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Bare-nitinol stent versus paclitaxel-coated balloon for femoro-popliteal revascularization. An adjusted indirect comparison meta-analysis of randomized trials

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Background: In femoro-popliteal artery (FPA) disease, Bare-Nitinol Stent (BNS) and Paclitaxel-coated balloon (PCB) improved outcomes as compared to Uncoated-Balloon (UCB) angioplasty. Nevertheless, the relative efficacy of BNS vs. PCB remains unknown, due to the lack of head-to-head comparisons. We performed an adjusted indirect comparison meta-analysis of randomized trials to evaluate outcomes of BNS versus PCB in FPA disease.
Methods: A systematic literature search (PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, scientific session abstracts and relevant websites) through December 2011 was performed. Selected search words were: superficial-femoral artery, popliteal artery, angioplasty, self-expanding stent, nitinol-stent, bare-stent, drug-eluting balloon, paclitaxel-coated balloon, and randomized trial. Inclusion criteria were: randomized trial design, intention to treat analysis, ≥6-month follow-up (FU). Exclusion criteria were: other arterial segments treated than FPA, comparison other than BNS/PCB vs. UCB, irretrievable, duplicated or incomplete data. Odds ratio (OR [95% confidence intervals]) and z scores (z), with corresponding p values, were used as summary statistics. Main outcomes were target lesion revascularization (TLR), binary restenosis and all cause mortality.
Results: We identified 8 eligible trials, enrolling a total of 1,008 patients randomized to BNS/PCB or UCB angioplasty (BNS n= 342, PCB n= 186, UCB n= 480). Median FU was 11.5 months. Angioplasty with BNS was found inferior to PCB with respect to TLR (OR= 2.60 [1.27–5.32], z= 2.63, p= 0.008), with a trend toward higher binary restenosis (OR= 2.03 [0.99–4.18], z= 1.93, p= 0.052). No significance in mortality was evident among study groups (OR= 1.79 [0.37–8.55], z= 0.73, p= 0.46; BNS vs. PCB comparison).
Conclusions: In diseases of femoro-popliteal artery, PCB offers superior freedom from repeat revascularization as compared to BNS. Both revascularization strategies appeared safe. Adequately powered, randomized, head-to-head comparisons are needed.

TCT-174

EPIC Nitinol Stent Treatment of Iliac Artery Lesions: 12-Month Outcomes in the ORION Study

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Background: ORION is a prospective, multicenter, single-arm, long-term safety and efficacy study of the Epic™ vascular self-expanding stent for the treatment of iliac artery lesions.
Methods: Eligible patients had chronic, symptomatic iliac disease and received ≤2 stents for de novo/restenotic lesions in the common or external iliac arteries. Lesions were ≤13 cm in length with diameter stenosis ≥50%. Clinical, functional, hemodynamic, and duplex ultrasound follow-up was performed at 30 days and 9 and 12 months. Key endpoints evaluated at one year include primary, primary-assisted, and secondary patency, target lesion revascularization (TLR), stent thrombosis, amputation, assessment of the walking impairment questionnaire and ankle-brachial index (ABI). All deaths, revascularization, myocardial infarctions, amputations, and stent thromboses were adjudicated by an independent clinical events committee (CEC).
Results: A total of 125 patients were enrolled in the study. Through 12 months, primary patency, primary-assisted patency, and secondary patency was achieved in 94.4% (119/126), 96.0% (121/126), and 97.6% (122/125) of treated lesions and 95.4% of patients remained free from TLR. Improvement in ABI by ≥0.1 was seen in 63.6% (84/132) of treated limbs. Three patients had stent thrombosis through 30 days and 2 patients died through 12 months. There were no amputations performed. Across the patient population, statistically significant improvements from baseline in walking distance (P <0.0001), walking speed (P <0.0001), and stair climbing (P <0.0001) were reported through 12 months.
Conclusions: The Epic stent is a safe and effective tool for the treatment of iliac artery lesions. The reported results demonstrate marked improvements in clinical, hemodynamic, and functional outcomes.

TCT-175

Optimal Antiplatelet Regimen for Critical Limb Ischemia due to Pure Isolated Infrapopliteal Lesions

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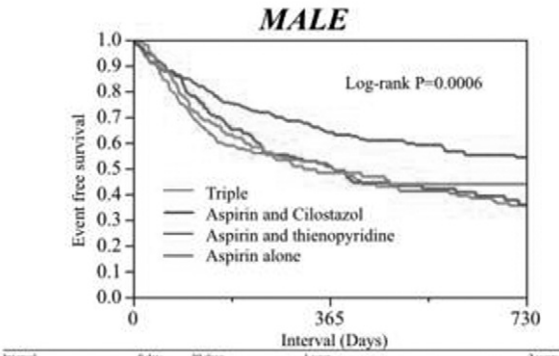
Background: Angioplasty for patients with critical limb ischemia (CLI) is effective to avoid major amputation. Although optimal antiplatelet therapy to improve the long term outcome following the angioplasty remains to be elucidated.
Methods: Between March 2004 and October 2010, 1057 limbs from 884 patients with CLI due to isolated infrapopliteal lesions were retrospectively analyzed. In hospital death cases (n=22) and patients who did not taking aspirin (n=216) were excluded. Primary endpoint is freedom-from MALE (major adverse limb event defined as major amputation or any reintervention) and assessed out to 2 years by the KaplaneMeier methods.
Results: Study population were divide into 4 groups due to antiplatelet status. Baseline characteristics was not different except for coronary artery disease. Freedom-from MALE at 2 years were 54% in aspirin and cilostazol (AC) group, 44% in triple antiplatelet therapy (T) group, 36% in aspirin alone (A) group and 35% in aspirin and thienopyridine (AT) group, respectively (p=0.0006). Cumulative incidence of major amputation was 12.8% in AC, 18.1% in AT, 22.4% in T and 35% in A group, respectively (p=0.0003).



Interval	0 day	30 days	1 year	2 years
Triple				
N of patients at risk	105	98	37	20
Incidence		4.9%	51.8%	56.1%
Aspirin and Cilostazol				
N of patients at risk	320	293	125	65
Incidence		3.7%	36%	45.7%
Aspirin and thienopyridine				
N of patients at risk	209	188	72	34
Incidence		8.3%	49.4%	64.6%
Aspirin alone				
N of patients at risk	185	157	55	20
Incidence		8.6%	49.1%	64.1%

Conclusions: The combination of aspirin and cilostazol associated with better outcome for CLI due to isolated infrapopliteal lesions. Further studies are warranted to investigate which antiplatelet regimen could be a optimal option in CLI patients.

TCT-176

Recanalization of infrapopliteal chronic total occlusions in critical limb ischemia.

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Background: Infrapopliteal (IP) chronic total occlusions (CTOs) are common in diabetics and patients presenting with critical limb ischemia (CLI). As endovascular procedures for CLI evolve, IP CTO recanalization is being attempted with increasing frequency. We analyzed the clinical and procedural outcomes following endovascular intervention for IP CTO at our institution.

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