CONCLUSION NIHS are unreliable predictors of baseline disease severity and response to EVT among CLI patients. Utilization of these thresholds for inclusion in studies of novel CLI therapies excludes many patients who would benefit from these treatments.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-793

Results of a Japanese IDE Trial Using Stent-Grafts for Treatment of SFA Disease confirm the importance of optimal sizing

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BACKGROUND To assess outcomes of stent-grafting of long lesions (≥10 cm) in the superficial femoral artery (SFA) and impact of stent-graft sizing on patency.

METHODS This study assessed the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface (WL Gore and Associates, Flagstaff, AZ) for treatment of long SFA lesions in Japanese subjects at 15 sites. Inclusion criteria were Rutherford category 2–5, ankle-brachial index (ABI) ≤ 0.9, and lesions length ≥ 10cm. Reference vessel diameters between 4.0 to 7.5 mm were allowed and were accurately measured as opposed to estimated. Sizing was based on the IFU (5 to 20% oversizing). The device was landed at least 1cm into healthy tissue. Dual antiplatelet therapy was required for 6 months. Patients were followed rigorously with 1, 3, 6 and 12 months duplex ultrasound.

RESULTS 103 patients were enrolled (age 74.2±7.0 years; 17.5% female). Average lesion length was 21.8±5.8 cm and 65.7% were totally occluded. Appropriateness of sizing was evaluated by the core lab and of those that could be reviewed, 74% were within IFU oversize range, while only 26% were outside this range. The Kaplan-Meier (KM) estimated primary patency (PP; defined as flow through the device with no TLR) rate was 92.1% (95% CI: 84.8–96.0%), primary assisted patency (PAP) rate was 94.1% (95% CI: 87.3–97.3%), and fTLR was 93.1% (95% CI: 86.1–96.7%) at 12 months. In a subgroup of patients with lesions ≤ 20cm, the primary patency was 100% (n=43). There was no acute limb ischemia (ALI) observed during follow-up, and no fractures were detected.The previously published VIPER trial with this device in US patients reported a sub-analysis grouped by sizing. For limbs with devices oversized ≤ 20% at the proximal edge, better results were shown than those oversized >20% (PP: 88% vs 70%, $p<0.05$). When the same definition of PP used in the VIPER trial is used in the current study (PSVR ≤ 2.5 with no TLR), the PP results are also 88%. Because of the rigorous sizing methods used, this study supports the earlier results.

CONCLUSION Endovascular stent-grafting of long, complicated SFA lesions leads to a high 92.1% PP rate and 94.1% PAP rate without incidence of ALI. For medium length lesions ≤ 20cm, PP was retained for all patients through 12 months. This study supports earlier study sub-analysis results and importance for proper sizing.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-794

Expanding The Paradigm of Treatment in Infrapopliteal Arterial Occlusive Disease: Quality of Life Benefits of Transpedal Access Single Tibial Vessel Intervention

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BACKGROUND For patients suffering from peripheral arterial disease (PAD), quality of life (QOL) is as important as mortality, morbidity and amputation, to evaluate the effect of disease and treatment. There is paucity of data to support single tibial vessel intervention for tibial occlusive disease. We report a first ever QOL data for endovascular single tibial vessel intervention via transpedal access.

METHODS Prospective analysis was performed of 36 consecutive patients with lifestyle limiting claudication who underwent single tibial vessel intervention via transpedal access (anterior (AT) or posterior tibial (PT), peroneal or dorsalis pedis (DP)) between 03/2016 and 05/2016. The validated Walking Impairment Questionnaire (WIQ) was completed by all patients at baseline and 30 days after treatment.

RESULTS A total of 36 patients (97% Rutherford Class 3-4, 3% class 5, age 70 ± 10 yrs, male 40%, hypertension 81%, smoker 28%, diabetes 56%) underwent single tibial vessel intervention (AT 72%, PT 19%, peroneal 9%, orbital atherectomy/balloon angioplasty 100%). After the intervention, there was a significant improvement in the WIQ score (6330.5 vs 6550.7, p=0.006) (**Figure**). On evaluating the individual components of WIQ, there was significant improvement in walking impairment (6288.61 vs 6995.83 p=0.013) and symptoms (18.8 vs 20.3, p=0.012).

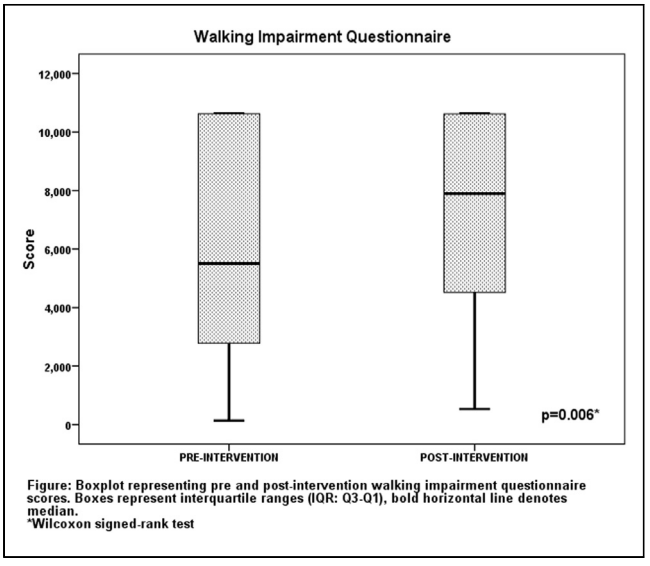

Figure: Boxplot representing pre and post-intervention walking impairment questionnaire scores. Boxes represent interquartile ranges (IQR: Q3-Q1), bold horizontal line denotes median.
*Wilcoxon signed-rank test

CONCLUSION Patients with tibial PAD with persistent lifestyle-limiting claudication despite maximal medical therapy can benefit from single tibial vessel intervention. Significant improvement in QOL is reported based on 30 day post-procedure Walking Impairment Questionnaire data.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-795

2-Year Outcome of Intravascular Ultrasound (IVUS) Guided Iliac Vein Stenting

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BACKGROUND Venous hypertension is one of the main reasons of venous insufficiency, which may lead to extremity swelling, ulceration, and venous claudication. The possible causes of venous hypertension include venous obstruction and compression. Iliac vein stenting is one of the treatment options for venous hypertension that has become popular in the recent years. However, the clinical evidence for iliac vein stenting remains limited in the literature. Patients who were treated for symptomatic iliac vein with intravascular ultrasound (IVUS)-guided stenting demonstrate the potential of such technique and its superiority over traditional treatment.

METHODS A cohort of 129 patients was treated for symptomatic iliac vein hypertension with IVUS-guided stenting from 2012 to 2015 by the same physician. The 129 patients were categorized into groups with