POSTERS

TCT-841

ORAl iMmunosuppressive therapy to prevent in-Stent rEstenosiS (RAMSES) cooperation: a patient-level meta-analysis of randomized trials

Salvatore Cassese[1], Giuseppe De Luca[2], Flavio L. Ribichini[3], Carmelo Cernigliaro[4], Francesco Versaci[5], Igino Proietti[6], Goran Stankovic[7], Sinisa Stojkovic[7], Fabrizio Tomai[8], Corrado Vassanelli[3], David Antoniucci[9], Patrick W. Serruys[10], Adnan Kastrati[1], Alfredo Rodriguez[11]
[1]Deutsches Herzzentrum, Munich, Germany, [2]Eastern Piedmont University, Novara, Italy, [3]University of Verona, Verona, Italy, [4]Interventional Cardiology, San Gaudenzio Clinic, Novara, Italy, [5]Department of Cardiology, Cardarelli Hospital, Campobasso, Italy, [6]Department of Cardiology, Vannini Hospital, Rome, Italy, [7]Department of Diagnostics and Catheterization Laboratory, Division of Cardiology, Belgrade, Serbia, [8]European Hospital, Rome, Italy, [9]Careggi Hospital, Florence, Italy, Florence, Italy, [10]Thoraxcenter, Rotterdam, Netherlands, [11]Otamendi Hospital, Buenos Aires, Argentina

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= 608 versus control therapy, 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<0.001). The proportion of patients complaining side effects associated with OIT was 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

Salvatore Cassese[1], Gjin Ndrepepa[1], Gunnar Tepe[2], Lamin King[1], Ilka Ott[1], Heribert Schunkert[1], Adnan Kastrati[1], Massimiliano Fusaro[1]
[1]Deutsches Herzzentrum, Munich, Germany, [2]Romed Klinikum Rosenheim, Rosenheim, Germany

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", "infrapopliteal 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= 307). Overall, median lesion length was 26.8 mm [IQR 18.2-30.0] with a reference vessel 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 reintervention 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.

Alessandro Lupi[1], Andrea Rognoni[1], Italo Porto[2], Gioel G. Secco[3], Maurizio Lazzero[1], Pieter R. Stella[4], Francesco Liistro[2], Leonardo Bolognese[2], Angelo S. Bongo[1], Imad Sheiban[5], Pierfrancesco Agostoni[4]
[1]AOU Maggiore della Carità, Novara, Italy, [2]San Donato Hospital, Arezzo, Italy, [3]University of Eastern Piedmont, Novara, Italy, [4]University Medical Center Utrecht, Utrecht, Netherlands, [5]University of Torino, Turin, Italy

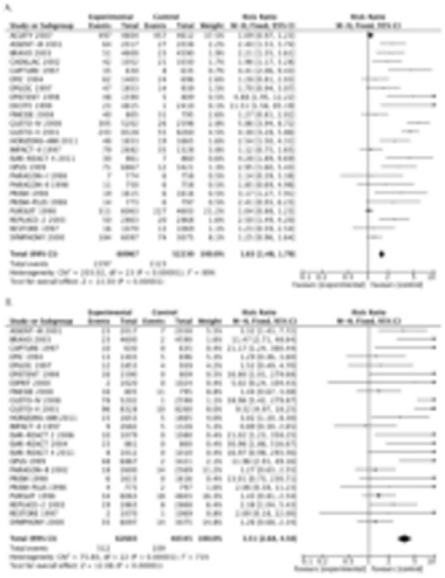
Background: Drug eluting balloons (DEB) have been developed to overcome the limitations of drug eluting stent (DES), but clinical results of different studies about DEB are still not consistent. Thus, we performed a meta-analysis to compare outcomes of DEB and DES in coronary artery disease (CAD).
Methods: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

Jeffrey D. Wessler[1], Robert Giugliano[2]
[1]Columbia University Medical Center, New York, NY, [2]Harvard Medical School, Boston, MA

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 (<100,000 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 2.68-4.58). These finding are consistent by route of administration. Abciximab, tirofiban, xemilofiban, orbofiban, and lotrafiban demonstrated significantly increased tcp; eptifibitide, lamifiban and sibrafiban 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 are 6-7 are severe.

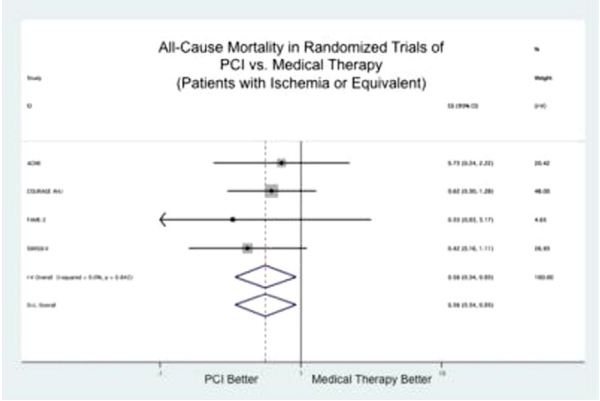


TCT-845

Percutaneous Coronary Intervention is Associated with Lower Mortality Compared with Optimal Medical Therapy in Patients with Stable Ischemic Heart Disease and Objective Evidence of Ischemia or Abnormal Fractional Flow Reserve: A Meta-Analysis of Randomized Controlled Trials

Ajay J. Kirtane[1], Hemal Gada[2], Sripal Bangalore[3], Dean Kereiakes[4], Gregg Stone[5]
[1]Columbia University / Cardiovascular Research Foundation, New York, NY, [2]Columbia University - Center for Interventional and Vascular Therapy, New York, NY, [3]New York University School of Medicine, New York, United States, [4]The Christ Hospital Heart & Vascular Center, Cincinnati, United States, [5]Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States

Background: Recent randomized controlled trials (RCTs) have called into question whether percutaneous coronary intervention (PCI) reduces death or myocardial infarction in patients with stable ischemic heart disease (SIHD). However, several of these trials randomized an unselected group of patients, including those with and without objective ischemia.
Methods: We performed a meta-analysis of RCTs comparing PCI with medical therapy (MT) in pts with either ischemia (identified on non-invasive testing) or abnormal fractional flow reserve (FFR), to determine whether PCI reduces all-cause mortality in this high-risk SIHD cohort.
Results: Four RCTs comparing PCI vs. MT in pts with objective ischemia (or FFR-equivalent) were found; these trials randomized a total of 1,769 pts with f/u from 7 months to 10 years. The point estimate of the hazard ratio (HR) for mortality following PCI vs. MT varied from 0.33-0.73, with no trial heterogeneity (I2=0%). Of note, the documented ischemia cohort of the COURAGE trial (Am Heart J 2012) comprised 48% of the weight of the included studies. Overall, 28/871 (3.2%) PCI pts died compared with 54/898 MT pts (6.0%), consistent with a significant reduction in all-cause mortality with PCI (HR 0.56; 95% confidence interval (CI): 0.34-0.93, p=0.02, Figure), which remained significant when 3 other ineligible RCTs were added which included a PCI vs MT arm (HR 0.61 [0.42,0.89], p=0.01).



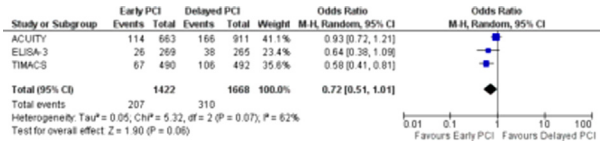
Conclusions: Despite conventional conclusions drawn from existing RCT data that PCI and MT result in comparable survival in SIHD, when analyses are restricted to pts with objective ischemia (or the FFR equivalent), PCI is associated with a significant and consistent 44% reduction in all-cause mortality compared with MT.

TCT-846

Early versus Delayed Percutaneous Coronary Intervention for High Risk patients with Non ST Elevation-Acute Coronary Syndrome: A Meta-analysis.

Naveen Rajpurohit[1], Colin Farritor[1], Muhammad Khan[2], Tom P. Stys[1], Marian Petrasko[1], Adam Stys[1]
[1]University of South Dakota, Sanford Heart Hospital, Sioux Falls, SD, [2]University of South Dakota, Sanford Heart hospital, Sioux Falls, SD

Background: Studies indicate no clear benefit of early percutaneous coronary intervention (PCI) (<24 hours) in non ST elevation acute coronary syndrome (NSTE-ACS) patients as compared to delayed PCI (>24 hours). However, high risk NSTE-ACS patients may benefit from early PCI. We pooled existing data and performed a meta-analysis.
Methods: Medline, PubMed and abstracts from major cardiology conferences were searched. Randomized control trials (RCTs) comparing the composite of death and/or myocardial infarctions (MI) and/or repeat revascularization within 6 months of early or delayed PCI for high risk patients with NSTE-ACS were included. High risk was defined as TIMI score >5 or GRACE score >140. The effects of both methods were analyzed by calculating pooled estimates for death, MI and repeat revascularization. Analyses were performed for the outcome by using odds ratio (OR) by random effects model. Heterogeneity among studies was assessed by calculating I'' measure of inconsistency.
Results: Three studies (ACUITY, ELISA-3 and TIMACS) with a total of 3090 patients met our inclusion criteria. The incidence of the composite of death and/or MI and/or repeat revascularization was not different between early PCI [207/1422 (14.5%)] as compared to delayed PCI [310/1668(18.6%)], (OR 0.72, 95% CI 0.51-1.01, P=0.06).



Conclusions: Coronary artery revascularization within 24 hours of presentation does not reduce composite of death and/or MI and/or repeat revascularization at 6 months in high risk NSTE-ACS as compared to intervention after 24 hours. More studies are needed on this subgroup of NSTE-ACS patients.

TCT-847

Strut Level Optical Coherence Tomography Evaluation of Coronary Stent Strut Coverage Temporal Trends: A Systematic Review

Kwan S. Lee[1], Justin Z. Lee[1], Irbaz B. Riaz[1], Muhammad Husnain[1], Haris Riaz[2], Kapil Lotun[1], Karl B. Kern[1]
[1]University of Arizona, Tucson, AZ, [2]Dow Medical College, Karachi, Sindh

Background: Delayed endothelial coverage of stent struts has been linked to late stent thrombosis, especially after drug-eluting stent implantation. The high-resolution capability of intravascular optical coherence tomography (OCT) enables visualization of strut coverage and has been used to quantify coverage at various time points post implantation. This has the potential application of predicting timing and safety of dual anti-platelet therapy discontinuation. We aim to summarize all known quantitative strut level analysis data of clinically implanted coronary stents in human subjects to date as evaluated by OCT.
Methods: A review of publications and online databases up to February 2013 retrieved 59 eligible articles and abstracts, 1843 initially identified studies. Data extracted for bare metal, (BMS), Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES-E & ZES-R) and Everolimus eluting stent (EES) strut coverage and malapposition was compared between stents at various time intervals post implantation.
Results: 13 abstracts and 46 papers were included in the analysis with studies performed from 1 week to 5 years post implantation. 2,278 patients were studied, comprising 2,716 stents, 2,044 lesions and strut level data on 532,533 struts, where data was recorded.
Conclusions: Bare metal stents achieved a threshold of < 2.0% uncovered struts within 1 month of implantation, SES within 48 months, PES within 60 months, Endeavor ZES within 2.5 months and EES within 20 months. Resolute ZES have a 7.4% uncovered strut rate at 13 months post-implantation and lack data beyond this. OCT enables direct visualization and quantification of coronary stent delayed endothelial coverage at a strut level, providing insight into drug eluting stent-specific effects on the timing of neo-intimal healing. This may have a role in predicting drug-eluting-stent specific safety of dual-antiplatelet therapy cessation.