CONCLUSIONS: CDT results excellent resolution of thrombus burden and PAH in patients with acute or sub-acute DVT with or without PTE with any significant complication.

TCT-539
Differences in Patients’ Selection and Outcomes of SilverHawk Atherectomy versus Laser Atherectomy in Treating In-Stent Restenosis of the Femoropopliteal Arteries: A Retrospective Analysis from a Single Center
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BACKGROUND: Treatment of in-stent restenosis (ISR) of the femoropopliteal (FP) artery remains a challenge to the endovascular specialist. SilverHawk (SA) and excimer laser atherectomy (ELA) use different mechanisms in restenotic tissue reduction. We report comparative FP treatment with SA and ELA in an unselected cohort of patients treated at a single center.

METHODS: Demographic, clinical, angiographic and procedural data was collected on all patients that underwent SA and ELA (laser Elites 83.3%; Booster or Tandem 16.7%) for FP ISR from January 2005 until the end of 2010. Major adverse events and one-year target lesion revascularization (TLR) were obtained by review of medical records and phone calls. Univariate analysis was used to compare the 2 groups. Cox Regression analysis for TLR over time was performed to adjust for differences between the 2 groups. Analysis was performed for the following: SA vs ELA, lesion length, TASC D lesions (versus A-B), diabetes, age, gender, and dialysis out-lying stent. For the 2 groups, patients with 25% or more restenosis as determined by core laboratory.

RESULTS: 81 consecutive patients (41 SA, 40 ELA) were included in the analysis. ELA was utilized more frequently in longer lesions, subacute presentation, TASC D lesions, and in patients with more angiographic thrombus. Percent stenosis post ELA was 56.6% ± 0.7% vs SA 33.8% ± 7.5% (p=0.015). Final percent stenosis post ELA was 56.6% ± 0.7% vs SA 33.8% ± 7.5% (p=0.015). Final angiographic success (>30% residual narrowing post final treatment) was similar between ELA and SA respectively (98.8% vs. 100%, p=0.12). Embolic filter protection was used equally in both modalities (ELA 57.5% vs. SA 56.1%, p=1.00). DE requiring treatment occurred in 2.5% in ELA vs 7.3% of SA (p=0.02). There were no device related complications. The primary outcome of TLR at 1 year occurred in 48.7% and 31.7% of ELA and SA respectively (p=0.171). ELA had a steeper failure rate than SA in the first 6 months post treatment and to a lesser extent after 6 months, whereas SA showed lesser TLR initially but a higher TLR after 6 months. Cox Regression analysis showed that SA was a predictor of TLR at 1 year.

CONCLUSIONS: Both SA and ELA continued to have high TLR rates in treating ISR of the FP arteries. SA appears to be a predictor of TLR at 1 year.

TCT-540
Pooled Analysis of the CONFIRM Registries: Outcomes in Critical Limb Ischemia Patients Treated for Peripheral Arterial Disease with Orbital Atherectomy
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BACKGROUND: Peripheral arterial disease (PAD) that results in critical limb ischemia (CLI) is associated with significant morbidity and mortality. Within the first year of diagnosis, 25% of CLI patients die and 30% will undergo amputation. In this patient population that includes advanced age, diabetes, and renal insufficiency, intra-arterial calcium is typically a predictor of poor endovascular treatment success.

METHODS: 3135 patients undergoing orbital atherectomy (OA) for treatment of PAD were enrolled on an “all-comers” basis in 3 consecutive patient registries. All patients were treated with the Orbital Atherectomy System manufactured by Cardiovascular Systems, Inc. (St. Paul, MN). CONFIRM 1 evaluated the Diamondback360®, CONFIRM II evaluated the Predator360®, and CONFIRM III evaluated Diamondback360®, Predator360®, and Stealth360®. An analysis of the CLI data as it pertains to the correlation of plaque morphology/calcification to the outcomes within the CLI patient population after OA treatment was performed using the CONFIRM registry series.

RESULTS: 44% of the patients in the CONFIRM series had CLI (Rutherford Categories 4-6) with documented lesion morphology, of which 87% presented with moderate/severely calcified lesions. There was no significant difference in the percentage of the disease (9.1% vs 12.2%), perfusion (0.9% vs 0.6%), slow flow (5.7% vs 4.7%), closure (1.6% vs 1.2%), or spasm (6.4% vs 9.3%), in CLI patients with moderate/severely calcified lesions vs those without moderate/severely calcified lesions, respectively. Patients with CLI with moderate/severe calcium had a lower rate of embolism (1.7% vs 5.2%, p<0.001) and lower rate of thrombus (0.9% vs 4.4%, p<0.001) compared to patients without moderate/severely calcified lesions.

CONCLUSIONS: The majority of the CLI patients in this study had lesions with moderate to severe calcification, yet the occurrence of adverse events was low after treatment with orbital atherectomy. Orbital atherectomy is a safe tool for restoring blood flow in the lower extremities of CLI patients regardless of arterial calcium burden.

TCT-541
Preliminary results from the Jetstream navitus system Endovascular Therapy post-market (JET) registry
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BACKGROUND: Treatment of complex lesions in the femoropopliteal (FP) artery including long, occluded, diffuse, thrombotic or calcified lesions carries an increased risk of major adverse events (MAE) and patient patency at 1 year and recurrent target lesion revascularization (TLR). The post market multicenter JET registry is currently evaluating the Jetstream atherectomy system in treating denovo or non stent restenotic lesions of the FP artery.

METHODS: JET is a multi-center, open-label, non-randomized registry in up to 75 sites with a target enrolment of 500 patients, Rutherford category 1-3 and with denovo or non stent restenotic FP lesions ≥ 4 cm in length and ≥ 70% in severity. Lesions with in-stent restenosis, or crossed via a subintimal approach or treated within 1 month prior to index procedure are excluded. The primary endpoint is binary stenosis at 12 months as defined by duplex ultrasound derived systolic velocity ratio >2.5. Secondary endpoints include procedural success as defined by successful revascularization of target vessel defined as ≤ 30% residual diameter stenosis following atherectomy ± adjunctive therapy, improvement in ankle-brachial index through 12 months compared to pre-procedural baseline and MAE through 30 days, MAE is defined as amputation, death, TLR, target vessel revascularization, myocardial infarction, or angiographic distal embolization requiring separate intervention or hospitalization. Index angiogram and duplex ultrasound assessment of binary stenosis will be evaluated by core laboratory.

RESULTS: Preliminary results from the first 60 patients enrolled in the JET registry are as follows: mean age 65.5 yrs, males 68.3%, diabetes 50%, smoking history 63.4%, hypertension 87.8%, Preprocedure ABI 0.68, non stent restenotic lesions 78.8%, lesion length 174 mm, reference diameter 5.7 mm, pretreatment stenosis 90%, post Jetstream stenosis 45% and post adjunctive treatment 9%. The Jetstream total run was 5.52 min, adjunctive stenting was 30.9%. Distal embolic protection was used in only 3.6% of patients. There were no in-hospital complications.

CONCLUSIONS: Jetstream atherectomy of FP lesions appears to have a high procedural success and reduced in-hospital complications.

TCT-542
False Lumen Thrombus Formation and Long-Term Outcomes in Type B Aortic Dissection
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BACKGROUND: The prognostic significance of false lumen thrombus formation in type B aortic dissection remains unclear.

METHODS: Aortic dissection cases were identified from the Kaiser Permanente-Registry of Aortic Dissections (KP-RAD). This is a population-based registry that captures consecutive cases of aortic dissections among the approximately 3,000,000 health plan members in Southern California. The presence of any false lumen thrombus by CT angiography during follow-up period was categorized as partial or complete thrombosis. The primary outcome was a composite of aorta related mortality, myocardial infarction, stroke, aortic rupture, or dissection extension.

RESULTS: There were 384 patients with type B aortic dissection, of which 293 had a patent false lumen and 91 had partial or complete thrombosis. The mean age (SD) for subjects with a patent false lumen was 69 (16) and 64 (13) with presence of false lumen thrombus (p<0.001). There was no difference between groups for gender (p=0.20). The median follow up was 4 years with maximum follow-up of 7 years. The cumulative incidence rate by presence or absence of false lumen thrombus was 30.0% vs 17.2% respectively (p=0.03) (see figure).

CONCLUSIONS: Whether TA is a risk factor of mortality or complications in type B aortic dissection remains unclear.

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