TCT-490

Frequency And Impact Of Nuisance Bleeding On Adverse Events After Percutaneous Coronary Intervention: 2-Year Results From The Patterns Of Non-Adherence To Antiplatelet Regimens In Stented Patients (PARIS) Registry

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Background: Major bleeding increases risk for adverse events following PCI. The frequency and impact of less severe, or nuisance bleeding, on adverse events after PCI remains unknown.
Methods: PARIS was a multinational, prospective registry of patients prescribed DAPT following PCI for any indication from 2009 to 2010 (n=5,018). Nuisance bleeding was defined as Bleeding Academic Research Consortium (BARC) type 1. Minor or major bleeding included BARC $\geq$ 2. Patients were categorized by bleeding severity. Associations between bleeding and adverse events were examined using Cox regression with bleeding entered as a time-update covariate. All events were independently adjudicated.
Results: Over 2 years, the cumulative occurrence of nuisance bleeding was 18.0% (n=835). Compared to those with more severe bleeding (n= 401, 8.3%), patients with nuisance bleeding were younger, less often female and less likely to receive triple therapy on discharge. Two-year rates of ischemic adverse events (def/prob stent thrombosis, myocardial infarction or cardiac death) were 5.6%, 4.9% and 20.1% among those with none, nuisance, and minor/major bleeding, respectively. Results were unchanged after multivariable adjustment (Table).

MI-myocardial infarction; Models adjusted for age, gender, region, acute coronary syndrome, stent type, warfarin use. Adjusted Hazard ratios calculated from Cox Models with bleeding entered as a time-updated covariate.

Table. Hazard Ratios (95% Confidence Intervals) for Ischemic Events Associated with Bleeding Severity

	Spontaneous MI	Cardiac Death	MACE
No Bleed	1.0 (ref)	1.0 (ref)	1.0 (ref)
Nuisance Bleed	1.19 (0.65-2.17)	0.63 (0.25-1.55)	0.91 (0.54-1.51)
Minor/Major Bleed	2.70 (1.68-4.32)	4.28 (2.82-6.47)	2.82 (2.0-3.98)

MI-myocardial infarction; Models adjusted for age, gender, region, acute coronary syndrome, stent type, warfarin use. Adjusted Hazard ratios calculated from Cox Models with bleeding entered as a time-updated covariate.

Conclusions: Although common, nuisance bleeding is not associated with an increased risk for ischemic adverse events following PCI.

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High incidence of stent thrombosis with new P2Y12 inhibitors after percutaneous coronary intervention in patients survivors of out-of-hospital cardiac arrest

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Background: Acute coronary syndromes (ACS) remain the leading cause of out-of-hospital cardiac arrest (OHCA). Current guidelines plead for early coronary angiography and ad-hoc primary percutaneous coronary intervention (PCI). But after cardiac arrest, shock, hypothermia and modification in antiplatelet pharmacokinetic may promote stent thrombosis (ST). The aim of this study was to evaluate incidence of ST in survivors of OHCA successfully revascularized with stent implantation.
Methods: We conducted a retrospective observational analysis of all OHCA survivors with successful PCI between 2011 and 2013. All patients were treated with mild therapeutic hypothermia for 24h, and dual antiplatelet therapy according to current guidelines. Clinical, angiographic and biological data were collected. Definite and probable ST were reported according to the Academic Research Consortium definition.
Results: A total of 101 consecutive patients have been included in the present analysis. Mean age was 61.3 years. 75% of patients had initial ventricular fibrillation. Mean no flow and low flow were 4.0 +/- 4.3 min and 18.2+/-11.4 min, respectively. All patients received aspirin before PCI. P2Y12 inhibitors were initiated after stent implantation and include clopidogrel (48%), prasugrel (22%) or ticagrelor (30%). In addition, 31% also received GpIIbIIIa inhibitors. The initial TIMI flow was 0 or 1 in 53% of patients. Mean post-procedural left ventricular ejection fraction was 39.6+/-12.4 %. Global survival rate at discharge was 45%. We identified 11 cases (10.9%) of definite or probable ST (acute, n=4 and subacute n=7) with median delay to PCI of 2 days. Stent thrombosis occurred with clopidogrel (n=2), prasugrel (n=4) and ticagrelor (n=5). Mortality was higher in patients with ST (82% vs 52%; p=0.06). We reported more ST with new P2Y12 inhibitors compared to clopidogrel (17 % vs 4 %; respectively, p=0.05). Moreover no benefit was observed with the use of pre-treatment with aspirin (p=0.94) or heparin (p=0.75).
Conclusions: Incidence of ST in OHCA survivors is high and associated with poor clinical outcome. Optimal antithrombotic therapy in this critical state remains to be determined.

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Stent Thrombosis With Ticagrelor Versus Clopidogrel After Percutaneous Coronary Intervention and Ticagrelor or Clopidogrel in Patients With Acute Coronary Syndromes in a Real World Setting

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Background: Dual antiplatelet therapy, aspirin in combination with a P2Y12 antagonist, has been shown to reduce occurrence of ischemic events after coronary stent implantation in randomized clinical trials. We compared 1-year risk of stent thrombosis among patients with acute coronary syndromes (ACS) having either primary percutaneous coronary intervention (PCI) due to ST-segment elevation myocardial infarction (STEMI) or sub-acute PCI due to non-STEMI or unstable angina pectoris and dual antiplatelet therapy with either ticagrelor or clopidogrel for 12 months.
Methods: From June 2010 to June 2012 all ACS patients treated with PCI at Odense University Hospital were identified from the Western Denmark Heart Registry. From June 2010 to June 2011 the standard dual antiplatelet therapy was aspirin and clopidogrel (600-mg loading dose, 75 mg daily thereafter): "clopidogrel group" and from June 2011 to June 2012 the standard dual antiplatelet therapy was changed to aspirin and ticagrelor (180-mg loading dose, 90 mg twice daily thereafter): "ticagrelor group". We assessed the 1-year risk of definite stent thrombosis after PCI with stent implantation including risk of acute, subacute and late definite stent thrombosis.
Results: The study cohort consisted of 2,335 patients with ACS, of whom 1,134 patients were in the "ticagrelor group" and 1,201 patients were in the "clopidogrel group". The 1-year risk rate of definite stent thrombosis was reduced significantly in the "ticagrelor group" n=5 (0.5%) compared to the "clopidogrel group" n=17 (1.4%) [hazard ratio (HR)=0.31 95% confidence interval (CI) 0.11-0.84]. Ticagrelor reduced especially the rate of early (within 30 days) definite stent thrombosis compared with clopidogrel: n=4 (0.4%) versus n=15 (1.2%); [HR= 0.28 95% CI 0.09-0.85] with a numerically lower number of acute (n=1 (0.1%) vs. n=5 (0.4%), p=0.219) and subacute (n=3 (0.3%) vs. n=10 (0.8%), p=0.093) whereas risk of late definite stent thrombosis did not differ between ticagrelor n=1 (0.1%) and clopidogrel n=2 (0.2%) treated patients.
Conclusions: In a real world setting, treatment with ticagrelor as compared with clopidogrel in ACS patients significantly reduced the risk of definite stent thrombosis.

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Abstract Withdrawn

TCT-494

Safety and Effectiveness of Prasugrel vs. Clopidogrel in the Setting of Bivalirudin vs. Heparin Use: 30-day Results from TRANSLATE-ACS

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Background: Few studies have examined the safety and effectiveness of prasugrel vs. clopidogrel in the context of bivalirudin vs. heparin use.
Methods: We evaluated 10,493 STEMI and NSTEMI patients treated with percutaneous coronary intervention (PCI) at 230 hospitals in the TRANSLATE-ACS observational study from 4/2010–10/2012. Patients were stratified based on anticoagulant (bivalirudin vs. heparin±GPI) and antiplatelet (prasugrel vs. clopidogrel) treatment. Outcomes of 30-day GUSTO-defined bleeding and MACE (death, MI, stroke, or unplanned revascularization) were compared between groups propensity matched for treatment.
Results: In the overall study population, there were significant differences in patient characteristics, such as age, sex, prior MI, prior CABG, diabetes, STEMI presentation, and coronary disease burden, between observed treatment groups. After 1:1 propensity matching, these characteristics were well-balanced between each set of comparison groups (Cramers $\Phi < 0.05$). In propensity matched comparisons, the risk of bleeding was lower among bivalirudin-treated patients compared with those who received heparin±GPI (Table). The 30-day risk of GUSTO bleeding was not significantly different between prasugrel and clopidogrel among bivalirudin-treated patients, nor among heparin-treated patients. The 30-day risk of MACE was also similar between prasugrel and clopidogrel regardless of bivalirudin or heparin use.
Conclusions: In routine practice, the patterns of use are quite different in patients treated with these antiplatelet and anticoagulant therapies. However, 30-day outcomes were not significantly different between prasugrel and clopidogrel, regardless of anticoagulant choice. Bleeding risk was lower with bivalirudin regardless of antiplatelet choice.