Background: There have been limited evidences regarding optimal treatment options for in-stent restenosis (ISR). We performed a Bayesian network meta-analysis comparing the efficacy and safety of drug-eluting balloon (DEB), drug-eluting stent (DES), or plain old balloon angioplasty (POBA) for treatment of ISR developed after PCI with bare-metal stent (BMS) or drug-eluting stent (DES) were included to this network meta-analysis. The primary outcome was target lesion revascularization (TLR) after treatment of ISR. The secondary outcomes were myocardial infarction (MI), all-cause mortality, MACE, or binary restenosis at follow-up angiography. The pairwise posterior median OR with 95% CrI in Bayesian meta-analysis was the effect measure.

Methods: Randomized controlled trials (RCTs) comparing DEB, DES, or POBA for treatment of ISR developed after PCI with bare-metal stent (BMS) or drug-eluting stent (DES) were included to this network meta-analysis. The primary outcome was target lesion revascularization (TLR) after treatment of ISR. The secondary outcomes were myocardial infarction (MI), all-cause mortality, MACE, or binary restenosis at follow-up angiography. The pairwise posterior median OR with 95% CrI in Bayesian meta-analysis was the effect measure.

Results: This analysis included 2,059 patients from 11 RCTs. The risk of TLR was markedly lower in patients treated with DEB (OR 0.22, 95% CrI 0.10-0.42) or DES (OR 0.24, 95% CrI 0.11-0.47), compared with POBA in random-effects model. The binary restenosis was also significantly lower in DEB (OR 0.13, 95% CrI 0.06-0.25) or DES (OR 0.20, 95% CrI 0.09-0.40), compared with POBA. In comparison between DEB and DES, the risk of TLR (OR 0.92, 95% CrI 0.43-1.90) or binary restenosis (OR 0.66, 95% CrI 0.31-1.30) was similar. The risk of MI or all-cause mortality were lowest in DEB group compared with DES or POBA. However, statistical significance was not reached. The rate of MACE was also significantly lower in DEB (OR 0.24, 95% CrI 0.12-0.39) or DES (OR 0.28, 95% CrI 0.14-0.53) group, compared with POBA, but it was similar between DEB and DES group (OR 0.84, 95% CrI 0.45-1.50). No significant inconsistency or heterogeneity was found across trials. The ranking probabilities for the best treatments were: DES (50.5% (DEB), 40.1% (DES), and 9.1% (POBA)) for the risk of TLR, whereas, 63.0% (DEB), 1.7% (DES), 35.3% (POBA) for the risk of MI, respectively.

Conclusions: DEB or DES showed markedly superior efficacy compared with POBA. Although DEB and DES showed similar efficacy for preventing repeat revascularization, DEB showed trend for less development of MI, compared with DES in this network meta-analysis.

TCT-271
BIOLUX P-II: A Randomized Clinical Trial of Passeo-18 Lux Drug Releasing Balloon versus Plain Old Balloon Angioplasty for the Treatment of Infrapopliteal Artery Lesions
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Background: Drug-releasing balloons have shown promising results in femoropopliteal disease; however, adequate evidence demonstrating improved outcomes in infrapopliteal arteries is currently lacking. BIOLUX P-II assesses the safety and performance of the novel BIOTRONIK Passeo-18 Lux Paclitaxel-releasing balloon compared to the uncoated BIOTRONIK Passeo-18 balloon (POBA) in the treatment of infrapopliteal lesions.

Methods: BIOLUX P-II is a prospective, international, multicenter, first-in-human, randomized, controlled trial with follow-ups at 30 days, 6 months, and 12 months. The subjects with single or sequential de novo or restenotic lesions in the infrapopliteal arteries (>30 mm) were included in the study. A maximum of two different lesions could be treated. The safety primary endpoint was Major Adverse Events (MAE) at 30 days (judged by an independent Clinical Events Committee). The performance primary endpoint was Target Lesion Primary Patency at 6 months by Quantitative Vascular Angiography (assessed by an independent core laboratory, coreLab Bad Kroizingen, Germany). Secondary endpoints included freedom from TLR and change in ABI and Rutherford Class. Clinicaltrials.gov NCT01867736.

Results: Seventy-two subjects, 79.2% men, mean age 71.3 ± 9.7 years, were randomized 1:1 at six European sites. At baseline, subjects presented with hypertension (86.1%), hyperlipidemia (68.1%), diabetes (66.7%) and critical limb ischemia (77.8%). At 30 days, MAE was 0.0% for the DRB vs. 8.3% for POBA, p = 0.239. At 6 months, target lesion primary patency showed a trend in favor of the DRB of 84.8% vs. 75.9% for POBA, p = 0.330 and major amputations were 3.3% for DRB (OR 0.59, 95% CI 0.24-1.37) compared to 11.0% for POBA, p = 0.655. Clinical improvement at 6 months, reflected by improvement in Rutherford class was 59% in favor of DRB vs. 47% for POBA, with 0% of DRB subjects worsening vs. 6% for POBA, p = 0.326. Clinical improvement of Rutherford 5 subjects was significant for the DRB group (p = 0.002) compared to POBA (p = 0.588).

Conclusions: The Passeo-18 Lux DRB, as compared to POBA, is associated with favourable functional and clinical outcomes and results in significant clinical improvement of Rutherford 5 subjects in the treatment of infrapopliteal lesions.

TCT-272
Paclitaxel-coated balloon angioplasty for drug-eluting stent restenosis: insight from randomized controlled trials
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Background: Drug-eluting stents (DES) significantly reduce the occurrence of in-stent restenosis and the subsequent need for repeat revascularization. Nevertheless, the incidence of DES restenosis remains high due to the continuous increase in DES implantation. Paclitaxel-coated balloon (PCB) angioplasty is superior to plain old balloon angioplasty (POBA) and noninferior to paclitaxel-eluting stent (PES) implanation. Whether the use of PCB angioplasty is also effective in DES restenosis remained controversial. Thus, we performed a meta-analysis to assess the safety and efficacy of PCB for the treatment of DES restenosis.

Methods: Trials were identified through a literature search from January 2005 through April 2014. All randomized controlled trials were eligible for inclusion if they compared PCB with a control treatment (DES) or POBA in patients with DES restenosis. Main endpoints of interest were major adverse cardiac events (MACE), target lesion revascularisation (TLR), binary in-segment restenosis, myocardial infarction (MI) and mortality. A random-effects model was used to calculate the pooled relative risks (RR) with 95% CIs.

Results: Five studies and a total of 864 patients were included in this analysis. Follow-up duration ranged from 6 to 12 months. Most endpoints were significantly reduced for PCB compared with the control groups. For MACE, the relative risk RR was 0.49 (0.28 to 0.85), p = 0.012; for TLR, it was 0.50 (0.25 to 0.98), p = 0.044; for angiographic in-segment restenosis, it was 0.41 (0.23 to 0.72), p = 0.002. There was a lower mortality for PCB (RR 0.29 [0.11 to 0.80], p = 0.017). The incidence of MI was numerically lower, but the differences were not statistically significant (RR 0.76 [0.30 to 1.90]; p = 0.549).

Conclusions: In-stent restenosis remains an important issue even in the DES era, and PCB angioplasty is a promising option for the treatment of DES restenosis. It reduces the risk for MACE compared with POBA or implantation of a DES.

TCT-273
Coronary Lumen Eccentricity is Associated with Amount of Drug Adhesion after Treatment with Drug Coated Balloon
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Background: Drug coated balloon (DCB) had efficacy of in-stent restenosis according to previous study. The areas of drug adhesion were not visible with angiography, but optical frequency domain imaging (ODFI) could show them as high intensity spots. The extent of drug adhesion was not always circumferential. The aim of study was to investigate the association between lumen eccentricities and drug adhesion after DCB inflation.

Methods: Patients with in-stent coronary artery restenosis were enrolled. ODFI was performed at baseline, after pre dilatation and after DCB inflation. Pre dilatation with balloon was performed followed by DCB treatment. Lumen eccentricity was indicated by difference between maximum and minimum lumen diameter. The ratio of drug adhesion area was represented by angle of the bright spot from light source.

Results: 12 patients with restenosis lesion were analyzed in this study. Men were 10 (83.3 %), age was 68.7 ± 5.29 years old. Left descending artery was 7 (58.3%), left circumflex artery was 2 (16.7%) and right coronary artery was 3 (25.0%). The restenosis stent was 1 bare metal stent (8.3%), 11 drug eluting stent (91.7%). The difference of maximum and minimum lumen diameter just before DCB treatment was inversely associated with drug adhesion (r=-0.295, p=0.004). Lower lumen diameter difference group had more drug adhesion than higher group (p=0.002).

Conclusions: Our study showed lumen eccentricity was associated with amount of drug adhesion. It was ideal to be more concentric coronary lumen before DCB inflation. Importance of pre dilatation was highlighted in our study.