posters was designed to evaluate long-term vascular biology response to fluoropolymer (polyvinylidene fluoride hexafluoropropylene, PVDF-HFP) coated self-expandable, low-dose paclitaxel-eluting nitinol stent (FP-PES, 0.167 mg/mm2) in a porcine ilio-femoral artery model.

Methods: FP-PES (6, 7 or 8mm x 80 mm, n=12 at 30 and 180d, n=13 at 90d) or BMS (n=12 at 30, 90 and 180d) with identical stent length and size were implanted in the iliac arteries of 37 pigs. Complete histomorphometric and histopathologic analyses were performed after termination of animals. In addition, an in vivo pharmacokinetic (PK) study was conducted for FP-PES (n=9/time-point) at 4, 10, 30, 60, 90 and 180d. Paclitaxel levels in systemic blood and major organs were also evaluated.

Results: Paclitaxel released steadily without burst phenomenon. Paclitaxel levels were below quantifiable levels in both blood and major organs at all time-points. Neointimal thickness was significantly inhibited by FP-PES (0.35±0.09, 0.55±0.15 mm) compared to BMS (0.70±0.25, 1.00±0.25 mm) at 30 and 90d (p<0.001, respectively), yielding reductions of in-stent stenosis 48.1% and 51.9% for FP-PES versus BMS (P<0.005 and <0.001, respectively). No difference in any of the histomorphometric parameters was apparent at 180d. Stents from both groups were completely re-endothelialized and there was no thrombus apparent in either group at any time point., Drug effect was observed as higher expression for both fibrin deposition and para-strat inflammation scores in FP-PES vs. BMS (p=0.05) at all time-points although the absolute scores were low for both groups.

Conclusions: Maintaining long-term patency after peripheral endovascular therapy remains a challenge. The FP-PES decreased neointimal formation at 30d and 90d compared to BMS, with a comparable vascular healing response and no evidence of systemic paclitaxel.

TCT-166
Association between leg wound site and prognosis of dialysis patients with critical limb ischemia after isolated infrapopliteal balloon angioplasty
Masatsugu Nakano1, Keisuke Hirano1, Osamu Iida2, Yasutaka Yamauchi3, with critical limb ischemia after isolated infrapopliteal balloon angioplasty remains a challenge. The FP-PES decreased neointimal formation at 30d and 90d scores in FP-PES vs. BMS (p<0.01). At the 3-year clinical results, the P group had 0.05), while there was no significant difference was detected in the baseline demographic, angiographic, and lesion characteristics. Technical success obtained 100%. Regarding acute or 12 months occlusion rate of IIA, no difference was seen between Cross-over group and Non-cross-over group: 4% vs 0%, 12-month 58% vs 8%.

Conclusions: Occlusion rate of internal iliac (IIA) were extremely low and complaints of pelvic organ ischemia were not seen when treated with either crossover or non-crossover stenting, for IIA in acute phase as well as 12 month.

TCT-167
Patency Rates of Intraluminal Versus Device Assisted Subintimal Endovascular Revascularization of the Chronic Total Occlusion in the Superficial Femoral Artery
Anvar Babarev1
1NYU MEDICAL CENTER, NEW YORK, NY

Background: Critical total occlusions (CTO) of the SFA are a challenging subset of lesions encountered in peripheral interventions. CTO’s of the SFA are commonly crossed either with an intraluminal (IL) or re-entry device assisted subintimal (SI) approach followed by stenting. While both these techniques have a high immediate procedural success rate the long term outcomes of each approach are not well studied.

Methods: We studied 112 patients (144 limbs) with obstructive SFA disease treated with nitinol self-expanding stents; there were 77 (53.5%) limbs with CTO. We analyzed in-stent restenosis (ISR) rates, as well as: age, sex, GFR, presence of diabetes and coronary artery disease, lesion lengths, TASC Classification, and stent diameter in 3 subgroups of patients: without CTO; with CTO crossed IL, and with CTO crossed SI. Results: In CTO group, 22 (28%) limbs were treated with SI approach, and 55 (72%) using IL. During mean follow up period of 27.6 ± 17 months, ISR was diagnosed in: 21 (31.3%) pts of non-CTO; 20 (36.4%) of IL CTO; and 13 (59.1%) of SI CTO, Figure 1. The number of pts with diabetes was (p<0.001) higher in CTO IL compared to CTO SI group, 73.8% versus 26% respectively. The mean lesion length was 206.4 ±110 mm in IL and 245.9 ± 118 mm (p=0.17) in SI. There was no significant difference in other parameters.

Conclusions: We observed similar SFA ISR rates between pts without and with CTO if CTO was crossed using IL approach. Device assisted SI approach in CTO pts was associated with higher ISR compared to non-CTO pts and trend to higher ISR compared to CTO IL group.

TCT-169
E-MISAGO – the largest ongoing real life registry of Misago SX nitinol stent in daily use – Clinical Outcome at 1 year
Johannes Ruerf1, Stefan Schulte2, Kersten Wahl3, Karl-Ludwig Schulte4, Johan Duchateau5, Ralf-Thorsten Hoffmann5, William Taieb6, Torsten Fuß7, Jose Urbano9, Luis Bagnaschino Barco10, Marian Wierzgon ´11, Frank Vermassen12, Karel Nedved13, Dai Do-Do14, Ivan Kralj15

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TCT-167
Clinical and angiographic outcome about External iliac artery (EIA)- internal iliac artery (IIA) bifurcation lesion which failed IIA comparison between crossover stenting strategy and non-crossover stenting
Takuro Takama1, Toshiya Muramatsu2, Reiko Tsukahara3

Background: Primary stenting from common iliac artery (CIA) to external iliac artery (EIA), failing internal iliac artery (IIA), has a risk of compromised IIA. The purpose of this study was to evaluate in-hospital and 12 month clinical outcome in patients treated with stent deployment at EIA-IIA bifurcation, especially in comparison between crossover stenting strategy and non-crossover stenting one, focusing on fate of jailed IIA.

Methods: A retrospective study was performed of patients who underwent endovascular intervention for iliac artery presented from February 2000 to April 2011. Subject was 60 patients/57 lesion with iliac artery who underwent attempted recanalization with the self-expandable or balloon expandable stent. And we divided these subjects into the two following groups: 44 patients (45 lesions) treated with Crossover stenting with jailed of IIA and 13 patients (15 lesions) underwent non-crossover stenting without coverage of IIA. We have investigated patients background/lesion background/Bifurcation type/EVT strategy/ Clinical outcome/acute and chronic occlusion rate of IIA.

Results: No significant difference was detected in the baseline demographic, angiographic, and lesion characteristics. Technical success obtained 100%. Regarding acute or 12 months occlusion rate of IIA, no difference was seen between Cross-over group and Non-cross-over group: 4% vs 0%, 12-month 58% vs 8%.

Conclusions: Occlusion rate of internal iliac (IIA) were extremely low and complaints of pelvic organ ischemia were not seen when treated with either crossover or non-crossover stenting, for IIA in acute phase as well as 12 month.

TCT-168
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Anvar Babarev1
1NYU MEDICAL CENTER, NEW YORK, NY

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