Background: In-stent restenosis (ISR) after femoropopliteal artery stenting is a significant problem occurring in up to 50% of cases. The EXCITE ISR trial aimed to demonstrate that procedural safety and efficacy after debulking ISR lesions with laser atherectomy is superior to balloon angioplasty (PTA) alone. Procedural complications were similar for both groups as well as the average number of Turbo Elite lasings trials. In amenable lesions (Group 1), there is little additional luminal gain with Turbo Tandem or PTA after optimal debulking with Turbo Elite (table). Furthermore, freedom from TLR is improved in Group 1. However, this is a statistical trend due to the low number of events until additional patients can be followed thru 6 months.

Conclusions: Conclusions: This sub analysis of the EXCITE ISR trial demonstrates that if optimal debulking is achieved with Turbo Elite, additional therapy is not necessary.

TCT-534

Economic Analysis of the Stellarex\textsuperscript{TM} Drug-Coated Balloon Compared to Uncoated Balloon for Treatment of Femoropopliteal Peripheral Artery Disease

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Background: Peripheral artery disease (PAD) has major worldwide health impact. Stellarex\textsuperscript{TM} (Coviden, Mansfield, MA, USA) is an experimental paclitaxel-coated PTA balloon designed for use in patients with PAD. The ILLUMINATE first in human (FIH) study was conducted at two German sites and enrolled patients with superficial femoral and/or popliteal artery lesions. Patients were followed for 24 months. This analysis was conducted to estimate the economic impact of the Stellarex drug-coated balloon (DCB) vs. uncoated PTA (PTA) at 12- and 24-month follow-up.

Methods: Data from the ILLUMINATE FIH pre-dilatation cohort was compared with a pooled and weighted PTA cohort from historical data. Costs for the baseline procedure and clinically-driven target lesion revascularizations (TLRs) were assigned to both groups using the 2013 German G-DRG reimbursement tariffs. Budget impact models were constructed for 12- and 24-month follow-up based on total cost of the baseline procedure plus TLR (determined by TLR rates) in both groups.

Results: The Stellarex and the pooled PTA cohorts (n=139) were balanced with respect to baseline characteristics. Between 12 and 24 months there were no additional TLR events for the DCB treated patients while there were 17 additional TLR’s in PTA patients. The budget impact model demonstrated cost advantages for Stellarex through 24 months. At 12 months, a patient treated with Stellarex cost $4506 less than PTA (3575$ vs. 4027$); at 24 months the difference increased to $8006 (3611$ vs 4409$). Extrapolated to 25,000 PAD patients, the use of Stellarex has the potential to save the healthcare system over 11,000,000$ at 12 months and nearly 20,000,000$ at 24 months. The number of patients treated with Stellarex (compared to PTA) to prevent one TLR was 4 at 12 months and 3 at 24 months.

Conclusions: An initial treatment strategy using the Stellarex DCB was associated with reduced long term TLR between 12 and 24 months vs. PTA. This has the potential to result in a significant reduction in healthcare expenditures through two years post-treatment. Prospective, comparative outcomes data are needed to validate this model.

TCT-535

I’ll Be Back – The Phenomenon of Recurrent Peripheral Vascular Interventions: Observations from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Vascular Interventions Collaborative (BMC2 VHC)

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Background: We explored the incidence and pattern of repeat peripheral vascular intervention (PVI) procedures in patients with peripheral arterial disease (PAD).

Methods: We studied patients undergoing percutaneous PVI in 2012 and 2013 among 70 Hospitals in Michigan that participate in the BMC2 - VIC registry. To identify patients undergoing repeat procedures, we applied a matching algorithm that used Date of Birth, Gender, Zip code, and Race.

Results: Of 18381 total PVI procedures, 3263 (17%) patients had multiple PVis and these patients accounted for 7720 (42%) of all PVis in the cohort. Of the multiple PVI patients, 235 (7.4%) had a PVI on the same vessel as the index PVI, 551 (17.4%) had PVI on both the same and an additional vessel, and 2377 (75.2%) had PVI on a different vascular bed. 94% of the PVis performed in the entire cohort were on lower extremity (LE). The most frequently used devices for initial LE PVI were balloon (B),...
balloon and stent (BS), and atherectomy and balloon (AB) (B-29%, BS-27%, and AB-31%). In repeat PVI, B and BS use were different from the initial PVI (B: 39%, BS 17%, respectively p< 0.001), and AB use was not different (34%, p=0.2). A network plot of device use and change from initial to repeat procedure is shown (p< 0.001 for pattern).

Conclusions: In a contemporary PAD patient population, multiple PVI procedures occur commonly, but the majority are procedures in a different vascular bed. Repeat PVI in the same vessel occurs less often. Balloon angioplasty remains the dominant procedure for both the initial or repeat LE PVI, either as stand-alone therapy or in combination with stent or atherectomy.

TCT-536
Trends In Revascularization For Patients With Lower Extremity Peripheral Artery Disease: The Impact of Medicare Coverage Determination
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Background: Peripheral endovascular intervention (PVI) has changed the treatment landscape for patients with PAD. The primary aim of this analysis is to understand the trends and variation in PVI after changes in Medicare Coverage Determination (MCD) in 2008 that affect professional and technical reimbursement under the Medicare Fee-For-Service program. The MCD resulted in a change to the MCD code that impacted reimbursement for PVI.

Methods: We utilized a 5% sample of Medicare beneficiaries from 2006 to 2011, and patients were required to have a procedure code for revascularization and a diagnosis code for PAD. Rates of revascularization were age- and sex-adjusted to the Medicare fee-for-service population. Rates by treatment location, year, and physician specialty were reported per 100,000 beneficiaries.

Results: 39,339 patients underwent revascularization for PAD and were included in the analysis. The PVI rate increased from 4.986 in 2006 to 5.548 in 2011, while the rate of surgical revascularization decreased from 1,562 in 2006 to 1,172 in 2011 [Panel A]. Surgeons (50%) and cardiologists (33%) performed the majority of PVI [Panel B]. The rate of PVI performed in outpatient hospital settings declined significantly while the rate of PVI performed in office-based clinics increased significantly [Panel C]. The use of atherectomy increased 50-fold in office-based clinics since 2006.

Conclusions: The overall rates of PVI increased by 10%, mostly performed by surgeons and cardiologists. PVI and especially atherectomy use in outpatient settings increased dramatically, highlighting possible unintended consequences of coverage decisions and need for studies demonstrating benefit for endovascular technologies.

TCT-537
12-Month Primary Patency Rates of Contemporary Endovascular Device Therapy for Femoro-Popliteal Occlusive Disease in 6024 Patients: Beyond Balloon Angioplasty
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Background: Endovascular approach to superficial femoral artery (SFA) disease, the most common cause of symptomatic PAD, remains fraught with high failure rates. Newer devices including second-generation nitinol stents, drug-coated stents, drug-coated balloons, covered stents, cryo-therapy, LASER and directional atherectomy, have shown promising results. Clinical equipoise still persists regarding the optimal selection of devices, largely attributable to the different inclusion criteria, study population, length of lesions treated, definition of “patency” and “restenosis” and follow-up methods in the pivotal trials.

Methods: A prospective protocol was developed. We performed a literature search using PubMed from January 2006 – November 2013. Published articles including endovascular interventions in SFA or popliteal arteries with reported 12-month “primary patency” or “binary restenosis” rates as endpoints were included.

Results: We identified 6024 patients in 61 trials reporting 12-month primary patency rates in patients with femoropopliteal disease. Primary patency rates were (weighted average) 78% for nitinol stents, 68.8% for Covered stents, 84% for Drug eluting stents, 78.2% for DEB, 60.7% for cryoballoon, 51.1% for LASER atherectomy, 63.5% for directional atherectomy and 70.2% with a combination of endovascular devices.

Conclusions: The most frequently used endovascular devices yielded various 12-month primary patency rates ranging from 51% to 85%. The increased variation in inclusion criteria, length and complexity of lesions between studies does not allow direct comparison between them. Larger randomized trials in specific patient populations comparing those modalities is needed before we can make safe recommendation of the superiority of one device over the other.

TCT-538
Lumivascular Approach To Crossing Chronic Total Occlusions Without Fluoroscopy
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Background: Case series where the use of optical coherence tomography (OCT) greatly reduced or eliminated fluoroscopy during the crossing of peripheral arterial chronic total occlusions (CTOs) when using the Ocelot catheter (Avinger Inc, CA).

Methods: Fifteen patients, with sixteen lesions (n=16) were successfully treated for peripheral arterial CTOs between January 2013 and June 2013. Ocelot imaging identifies arterial structures to guide catheter crossing within the true lumen. By placing the middle marker over arterial structures, the catheter tip is deflected in the opposite direction towards atheroma (Figure 1). Time measurements were recorded for diagnostic angiography, CTO crossing fluoroscopy, and therapeutic fluoroscopy times.