CONCLUSIONS The data from this single center feasibility trial indicate that the CorPath robotic system can be successfully used to treat PAD. Technical and clinical procedural success was obtained in all 20 patients and no device-related periprocedural adverse events were reported. Further studies are needed to confirm the results and elucidate their impact on outcomes.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Peripher al vascular intervention, Robotics

TCT-808 Evaluation of the Multilayer Flow Modulator in the Management of Complex Thoracoabdominal Aortic Pathology: A Systematic Review and Meta-analysis

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BACKGROUND The aim of this review is to consider evidence for the Multilayer Flow Modulator (MFM) device in management patients with complex thoracoabdominal aortic aneurysm (TAAA) or dissection.

METHODS A methodical search of all health databases was conducted from January 2008 to 2015 for health related and biomedical science literature, pertaining to the MFM. Primary outcome was aneurysm-related survival. Secondary outcomes were all-cause survival, stroke, spinal cord ischemia, renal impairment and branch vessel patency.

RESULTS A total of 15 studies (3 prospective studies, 3 observational reviews and 9 case reports) were included. The mean age of patients was 68.85 years (+/-12.34 years), mean aneurysm diameter was 6.67 cm (+/-5.7 cm). Technical success reported in 15 studies was 77.2%. Aneurysm related survival at one year was 78.7% (+/-3.9%). One year all-cause survival was 53.7% (+/-3.9%). There were no reported cases of spinal cord ischemia or renal insult.

CONCLUSIONS The MFM appears safe in management of TAAA, once operators abide to its Indications for Use. Since the MFM is a new technology, there is paucity of long-term follow-up data, a lack of comparative studies and a requirement for randomized clinical trials and continued assessment.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Meta-analysis, Multilayer Flow Modulator, Thoracic aorta

TCT-809 Abstract Withdrawn

TCT-810 “The Phantom Streamliner” as a Therapeutic Option in the Management of Total Body Thoracoabdominal Aortic Pathology (TAAA). Early Results

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BACKGROUND The multilayer flow modulator (MFM) increases visceral branch outflow velocities by up to 8% in TAAA. The phantom streamliner configuration generates double renal outflow percentage increase. Moreover, there are differences in flow laminarization between anatomical and ballerina outflow configurations to the iliac arterial tree.

METHODS Out of 13 patients managed by Phantom Streamliner configuration, of which 10 were males with mean age of 69.57 +/-9.8 years. Mean aneurysm diameter was 6.4 cm with mean aneurysm length of 26.96 cm. All were ASA IV. There were four Crawford type II, IV with AAA, seven supra/juxtarenal AAA and two complicated type B dissection.

RESULTS Numbers of side branches covered were 61 branches with mean of 4.7 side branch per case. Total numbers of stent used were 63 with mean of 6.25 MFM stents per case. There were no aneurysm-related death, no paraplegia nor stroke, no renal impairment and no loss of branch patency. Quantile-Quantile plot demonstrated that mean aortic length; diameter and thrombus are statically lower at post op from pre op with alpha level of 5%. Moreover, there was evidence of postoperative lower thrombus volume with no change in total volume from pre to post. Length and diameter demonstrated the most significant change. The aortic lumen barely hits any significance. There were a decrease in mean diameter, length and thrombus signifying a different mechanism in remodeling and laminar flow.

CONCLUSIONS Phantom Streamliner is a promising technology, safe with physiological modulation of TAAA with off the shelf availability and must be utilized under strict IFU.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Aortic aneurysm, Aortic dissection, Multilayer Flow Modulator

TCT-811 Comparison of Outcomes of Different Revascularization Strategies for Femoro-popliteal Disease: A Network Meta-analysis

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BACKGROUND Controversy exists regarding the best revascularization strategy for femoro-popliteal disease. We performed a network meta-analysis of randomized controlled trials (RCTs) in patients undergoing peripheral endovascular intervention for femoro-popliteal lesion to seek relative clinical outcomes of drug-coated balloon (DCB), drug-eluting stent (DES), or bare-metal nitinol stent (BMS) compared with balloon angioplasty (BA).

METHODS MEDLINE/PubMed, Cochrane CENTRAL, EMBASE, and ClinicalTrials.gov were searched for RCTs comparing two treatment modalities among DCB, DES, BMS, or BA in patients with femoropopliteal disease. Mixed treatment comparison model generation was performed to directly and indirectly compare DCB, DES, and BMS on outcomes including target lesion revascularization (TLR), primary patency, death, and amputation at 12 and 24 month with BA. Odds ratios with 95% confidence intervals (OR [95% CIs]) were generated with random-effect models to compare outcomes.

RESULTS Our meta-analysis included 15 RCTs with 2,843 patients that were randomized to DCB (n = 752), DES (n = 288), BMS (n = 581), or BA (n = 1,222). The mean age was 68.3 +/-5.4, 65% were male, 41% had coronary artery disease, 84% had hypertension, 41% had diabetes mellitus, 11% had re-stenotic lesion, 32% had total occlusion, 7% had critical limb ischemia, baseline ankle-brachial index of 0.68:0.38, and baseline lesion length of 68.7 +/-7.2 mm. At 12 month, DCB significantly reduced the risk of TLR (OR 0.29 [95% CI 0.13-0.56]), and DCB (OR 0.41 [95% CI 0.22-0.74]) and BMS (OR 0.61 [95% CI 0.36-1.00]) significantly improved primary patency compared with BA. DES had a trend toward improvement in primary patency and TLR compared with BA.
CONCLUSIONS DCB is associated with improved TLR and primary patency at 12-months compared with BA with a trend toward improved outcomes for DES and BMS compared with BA. Head to head comparison for DCB vs stenting strategies is warranted.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-B12
Efficacy and Safety Evaluation of a Novel Endovascular Occlusion System in a Large Peripheral Preclinical Model
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BACKGROUND Endovascular occlusion of blood vessels represents a key component of interventional therapy. While coils are most commonly used, vessel occlusion is generally not achieved immediately and may necessitate a large number of devices. It has been suggested that endovascular plugs may overcome these limitations; however, immediate and durable occlusion remains a challenge with plugs as well. This study evaluates a newly designed endovascular occlusion system (ArtVentive EOS™).

METHODS The EOS combines a nitinol scaffold with an impermeable membrane made of expanded polytetrafluoroethylene (ePTFE). The scaffold offers sufficient radial force to create a sufficient vessel wall apposition and minimize post-deployment migration. Eight test devices were deployed in the left renal arteries of four miniature swine. Follow-up angiography was performed 1 and 10 minutes after device implantation. Follow-up angiography was obtained on day 30 (four devices) and day 60 (four devices) prior to devices harvesting for histological evaluation and biocompatibility assessment.

RESULTS All test devices were deployed as intended, and produced complete and immediate vessel-occlusion. No clinical complications were observed in the animals throughout the study course. No recanalization, acute or chronic device migration was observed in the renal arteries. Complete and durable vessel-occlusion without any sign of recanalization and evidence of distal ischemia (renal atrophy) was observed in all EOS devices during the follow-up period.

CONCLUSIONS The EOS is a safe and reliable device resulting in immediate and durable vessel occlusion in the renal arterial circulation and evidenced by complete end organ ischemia.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Endovascular Occlusion System

TCT-B13
Role Of Wallstents In The Treatment Of Chronic Inferior Vena Cava Filter Occlusion
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BACKGROUND Occasionally inferior vena cava (IVC) filters can become occluded leading to significant lower extremity morbidity. Percutaneous endovascular intervention (PEVI) with different modalities is the procedure of choice. Stents have been successfully used in maintaining patency of the IVC filter which is often contracted and fibrosed. In this report we discuss the outcome of placement of Wallstents in IVC filters at 28±5 months of follow-up.

METHODS We placed Wallstents in 37 patients who had presented with chronic IVC filter occlusion. These stents were placed within or adjacent to the occluded IVC filter. The patients had presented with chronic bilateral lower extremity obstructive symptoms. Bilateral popliteal venous access sites were used in all patients as the initial approach. In 24 patients catheter directed thrombolysis was given with t-PA for 18-28 hours. All patients were placed on indefinite anticoagulation post-procedurally with rivaroxaban in 19 patients and apixaban in 18. Aspirin at 81 mg was given to 34 of 37 patients for 6 months.

RESULTS The patients’ average age was 66±7 years. The duration from IVC implantation was 5.7±2 years. Crossing the IVC filter was from the popliteal vein in 31 patients and the right internal jugular vein in 6. The adjacent space between the filter and IVC wall was crossed in 9 and through the filter in 28 patients. Following placement of a Wallstent, post dilatation to burst pressure was performed by a high pressure balloon. The average diameter and length of the Wallstents were 16±0.7 X 73±9 mm. Within hours of PEVI, patients’ symptoms substantially improved. The stents were patent at a mean follow-up of 28±5 months. There was no bleeding or recurrent venous thromboembolic disease (VTE) during the procedure or at follow-up.

CONCLUSIONS The results demonstrate that juxta or intra IVC filter stenting with a Wallstent is safe and effective in chronic IVC filter occlusions. Furthermore administration of new oral anticoagulants plus low-dose aspirin would prevent further IVC obstruction and VTE.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Inferior Vena Cava Filter, Inferior Vena Cava Filter Occlusion, Venous intervention