

was designed to evaluate long-term vascular biology response to fluorocopolymer (poly-vinylidene fluoride hexafluoropropylene, PVDF-HFP) coated self-expandable low-dose paclitaxel-eluting nitinol stent (FP-PES, 0.167 $\mu$ g/mm<sup>2</sup>) 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 ilio-femoral 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=8/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 $\pm$ 0.09, 0.55 $\pm$ 0.15 mm) compared to BMS (0.70 $\pm$ 0.25, 1.00 $\pm$ 0.25 mm) at 30 and 90d (p=0.001, respectively), yielding reductions of in-stent stenosis by 48.1% and 51.9% for FP-PES versus BMS (P=0.005 and <0.0001, 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-strut 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 hemodialysis patients with critical limb ischemia after isolated infrapopliteal balloon angioplasty

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**Background:** Little data are available regarding the association between the site of the leg wound occurring from critical limb ischemia (CLI) and the prognosis of hemodialysis patients with CLI after isolated infrapopliteal balloon angioplasty(BA).

**Methods:** This study used data obtained from a multi-center retrospective study. Among serial 884 CLI patients who underwent BA for primary treatment of isolated infrapopliteal lesions from 2004 to 2011, subjects were 449 serial patients on hemodialysis with a CLI wound (ulcer or gangrene). The site of the CLI wound was observed before the initial treatment and all wounds were confirmed to be either confined distal from the metatarsals-phalanx(MP) joint to the tips of the toes or proximal from the MP joint to the ankle. Patients with wounds confined distal to the MP joint were defined as the Distal(D) group (109 patients, 109 limbs, age: 66.5 $\pm$ 10.4 years) and those whose wounds were not confined here were defined the Proximal(P) group (340 patients, 340 limbs, age: 69.2 $\pm$ 9.6 years). The two groups were compared for average 3.0 $\pm$ 1.5 years clinical outcomes.

**Results:** There was no significant difference in the percentage of patients with diabetes mellitus (75.2 vs. 76.5%), contralateral CLI limb (23.9 vs. 21.5%), or coronary artery disease (57.8 vs. 58.2%). For the target vessel, there was no significant difference in the ratio of target vessels with total occlusion (69.9 vs. 70.0%). The percentage of getting direct flow to wounds site based on the angiosome concept was lower in P group than that of D group (P:45.9 vs. D:63.5%, P<0.01). At the 3-year clinical results, the P group had high rates of major amputation (P:21.2 vs. D:12.3%, P<0.05), while there was no difference in the percentage of death (39.4% vs. 31.4%). The P group had a significantly lower major amputation-free survival rate estimated using the Kaplan-Meier methods compared to D group (P: 31.0 vs. D: 45.6%, Logrank; p<0.01).

**Conclusions:** The limb salvage rate of hemodialysis patients after isolated infrapopliteal BA whose CLI wounds were confined distal to the MP joint was better than that of patients who had wounds proximal to the MP joint, but the mortality of all hemodialysis patients with CLI wounds was high.

#### TCT-167

##### Clinical and angiographic outcome about External iliac artery (EIA)- internal iliac artery (IIA) bifurcation lesion which jailed IIA comparison between crossover stenting strategy and non-crossover stenting

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**Background:** Primary stenting from common iliac artery (CIA) to external iliac artery (EIA), jailing 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 arteries 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(acute: 4% vs 0%,12-month :4% vs 0%.

**Conclusions:** Occlusion rate of internal iliac(IIA) were extremely low and complains 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

##### Patency Rates of Intraluminal Versus Device Assisted Subintimal Endovascular Revascularization of the Chronic Total Occlusion in the Superficial Femoral Artery

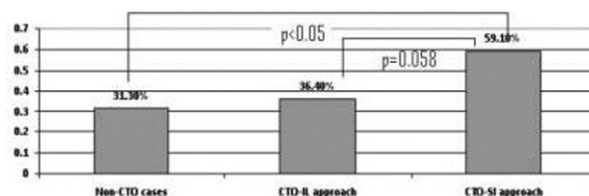
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**Background:** Chronic total occlusions (CTO) of the SFA are a challenging subset of lesions encountered in peripheral interventions. CTO's of the SFA are commonly crossed either with an intraluminal (IL) or re-entry device assisted subintimal (SI) approach followed by stenting. Even though 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  $\pm$  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  $\pm$  110 mm in IL and 245.9  $\pm$  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

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**Background:** Interim analysis of the first 1000 patients treated with Misago RX nitinol stent in iliac and femoropopliteal arteries at 1 year follow-up.