results often show increased localized haziness at the treated segment that is attributable to multiple factors, including inflammation and atheromatous tissues. We analyzed the safety focused on the rates of acute stent thrombosis after DCB in de-novo lesions without additional stenting (the so called drug-eluting balloon only strategy) in a clinical setting.

Methods: A retrospective review was done of 191 consecutive patients who underwent percutaneous coronary intervention procedure with the paclitaxel eluting balloon SeQuent Please at a high-volume Heart Center in Potsdam. DCB was used for the treatment of de-novo lesions in 85 patients (male n=61, age 67.1 ± 10.9 years) in 102 interventions. Interventions included small coronary arteries, long lesions, ostial lesions and bifurcation lesions. All patients were pretreated with aspirin and clopidogrel/prusagrel (DAPT), which was continued for at least 4 weeks.

Results: A localized haziness at the treated segment was found in 17 interventions (16.8%). During hospital stay none of the 85 patients (0%) had suffered from acute coronary thrombosis in the clinical setting. Unscheduled coronary angiography was performed in overall 35.8% (50) within 72 hours after DCB because of recurrent chest pain and showed an excellent short-term result with TIMI III flow and without need for revascularization.

Conclusions: Incidence of localized haziness after DCB angioplasty in de-novo lesions is comparable to treatment with plain old balloon angioplasty and does not increase the risk of acute coronary thrombosis.

TCT-459
Incidence of late thrombosis after paclitaxel-coated balloon angioplasty in de-novo coronary artery disease
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Background: Clinical studies demonstrated the safety and effectiveness of drug-coated balloon (DCB) in various clinical scenarios and support the use of paclitaxel-eluting balloon for the treatment of in-stent restenosis, of small coronary arteries and bifurcation lesions. We analyzed and compared the safety, focused on the rates of late coronary thrombosis (LT), after DCB in de-novo lesions without additional stenting - the so called "Drug-eluting balloon only" strategy - in four current studies with the outcome in a clinical setting.

Methods: A retrospective review was done of 191 consecutive patients who underwent percutaneous coronary intervention procedure with the paclitaxel eluting balloon SeQuent Please at a high-volume Heart Center in Potsdam. DCB was used for the treatment of de-novo lesions in 85 patients (male n=61, age 67.1 ± 10.9 years) in 102 interventions. The primary evaluation was LT. Mean clinical follow-up was 16.3 ± 5.5 months. Duration of dual antiplatelet therapy was 5.4 ± 4.1 months.

Results: DCB used in de-novo coronary arterial disease is not associated with a higher rate of LT. Beside the proven possible reduction in the duration of DAPT to one month may represent additional advantages regarding safety, patient compliance and costs for the Drug-eluting balloon only strategy. Further larger scale studies are needed before DCB can be recommended for routine initial use in all cases as an alternative approach.

TCT-460
Magnitude of Stent Expansion Influences Local In-Stent Hyperplasia and Lumen Changes Following Stent Implantation in Humans
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Background: In-stent restenosis (ISR) remains as a limitation of percutaneous coronary intervention (PCI). Post-implantation stent expansion assessed by intravascular ultrasound (IVUS) has been used to optimize PCI outcomes, but there are limited data regarding the effect of local stent expansion on ISR. The objective of this study was to assess the relationship between local stent expansion and in-stent hyperplasia (ISH) and lumen modifications.

Methods: Vascular Access and 3D coronary reconstruction by angiography & IVUS was performed in 374 patients at baseline (BL) and 6-10 months follow-up (FU). Each reconstructed coronary artery was divided into 1.5-mm segments for serial study. A total of 80 bare-metal stents (BMS), 51 sirolimus-eluting stents (SES) and 25 paclitaxel-eluting stents (PES) were analyzed. At baseline, local stent expansion was defined as the ratio of stent area to the respective reference lumen area. Stent expansion ratio was categorized as underexpansion (stent expansion <0.8), normal (stent expansion 0.8–1.2) and overexpansion (stent expansion >1.2). Results:ISH area in overexpansion group is significantly larger than in underexpansion group at FU (3.3 ± 2.0 mm² vs 2.0 ± 1.4 mm², p<0.001 in BMS; 0.33 ±

0.53 mm² vs 0.0036 ± 0.028 mm², p<0.001 in SES; and 0.71 ± 0.78 mm² vs 0.44 ± 0.42 mm², p<0.001 in PES). Significantly larger changes in local lumen were observed in SES/DES-ISR expansion group at FU compared to underexpanded group in all stent types (delta=3.3 ± 2.0 mm² vs 0.61 ± 2.3 mm², p<0.001 in BMS; delta=0.55 ± 1.15 mm² vs -1.7 ± 1.6 mm², p<0.001 in SES; and delta=1.2 ± 1.2 mm² vs -0.52 ± 1.1 mm², p<0.001 in PES). Lumen area in overexpansion group in SES became smaller than in underexpansion group (8.1 ± 1.5 mm² vs 9.2 ± 3.0 mm², p<0.01 in SES). In BMS and PES, the relationship in lumen area at FU between overexpansion and underexpansion groups were similar (8.7 ± 2.5 mm² vs 9.0 ± 4.6 mm², p=0.58 in BMS; 8.1 ± 1.2 mm² vs 7.7 ± 1.8 mm², p=0.12 in PES).

Conclusions: Overexpanded stent segment showed greater ISH and lumen loss at FU regardless of stent type. There is less advantage of aggressive dilation at stent deployment to gain larger lumen.