Meta-analysis of Randomized Trials Comparing Drug-Coated Balloon with Drug-Eluting Stent for Treatment of Coronary In-stent Restenosis

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Background: Drug-coated balloon (DCB) has been proposed as an alternative to drug-eluting stent (DES) for treatment of coronary in-stent restenosis (ISR). Several studies have examined the relative performance of these devices. However, their statistical power and the duration of clinical endpoints have been limited due to their small sample size. Therefore, we performed a meta-analysis of randomized trials comparing DCB with DES in patients with ISR.

Methods: We searched for randomized trials comparing DCB with DES with no less than 6-month follow-up. We excluded studies in which a BMS was used in conjunction with DCB. Outcomes of interest were repeat revascularization, death, myocardial infarction and the occurrence of major cardiac events (MACE). Odds ratios (ORs) with 95% confidence intervals (CIs) were computed as summary statistics.

Results: Five studies were included in this meta-analysis. In all studies, the DCB consisted of a paclitaxel-coated balloon while the DES was either a paclitaxel-eluting or an everolimus-eluting stent. There were no differences regarding the two treatment modalities regarding the odds of repeat revascularization [OR 0.92 (95% CI 0.63 to 1.33)], death [OR 0.81 (95% CI 0.32 to 2.05)] or myocardial infarction [OR 0.90 (95% CI 0.36 to 2.21)]. Similarly, patients treated with DCB and DES had comparable odds of suffering a MACE [OR 1.05 (95% CI 0.72 to 1.54)].

Conclusions: Among patients with coronary ISR, treatment with DCB is associated with similar efficacy and safety profile compared to treatment with DES.

Systematic treatment of the side branch in a bifurcation lesion with a new drug eluting balloon: the DEBSIDE study.

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Background: The optimal treatment of the side branch(SB) in a bifurcation coronary lesion is still a debate. Presently no study have evaluated the role of drug eluting balloon SB inflation after placement of a drug eluting stent in the main branch(MB).

The DANUBIO balloon with a new drug eluting technology combining an excipient (BTHC) with taxoice is in a first in human randomized multi-center study evaluating the DANUBIO balloon for the treatment of a SB/MB≥2mm diameter/lengther placement of a dedicated Paclitaxel stent(NILE Pax)in the MB.

Methods: From 8 French centers, 50 patients(male 79%,Diabetic 26%,acute coronary syndrome 22%) with bifurcation lesion were enrolled. After balloon pre-dilatation, the ostium of the SB and secondary endpoints MB LL,binary restenosis rate of >80% was scheduled at 1,6 and 12 months. The primary endpoint involved 6 months late dissection not beyond B according to NHLBI classi

Conclusions: Combining the DANUBIO balloon with a dedicated bifurcation stent to the main branch with provisional side branch stenting. While this provided very promising results in lesions with high risk for restenosis.

Consecutive Drug Coated Balloons plus Second-generation Drug Eluting Stents in lesions with high risk for restenosis

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Background: Limited data are available as to whether the combination of drug coated balloons (DCB) plus drug eluting stents (DES) would be more efficacious than DES in lesions or patients at high risk for restenosis. A combination of paclitaxel (present in coated balloons) and a limus drug may exert a synergistic effect in preventing major adverse cardiac events (MACE). We report the long-term follow-up data from a real-world cohort.

Methods: Between 2009 and 2013, 68 patients (82 lesions) were treated with a combination of DCB and implantation of a second-generation DES. The study end-points were MACE, defined as all-cause death, myocardial infarction (MI), and target vessel revascularisation (TVR). Furthermore, individual parameters, including cardiac death, MI, TL and TVR during the follow-up period, were evaluated. Cox regression analysis was performed to determine the independent predictors of MACE.

Results: In our study cohort, baseline patient characteristics were severe. The cohort had 31 lesions with in-stent restenosis (ISR) (37.8%), 18 lesions (22%) with multiple ISR (more than 2 times) and 23 patients with diabetes mellitus (DM) (34.3%). The mean lesion length was 23.8±13.7 mm, and 13% were CTO lesions. At median follow-up of 19.8 months, (interquartile range [IQR]: 11.5–30.4), the MACE rates were 9.2 and 27.4% at 1 and 2 years, respectively. The TL and TVR rates at 1 year were 5.9 and 13.5%, respectively. After 1-year, these rates increased to 24.7% and 32.5%. Very late stent thrombosis occurred in 1 patient on 1036 days after PCI. The final Cox regression model showed only independent-DM as the independent predictor of MACE [HR 5.16, (95% CI, 1.04–25.6); P = 0.05].

Conclusions: In our study, dual drugs with DCB and DES in lesions with high risk for restenosis may be synergistic that may explain the favorable outcome. Insulin-like growth factor 1 (IGF-1) is the only independent-DM as the independent predictor of MACE in our study. The efficacy of DCB plus DES combination in selected high-risk lesions for restenosis.

Percutaneous Coronary Intervention With Drug Coated Balloons Only For Coronary Bifurcation Lesions - Results Of The Randomized PEPCAD-BIF Trial

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Background: The standard treatment of bifurcation lesions is application of a drug eluting stent to the main branch with provisional side branch stenting. While this resulted in considerable improvement in overall MACE rate suboptimal side branch results remained a problem. A pooled good results of randomized DCB trials in small vessels, we set out to explore the benefit of distal main or side branch treatment with a DCB and compared this to regular balloon angioplasty (POBA).

Methods: The study was performed from 2011 to 2013 in 6 German centers. All patients planned for elective or de novo treatment of lesions involving bifurcations were screened for participation in the trial. Native bifurcation lesions were included if side branch vessel diameter was >2 mm and ≤3.5 mm and no proximal main branch lesions was found. After successful predilatation (TIMI III flow, recoil ≤30%, dissected not beyond B according to NIHIII classification) randomization was...