## CRT-200.18

### Percutaneous Angioplasty versus Atherectomy-assisted Interventions for Treatment of Symptomatic Infrainguinal Arterial Disease

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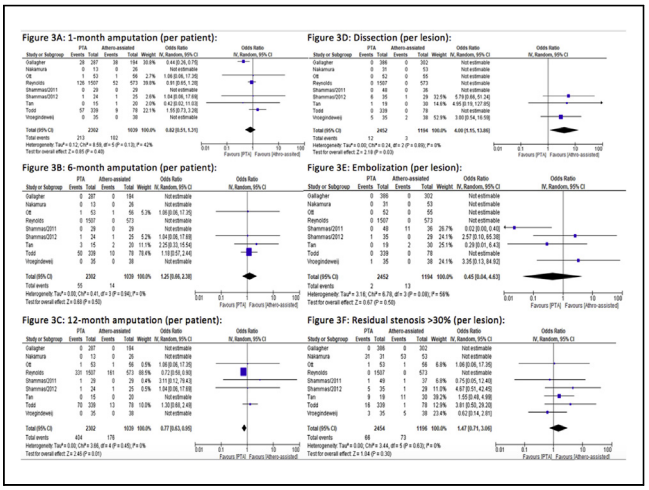
**BACKGROUND** Atherectomy (ATHRO) role for treatment of symptomatic infrainguinal arterial lesions is controversial. In this study, we aim to evaluate the effectiveness and safety of atherectomy-assisted endovascular interventions in comparison with percutaneous angioplasty (PTA).

**METHODS** Medline, PubMed and the Cochrane Central Register of Controlled Trials were queried from February 1995 through May 2017. Only studies comparing ATHERO with PTA were included. Study endpoints included: embolization, residual stenosis (>30%), and amputation rates at 1, 6, and 12 months, as well as vessel dissection.

**RESULTS** A total of 3344 patients (mean 70.29 years; 62.9% male) were included from 9 studies (5 prospective randomized and 4 retrospective) comparing ATHERO with PTA. There was no significant difference between the two approaches in terms of embolization [OR 0.45 with 95% CI 0.04 to 4.63] or residual stenosis [OR 1.47 with 95% CI 0.71 to 3.06]. Outcomes did not differ in terms of limb amputation at 1 month [OR 0.82 with 95% CI 0.51 to 1.31] or 6 months [OR 1.25 with 95% CI 0.66 to 2.38]. However, at 12 months, amputation rates were less likely to occur with PTA [OR 0.77 with 95% CI 0.63 to 0.95]. Vessel dissection was less likely to occur with ATHERO [OR 4.00 with 95% CI of 1.15 to 13.86].

**CONCLUSION** In patients undergoing infrainguinal endovascular interventions, incidence of amputation at 12 months occurred less frequently with PTA when compared with ATHERO. Vessel dissection was less likely to occur with ATHERO. Both modalities yielded similar outcomes in terms of residual stenosis, embolization, and limb amputation at 1 and 6 months.




## CRT-200.19

### Ostial Superficial Femoral Artery Disease: Is Stenting the Best Strategy?

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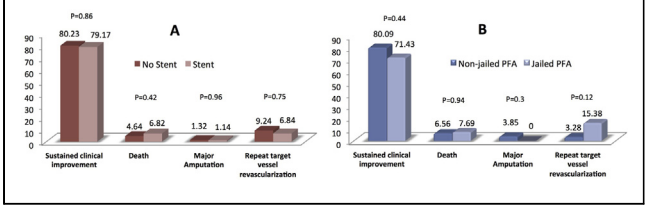
**BACKGROUND** There is significant uncertainty regarding stent or no-stent endovascular treatment of symptomatic peripheral artery disease involving the ostium of the superficial femoral artery (SFA).

**METHODS** One hundred eighty-two patients with ostial SFA intervention were selected from the multicenter Excellence of Peripheral Artery Disease (XLPAD) registry. Non-parametric tests were performed to test group differences in patients' baseline characteristics, periprocedural complications, and midterm outcomes between stented and non-stented lesions.

**RESULTS** Fifty-three percent of patients had a stent placed in the ostial SFA. Both groups had similar baseline characteristics. Profunda Femoral Artery (PFA) jailing occurred in 29% of the stent group. There were no significant differences in periprocedural complication rates. At 12-month follow-up, clinical outcomes, including sustained clinical improvement (freedom from death, endovascular or surgical revascularization, and amputation) and target vessel revascularization (TVR) were similar between groups (Figure 1). TVR rates were numerically higher in the jailed PFA subgroup compared with the non-jailed PFA subgroup (15.38% vs. 3.28%, p=0.12) (Figure 1).

**CONCLUSION** While stented ostial SFA lesions showed similar 1-year clinical outcomes to non-stented lesions, there was a strong trend for higher TVR with jailed PFA with stent. These results also indicate the feasibility of a non-stent approach to ostial SFA lesions.

Figure 1: 12 month clinical outcomes between stented and non-stented ostial lesions (A) and between jailed and non-jailed Profunda Femoral Artery within the stent group (B)




## RENAL INTERVENTION

## CRT-200.21

### Alcohol-mediated Renal Denervation to Treat Hypertension-The Peregrine Post-market Study

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**BACKGROUND** The Peregrine post-market study is a prospective, single-arm, open label, multicenter European trial evaluating the safety and performance of the Peregrine System™ Infusion Catheter (Ablative Solutions Inc., Palo Alto, CA, USA) to perform chemical

(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