TCT-413

Late outcomes for SequentPlease paclitaxel-drug eluting balloons in PCI of de-novo lesions and in-stent restenosis: a single-center, all-comer registry

Leia Hee,[1] Andrew Terluk,[1] Liza Thomas,[1] Andrew Hopkins,[1] Craig P. Juergens,[1] Sidney Lo,[1] John K. French,[1] Christian J. Mussap[1]
[1]Liverpool Hospital, Sydney, NSW, Australia

BACKGROUND Paclitaxel drug-eluting balloons (pDEB) are indicated for PCI of in-stent restenosis (ISR), and may have a role in revascularization of de-novo lesions (DNL). While the short-term efficacy and safety of pDEB has been reported from registries and a few randomized controlled trials, late follow-up is lacking. Thus we studied the late efficacy and safety of SequentPlease pDEB (B. Braun, Germany) in PCI of DNL and ISR.

METHODS All 147 patients (188 lesions) undergoing PCI using pDEB at Liverpool Hospital, Sydney from Oct 2011 to Mar 2015 were included. According to the PCI lesion-type, patients were categorized into 2 groups: DNL and ISR [prior bare-metal stent (BMS) or drug-eluting stent (DES)]. Baseline, procedural, and clinical outcome data were obtained from the departmental database and treating physicians. The primary outcome was MACE: composite of cardiac death, clinically driven pDEB target-lesion revascularization (pDEB-TLR), and myocardial infarction (MI).

RESULTS Mean patient age was 67±11 years (79% male), 39% presented with an acute coronary syndrome (ACS). Clinical follow up was 1.3±1.0 years. Lesions treated for ISR (n=118) were more likely than DNL (n=70) to be in patients with diabetes mellitus (DM, 64 vs 37%; p<0.001), impaired renal function (43 vs 20%; p<0.001), and multivessel PCI (66 vs 46%; p=0.006). Among patients with prior coronary bypass grafting (CABG), DES ISR was more common than BMS ISR (39% and 18%; p=0.02). ACS patients were more likely treated for DNL than ISR (50 vs 33%; p=0.02). There was no difference between DNL and ISR groups in target lesion complexity (61% type B2/C), target lesion length (21±12mm), and pDEB length (20±5mm). Smaller caliber pDEBs were used for DNL compared to ISR (2.4±0.4 vs 2.8±0.6mm; p<0.0001). For DNL compared to ISR: cardiac death was 3% vs 0% (p=0.06), DEB-TLR was 1% vs 12% irrespective of stent type (p=0.02); and respective dissection (grade D-F) rates were 7% and 5% (p=0.56). MACE event rates (Table 1) were similar for DNL and ISR (14 vs 25%, p=0.105), and for DES and BMS ISR subgroups (23 vs 27%, p=0.55). Cox multivariate analysis showed diabetes and prior CABG are independent predictors of MACE in patients with ISR (HR 4.48, 1.34-15, P=0.015 and HR 3.22, 1.51-6.89, p=0.003, respectively).

Table 1. Long-Term Clinical Outcomes for pDEB

Outcomes	De novo (n=70)	ISR (n=118)	*p*-value	BMS-ISR (n=39)	DES-ISR (n=79)	*p*-value
Cardiac death (%)	2 (3)	0	0.06	0	0	
MI (%)	5 (7)	20 (17)	0.12	6 (15)	14 (18)	0.64
pDEB-TLR (%)	1 (1)	15 (12)	0.02	3 (8)	12 (15)	0.22
MACE (%)	8 (14)	30 (25)	0.15	9 (23)	21 (27)	0.55

CONCLUSIONS In our real-world all-comer registry, pDEB appears to be a safe and effective stent-sparing strategy for DNL in smaller caliber arteries. pDEB use in DNL was associated with low rates of re-intervention, and had similar MACE rates to ISR groups. DM and prior CABG predict poorer outcomes for pDEB used in (BMS and DES) ISR.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Outcomes, long-term, Paclitaxel-eluting balloon, PCI - Percutaneous Coronary Intervention

TCT-414

A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: Two Years Follow-up Results from the PATENT-C First in Human Trial

Bruno Scheller,[1] Daniel Chamié,[2] Norman Mangner,[3] Stefan Hoffmann,[4] Klaus Bonaventura,[5] Yvonne P. Clever,[6] Tobias Fontaine,[7] Jose D. Costa, Jr,[8] Gary Gershony,[9] Bettina Kelsch,[10] Maren Kutschera,[10] Philippe Genereux,[11] Bodo Cremers,[12] Ulrich Speck,[10] Alexandre Abizaid[13]
[1]University of Saarland, Germany, Homburg, Germany; [2]Dante Pazzanese, São Paulo, Brazil; [3]Heart Centre Leipzig, Leipzig, Germany; [4]Vivantes Klinikum im Friedrichshain, Berlin, Germany; [5]Klinikum Ernst von Bergmann, Potsdam, Germany; [6]Saarland University Medical Center, Homburg/Saar, Germany; [7]University of Saarland, Homburg/Saar, Germany; [8]Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil; [9]John Muir Cardiovascular Institute, Piedmont, United States; [10]Charite, Berlin, Germany; [11]Columbia University Medical Center, New York; [12]Universitätsklinikum des Saarlandes, Homburg, Saarland; [13]Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil

BACKGROUND Scoring balloons produce excellent acute results in the treatment of in-stent restenosis, fibro-calcific and bifurcation lesions but have not been shown to affect the restenosis rate. A novel paclitaxel-coated scoring balloon (SB) was developed and tested to overcome this limitation.

METHODS SB were coated with paclitaxel admixed with a specific excipient. Patients at four clinical sites in Germany and one in Brazil with in-stent restenosis (ISR) of coronary bare metal stent (BMS) were randomized 1:1 to treatment with either a drug-coated or uncoated SB. Baseline and 6-month follow-up quantitative coronary angiography was performed by an independent blinded core lab and all patients will be evaluated clinically for up to one year. The primary endpoint was angiographic in-segment late lumen loss (LLL). Secondary endpoints included the rate of clinically driven target lesion revascularization (TLR), composite of major adverse cardiovascular events (MACE), stent thrombosis and other variables at two years follow-up.

RESULTS Sixty-one patients were randomized (28 uncoated and 33 drug-coated SB); mean age 65 years, males 72 %, and presence of diabetes 39 %. At 6-month angiography, in-segment LLL was 0.48 ± 0.51 mm in the uncoated SB group versus 0.17 ± 0.40 mm in the drug-coated SB group (p=0.01; ITT analysis). The rate of binary restenosis was 41 % in the uncoated SB group versus 7 % in the drug-coated SB group (p<0.01). The MACE rate at 2 years was 32 % with the uncoated SB vs. 9 % in the drug-coated SB group (p<0.05). This difference was primarily due to the reduced need for clinically driven TLR in the coated SB group (3 % vs. 32 % p<0.01).

CONCLUSIONS A novel paclitaxel-coated coronary SB has been developed and successfully used in a first-in-human randomized controlled trial [ClinicalTrials.gov Identifier: NCT01495533].

CATEGORIES CORONARY: Cutting and Scoring Balloons

KEYWORDS Drug-eluting balloon, In-stent restenosis, Scoring Balloon

TCT-415

OCT-based Gray-scale Signal Intensity Analysis For In-stent Restenosis And Treatment With Drug-coated balloons

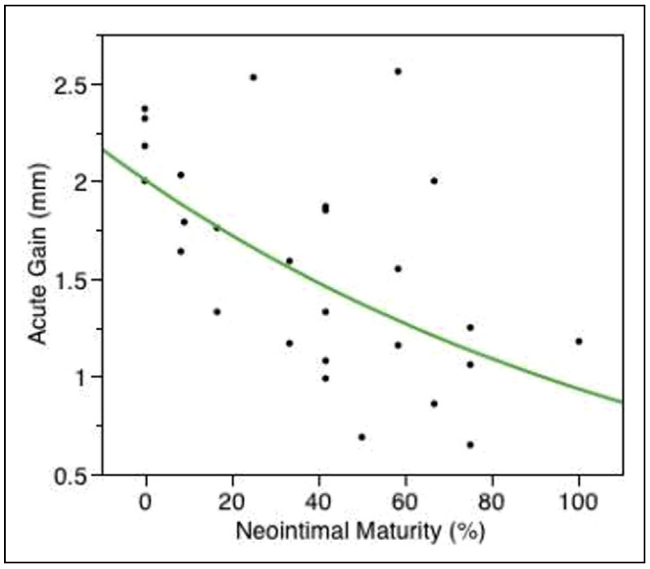
Tomohisa Tada,[1] Ryusuke Nishikawa,[2] Eriko Takagi,[2] Hiroki Sakamoto[3]
[1]Shizuoka General Hospital, Shizuoka, Shizuoka; [2]Shizuoka General Hospital, Shizuoka, CA; [3]National cerebral and cardiovascular center, Osaka, Japan

BACKGROUND The aim of this study was to evaluate the impact of neointimal tissue characteristics assessed by OCT using gray-scale intensity (GSI) on treatment for in-stent restenosis (ISR) with drug-coated balloon (DCB).

METHODS Neointimal tissue characterization using OCT-based GSI analysis was performed for a total of 25 patients with 32 ISR lesions undergoing DCB treatment for ISR. Neointima were classified into mature and non-mature tissue according to our previous data with animal models and autopsy specimens.

RESULTS Of 637 regions of interest (ROI) assessed for neointimal maturity, 248 ROIs (39%) were mature neointimal tissue. The higher percentage of mature tissue was associated with smaller acute gain after PCI with DCB (Figure). Clinical events and OCT findings at 6-8 month after DCB treatment for ISR lesions will be available at presentation. Conclusions: OCT GSI analysis for neointima might predict reactions after treatment with DCB for ISR lesions.

CONCLUSIONS OCT GSI analysis for neointima might predict reactions after treatment with DCB for ISR lesions.



CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Optical coherence tomography, Restenosis, in-stent

TCT-416

Drug eluting balloon: a real world three centers experience

Carlo Zivelonghi,[1] Matteo Ghione,[2] Alfredo Fede,[1] Stefano Cordone,[2] Marco Botta,[2] Magdalena Cuman,[1] Andrea Pacchioni,[3] Bernhard Reimers,[3] Flavio L. Ribichini[1]
[1]University of Verona, Verona, Italy; [2]Ospedale San Paolo, Savona, Italy; [3]Mirano Hospital, Mirano, Italy

BACKGROUND The use of drug-eluting balloons (DEB) for the treatment of in-stent restenosis (ISR) and lesions in small vessels has not been extensively investigated in the real-life clinical practice. According to the most recent guidelines, the use of DEB is indicated only for the treatment of ISR. We aim to report a three-centers "all comers" registry on the safety and efficacy of DEB in the treatment of ISR and de novo coronary artery disease.

METHODS Consecutive patients treated with the In.Pact Falcon™ (Medtronic Inc., Minneapolis, MN, USA) paclitaxel-eluting balloon between January 2012 and November 2014 in the centers of Verona, Mirano and Savona were retrospectively analyzed in our registry. The measured clinical end-points were cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), while procedural success was defined as the ability to reach, cross and dilate a lesion with the study device, with a residual stenosis <30% and a final TIMI 3 flow in the culprit vessel. Primary end point of the study was the occurrence of major adverse cardiac events (MACE), defined as combination of cardiac death, MI, and TLR, at 12 and 24 months of follow up.

RESULTS A total of 167 lesions were successfully treated in 143 patients. The mean age was 67±10 years, and 82.5% were males. The main risk factors were represented by hypertension and dyslipidemia while 39.4% of patients were diabetics. The 73.5% of the population had a prior PCI and the main indication for PCI was because of ACS (73.5% while 26.5% of patients suffered from stable angina). The predominant indication for DEB use was ISR (75%), mainly focal (34.1%), involving a DES in the 79% of cases. Procedural success was achieved in 97.6%. A mean of 1.1±0.18 DEB were used per patient. Bailout stenting was required in 2 lesions. No events were recorded during the hospitalization. Long term follow up was available for 100% of the study population. The overall incidence of MACEs at 12 months was 5.6%, while at 24 months was 9.1%, with an overall event free survival of 85%. Of interest, the primary endpoint occurred in 18% of patients treated for de novo lesions, against a 5.7% of ISR patients (p=0.01). Patients presenting with focal restenosis had an incidence of events comparable to those with more aggressive restenotic pattern (diffuse or proliferative, p=0.71).

CONCLUSIONS Our results confirm the safety and efficacy at short and long term follow up of DEBs, especially in patients presenting with ISR. On the contrary, the use of DEB in de novo lesions is associated with a poorer clinical outcome. Larger trials are needed to confirm our data.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Restenosis, in-stent, Small coronary vessels

TCT-417

Treatment of coronary artery disease with a new-generation drug-coated balloon: preliminary results from the Italian Elutax SV Registry

Bernardo Cortese,[1] Raffaela Fetiveau,[2] Alessandro Carrera,[3] Simonetta Blengino,[4] Vruyr Balian,[5] Renata Rogacka,[6] Corrado Lettieri,[7] Andrea Pavei,[8] Carlo Pierli,[9] Marco Crenna,[5] Simone Tresoldi,[10] Francesca Buffoli,[11] Arnaldo Poli[12]
[1]A.O. Fatebenefratelli Milano, Milano, Italy; [2]Ospedale di Legnano, Legnano; [3]AO Le Scotte, Siena; [4]Istituto Auxologico, Milano; [5]ospedale Busto, Busto arsizio; [6]Ospedale di Desio, Desio; [7]Azienda Ospedaliera Carlo Poma, Mantova, Italy; [8]Conegliano Hospital, Conegliano, Italy; [9]Azienda Ospedaliera Senese-Policlinico Le scotte, Siena, Italy; [10]Ospedale di Desio, Milan, MB; [11]Interventional Cardiology Unit, Ospedale di Mantova, Mantova, Italy, Mantova, Italy; [12]Azienda Ospedaliera Legnano, Legnano, Italy

BACKGROUND drug-coated balloons (DCB) have shown to be a valuable alternative to stents for the treatment of in-stent restenosis, and there is some initial evidence of their efficacy for the treatment of small coronary vessels. Newer generation DCB were developed to overcome the reduced deliverability of the previous generation of devices, warranting an effective drug delivery to the vessel wall. However, the vast majority of such devices still lack of reliability due to paucity of clinical data.

METHODS between 2012-2014 all patients intended to be treated with this type of DCB at 9 italian centers were enrolled in this retrospective registry. We did not have specific exclusion criteria. Coronary interventions were performed following the Italian Position paper on DCB-PCI published in 2014. Primary outcome was the occurrence of target lesion revascularization (TLR) at the longest available follow up.

RESULTS we enrolled 247 consecutive patients/283 lesions, whose clinical, angiographic and procedural characteristics are depicted in Table. At the longest available clinical follow up (average 225 days, I.Q. ranges 67 days), 5 patients suffered a TLR, all but one managed with re-PCI (2 with another type of DCB, 2 with DES). We registered 2 cases of cardiac death (one for heart failure and one for fatal myocardial infarction related to another vessel), 4 non-cardiac deaths (2 malignancies and 2 intracranial hemorrhages) and no cases of target vessel myocardial infarction/thrombosis.