

Trends in baseline characteristics and outcomes of Medicare beneficiaries who underwent PCI from 1/2000-11/2012

	Overall	2000	2002	2004	2006	2008	2010	2012
number	3387976	246528	293391	332988	318622	243418	204409	161667
median age(years)	75	75	75	75	75	75	75	75
female (%)	42.1	43.5	43.1	42.5	41.8	41.5	41	40.4
white (%)	90	91.5	90.9	90.4	89.9	89.5	88.6	88.1
HTN (%)	65.6	58.4	61.7	63.5	62.2	65.2	74.3	80.1
DM (%)	29.9	26	27.3	28.2	28.1	29	35.5	40.2
PVD (%)	4.9	4.3	4.7	4.5	4.7	4.7	5.2	6.6
Stroke/TIA (%)	4.2	4.4	4.2	3.9	3.7	4	4.7	5.6
HF (%)	23.4	22.3	22.3	22.4	22.6	21.3	26.2	29.9
renal failure (%)	10	3.6	4.5	5.4	12.2	10.5	17.6	24.5
acute MI (%)	29.9	26.9	27.5	26.1	25.9	30.8	37.6	45.8
elective (%)	43.1	39.1	41.5	45.3	47.4	40.1	40.2	47
post-procedure LOS (days)	2	2	2	2	2	2	2	3
hospital mortality (%)	2.1	2.1	2	1.8	1.8	2.1	2.4	3.1
30 day mortality (%)	3.1	3	2.8	2.6	2.7	3.2	3.7	4.6

**CONCLUSIONS** Patients presenting for PCI are increasingly characterized by higher comorbidity burden and higher incidence of acute MI. Hospital mortality increased significantly over time, especially for patients presenting electively. Following adjustment for worsening baseline characteristics over time, adjusted hospital mortality was 42% higher in 2012 compared to 2000, OR 1.42 (95% CI 1.36-1.48).

**CATEGORIES CORONARY:** PCI Outcomes

**KEYWORDS** Coronary artery disease, Outcomes research, PCI - Percutaneous Coronary Intervention

**TCT-166**

**Angiographic and Long-term Clinical Outcomes after Bare-metal, First-generation, and Second-generation Drug-eluting Stent Implantation for Left Main Coronary Artery Disease: from the Japanese Left Main Coronary Stenting Registry**

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**BACKGROUND** We aimed to evaluate the angiographic and long-term clinical outcomes after treatment for left main coronary artery disease (LMCAD) with bare-metal stents (BMS), first-generation, and second-generation drug-eluting stents (G1-DES and G2-DES).

**METHODS** The Left Main Coronary Stenting Registry in Japan is a multicenter registry enrolling 1800 consecutive patients with LMCAD treated with stent implantation between 2004 and 2012: 355 patients with BMS, 875 with G1-DES, and 570 with G2-DES. The clinical endpoints assessed included all-cause death, cardiac death, sudden death, definite or probable stent thrombosis, and target-lesion revascularization (TLR). We distinguished in-hospital death from long-term clinical outcomes. The 6-year cumulative rates of adverse events were estimated by Kaplan-Meier methods with p values from log-rank tests. The angiographic endpoint was defined as in-stent restenosis within one year after procedure. In addition to restenosis at stent-implanted site, restenosis at bifurcation site was defined as a percent diameter >50% within 5 mm from the stent-implanted bifurcation lesion in both main and side branches.

**RESULTS** The median follow-up duration was 3.9 years (the first and third quarters, 2.2 and 5.9 years). Among patients with BMS, G1-DES, and G2-DES, there were no significant differences in the cumulative 6-year incidences of all-cause death (24.8% vs. 23.0% vs. 23.8%, p=0.48), cardiac death (8.3% vs. 10.2% vs. 5.4%, p=0.65), sudden death (2.4% vs. 3.7% vs. 2.0%, p=0.95), and definite or probable stent thrombosis (1.6% vs. 0.8% vs. 2.1%, p=0.11),

whereas patients with BMS had a significantly higher cumulative rate of TLR than those with G1- and G2-DES (26.6% vs. 15.4% vs. 10.4%, p<0.001). In this study sample, 1394 patients (77.4%) underwent follow-up angiography within one year after the initial procedure. The in-stent restenosis rate was significantly higher in patients with BMS than in those with 1st and 2nd DES (27.2% vs. 11.7% vs. 5.7%, p<0.001). The restenosis rate in the proximal left main stem showed no significant difference between patients with G1- and G2-DES (3.2% vs. 2.4%, p=0.48), whereas the main and side bifurcation restenosis rates were significantly higher in patients with G1-DES than in those with G2-DES (5.0% vs. 2.4%, p=0.04 and 5.3% vs. 1.3%, p<0.001).

**CONCLUSIONS** DES for LMCAD appeared to be associated with more favorable outcomes of TLR than BMS. Although G2-DES improved the in-stent restenosis rate compared with G1-DES, especially in both main and side bifurcation lesions, long-term clinical outcomes after stent implantation for LMCAD were comparable between G1- and G2-DES.

**CATEGORIES CORONARY:** PCI Outcomes

**KEYWORDS** Bare-metal stent, Drug-eluting stent, Left main coronary artery disease

**TCT-167**

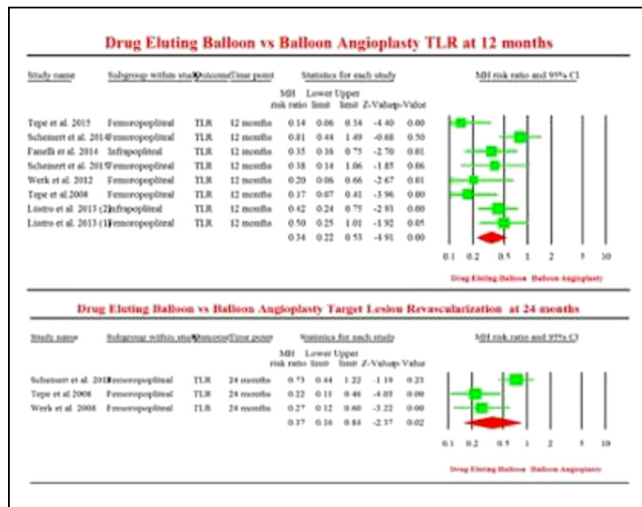
**Drug Eluting Balloons Versus Balloon Angioplasty in Femoropopliteal and Infrapopliteal Vascular Disease Interventions: A Meta-analysis of Randomized Controlled Studies**

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**BACKGROUND** Peripheral vascular interventions with drug eluting balloons (DEB) have been demonstrated to be superior to balloon angioplasty (BA) in short-term follow up (6 months). Long-term outcomes remain uncertain and we therefore assessed the long-term outcomes at or beyond 12 months in this meta-analysis.

**METHODS** PubMed, EBSCO and Ovid databases were searched to identify randomized controlled trials (RCT) comparing drug-eluting balloons with balloon angioplasty for the management of femoropopliteal and or infrapopliteal vascular disease. Outcomes of target lesion revascularization (TLR), patency rates, death and amputations were compared between the two groups using random effects models and risk ratio (RR) with 95% confidence intervals were calculated.

**RESULTS** A total of 9 RCT's were identified and included 1058 patients. Of these, 585 and 473 patients were randomized to DEB and BA groups, respectively. The risk of TLR was significantly lower in the DEB group at 12 months (RR 0.34, 95% CI 0.22 - 0.53, p<0.01) and 24 months (RR 0.37, 95% CI 0.16 - 0.84, p=0.02) compared to BA group. The patency rates were higher with the use of DEB (RR 1.64, 95% CI 1.44 - 1.86, p<0.01). The risk of death was similar in both the groups (RR 1.23, 95% CI 0.65 - 2.34, p=0.52). There was a favorable trend towards decrease in amputations with the use of DEB, however this finding was not statistically significant (RR 0.64, 95% CI 0.17 - 2.53, p=0.54). Heterogeneity was very low among the included studies as assessed by Cochrane Q statistic (I<sup>2</sup>=25%). Publication bias was assessed by means of funnel plot and this was deemed to be minimal.



**CONCLUSIONS** Angioplasty of femoropopliteal and infrapopliteal vascular stenosis with DEB is associated with significantly lower risk of TLR at both 12 and 24 months. DEB use is also associated with 64% higher patency rates compared to BA. Further studies are necessary to assess the benefits of mortality with the use of DEB for peripheral vascular interventions.

**CATEGORIES ENDOVASCULAR:** Peripheral Vascular Disease and Intervention

**TCT-168**

**Prosthesis-Patient Mismatch after Aortic Valve-In-Valve Implantation: Insights from the Valve-in-Valve International Data (VIVID) Registry**

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**BACKGROUND** Implantation of a transcatheter valve into a degenerated surgical bioprosthesis during aortic valve-in-valve (ViV) procedure may significantly reduce the effective orifice area (EOA) available for blood flow. We sought to investigate the impact of prosthesis-patient mismatch (PPM) on hemodynamics and survival in these patients.

**METHODS** A total of 657 data sets of aortic ViV procedures from the Valve-in-Valve International Data Registry were investigated for the current analysis. Severe PPM after ViV procedure was defined as an indexed EOA < 0.65cm<sup>2</sup>/m<sup>2</sup> patient body surface area (BSA).

**RESULTS** Severe PPM was present in 202 patients after aortic ViV implantation (30.7% total, 61.4% men, STS score 10.6%). The

incidence of severe PPM was higher in patients who received a balloon-expandable device than a self-expandable device (38.4% vs. 21.5%, p<0.0001). Patients with severe PPM were younger (77.2 ± 9.4 years vs. 78.7 ± 8.1, p = 0.05) and had larger body weight (80.9 ± 18.9 kg vs. 72.6 ± 14.1, p<0.0001) than those without severe PPM. In addition, patients with severe PPM had higher aortic mean gradient after the procedure (21.6 ± 10 mmHg vs. 14.1 ± 7.4) and lower aortic valve area (1.03 ± 0.2 cm<sup>2</sup> vs. 1.66 ± 0.44), in comparison with patients without severe PPM. Multivariate analysis revealed independent predictors for having severe PPM after aortic ViV: effective orifice area before the procedure (Odds Ratio, OR 0.53 per 1cm<sup>2</sup>, confidence interval, CI, 0.3-0.94, p=0.03), patient age (OR, 0.97 per 1year increment, CI, 0.94-0.99, p=0.01), using a balloon expandable device (OR, 2.82, CI, 1.78-4.46, p<0.001). In patients who survived aortic ViV implantation procedure, one-year survival was not affected by having severe PPM (93.3% vs. 93.8% in patients without severe PPM, log rank p=0.9).

**CONCLUSIONS** Severe PPM is common after aortic ViV implantation, occurring in approximately one-third of patients. Predictors for severe PPM include young age, stenotic surgical valves and balloon-expandable device implantation. Despite higher valve gradients in patients with severe PPM, one-year survival was similar to those without severe PPM. Therefore, the risk of severe PPM should not discourage operators from performing ViV procedures in inoperable elderly patients.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

**KEYWORDS** Patient-prosthesis mismatch, Transcatheter aortic valve replacement, Valve-in-valve

**TCT-169**

**Increased troponin concentrations in patients with stable coronary artery disease are associated with thin-cap fibroatheroma and future major adverse cardiovascular events**

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**BACKGROUND** Cardiac troponin-I (cTnI) is a marker of myocardial injury and improvements in assay sensitivity allow precise quantification at extremely low serum concentrations. Increased cTnI concentrations are known to predict outcomes in patients with stable coronary artery disease, although the underlying mechanisms remain unknown. As rupture of thin-cap fibroatheroma (TCFA) is thought responsible for the majority of myocardial infarctions, we tested the association between baseline cTnI concentration and plaque classification.

**METHODS** Patients undergoing planned percutaneous coronary intervention (PCI) for stable angina pectoris (n=99) underwent 3-vessel virtual-histology intravascular ultrasound imaging (VH-IVUS, Eagle-Eye Gold, Volcano Corp) before intervention. Virtual-histology (VH)-TCFA were defined as plaques (plaque burden >40%) with >10% necrotic core in contact with lumen for 3 consecutive frames. High-sensitivity cTnI was taken before PCI (ARCHITECT STAT high-sensitivity cTnI assay, Abbott Laboratories, Abbott Park, IL, USA), with patients subsequently stratified into tertiles. Major adverse cardiovascular events (MACE) were determined at follow-up (median 1,115 days).

**RESULTS** Serum cTnI concentrations for each tertile were; low 2.0 [2.0-3.0]ng/L, intermediate 4.0 [4.0-5.0]ng/L and high 7.0 [6.0-18.0] ng/L. In comparison with the lowest cTnI tertile, highest tertile patients were older (67±9.7 vs. 59.8±10.6yrs, p=0.002). However, there were no other differences in demographics between these groups, including diabetes mellitus (14.8 vs. 12.0%, p=0.98), hypertension (55.6 vs. 44.0%, p=0.33) and serum creatinine (1.00±0.15 vs. 0.97±0.21mg/dL, p=0.37). On 3-vessel VH-IVUS, total plaque number (p=0.27), plaque volume (p=0.09), % necrotic core (p=0.17) and % calcification (p=0.21) were similar between lowest and highest tertiles. However, patients in the highest cTnI tertile had a higher number of VH-TCFA, when compared with lowest tertile (2.0 [1.0-2.8] vs. 1.0 [0.0-1.3], p=0.027). On multivariable linear regression analysis, cTnI concentration (p=0.01) was independently associated with