th 2014 comparing the outcomes of DES versus CABG for recanalization of isolated proximal LAD stenosis. Outcomes assessed were all-cause mortality, cardiovascular mortality, myocardial infarction (MI), peri-procedure stroke and TVR. Study quality, publication bias and heterogeneity were assessed. Analysis was done using DerSimonian and Laird random effect model.

Results: From 339 publications, we identified 4 studies (2 randomized & 2 observational) with 1182 patients (DES=634 CABG=548). Mean age was 62 years and 79% were males in both groups. Follow-up period varied from 6 months to 10 years with a mean follow up of 4730 patient-years. DES types used included Paclitaxel, Sirolimus and Everolimus eluting stents. All CABG surgeries involved IMA graft while 78% of the CABG were done off-pump using lateral thoracotomy approach. There was no difference in all-cause mortality (RR: 1.20 95% CI: 0.51-2.83, p=0.67), cardiovascular mortality (RR: 0.43 95% CI: 0.11-1.64, p=0.21), MI (RR: 0.56 95% CI: 0.20-1.52, p=0.25) & stroke (RR: 0.55 95% CI: 0.08-3.44, p=0.51) rates between DES and CABG. TVR rate was also similar between two groups (DES vs CABG RR: 2.20 95% CI: 0.74-6.49, p=0.15). Subgroup analysis of these outcomes both early (<30 days) and late (>30 days) after the procedure did not show any difference between both treatment strategies. Hospital stay however was significantly lower in the DES group as expected (SMD= -9.1 days 95% CI: 14.06-4.14, p<0.001).

Conclusions: DES in comparison to CABG for recanalization of isolated proximal LAD stenosis is associated with similar outcomes including the TVR rates while the hospital stay is significantly lower.

TCT-108

Multi-Vessel Versus Single-Vessel Treatment with Resolute Zotarolimus Eluting Stent in the RESOLUTE Global Clinical Program

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Background: The treatment of patients with multi-vessel (MV) disease for percutaneous coronary intervention has increased, especially since the introduction of drug eluting stents, although MV stenting is associated with increased risk of clinical events compared to patients with single-vessel (SV) treatment. As the appropriate treatment of which lesions and vessels to stent continues to be investigated, we sought to evaluate clinical outcomes of MV (≥ 2 vessels) stenting with ResoluteTM zotarolimus-eluting stent (R-ZES).

Methods: The RESOLUTE global clinical program enrolled 7618 patients treated with R-ZES. Target Lesion Failure (TLF) is defined as a composite of death from cardiac causes, target vessel myocardial infarction (TV-MI), and clinically-indicated target lesion revascularization (TLR). All clinical results in the extended pooled analysis are calculated using the Kaplan Meier (KM) method. Given differences in baseline characteristics, patients were matched by propensity scores based on 26 baseline variables and adjusted p-values are provided.

Results: Among 1562 patients treated by MV and 6056 by SV, MV patients had more complex baseline characteristics than SV patients. At 3 years, TLR (Figure), TLF and death (RR: 1.54 95% CI: 1.06-2.23, p=0.02), TV-MI (RR: 2.23 95% CI: 1.46-3.41, p<0.001), MI (RR: 1.80 95% CI: 1.04-3.11, p=0.04), stroke (RR: 2.12 95% CI: 1.24-3.63, p=0.005), and TVR (RR: 0.57 95% CI: 0.40-0.82, p=0.004) were similar in MV and SV patients, respectively.

Conclusions: Across the RESOLUTE global clinical program, R-ZES for MV treatment provided excellent clinical outcomes, with no increased risk as compared with SV treatment, through long-term follow-up. Submitted on behalf of the RESOLUTE Global Clinical Program.