(alcohol) renal denervation (cRDN) to treat resistant hypertension (rHTN).

METHODS The trial allows treatment of up to 120 subjects at up to 20 centers in Europe. Eligible subjects have rHTN. After confirmation of anatomical eligibility, subjects undergo bilateral cRDN with 0.6 mL of alcohol per renal artery using the Peregrine catheter. Major safety endpoints are assessed at 1 month. The major efficacy endpoint is the reduction of 24-hour mean systolic ambulatory blood pressure (SABP) at 6 months compared to baseline. It is anticipated that the first 30 subjects with 1-month ambulatory blood pressure measurement, and follow-up data through 3 and 6 months, will be presented.

RESULTS All procedures (n=26) were technically successful. There were 2 minor renal artery dissections that resolved without intervention. There were 2 (9%) vascular access site complications without sequelae. There were no deaths, myocardial infarctions, strokes, transient ischemic attacks or renal events. Mean procedure time was 8±3 minutes/artery (n=50); mean contrast use 97±42 ml (n=26), and mean fluoroscopy time 11.0±11.0 minutes (n=26). At 1 month, mean systolic office blood pressure (SOBP) and SABP reductions were -27±20 mmHg (n=25; from 176±17 to 148±21 mmHg, p<0.001) and -13±13 mmHg (n=23; 153±15 to 140±18 mmHg, p<0.001), respectively. At 3 months, mean SOBP and SABP reductions were -22±26 mmHg (n=21; 177±18 to 155±24 mmHg, p=0.002) and -14±16mmHg (n=15; 154±15 to 140±19 mmHg, p=0.005), respectively. In 2 of 25 subjects (8%), antihypertensive medications were reduced at 1 and 3 months. In 1 subject, antihypertensive medications were increased at 6 months. This abstract serves as a promissory for updated data to be presented.

CONCLUSION 1) Alcohol-mediated RDN using the Peregrine catheter is feasible and safe and accompanied by a significant blood pressure reduction. 2) Additional data from larger randomized, double-blind, clinical trials will be needed to confirm these results.

CRT-200.22

Safety And Efficacy Of Renal Sympathetic Denervation Using Circumferential Ultrasound: 12-month Results of the ACHIEVE Study

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BACKGROUND The efficacy of first-generation radiofrequency renal denervation devices may have been limited due to incomplete circumferential denervation and dependence on individual operator technique. The Paradise Renal Denervation System (ReCor Medical, Palo Alto, CA) was designed to maximize nerve coverage by delivering targeted circumferential ultrasound energy to perform renal sympathetic denervation.

METHODS The ACHIEVE study was a prospective, multi-center, non-randomized, post-market study to evaluate the clinical outcome of renal denervation with the Paradise System in patients with resistant hypertension. Inclusion criteria included non-pregnant adult patients who met established ESH/ESC guidelines for resistant hypertension. Major exclusion criteria included renal artery stenosis and moderate to severe renal insufficiency. Patients were treated with the Paradise system and followed for 12 months. Safety and efficacy endpoints included procedural and renal safety, changes in systolic office and 24-hour ambulatory BP measurement (ABPM), and changes in antihypertensive medication.

RESULTS The study included 96 patients from 8 European sites. Mean age at treatment was 64±10 years, and 41% of patients were female. Baseline mean office systolic BP was 176±19 mmHg and mean 24-hour ambulatory systolic BP was 156±15 mmHg. At 12 months, patients had an average office BP change of -15±27 mmHg (p<0.001) and an average 24-hour systolic ABPM change of -7.5±18 mmHg (p<0.001). At 1 year, there was a single patient death (1%) that was unrelated to the device or procedure. Full safety and efficacy results will be presented at the meeting.

CONCLUSIONS This single-arm study represents the largest cohort of patients treated with the Paradise Renal Denervation System to date. Within the ACHIEVE trial, the therapy appeared to be safe and effective and resulted in sustained reductions in both office BP and 24-hour ABPM. The ongoing randomized RADIANCE-HTN trial is designed to demonstrate efficacy of this therapy as compared to sham in both resistant hypertension (TRIO group) and non-resistant hypertension (SOLO group).

THORACIC AND AORTIC GRAFTS

CRT-200.23

A First Time Repair of Pseudoaneurysm of the Ascending Aorta with Valiant Evo Endograft

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Pseudoaneurysm of the ascending aorta is a potentially fatal condition with estimated mortality up to 61% if left untreated. Mortality rates associated with surgical treatment range from 29-46%.There have been isolated case reports and review of the literature detailing endovascular management of this condition. Most have reported short-term success with placement of vascular plugs and occluders to exclude the pseudoaneurysm and induce thrombosis. We report the case of a middle-aged female patient who had undergone total arch replacement with re-suspension of the aortic valve when she presented in extremis with intrapericardial rupture of a type A aortic dissection. She did well, only to present six months later with a pulsatile mass in the mid-sternal region. CTA revealed a large pseudoaneurysm arising from the Dacron interposition graft in the mid ascending aorta. We felt that she was a prohibitive risk for open surgical repair of this pseudoaneurysm, which was at imminent risk of rupture. Additionally, her access vessels were small. We requested the Medtronic Company to release the Valiant Evo device for compassionate use to save the life of this patient. A left subclavian to left common carotid artery bypass was performed as we intended to cover the origin of the innominate and left common carotid arteries which had a common origin. Perfusion to the cerebral vessels would be provided by virtue of the bypass graft being directly perfused from the left subclavian to the left common carotid artery. This coverage of the great vessels of the arch except for the left subclavian artery was necessary to gain a sufficient seal zone distally to provide a durable endovascular repair of the pseudoaneurysm. Access was obtained from bilateral common femoral arteries, which were preclosed. Additionally, the common femoral vein was accessed for rapid ventricular pacing. With rapid ventricular pacing and appropriate hypotension, we deployed a Valiant Evo device just above the sino-tubular junction with the nose cone of the delivery device embedded deep in the left ventricle. The device lay at an angle resulting in an endoleak with the pseudoaneurysm still pressurized. A second Valiant Evo device was next placed in overlapping fashion with the first extending further distally in the arch. The second device corrected the angulation of the first and obtained a perfect seal of the pseudoaneurysm. Six-month follow-up CT indicates complete exclusion of the pseudoaneurysm.

VASCULAR ACCESS

CRT-200.25

Influence of Operator Experience and PCI Volume on Transfemoral Access Techniques: A Collaboration of International Cardiovascular Societies

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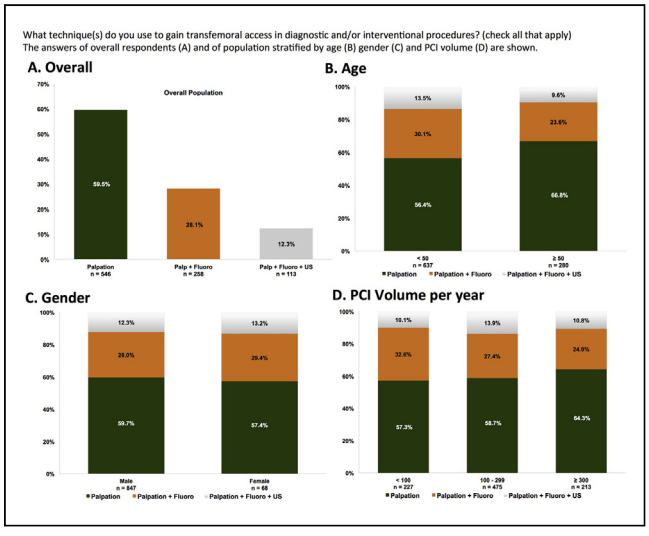
BACKGROUND Transfemoral access (TFA) is widely used for coronary angiography and percutaneous coronary intervention (PCI). The

influence of operator experience and PCI volume on adherence to transfemoral access best practices has not been studied. This international survey aimed to examine the influence of operator experience on TFA practices and fill important gaps to improve the quality of care in the cardiac catheterization laboratory.

METHODS A survey instrument was developed and distributed via email from professional societies to interventional cardiologists worldwide between March and December 2016.

RESULTS A total of 988 physicians from 88 countries responded to the survey. TFA is the preferred approach for patients with cardiogenic shock, left main or bifurcation PCI, and procedures with mechanical circulatory support. Older (<50 years: 56.4%; ≥50 years: 66.8%, $p < 0.0039$) and high PCI volume operators (<100 PCI: 57.3%; 100-299 PCI: 58.7%; ≥300 PCI: 64.3%, $p < 0.134$) utilize palpation alone without imaging (fluoroscopy or ultrasound) for TFA (Figure). Most respondents do not use micropuncture needle to gain arterial access regardless of age or experience. Older operators (<50 years: 71.5%; ≥50 years: 64.4%, $p < 0.04$) and high PCI volume operators (<100 PCI: 67.9%; 100-299 PCI: 72.6%; ≥300 PCI: 64.1%, $p < 0.072$) are less likely to perform a femoral angiogram (FA) during PCI. Of those performing FA, the majority (67%) does so at the end of the procedure.

CONCLUSION Despite best-practice guideline recommendations, older and high PCI volume interventional cardiologists prefer not to use imaging (fluoroscopy or ultrasound) for femoral access or to perform femoral angiography during TF PCI. Future studies should investigate whether the lack of adoption of best practices in TFA is associated with adverse events.



CRT-200.26

Does Micropuncture Technique Really Help Reduce Vascular Complications?

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BACKGROUND Femoral arterial access (FAA) in Coronary Angiography (CAG), and Percutaneous Coronary Interventional (PCI) is associated with 2-6% vascular complication (VC) rate. FEMORIS randomized study comparing 21-gauge Micropuncture technique (MPT) with 18-gauge failed to demonstrate statistical superiority in reducing VCs. We initiated a quality improvement project in our cardiac catheterization laboratory to reduce the FA access site complications via utilization of MPT.

METHODS We utilized MPT on all of our FAA non-emergent cases starting in September 2016 in addition to collecting data since April 2016 retrospectively. Anatomic localization of FA and fluoroscopic marking of femoral head were utilized in all cases. VCs were defined as any hematoma>3cm, major bleeding requiring PRBCs or Hb drop > 2gm, retroperitoneal bleed, pseudoaneurysm, AV fistula, arterial thrombosis, distal embolism, dissection, transient limb ischemia, and access site infection. Chi-Square and Fisher's exact test with p<0.05, as well as multiple logistic regression analysis were utilized.

RESULTS A total of 647 patients (M 357, F 290; MPT 333) were included in the analysis. MPT as compared to regular 18-gauge needle access did not demonstrate a reduction in VC rate (2.4% vs. 2.2%; p=1.0). On multivariate analysis, the only variable that was associated with a reduction in VCs is the utilization of VCDs, when adjusted for parameters listed in Table 1. Manual compression (MC) for hemostasis is associated with 4.1 times the odds of VCs as compared to VCD use (95% CI 1.111-15.574).

CONCLUSION Utilization of MPT did not contribute to statistically significant reduction in VC rate. The only factor that correlated with reduction in VC rate is the utilization of VCDs. Further large randomized studies are required to demonstrate benefit if any, in utilizing MPT on a routine basis.

Contributors to Vascular Complications

Multivariate Variables	Odds Ratio	95% Wald CI_Lower limit	95% Wald CI_Upperlimit
Race, Age, Gender, BMI, Sheath size, CAG vs. PCI, h/o HTN, HLD, DM, CKD, Smoking, CAD, PCI, CABG, PAD, intra/peri-procedural use of Aspirin, Clopidogrel, Brilinta, Heparin, Bivalirudin (Not Significant)	Not Significant		
18-gauge vs. Micropuncture technique	1.18	0.37	3.71
ManualHemostasis vs. Vascular Closure Device	4.15	1.11	15.57

CRT-200.27

Are We Closing The Gender Gap In 2017? Vascular Complications Following Common Femoral Arterial Access: Then and Now

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BACKGROUND Femoral arterial access (FAA) in diagnostic (DA) and interventional (PCI) coronary and peripheral procedures is associated with 2-6% vascular complication (VC) rate. FEMORIS randomized study comparing 21-gauge Micropuncture technique (MPT) with 18-gauge failed to demonstrate statistical superiority in reducing VCs.

METHODS Two thousand six hundred seventeen patients who underwent DA and PCI via FAA were retrospectively separated into Period 1 (2005 to 2008; 1970 patients; M 1045; F 925) and Period 2 (2016-2017; 647 patients; M 357; F 290; MPT in 333). FAA was preceded by anatomic FA localization during Period 1 vs. additional fluoroscopic marking of femoral head during Period 2. VCs were defined as hematoma>3cm, major bleeding requiring PRBCs or Hb drop > 2gm, retroperitoneal bleed, pseudoaneurysm, AV fistula, arterial thrombosis, distal embolism, dissection, transient limb ischemia, and access site infection. Chi-Square and Fisher's exact test with p<0.05, as well as multiple logistic regression analysis were utilized for analysis.

RESULTS The rate of VCs remain unchanged from Period 1 to 2 (2.44% vs. 2.32%, p=1.0). An elevated rate of VCs experienced by women of Period 1 (F 3.68% vs. M 1.34%, p<0.05) is no longer noted in Period 2(F 2.07% vs. M 2.52%, p=0.79). Multivariate analysis limited to Period 1 has revealed OR for VCs of 4.623 (95% CI: 2.14-9.97) in women, 0.1 (95% CI: 0.03-0.34) for DA vs. PCI, and 3.7 (95% CI: 1.7-7.6) for MC vs. VCD. Age, Race, BMI, h/o HTN, HLD, DM, Smoking, CABG, PCI, PAD, intra/peri-procedural use of Heparin, Bivalirudin, Clopidogrel, did not contribute to VCs. Multivariate analysis limited to Period 2 has revealed that the only variable that contributed to VCs was utilization of MC over VCDs (OR 4.15; 95% CI: 1.11-15.57). Age, Race, Gender, BMI, h/o HTN, HLD, DM, CKD, Smoking, CAD, PCI, CABG, PAD, PCI vs DA, intra/peri-procedural use of Heparin,