

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 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 < 0.65 cm2/m2 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 \pm 9.4 years vs. 78.7 \pm 8.1, p = 0.05) and had larger body weight (80.9 \pm 18.9 kg vs. 72.6 \pm 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 \pm 10 mmHg vs. 14.1 \pm 7.4) and lower aortic valve area (1.03 \pm 0.2 cm2 vs. 1.66 \pm 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 1cm2, 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 \pm 9.7 vs. 59.8 \pm 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 \pm 0.15 vs. 0.97 \pm 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

VH-TCFA number. Finally, cTnI was also associated with future MACE on univariate analysis (HR 2.2, 95%CI 1.2-4.0, p=0.007).

CONCLUSIONS Increased baseline cTnI in patients with stable angina is associated with the presence of vulnerable plaques and future MACE. These results suggest a potential mechanism underlying the prognostic value of cTnI in patients with stable angina.

CATEGORIES IMAGING: Vulnerable Plaque

ACUTE CORONARY SYNDROMES

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TCT-170

Safety and efficacy of bivalirudin during percutaneous intervention in acute coronary syndrome in the real world. The CARTAGOMAX study

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BACKGROUND The role of anticoagulants during percutaneous coronary intervention (PCI) in acute coronary syndrome (ACS) is increasingly important. The CARTAGOMAX study aims to assess the efficacy and safety of bivalirudin (BIVA) versus unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) during PCI in the real world.

METHODS We performed a single-center and prospective study. All patients with acute coronary syndrome (with and without ST segment elevation) who underwent percutaneous coronary intervention in our cardiac catheterization laboratory between January 2010 and December 2014 were eligible for inclusion. All received loading dose of aspirin and clopidogrel. Patients were successively anticoagulated either with BIVA or with UFH plus GPI, in a 2:1 ratio. The main objective was to compare mortality and major bleeding rates at 1, 6 and 12 months of follow-up. As secondary objectives, the presentation of stroke, reinfarction and stent thrombosis was analyzed. All patients signed informed consent. Study protocol was approved by our hospital ethics committee. We performed univariate analysis and binary logistic regression analysis. Survival analysis was performed using Kaplan-Meier method using the log rank test, which is expressed followed by relative risk (RR) with the 95% confidence interval.

RESULTS A total of 1800 patients were included. 31,6% were diagnosed with ACS with ST segment elevation and 68,4% with ACS without ST segment elevation. 1183 (65,7%) of patients received BIVA and 617 (34,3%) were treated with UNH+GPI. Baseline characteristics are shown in table 1. No significant differences in mortality were observed between the two groups at 30 days (p=0,231; RR 0,8-2,2) and at 6 months follow-up (p=0,12; RR 0,9-2,1). At one year followup, a non-significant trend to lower mortality was observed in the bivalirudin group (p=0,052; RR1,01-2,15). The incidence of major bleeding was higher in the arm treated with UNH+GPIat 1 month (p=0,001; RR 1,4-40,9), at 6 months (p=0,009 RR 1,2-5,05) and at 12 months (p=0,061; RR 0,9-3,3). Similar results were obtained when the occurrence of cerebral ischemic events was analyzed. The incidence of stroke ratio was lower in the BIVA arm at 1 month (p=0.015; RR 1,4-40,9), at 6 months (p=0,003; RR 1,6-24,6) and at 1 year (p=0,032; RR 1,03-7,8). The rates of re-infarction were similar in both groups. A nonsignificant trend to higher stent thrombosis in the BIVA arm was observed.

	Heparin + IGP	Bivalirudin	Total	p value
Age, years	66,18 ± 12,2	67,14 ± 12,5	66,61 ± 12,49	0,119
Female gender	129 (20,9)	327 (27,7)	456 (25,3)	0,002
dyslipidemia	280 (45,4)	620 (53,4)	900 (50)	0,005
Hypertension	339 (54,9)	754 (63,7)	1093 (60,7)	0,001
Diabetes	211 (34,2)	513 (43,4)	724 (40,2)	0,001
Smoking	286 (46,4)	537 (45,4)	823 (45,7)	0,698
Radial access	278 (45,2)	723 (61,6)	1001 (56)	0,001
LVEF	54,36 ± 11	54,38 ± 11	59,41 ± 14,76	0,971
N <u>o</u> diseased vessels	1,73 ± 0,76	1,76 ± 0,81	1,75 ± 0,8	0,527
N <u>o</u> treated vessels	1,15 ± 0,39	1,24 ± 0,46	1,21 ± 0,44	0,001
No implanted stents	1,8 ± 1,06	1,77 ± 1,04	1,78 ± 1,05	0,654
GFR, ml/min/ 1,73m2	87,9 ± 44,57	87,7 ± 42,52	87,8 ± 43,17	0,925
Platelets, mcL	217610 ± 64750	221380 ± 91120	220200 ± 83773	0,405
Contrast, ml.	340 ± 178,68	286 ± 128,18	305,1 ± 149,53	0,001

CONCLUSIONS In the CARTAGOMAX study the use of bivalirudin during PCI is presented as an effective and safe option, with a lower rate of major bleeding and stroke, and similar mortality and stent thrombosis over the use of UFH plus a GPI.

CATEGORIES CORONARY: Acute Coronary Syndromes KEYWORDS ACS, Bivalirudin, Coronary Angioplasty

TCT-171

Clinical Outcomes Using Prasugrel or Ticagrelor Based On Physician Treatment Decisions In Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention: Comparative Results Using Propensity Analysis Of A Payer Database

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BACKGROUND Prasugrel and ticagrelor are potent P2Y12 ADP receptor inhibitors that have greater clinical efficacy compared with clopidogrel, but more non-CABG bleeding. There are no direct comparisons of clinical outcomes between the drugs with follow-up through 1 year. This retrospective study compared 1 year post discharge outcomes between the 2 agents in acute coronary syndrome patients (pts) managed with percutaneous coronary intervention (ACS-PCI) using a claims database.

METHODS ACS-PCI pts \geq 18 years, with no history of TIA or stroke, a physician visit \leq 90 days post discharge, and at least 1 outpatient pharmacy fill \leq 30 days post discharge for prasugrel or ticagrelor, but not both, were included. Data from the ProMetis Lx database were propensity matched for prasugrel use with a 3 prasugrel:1 ticagrelor ratio. Unadjusted clinical outcomes were assessed using descriptive methods on an as treated basis. Propensity matched clinical outcomes were compared using Cox proportional hazards models and Kaplan-Meier analysis. Post discharge net adverse clinical events (NACE) at 1 year was evaluated for non-inferiority of outcomes between the 2 populations using a 20% margin. NACE was a composite of major adverse cardiovascular events (MACE) or rehospitalization for bleeding. MACE was the composite of all-cause death, coronary revascularization, or rehospitalization for MI, unstable angina (UA), TIA/stroke, or CHF.

RESULTS Of the 173,484 ACS-PCI pts in the database, 15,788 were included (prasugrel 12,797; ticagrelor 2,991). Compared with ticagrelor pts, prasugrel pts were younger, less likely to be female, have prior MI, diabetes, or present with NSTEMI; more likely to have UA; no significant difference in the rate of STEMI. Prior to matching, prasugrel pts had lower rates of NACE and MACE (p<0.01), with no difference in bleeding (Table), compared with ticagrelor pts. After propensity matching, there was no significant difference in baseline characteristics between the two groups. Non-inferiority was demonstrated related to outcomes associated with prasugrel use compared with outcomes associated with ticagrelor use (Table). Rates of NACE and MACE remained significantly lower in the