Conclusions: Our meta-analysis shows that DES significantly improves patency and symptoms when compared to BMS for the revascularization of below-knee arterial disease.

TCT-165
Evaluation of Long-term Vascular Reactions to Fluorocopolymer coated Self-Expanding low-dose Paclitaxel-eluting Stent in Porcine Ilio-femoral Model
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Background: Peripheral interventional therapy to treat occlusive disease for patients with symptomatic claudication is considered standard clinical practice. The present study

Methods: Between December 2008 and December 2010, 75 (48 males) consecutive patients underwent percutaneous revascularization of below-knee (BTK) arteries in our institution due to CLI (58/72.5%) and CLI (17/23.5%). Functional status was Rutherford class 3 in 4 (5%) patients, class 4 in 24 (31.9%) patients, class 5 in 37 (50%), and class 6 in 15(20%). All patients (98 lesions) were treated predilating with an undersized standard balloon and then with Pacltaxel Eluting Balloon In.Pact Amphirion (Medtronic). No adverse events were reported.

Results: Procedure success rate was 98% (96/98) lesions and 48/49 patients treated. No in-stent restenosis was observed. One patient required 2 reinterventions (5.2%). One year primary patency was 92% (95/103). Secondary patency was 96% (99/103). Mortality, amputations, and reinterventions were not reported.

Conclusions: The combination of drug eluting balloon for percutaneous transluminal angioplasty of below the knee arterial lesions is feasible, safe, and provides favourable one-year clinical results in patients with CLI.

TCT-164
Below-Knee Drug Eluting Stents Have Improved Patency, and Symptoms Compared to Bare Metal Stents: a meta-analysis
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Background: Drug eluting stents (DES) have become the standard therapy for coronary interventions, however its benefits on peripheral artery disease are not as clear, particularly in below knee peripheral arterial disease.

Methods: All randomized controlled trials of drug eluting stents in below-knee peripheral artery disease were sought in PubMed, and Cochrane databases during May 2012. Data was extracted by 3 reviewers and analyzed with RevMan 5.1 software.

Results: Four randomized controlled trials were found. Our analysis demonstrated a clear benefit in patency manifested by a freedom of target lesion revascularization up to four times higher with DES (p<0.001, Figure1) and an improvement of at least one level on the Rutherford classification up to two times higher at 6 to 12 months (p<0.005, Figure 2). There was a non significant trend favoring DES in reducing major amputations (Figure 3) and death incidence was similar.

TCT-162
Distal Embolization and Protective Devices: Mortality, Operating Room Time, Length of Stay, and Costs
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Background: Distal embolization (DE) events are commonly reported in percutaneous atherectomy procedures. drug protection (EP) devices reduce these events. This study compared inpatient hospital costs and resource utilization in two non-coronary (presumed lower extremity) atherectomy patient populations: (1) a DE event group, and (2) an EP group.

Methods: All inpatient discharges for atherectomy of non-coronary vessels (ICD-9-CM procedural code 39.50) were selected from a comprehensive hospital admissions database (Premier Perspective CY2005-20 10). DE patients were identified using ICD-9-CM diagnosis codes (444.XX, 434.0, and 434.1). Patients receiving EP devices were identified using a billing data keyword search. Discharges in the DE and EP groups were propensity matched adjusting for age, gender, race and severity scores. Inpatient mortality, length of stay, operating room (OR) time, and costs were compared between the groups.

Results: After propensity matching DE and EP groups, there were n=1,497 matched pairs. The inpatient mortality rate was significantly higher in DE compared to EP (2.7% vs. 1.3%, p<0.005). Hospital stay averaged 1.4 days longer in the DE patients (p<0.05). Resource and indirect costs, surgery and pharmacy costs were significantly higher for DE (p<0.05). OR time was 24 minutes longer for DE patients. Total costs were higher but not significant for the DE group ($24,326 vs. $23,594, p=0.38). As a reference, the total rate of embolic events detected in this inpatient population was 13.5 percent.

Conclusions: The use of embolic protection is strongly associated with lower inpatient mortality rates, shorter hospital stays, and shorter OR times. Cumulatively, these findings demonstrate embolic protection devices may significantly reduce consumption of hospital resources.

TCT-163
Drug eluting balloon for below the knee angioplasty- one year results from a single center DEB-BTK Registry
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Background: Recent registries and randomized trials support the role of percutaneous revascularization in patients with critical limb ischemia (CLI) and life limiting claudication (LLC) due also to infrapopliteal atherosclerotic disease. However, the percutaneous transluminal angioplasty (PTA) may result in high restenosis rate and target lesion revascularization.Promising results are coming from ond randomised controlled study an single center registry using drug eluting balloon (DEB) in this arterial distict.

Methods: Between December 2008 and December 2010, 75 (48 males) consecutive patients underwent percutaneous revascularization of below the knee (BTK) arteries in our institution due to CLI (58/72.5%) and LLC (17/23.5%). Functional status was Rutherford class 3 in 4 (5%) patients, class 4 in 24 (31.9%) patients, class 5 in 37 (50%), and class 6 in 15(20%). All patients (98 lesions) were treated predilating with an undersized standard balloon and then with Pacltaxel Eluting Balloon In.Pact Amphirion (Medtronic).No limitation in number of vessels treated, lesion length were considered (mean treated length 61, SD 61). A total occlusion was the target lesion in 47% of cases. In 22 cases above the knee arteries were previously treated. Polytelipical artery was the target lesion in 17 cases, anterior tibial artery in 28 cases, posterior tibial artery in 23 cases, peroneal artery in 16 cases.

Results: Procedural success, meaning angiographic evidence of restored antegrade flow, was achieved in 70 (94%) patients. Bail-out stenting for flow limiting dissection or abrupt target vessel occlusion was needed in 7 patients(10%). Procedural complication:distal embolization 2(2.5%),access site complication 1(1.5%), intra-hospital mortality 1(1.5%).The rate of angiographic restenosis at twelve months was 24% (n=15). Only symptomatic patients were planned for a reintervention(n=9). One-year primary patency was 76% (n=52); secondary patency was 91 % (n=61).

Conclusions: The outcome of this single center experience suggest that the use of drug eluting balloon for percutaneous transluminal angioplasty of below the knee arterial lesions is feasible, safe, and provides favourable one-year clinical results in patients with CLI.