Oral Session 8
Antithrombotic therapy and coronary revascularization

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Short versus standard 12-month dual antiplatelet therapy duration after drug-eluting stent implantation

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Introduction: Current guidelines recommend up to 12 months dual antiplatelet therapy (DAPT) after drug-eluting stents (DES) implantation, however optimal DAPT duration after DES implantation is still a matter of debate. We aimed to evaluate clinical outcomes with short-term (<12 months) DAPT as compared to standard 12-months DAPT in patients treated with DES.

Method: In December 2013, we searched PubMed and conference proceedings for randomized trials directly comparing short-term (<12 months) versus 12-months DAPT after DES implantation. Random-effects meta-analyses were performed comparing clinical outcomes at 12 months in patients allocated to short-term DAPT and patients allocated to 12-months DAPT. Heterogeneity was assessed with I-squared. The primary safety and efficacy endpoints were bleeding and the composite of cardiac death and myocardial infarction, respectively. The secondary safety endpoint was definite or probable stent thrombosis according to ARC criteria.

Results: We identified 3 trials: EXCELLENT (6-months vs. 12-months DAPT, N=1,443), RESET (3-months vs. 12-months DAPT, N=2,117), and OPTIMIZE (3-months vs. 12-months DAPT, N=3,119) – including a total of 6,679 patients with 12-months follow-up. At 12 months, short-term DAPT was associated with a reduced risk of any bleeding (RR 0.68, 95%CI 0.47-1.00) and a trend towards a reduced risk of major bleeding (RR 0.59, 95%CI 0.30-1.10) as compared to 12-months DAPT. With respect to efficacy, risks cardiac death or myocardial infarction (RR 1.10, 95%CI 0.82-1.47) and stent thrombosis (RR 1.30, 95%CI 0.50-3.36) did not differ between patients allocated to short-term DAPT compared with 12-months DAPT. Noteworthy, landmark analyses at the time of DAPT interruption showed that risks of cardiac death or myocardial infarction (RR 0.96, 95%CI 0.60-1.58) as well as stent thrombosis (RR 1.34, 95%CI 0.17-10.76) did not differ between the two groups after DAPT interruption up to 12 months follow-up. No evidence of significant heterogeneity was observed across trials for any of the analyzed endpoints.

Conclusion: Compared with standard 12-months DAPT, short-term DAPT reduces the risk of bleeding without compromising efficacy as indicated by similar risks of cardiac death, myocardial infarction and stent thrombosis throughout 12-months follow-up.

Disclosure of Interest: None declared

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Frequency and predictors of gastrointestinal bleeding in unselected patients undergoing percutaneous coronary intervention

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Introduction: Patients undergoing PCI with subsequent need for dual antiplatelet therapy are at risk for gastrointestinal bleeding (GIB) complications.

Method: Between March 2009 and June 2012, 6,190 patients with coronary artery disease underwent PCI at a tertiary care center and were prospectively followed for one year. Bleeding was assessed according to the BARC criteria (Type 2-5). Predictors of bleeding were examined using a case control design (1 case vs 5 controls). All patients were prescribed dual antiplatelet therapy consisting of aspirin and clopidogrel for a duration of 12 months, with the exception of STEMI patients who were treated with prasugrel instead of clopidogrel since September 2009 and NSTE-ACS patients who were treated with ticagrelor instead of clopidogrel since November 2011.

Results: A total of 210 patients (3.4%) had a bleeding event at one year follow-up, of which 62 (1%) bleeding events were due to gastrointestinal bleeding (GIB). GIB bleeding events were categorized as BARC 2 bleeding events in 24%, as BARC 3a bleeding events in 29%, and as BARC 3b bleeding events in 46% of cases. ¨

No GIB case was fatal (BARC 5a or b). In univariate analyses, current smoking (OR 1.9, 95%CI 1.1 – 3.9, p=0.02), anemia at admission (OR 1.9, 95%CI 1.05 – 3.5, p=0.035), and history of malignancy (OR 2.4, 95% CI 1.2 – 5.0, p=0.02) were predictors of GIB. In multivariate analyses, history of malignancy emerged as the only independent predictor of GIB (OR 2.3, 95% CI 1.0-5.1, p=0.049).

Conclusion: In this unselected PCI cohort, one third of all bleedings were gastrointestinal with a frequency of 1% at one year. History of malignancy emerged as the only independent predictor of GIB.

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Safety and efficacy of concurrent administration of clopidogrel and prasugrel loading doses among patients with acute myocardial infarction undergoing primary percutaneous coronary intervention

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Introduction: Current STEMI guidelines recommend the use of prasugrel in clopidogrel-naïve patients. We assessed the safety and efficacy of the concurrent administration of a clopidogrel and prasugrel loading dose (LD) among patients with acute STEMI undergoing primary PCI.

Method: Between September 2009 and October 2012, 2,025 STEMI patients were enrolled into the randomized COMFORTABLE AMI trial and the SPUM ACS cohort study. Patients were divided into three groups according to type of peri-procedural antiplatelet loading: (1) clopidogrel and subsequent prasugrel LD [CP], (2) prasugrel LD [P] (3) clopidogrel LD [C]. Safety was assessed by the composite of BARC type 3, 4, and_5 bleeding and efficacy by the composite of cardiac death, nonfatal MI and stroke, both at 30 days.

Results: Out of 2,025 patients, 428 (21.1%) had received CP, 447 (22.1%) P, and 1,150 (56.8%) C. At 30 days, the safety endpoint was observed in 1.9% of CP, 3.1% of P, and 2.9% of C patients (CP vs C adjusted HR_0.91; 95% CI 0.40-2.03), CP vs P adjusted_HR 0.60; 95% CI 0.24-1.49). The efficacy endpoint tended to occur less frequent among CP compared with C patients (1.9% vs. 5.0%, adjusted_HR_0.46; 95% CI 0.20-1.06) and no difference was observed between CP and P patients (1.9% vs 2.9%, adjusted HR 0.55; 95% CI 0.21-1.43).