

correlated. Eighteen animals have been studied have been studies to assess the rate of depreciation of the drugs over 6 months' duration.

Results: Whereas specimens of the 2 S. aureus-treated unbonded grafts had high bacterial counts (6.25×10^6 and 1.38×10^7 CFU/graft), specimens of the 2 S. aureus-treated bonded grafts showed no bacterial growth. Bacterial growth in the 2 control pigs' grafts (1.8×10^3 and 7.27×10^3 CFU/graft) reflected direct accidental perioperative bacterial contamination; the organisms isolated were not S. aureus (S. cohnii spp urealyticus and S. chromogenes). The histopathologic and clinical data confirmed the microbiological findings. Only pigs that received unbonded grafts showed histopathologic evidence of perigraft abscess.

Conclusions: The quantitative results of our studies showed that bonding 3 antimicrobial agents to aortic grafts prevented aortic graft infection by synergistically prolonging antistaphylococcal activity. After the safety and preventive effect of this graft have been further assessed, its use may be recommended for the in situ replacement of infected grafts and possibly for routine primary cases, especially in immunocompromised patients, patients with a hostile abdomen, and patients undergoing redo procedures.

TCT-126

Endurant US Pivotal Trial: 2-year outcomes

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Background: This study reports the 2-year outcomes of the United States (US) regulatory trial of the Endurant Stent Graft System (Medtronic Vascular, Santa Rosa, CA) for the treatment of abdominal aortic aneurysms (AAA).

Methods: This was a prospective, single arm, multicenter trial conducted at 26 sites in the US. From April 2008 to May 2009, 150 patients with AAA were treated with the Endurant bifurcated stent graft. The main inclusion criteria were an AAA diameter >5 cm, proximal neck length ≥ 10 mm, bilateral iliac fixation length ≥ 15 mm, and a neck angulation of ≤ 60 degrees. The primary safety endpoint was freedom from major adverse events at 30 days. The primary effectiveness endpoint was successful aneurysm treatment at 12 months. Two years results are site reported.

Results: One hundred forty-nine patients (99.3%) had a successful implantation of the Endurant stent graft. The one failure was due to the inability to cannulate the contralateral gate. Patients within this trial were mostly male (91.3%), with a mean age of 73.1 and who had significant comorbidities. Mean estimated blood loss was 185 mL (range, 0-1450 ml), with one patient requiring a blood transfusion. The average hospital stay was 2.1 days. Through the 24 month follow up, there were no ruptures, migrations or conversions to open repair. The technical observations found no graft kinking or twisting, and no fractures. A total of two (1.5%) stent graft occlusions were observed at the 2 year follow-up. There were no type I or type III endoleaks observed at 24 months. Aneurysm sac diameter decreased greater than 5mm occurred in 60.8% of patients and remained stable in 36.9% of patients. There were only three patients (2.3%) that had an increase sac of more than 5mm. There were no aneurysm related deaths (100% Freedom from ARM) through two years.

Conclusions: The two year results of this pivotal trial continue to show that the Endurant Stent Graft is a safe, durable, and effective device for the treatment of abdominal aortic aneurysms.

TCT-127

The Impact of Later Generation Thoracic Aortic Stent Grafts as Demonstrated in the VALOR II Trial

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Background: Improvements in technique and devices promise improved outcomes following endovascular repair of aneurysms of the descending thoracic aortic. This mid-term report provides an update to the VALOR II trial results.

Methods: VALOR II is a prospective, multicenter, observational study of endovascular treatment with the Valiant thoracic stent graft (Medtronic Endovascular Therapies, Santa Rosa, Calif) in patients with descending thoracic aortic aneurysms (TAA) of degenerative etiology.

Results: VALOR II enrolled 160 patients between December 2006 to September 2009 and 1-year results have been previously reported. In this update, follow-up was available on 72% of patients through 3 years. One additional aneurysm-related death occurred after 1 year. One conversion to surgery was performed at 3 years in a patient who had continued aneurysm expansion in the absence of any observable endoleak. Seven secondary stent graft procedures were performed in 6 patients; 1 in the first 30 days, 3 after 1 year and 3 after 2 years. Freedom from secondary stent graft procedures was 94.9% at 3 years (95% CI: 88.8%-97.7%), which compared favorably with the earlier VALOR trial (85.1% at 3 years; 95% CI: 78.5%-89.8%), a study of the Talent thoracic stent graft with similar objectives and inclusion criteria. There was no type I or III endoleak reported at 2 or 3 years.

Conclusions: Mid-term results with the Valiant thoracic stent graft are acceptable and compare favorably to an older generation device implanted in an earlier series of similar patients. Long term results are needed to confirm this positive trend.

TCT-128

Disruptive Endovascular Technology with Multilayer Flow Modulator Stents (MFM) as a Therapeutic Option in the Management of Thoraco-abdominal Aortic Aneurysms. Early results from MFM Registry.

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Background: Out of 172 cases implanted worldwide we present the first 26 cases that were scrutinized. All were Crawford thoraco-abdominal AAA. 75% were male with median age of 73. Mean aneurysm diameter was 67mm with mean length of 167mm. 79.7% were ASA IV E. 62 % were redo after previous TEVAR.

Methods: Primary Endpoints are Freedom from Rupture and Aneurysm-related Death, Aneurysm Sac and Lumen Volume Modulation, Patency of Visceral Branches, and Freedom from Stroke and Paraplegia. Secondary Endpoints were technical success and all-cause mortality. Finite Element Analyses was achieved on aortic sac pressure, shear stress, wall displacement and blood flow velocities. All stents were deployed to their intended target. No Aneurysm-related death occurred within 18 Months. No perioperative Visceral or Renal insult occurred. There were no Cerebro-vascular accidents, paraplegia or loss of visceral branches patency. Two patients required reintervention because of device foreshortening.

Results: At 6 months there was decline in average total sac volume, thrombus volume and average diameter. Mean sac volume shrunk by 8% with lumen volume reduction of 14%. Average thrombus volume increased but thrombus to lumen ratio decreased by 23%. Finite Element Analysis post MFM documented dampening of wall displacement by 80% with immediate depressurization of the aortic sac and dissipation of the maximum pressure zone. There was 55% immediate reduction in Wall Stress.

Conclusions: MFM carries no risk of critical shuttering or loss of native side branches. MFM offers immense promise for resolution of complex thoraco-abdominal aneurysms. A Global MFM Registry is required and long-term follow-up is mandatory.

TCT-129

Contemporary comparison of the Paradigm Shift in Rupture AAA Management; Twelve years experience in a tertiary referral centre of Endovascular repair of RAAA(REVAR) vs open repair (OR)

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Background: Out of 683 AAA operated upon, 120 patients presented with RAAA over 12 years, 42 had REVAR and 78 had OR.

Methods: Parallel Group comparison.

Results: Mean length of ICU was halved with REVAR VS OR (P<0.008). Blood product requirements were 60% less in REVAR (P<0.0001). The Risk of ARDS and cardiac events were doubled if OR were performed. However there were no statistical significance in acute renal injury. Mean length of hospital stay was 7+/-3 days for REVAR, and 12+/-6 for OR (P<0.042). Thirty day mortality was 16% for REVAR vs 32% for OR (P<0.001). Total Emergency mortality rate decreased from 64% to 28.2%. we attributed the Low Mortality Rate of 16% for REVAR Vs 32% in OR was due to introduction of an REVAR Programme which constitutes screening for prevention with early intervention and REVAR for rupture which has an absolute perioperative mortality reduction of 49% over OR. 5 years Survival of Patients with RAAA were 75% REVAR vs. 60% OR (p=0.0205). During 20th century 95% of all AAA were done surgically. However during 21st century 80% of AAA is done endovascularly. Mean Annual number of OR dropped (P<0.845) however Mean Annual number of EVARs had rocketed (P<0.006). Overall number of AAA repairs has increased by 65% over twelve year's period but the absolute number of RAAA had declined by 24%.

Conclusions: Para-Millennium and Contemporary Trends in AAA Management had shown Increased in Elective EVAR which increased the mortality advantage in favour of REVAR and it should be the Gold standard for RAAA.

TCT-130

Clinical Efficacy and Cost per Quality-Adjusted -Life Years with Pararenal Endovascular Aortic Repair (PEVAR) for Para-renal AAA compared with Open Surgical Repair.

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Background: EVAR affords more propitious peri-operative and long-term survival than Open Surgical Repair (OSR). However, up to 70% of AAAs are anatomically incompatible with EVAR.

Methods: We aim to gauge the feasibility of applying commercially-available endografts to pararenal aneurysms compared with OSR. Primary endpoints were aneurysm-related survival and cost per Quality-Adjusted-Life-Years (QALY). From 2002-2009, 1868 patients with pararenal AAA were investigated. 118 had intervention and were described