femoropopliteal (fem-pop) artery disease with drug-coated balloons (DCB) vs. standard PTA. The overall impact of DCB use on medical care costs is unknown.

Methods: We performed a prospective economic study alongside the IN.PACT SFA II trial, which randomized patients with symptomatic fem-pop disease to DCB vs. standard PTA and followed them for a minimum of 12 months. Detailed medical resource utilization data were collected and costs were assigned for all US patients using resource-based accounting (for revascularization procedures, medications and outpatient vascular care) and hospital billing data for costs associated with the index and follow-up hospitalizations for treatment of the target limb. The DCB was assigned a cost of $1350/balloon.

Results: A total of 181 US patients were enrolled (121 DCB, 60 PTA). Initial hospital costs were approximately $1100/patient higher in the DCB group than the PTA group ($8258 vs. $7164, p<0.001), driven mainly by the cost of the DCB itself (see Table). From discharge through 12 months, follow-up target-limb related medical care costs were $750/patient lower in the DCB group, such that total 1-year costs were similar for the 2 groups ($10,034 vs. $9694, p=0.82) with a resulting incremental cost-effectiveness ratio of $2906 per repeat revascularization avoided - similar to that for coronary drug-eluting stents.

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-533

Optimal Excimer Laser Atherectomy for Treatment of Femoropopliteal In-Stent Restenosis. Does debulking matter?
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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. Procedurally, the Turbo Elite laser catheter (Spectranetics Inc., Colorado Springs, CO) was used to recognize the ISR lesion prior to additional debulking with the Turbo Tandem (Spectranetics Inc., Colorado Springs, CO) laser catheter. In this sub analysis, outcomes were evaluated when optimal debulking was achieved with Turbo Elite.

Methods: Angiographic residual stenosis post-Turbo Elite was available for 95 patients. Group 1 consisted of 25 patients in which attherectomy with Turbo Elite achieved ≤30% residual stenosis prior to any additional debulking with Turbo Tandem or PTA treatment. Group 2 consisted of 70 patients in which ≤30% residual stenosis was not achieved with Turbo Elite. Lesion characteristics and freedom from TLR through 6 months follow up is evaluated.

Results: Lesion length was similar: 19.5 cm vs 20.9 cm, Group 1 vs Group 2 respectively. Baseline diameter stenosis was similar (85% vs 89%; Group 1 vs Group 2), however there were more occlusions in Group 2 (28% vs 36%, p=ns). Procedural complications were similar for both groups as well as the average number of Turbo Elite lasing trains. 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: This study supports the recommendation that if optimal debulking of ISR is achieved with Turbo Elite, additional therapy is not necessary.

TCT-534

Economic Analysis of the Stellarex™ 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™ (Covidien, Mansfield, MA, USA) is an experimental paclitaxel-coated PTA balloon designed for use in patients with PAD. The ILLUMENATE 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 ILLUMENATE 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 (n=50) 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 about $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 VIC)
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2Spectrum Health System, Grand Rapids, MI
3Detroit Medical Center, Detroit, MI
4St. John Hospital and Medical Center, Detroit, MI
5Metro Health Hospital, Wyoming, MI
6Munson Medical Center, Traverse City, MI
7University of Michigan, Ann Arbor, MI

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 92 Hospitals in Michigan that participate in the BMC2 - VIC registry. To identify repeat PVI 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, 215 (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),

**Table 1**

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency (n/N)</th>
<th>PVI TLR %</th>
<th>Post-TL</th>
<th>Post-TE</th>
<th>Final</th>
<th>TLR %</th>
<th>Cost (n/N)</th>
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<td>#3 PVI</td>
<td>#4 PVI</td>
<td>#5 PVI</td>
<td>#6 PVI</td>
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