TCT-281

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

Alban Dibra[1], Laureta Dibra[1], Elvis Pavli[1]
[1]University Hospital Center, Tirana, Albania

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 regarding the evaluation of clinical endpoints has 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.

TCT-282

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

jacques berland[1], PATRICE GUERIN[2], Thierry Lefevre[3], Jean Fajadet[4]
[1]clinique saint hilaire, rouen, France, [2]HOPITAL GUILLAUME ET RENE LAENNEC, NANTES, France, [3]ICPS, Massy, France, [4]CLINIQUE PASTEUR, Toulouse, France

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 infation after placement of a drug eluting stent in the main branch(MB). The DANUBIO balloon integrates Speed Pax technology combining an excipient(BTHC)with Paclitaxel(2.5µg/mm2) The DEBSIDE study is a prospective non randomized multicenter study evaluating the DANUBIO balloon for the treatment of a SB(SB>2mm diameter)after 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, placement of the Nile Pax stent and kissing inflation(80%)without significant residual dissection, a DANUBIO balloon according to the SB size was inflated for 30s at 9.5±2.1 atm . Coronary angiography pre procedure before and after DANUBIO inflation and at 6 months were recorded and analysed by an independent core laboratory.Clinical follow up was scheduled at 1,6 and 12 months. The primary endpoint involved 6 months late loss(LL) of the ostium of the SB and secondary endpoints MB LL,binary restenosis rate of SB and MB and clinically driven revascularisation rates for main and secondary branches.
Results: Bifurcation lesions reached LAD/diag 74%,Circumflex/marginal 18% and distal right coronary in 8%.Significant SB lesion(Medina 111,101,011) was noted in 62% of the patients.Procedural success rate reached 100% after 3 additional stents in the main branch .Per protocol no additional stent was placed in the SB. 2 patients without cardiac events did not accept the angiographic control For the 48 others(96%) at 6 month the minimal luminal diameter of the SB(1.58±0.34mm)was identical to the post procedure one(1.53±0.3mm)resulting in a very low LL of 0.0065±0.4mm. Accordingly the SB target lesion revascularisation(TLR) rate reached only 2%. For the MB specifically the TLR reached 8% and 2 patients got non Target vessel angioplasty.
Conclusions: Combining the DANUBIO balloon with a dedicated bifurcation stent seems to be a very effective strategy and needs to be confirmed in a larger study.

TCT-283

Results Of Percutaneous Coronary Intervention With Sequent Please® Paclitaxel Eluting Balloon Catheter At A Very Long-Term Follow-Up.

Ignacio Sanchez-Perez[1], Alfonso Jurado-Roman[1], Manuel Marina-Breysse[1], Natalia Pinilla[1], Maria T. Lopez-Lluva[1], Jesus Piqueras-Flores[1], Javier Benezet[2], Fernando Lozano[1]
[1]Hospital General Universitario de Ciudad Real, Ciudad Real, Spain, [2]Hospital Universitario de Jerez, Jerez de la Frontera, Cadiz

Background: Drug eluting balloons currently constitute one of the therapeutic tools used in percutaneous coronary intervention (PCI) of both stent restenosis and de novo coronary lesions, mainly in bifurcations and small vessels. Nowadays, their results at a very long-term follow up are unclear. The main objective of this study was to evaluate the efficacy and safety of second-generation Sequent Please® paclitaxel eluting balloon (PEB) at 5 years.
Methods: We prospectively included 157 consecutive patients (69±12 years, 71.3% male) with 191 lesions (de novo or restenosis) treated with PEB between May 2009 and April 2013. We evaluated the presence of major cardiac events (MACE) after a prolonged clinical follow-up (median 36 months): death, nonfatal myocardial infarction, target lesion revascularization (TLR) and thrombosis.
Results: 40.8% of patients had stable coronary artery disease and 58.2% acute coronary syndromes (46.6% Non-STEMI and 12.7% STEMI). 50.3% of patients were diabetic and 24.3% of the lesions were bifurcations. Of the 191 lesions, 79 were de novo lesions and 110 restenosis [77 restenosis of bare metal stent (BMS) and 33 of drug-eluting stents (DES)]. 87.8% of the lesions were treated with PEB, 9.5% with PEB and BMS and 2.6% with PEB and DES. There were no significant differences regarding baseline characteristics of these three groups neither in the MACE rate after a long-term follow-up (p=0.545). During follow-up, 10 patients died (2 cardiovascular and 8 non-cardiovascular deaths) and a TLR rate of 2.6% was observed. No cases of thrombosis were observed, immediately after the procedure nor during follow-up. 20.1% of patients had an angiographic follow-up. We observed a higher need for additional stent after dissection due to PEB in de novo lesions (p=0.045) and especially in diffuse lesions (p=0.048) and bifurcations (p=0.026).
Conclusions: Percutaneous coronary intervention of de novo coronary lesions and in-stent restenosis (both of BMS and DES) with Sequent Please® PEB provide very favorable results at a very long-term follow up.

TCT-284

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

Hiroyoshi Kawamoto[1], Azeem Latib[2], Katsumasa Sato[1], Tadashi Miyazaki[1], Vasileios F. Panoulas[2], Filippo Figini[2], Alaide Chieffo[2], Matteo Montorfano[2], Mauro Carlino[2], Antonio Colombo[1]
[1]EMO GVM Centro Cuore Columbus/San Raffaele Scientific Institute, Milan, Italy, [2]San Raffaele Scientific Institute, Milan, Italy

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 endpoints were MACE, defined as all-cause death, myocardial infarction (MI), and target vessel revascularization (TVR). Furthermore, individual parameters, including cardiac death, MI, TLR 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, baselines 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 25.8 ± 13.7 mm, and 13% were CTO lesions. At median follow-up of 19.8 months, (interquartile range [IQR]: 11.5–80.4), the MACE rates were 9.2 and 27.4% at 1 and 2 years, respectively. The TLR 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 identified only insulin-dependent 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-dependent DM was only the independent predictor of MACE. A large randomized study is essential to evaluate the efficacy of DCB plus DES combination in selected high-risk lesions for restenosis.

TCT-285

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

Franz X. Kleber[1], Antonia Schulz[2], Detlef Mathey[3], Harald Rittger[4], Bruno Scheller[5], Ralf Degenhardt[6], Michael Boxberger[7], Ruth H. Strasser[8]
[1]Cardio Centrum Berlin, Berlin, Germany, [2]Charité University Medicine, Berlin, Germany, [3]University Cardiovascular Center Hamburg, Hamburg, Germany, [4]Universitätsklinikum Erlangen, Medizinische Klinik 2, Erlangen, Germany, [5]University of Saarland, Germany, Homburg, Germany, [6]Clinical Research Institute, Rotenburg a.d.F., Germany, [7]BBraun Melsungen, Berlin, Germany, [8]Technische Universität Dresden, Herzzentrum Dresden, Universitätsklinik Dresden, Dresden, Germany

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. Given the good results of drug coated balloons (DCB) 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 deferred 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 successfull predilatation (TIMI III flow, recoil ≤30 %, dissection not beyond B according to NHLBI classification) randomization was