results often show increased localized haziness at the treated segment that is attributable to multiple intimal flaps, dissection and atheromatous tissues. We analyzed the safety, focused on the rates of acute 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/prasugrel (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 one patient (1%) 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 without additional stenting was used in different clinical and interventional settings. During follow-up none of the 85 patients (0%) had suffered from late coronary thrombosis in the clinical setting. This is remarkable since DCB were mostly used in complex interventions. Three patients died due to renal failure, one of them after elective cardiac surgery and one patient died due to non-cardiovascular disease. Four DCB trials used the "Drug-eluting balloon only" strategy in de-novo lesions: PEPCAD I SVD, PEPCAD V (side branch), PICCOLETO and DEBUIT. Summarizing the rates of LT after 6 to 12 months LT was reported in none of the 179 patients (0%).
Conclusions: The use of DCB in de-novo coronary artery disease is not associated with a higher rate of LT. Beside the proven efficacy the 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 on 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 loss.
Methods: Vascular profiling (3-vessel 3D coronary reconstruction by angiography & IVUS) was performed in 374 patients at baseline (BL) & 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=0.014 in PES). There was significant lumen area decrease in overexpansion group at FU compared to underexpansion 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 ± 1.5 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 get larger lumen.

TCT-461

Isolated Left-Anterior-Descending Artery In-stent Restenosis: Comparison Between Treatment With PCI-DES And CABG With Left-Internal-Mammary Artery

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Background: The treatment of isolated in-stent restenosis (ISR) of the left-anterior-descending artery (LAD) can be performed either with PCI with drug-eluting stent(DES) or with surgical bypass with left-internal-mammary artery(LIMA). So far, no data are available on the comparison between these two revascularization techniques in this particular clinical context.
Methods: We compared clinical outcomes (MACCE:Major adverse cardiac cerebrovascular events and procedure-related complications)of PCI with DES(DES group) to surgery with LIMA(CABG group)for the treatment of pts with isolated LAD-ISR.Continuous and categorical data were compared with t-Student and X2-test,respectively.Kaplan-Meier method was used for comparisons during follow-up whereas Cox-regression analysis to assess predictors of new revascularizations.
Results: We enrolled 141 consecutive patients with isolated LAD-ISR:70 pts in PCI group and 71 pts in CABG group.The two groups were well-matched for clinical characteristics. DES-ISR was present in 79% and BMS-ISR in 21% of cases in the PCI group,while DES-ISR was found in 21% and BMS-ISR in 79% in the CABG group(p<0.001).A 3-year clinical follow-up was achieved in>90%. MACCE were observed in 22.8% of pts in PCI group and 30.9% in CABG group (log-rank p =0.38).Target-lesion revascularization(TLR) was observed in 8.5% pts in the PCI group whereas LIMA failure in 8.4% of the CABG group (P=0.9).Non-Target vessel revascularization occurred in 8.6 % and 14.1% of patients in the PCI and CABG group,respectively (p=0.22).At multivariable Cox-regression analysis, predictors of any revascularization were chronic renal failure(HR 1.32; 95%CI 1.09-1.59),LDL-cholesterol levels(HR 1.29; 95%CI 1.09-1.51)and HbA1c levels (HR 1.59; 95%CI 1.0-1.90). When compared with PCI group, CABG group was characterized by higher rates of in-hospital complications/need for transfusion (1.4% vs 28.1%, p<0.0001) and length of hospitalization (2.1 vs 5.7 days, p<0.0001)
Conclusions: Isolated LAD-ISR may be effectively treated either PCI with DES and CABG with LIMA. However, CABG treatment is characterized by higher rates of in-hospital complications and requires longer hospitalization.

TCT-462

The difference in Temporal Change of Peri-stent Contrast Staining Between Drug-eluting Stent and Bare-metal Stent

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Background: It was reported that peri-stent contrast staining (PSS) was one of abnormal vessel reactions including incomplete stent apposition assessed with optical coherence tomography. Little is known about the differences in temporal change of PSS among various stents.
Methods: Between October 2001 and February 2012, percutaneous coronary intervention was performed with bare-metal stent (BMS) in 2138 lesions and with drug-eluting stent (DES) in 11138 lesions. We routinely performed follow-up coronary angiography (CAG) at 6th and 18th month after BMS implantation and 8th and 20th month after DES implantation, and found PSS in 56 lesions with BMS and 281 lesions with DES (2.62% vs. 2.52%, p=0.764). The temporal change of PSS between 6-8 and 18-20 months after stent implantation was confirmed with CAG in 36 lesions with BMS and 191 lesions with DES, which were classified into 3 groups: progressive, unchanged, and regressive PSS. We examined the difference in temporal change of PSS between DES and BMS. Furthermore, the temporal change after the 20th month of stent implantation was examined with unscheduled CAG in 9 BMS lesions and 53 DES lesions. DES were classified into SES and non-SES.
Results: The results are shown in the figure. Progressive PSS after 20th month of stent implantation was observed only in 9 of 43 lesions (20.9%) after SES implantation.

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