TCT-274
Drug-eluting balloon in 001 bifurcated lesions: 1 year clinical and 7-months angiographic outcomes
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Background: In the DES era, the best strategy to treat 001 bifurcated lesions remains unanswered. This is the first prospective registry assessing the efficacy and safety of second generation of drug-eluting balloon (DEB) (EurocorGm), (3/5mm2 balloon surface area), in patients with 001 bifurcated lesions placed in secondary branches Methods: After 2.7 years, 51 patients with 001 bifurcated lesion and clinical evidence of myocardial ischemia related to the target lesion were prospectively included in this multi-center 001 first-in-human registry. After optimal dilatation, a PEB was inflated for a minimum of 45 seconds. Left main bifurcated lesions, severe calcification and carcinoma shock, were the only exclusion criteria. In 2 eligible patients after regular balloon pre-dilatation the DEB could not be used and patients were excluded of the registry.

Results: Patients were 62 ± 12 years old, 42% diabetic, 56% ACS as clinical presentation. The most frequent lesion treated was first diagonal (41%). Radial approach was done in most cases (84%). Pre-dilatation was done in all the cases, with cutting balloons (84%). Post-dilatation plus PEB in 12% of the cases and because of significant acute recoil (3) of coronary dissection more than that type B (2). At 1 month (follow-up completed in all the patients) there was no adverse event (MACE). At a mean of 11.2 ± 2.2 months (12 months completed in 81% of patients) there was 14.2% cumulative non-hierarchical MACE (1 MI, 0 cardiac deaths, 12 years old, 42% diabetic, 56% ACS as clinical presentation.

Conclusion: The DEB could be effective at mid-term follow up with a 14% MACE at 1 year.

TCT-275
A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: One Year Results of the PATENT-C First-in-Human Trial
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Background: Scoring balloons are useful in the acute treatment of in-stent restenosis, fibro-calcific and bifurcation lesions but have not shown to affect the restenosis rate as compared to conventional balloons. A novel paclitaxel-coated scoring balloon (SB) was developed to overcome these limitations. Prior studies in a coronary swine model showed a high reduction in restenosis using these SB and no evidence of local or systemic adverse effects.

Methods: SB were coated with paclitaxel admixed with a specific excipient. Patients at 5 sites (4 in Germany and one in Brazil) with bare metal stent in-stent restenosis (ISR) were randomized 1:1 to treatment with either a drug-coated or bare SB. Baseline and 6-month follow-up quantitative coronary angiography was performed by an independent blinded core lab and all patients were evaluated clinically at 30 days, 6 and 12 months. The primary endpoint was angiographic in-segment late lumen loss (LLL). Secondary endpoints included clinically driven target lesion revascularization (TLR), major adverse cardiac events (MACE), stent thrombosis (ST) and other clinical and angiographic variables. Patients will be followed clinically for 2 years.

Results: A total of 61 patients were randomized (28 uncoated and 33 coated SB); mean age 63.3 yrs, males 72%, and presence of diabetes 38%. At 6-month angiography, mean in-segment late lumen loss was 0.48±0.51 in the uncoated SB group versus 0.09±0.43 mm in the drug-coated SB group (p=0.002; ITT analysis). The rate of binary restenosis was 41% in the uncoated SB group versus 6.5% in the drug-coated SB group (p<0.05). At one year, the MACE rate was 32% with the uncoated SB vs. 6.7% with the drug-coated SB (p<0.05).

Conclusions: A novel paclitaxel-coated coronary SB has been developed and achieved successful results in a first-in-human randomized controlled trial [ClinicalTrials.gov Identifier: NCT01495533].

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Characterization of vascular response and pharmacoekinetics after application of paclitaxel-coated angioplasty balloons in non-diseased swine coronary arteries
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Background: Drug-coated balloons (DCB) rapidly transfer antirestenotic drug along the arterial vessel wall without a metallic implant. DCBs, coated with a mixture of paclitaxel (and an excipient to modulate drug release), may have clinical application in treating coronary in-stent restenosis and in peripheral arterial stenoses. This study characterizes the in vivo elution of paclitaxel and vascular compatibility of the novel Agent™ Paclitaxel-coated PTCA balloon for coronary vasculature.

Methods: The Agent DCB TransPAX coating consists of 80% Paclitaxel/20% excipient (2ug/mm2 dose density [Boston Scientific Corporation, Natick MA], “test DCB”). Controls included a commercially available paclitaxel-coated balloon (3ug/mm2, Pantera Lux [Biotronik AG, Switzerland] “control DCB”) and an uncounated balloon (“POBA”). Balloons were inflated distal to a marker stent (BMS) or a BMS was implanted prior balloon inflation in the same position. The level of paclitaxel was measured at time points through 28d and vascular response was analyzed 28d post implantation.

Results: The level of paclitaxel in the coronary arteries was equivalent between test DCB and control DCB (reaching 50% of initial levels between 7 and 14d). Vessel areas were similar and endotheliozalation of luminal surfaces was nearly complete in all groups by 28d. Neointimal area was similar between test DCB and POBA; both were statistically less than control DCB. Medial smooth muscle cell loss and inflammation were greatest in control DCB vessels compared to test DCB vessels followed by POBA. Similarly, mean fibrin score (inintima/media) was highest in the control DCB, followed by test DCB vessels and then POBA vessels (See Table).

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Synergy of Drug Coated Balloons plus Second-generation Drug Eluting Stents versus Second-generation Drug Eluting Stents: A Propensity Matched Analysis
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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 target lesion revascularization (TLR).

Methods: Between 2009 and 2013, 68 patients (82 lesions) were treated with a combination of DCB and implantation of a second-generation DES. These were compared to 513 lesions treated with conventional second-generation DES in the same period. Primary endpoint was TLR at 1- and 2-years of follow-up.

Results: The DCB plus DES group had more in-stent restenosis (ISR); 42.3% vs. 9.5%, p < 0.001 and higher prevalence of diabetes mellitus (DM); 36.4% vs. 22.2%, p = 0.007 compared to the DES group. After propensity matching, there were no