TCT-841
ORAL Immunosuppressive therapy to prevent in-Stent rESTENOSIS (RAMSES) cooperation: a patient-level meta-analysis of randomized trials
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Background: The role of oral immunosuppressive therapy (OIT) after percutaneous coronary intervention (PCI) and stenting still remains to be defined. We sought to evaluate the efficacy and safety of oral administration of sirolimus or prednisone to prevent in-stent restenosis.

Methods: We undertook a meta-analysis of trials in which PCI-patients were randomly assigned to OIT or control therapy. The primary endpoint was the composite of death/myocardial infarction (MI) or target lesion revascularization (TLR). Secondary endpoints were the composite of death/MI, the individual components of the primary endpoint and in-stent late lumen loss (LLL) at angiographic surveillance.

Results: We obtained individual data of seven trials enrolling 1,246 patients (OIT, n = 638) with 1,456 coronary lesions. At a median follow-up of 360 days [interquartile range 360-1440] OIT as compared to control therapy significantly reduced the risk of the composite primary endpoint (hazard ratio [95% CI]= 0.62 [0.39-0.96], P = 0.03), without significant difference in terms of death/MI (0.84 [0.46-1.52], P = 0.57), death (1.12 [0.61-2.06], P = 0.71) and MI (0.67 [0.33-1.38], P = 0.28). OIT as compared to control therapy significantly reduced the risk of TLR (0.55 [0.34-0.89], P = 0.01) as well as the degree of in-stent LLL (0.62±0.65 mm versus 0.94±0.70 mm; mean difference 0.32 mm [0.22-0.42], P <0.0001). The proportion of patients complaining side effects associated with OIT was associated with 13.4% and 1.1% permanently discontinued the therapy.

Conclusions: The use of oral immunosuppressive therapy as compared to control therapy reduces the composite of death/myocardial infarction or target lesion revascularization after stenting without safety issues. The advantage of oral immunosuppressive therapy is predominantly related to the lower risk of restenosis after revascularization.

TCT-842
Drug-eluting stents for revascularization of infrapopliteal arteries. Updated meta-analysis of randomized trials
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Background: In atherosclerotic disease of infrapopliteal arteries, drug-eluting stents (DES) improve patency rates as compared with plain balloon or bare metal stents (BMS). However, the clinical impact of DES in this vascular territory remains still uncertain.

Methods: We undertake an updated meta-analysis of randomized trials investigating the outcomes of percutaneous revascularization with primary drug-eluting stenting in patients with atherosclerotic disease of infrapopliteal arteries. We searched Medline, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), scientific session abstracts and relevant websites. Keywords were: “below the knee”, “infra-popliteal artery”, “angioplasty”, “drug-eluting stent(s)”, “bare metal stent(s)”, “trial”, and “randomized trial”. Inclusion criteria were: (1) randomized design; (2) intention to treat analysis; (3) a minimum of 6-month follow-up. Exclusion criteria were: (1) vessels treated other than infrapopliteal arteries; (2) devices used other than DES, plain balloon or BMS, and (3) duplicated data. The primary endpoint was target lesion revascularization (TLR); secondary endpoints were restenosis, amputation and death.

Results: A total of 611 patients from 5 trials were randomly assigned to DES (n = 294) versus control therapy (plain balloon/BMS, n = 317). Overall, median lesion length was 26.8 mm [IQR 18.2-30.0] with a reference diameter of 2.86 mm [IQR 2.68-3.00]. At a median follow-up of 12 months [interquartile range 12-36], DES reduced the risk of TLR (odds ratio [95% Confidence interval] = 0.31 [0.18-0.54], P<0.001), restenosis (0.25 [0.15-0.43], P<0.001) and amputation (0.50 [0.26-0.97], P=0.04) without significant difference in terms of death (0.81 [0.45-1.49], P=0.50) versus control therapy.

Conclusions: In focal disease of infrapopliteal arteries, drug-eluting stent therapy reduces the risk of re-intervention and amputation as compared with plain balloon or bare metal stent without impact on mortality at 1-year follow-up.

TCT-843
Drug eluting balloon vs drug eluting stent in PCI: insights from a meta-analysis of 1462 patients.
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Background: Drug eluting balloons (DEB) have been developed to overcome the limitations of drug eluting stent (DES), but clinical results of different studies about DEB are still not consistent. Thus, we performed a meta-analysis to compare outcomes of DEB and DES in coronary artery disease (CAD).

Methods: Medline/Web databases were searched for studies comparing DEB and DES for obstructive CAD, reporting late lumen loss (LLL) and rates for overall mortality, myocardial infarction (MI), stent thrombosis (ST) and target lesion revascularization (TLR).

Results: Eight studies (1462 patients) were included in the meta-analysis. Compared with DES, DEB treated patients showed non-significantly higher LLL (weighted mean difference [WMD] 0.32, 95% confidence interval [CI] -0.15 to 0.78, P=0.18) and non-significantly higher rate of binary restenosis (odds ratio [OR] 1.40 [0.68-2.48], P=0.36). Mortality (OR 1.13 [0.54-2.37], P=0.74), MI (OR 0.95, 95%CI 0.50-1.80, P=0.87), ST (OR 1.12, [0.34-4.19], P=0.77) and TLR rates (OR 1.19 [0.60-2.38], P=0.61) were similar between the 2 treatments. A pre-specified meta-regression analysis showed that LLL WMD and TLR OR were inversely correlated to the prevalence of diabetes (P<0.0001) and directly correlated to reference coronary diameters (P<0.001).

Conclusions: The present meta-analysis showed that, in comparison with DES, DEB use was not followed by significantly higher LLL, with similar clinical efficacy and safety. Thus DEB could be considered a reasonable alternative for interventional cardiologists to limit the use of DES in selected clinical settings.

TCT-844
Risk of Thrombocytopenia with Glycoprotein IIb/IIIa Inhibitors Across Drugs and Patient Populations: A Meta-analysis of 28 Large Placebo-Controlled Randomized Trials
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Background: Thrombocytopenia (tcp) is associated with poor clinical outcomes in patients receiving glycoprotein IIb/IIIa inhibitors (GPI), yet the extent of this risk and differences between drugs and patient populations are uncertain. We evaluated the risk of tcp associated with GPI compared to placebo.

Methods: Rate ratios were calculated for tcp (<50,000 platelets/mm3) and severe tcp (>50,000 platelets/mm3) in 28 randomized large trials (>1000 patients) of GPI versus placebo involving a total of 123,419 patients. We used meta-analysis techniques to estimate the summary effect across all trials, in pre-specified subgroups, and in sensitivity analyses to assess the robustness of the data.

Results: GPI use increases the rate of tcp (RR = 1.63, 99%CI 1.48-1.79) and severe tcp (RR = 3.51, 99%CI 2.68-4.88). These findings are consistent by route of administration, Abciximab, tirofiban, xemilofiban, orbitiban, and tirofiban demonstrated significantly increased tcp; eptifibatide, lamibintan and sibraliban had non-significant increases compared to placebo. Patients with STEMI (RR 2.84, 99%CI 2.23-3.61) and elective PCI (RR 2.78, 99%CI 1.76-4.40) had higher rates of tcp than patients with nSTE-ACS (RR 1.41, 99%CI 1.25-1.58; p<0.001 for heterogeneity by subgroup).

Conclusions: The administration of GPI compared to placebo was associated with a 63% increased risk of tcp (<100,000 platelets/mm3) and >3-fold increased risk of severe tcp (<50,000 platelets/mm3). This corresponds to an average of 10-20 additional cases of tcp per 1000 patients given GPIs, of which 6-7 are severe.