Conclusions: CDT results excellent resolution of thrombus burden and PAH in patients with acute or sub-acute DVT with or without PTE without 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 data on FP ISR 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 Elite 83.3%, Booster or Tandem 16.7%) for FP ISR from January 2005 until June 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 cohorts and modeled for the following variables: SA vs. ELA, lesion length, TASC D lesions (versus A-C), diabetes, age, gender and bail out stenting.
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). 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 (92.5% 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=0.2). 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 will 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 I 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 dissection (9.1% vs 12.2%), perforation (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=0.01) 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), reduced 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%, diabetics 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 3.52 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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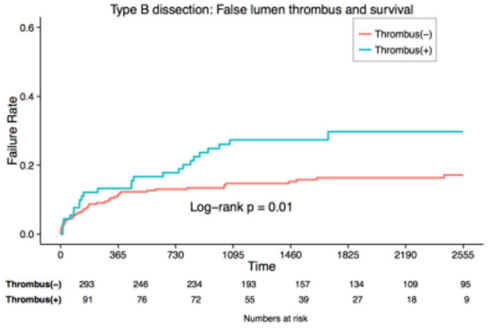
Background: The prognostic significance of false lumen thrombus formation in type B aortic dissection remains unclear.
Methods: Aortic dissection cases were identified from the Kaiser Permanente-Registry of Aortic Dissections (KP-RAD). This is a population-based registry that captures consecutive cases 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 thrombus. 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=0.01) (see figure).



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Conclusions: The presence of false lumen thrombus is associated with an increase in long-term aorta related morbidity and mortality. These findings may have implications on risk stratification, frequency of surveillance imaging, and future treatments.

TCT-543

Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique for treating extensive aortoiliac occlusive disease.

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Background: We developed the Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique for extensive and/or recurrent aortoiliac occlusive disease using V12 covered balloon expandable stents (Atrium Maquet Getinge Europe BV) to rebuild the aortic bifurcation.
Methods: Endovascular bifemoral recanalisation of the aortoiliac axes,; placement and expansion of a 12 mm V12 Large Diameter in the distal aorta (9 Fr). Pick up of the already expanded V12 stent with an large balloon (adapted to the aortic diameter). The balloon is so positioned that the distal marker is about 15 mm proximal to the distal stent margin. After positioning and expansion, the distal stent part becomes funnel-shaped. Two iliac covered stent-grafts are then placed in this segment, in a "kissing-stent" configuration and inflated. Both stents are now making a very tight combination with the aortic stent, as were they moulded together, simulating a new bifurcation
Results: Two-centre prospective, non-randomised, follow-up study. We treated now 70 patients with acute, chronic or recurrent aortoiliac occlusive disease. Technical success rate up till now was almost 95%. Follow-up 52 – 1 months. 5 patients died of non-interventional causes . Five patients re-occluded, mainly due to progressive distal peripheral disease. They received successfully thrombolysis and treatment of the outflow problems. The other patients showed no complications.
Conclusions: Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB is safe and feasible and can be performed completely percutaneous. A larger population, longer follow-up, further haemodynamic investigation is needed Distal peripheral outflow needs to be sufficient enough. It can be combined as a "hybrid" procedure. CERAB can be used for the treatment of recurrent or in-stent disease It is even feasible to treat lesion that extend to the iuxta and/or supral renal aortic region

TCT-544

The Potential Role of Statin in Patients with Critical Limb Ischemia.

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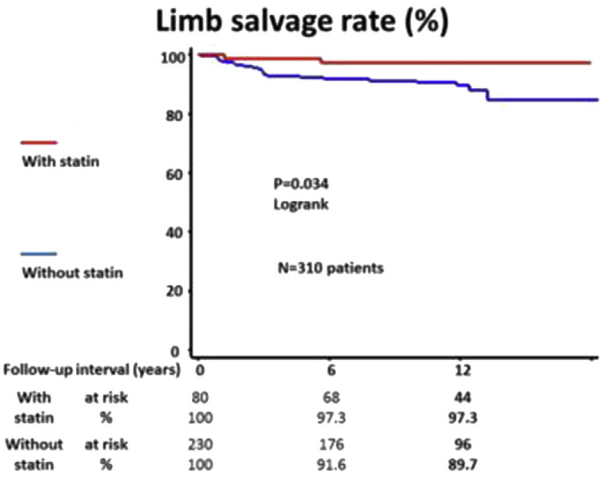
Background: Revascularization is the optimal treatment to avoid major amputation for critical limb ischemia (CLI) patients. Although previous studies report that statin administration is associated with a reduced risk for cardiovascular events, the efficacy for CLI patients is unclear. In this study, we aimed to compare the outcomes in CLI patients with statin administration and without statin administration after endovascular therapy (EVT).
Methods: This study is a subanalysis from Endovascular Treatment for Infra-inguinal Vessel, in patients with critical limb ischemia, - A Prospective, Multi-center, 12 month follow-up Registry in Japan: Olive Registry. From November 2009 to December 2011, a total of 310 patients with CLI who underwent EVT for infrainguinal artery disease were enrolled. The outcome measures were limb salvage and major adverse limb event (MALE). MALE was defined as major amputation or major reintervention including surgical procedure.
Results: The mean follow-up period was 294 ± 138 days. Sixty-five percent were male, 26% had statin administration. Rutherford class IV was found in 38 patients, V in 217 patients and VI in 55 patients. Kaplan-Meier survival curve showed that the limb salvage rate at one year was 97.3% in the statin group, 89.7% in the without statin group (P=0.03). In adjusted model, limb salvage rate and freedom from MALE were statistically higher in the statin group (P<0.01).
Conclusions: Statin administration after infrainguinal angioplasty for CLI patients improved limb salvage rate and freedom from MALE.



TCT-545

The AURORAA registry : 1 year reults using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease.

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Background: In the endovascular treatment of extensive disease in the distal superficial femoral and popliteal level, you can encounter flow limiting problems, where stent placement is needed after balloon angioplasty. At the moment most of the standard bare nitinol stents will have difficulties in these areas. With the introduction of the Supera stent (IDEV Technologies, Inc., Texas, US) we may have an answer in treating those problematic lesions
Methods: Because of the Superas new design; with 6 interwoven nitinol wires, it has extraordinary characteristics : very flexible, kink, fracture and crush resistant together with great radial force. We have treated more than 100 patients with extensive distal femoropopliteal disease (TASC II C & D) with heavy calcifications, occlusions, recurrent disease, stent fractures etc. These lesions, that not responded to balloon angioplasty and that needed stent placement, were al treated with placement of Supera stents.
Results: Results of the single centre prospective AURORAA registry : Follow up done by ultrasound. Five patients died of non-interventional causes.. Six months primary patency was more then 90%. Twelve months primary patency was around 81%. We observed further more no stent fractures or flow limiting kinking in this very difficult "to stent" area (distal superficial femoral artery & popliteal artery). Average lesion length: 14 cm; average stent length : 18 cm. Technical success rate :96 %
Conclusions: The Supera stent can be a solution when the use of a "classic" nitinol stent is not indicated or favourable , especially in the femoropoliteal area. It has very good patency rates, despite the very difficult region to treat This self expandable stent system can be a necessary complement in your tool box due to its special characteristics

TCT-546

Safety and feasibility of one day discharge after endovascular revascularization of lower extremities in elderly.

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Background: The elderly have a high prevalence of peripheral arterial disease (PAD) and it seems that they may be less suitable for a one day discharge after endovascular revascularization (ER) mainly due to a higher ratio in hemorrhage complications. Therefore we sought to evaluate whether the advantages of one day discharge after ER on lower extremities can be safely extended for the elderly.
Methods: Between January 2008 and June 2012, 455 ER were performed on lower extremities with Bivalirudin as an anticoagulant. The decision of deployment the vascular closure device (VCD) was left to the operator discretion. Patients 70 years old and older were included to the study group (n=235). The rest of the patients created the control group (n=220). The follow up was done at 24 hours and 30 days after

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