CRT-300.12

Efficacy of a Balloon-expandable Vascular Access System in Tavi Patients With Borderline Sheath to Femoral Artery Ratio

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BACKGROUND Vascular complications (VC) are a serious and frequent complication of transfemoral transcatheter aortic valve implantation (TAVI) and result in increased morbidity and mortality. It has been suggested that newly developed vascular sheaths may increase the ability to perform transfemoral TAVI in patients with normal and access-limiting peripheral artery disease and reduce vascular complications.

OBJECTIVE We sought to assess the safety and efficacy of the 19 French (F) SoloPath® balloon-expandable transfemoral vascular access system in patients who underwent transfemoral TAVI at our center between 2011 and 2014.

METHODS AND RESULTS Single-center retrospective study of 90 patients who underwent transfemoral TAVI with the use of the SoloPath sheath. Patients were categorized into two groups according to a sheath to femoral artery ratio (SFAR) of less than or equal to 1.05, or greater than 1.05. Overall, the incidence of major bleeding complications was low, 4.4%. No significant differences were found in technical or procedural success rates (100% in both groups and 100% vs. 91.3; p=0.09; respectively), total vascular complications (20.8 vs. 21.7; p=0.92) or total bleeding complications (20.8 vs. 30.4; p=0.36 between those with SFAR greater or less than 1.05.

CONCLUSION The use of the SoloPath® balloon-expandable sheath is feasible and safe even in patients with SFAR > 1.05, showing no increased vascular or bleeding complications compared to patients with larger vascular access.

Table. Univariate logistic regression for bleeding complications:

	Bleeding complications	p value	OR (95% IC)
Vessel calcification			
No	9/36 (25.0)	0.4618	0.68 (0.25 - 1.89)
Yes	10/54 (18.5)		
Tortuosity			
No	15/55 (27.3)	0.0810	0.34 (0.10 - 1.14)
Yes	4/35 (11.4)		
Aortic Aneurysm			
No	18/85 (21.2)	0.9501	0.93 (0.10 - 8.85)
Yes	1/5 20.0)		
Diabetes mellitus			
No	17/61 (27.9)	**0.0357**	**0.19 (0.04 - 0.90)**
Yes	2/29 (6.9)		
Female gender			
No	6/44 (13.6)	0.0952	2.49 (0.85 - 7.30)
Yes	13/46 (28.3)		
Chronic renal failure			
No	15/65 (23.1)	0.4640	0.64 (0.19 - 2.14)
Yes	4/25 (16.0)		
Borderline vessel size			
No	6/41 (14.6)	0.1684	2.11 (0.72-6.16)
Yes	13/49 (26.5)		
SFAR			
≤ 1.05	11/53 (20.8)	0.3643	1.67 (0.55 - 5.06)
> 1.05	7/23 (30.4)		
	No bleeding complications (n=71)	**Bleeding complications (n=19)**	**p value**	**OR (95% IC)**
Calcification score	0.83 ± 0.81	0.58 ± 0.61	0.2108	0.62 (0.30 - 1.31)
Tortuosity score	0.54 ± 0.67	0.21 ± 0.42	0.0588	0.35 (0.12 - 1.04)
Vessel lumen median (Q1,Q3; mm)	6.80 (6.30,7.95)	7.00 (6.10 - 7.60)	0.9927	1.00 (0.38 - 2.64)
Artery stenosis (%)	9.07 ± 11.43	7.89 ± 7.87	0.6709	0.99 (0.94 - 1.04)
Age	82.92 ± 7.39	84.61 ± 4.58	0.3453	1.05 (0.95 - 1.15)
BMI	28.20 ± 4.90	26.30 ± 3.73	0.1228	0.91 (0.80 - 1.03)

CRT-300.13

Renal Denervation by Chemical Neurolysis (Preliminary Data From the PEREGRINE Trial)

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BACKGROUND Alcohol-mediated endovascular renal denervation (RDN) using the Peregrine System™ has been shown to be safe, with a good indication of effectiveness as measured by office blood pressure (OBP). A safety and performance trial is on-going; we report preliminary data from the first 10 subjects.

METHODS The Peregrine Study is a prospective, multicenter study to treat up to 60 patients with refractory hypertension who are on a stable regimen of ≥ 3 antihypertensive drugs, including a diuretic. Patients are pre-screened for medication adherence and an OBP of ≥ 160 mm Hg. Enrolled subjects undergo both a physical exam and consult by a hypertensionist. For 28 days pre-procedure, subjects maintain journals of medications and home-measured BP. The daytime mean ABPM must be ≥ 135 mm Hg and renal artery anatomy is assessed by CTA. Other inclusion/exclusion criteria are typical for RDN studies. Endovascular chemical RDN is performed, usually without the need for sedation. The neurolytic agent is infused through the Peregrine catheter into the perivascular space of each renal artery. Alcohol at 0.3 mL/renal artery was chosen as the neurolytic agent. The primary safety endpoints include: major vascular complications, major hemorrhage, CVA, MI, and sudden death at the time of the procedure. The primary performance endpoint is the reduction in systolic OBP of 10% at 6-month compared to baseline.

RESULTS For these 10 subjects the primary safety endpoint has been met: All procedures have been completed successfully. There have been no device complications. Preliminary analysis shows a mean procedure time of 7±4 minutes and fluoroscopy time of 12±7 min. CTA evaluation of renal arteries at 1-month post procedure, and data from the performance endpoint will be presented. BP data from the interim time-points show a mean reduction in systolic OBP (mm Hg): at 1-month of 17.2% (-29±13), at 3-month of 21.7% (-37± 14). Mean 24-hour systolic ABPM (mm Hg) has been reduced as well: at 1-month -12±6, at 3-month -7±10.

CONCLUSION Preliminary analysis of the first 10 subjects in the Peregrine study show the acute safety endpoint has been met and that OBP has been reduced by more than 10% in 9 of 10 subjects.

CRT-300.14

Impact of Aspiration Thrombectomy During Carotid Artery Stenting on New Ischemic Lesions Identified by Diffusion-Weighted Magnetic Resonance Imaging: A Randomized Controlled Trial

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OBJECTIVE To determine whether routine aspiration, from the distal filter embolic protection device (EPD) back through the stent, during carotid artery stenting (CAS) would result in fewer clinical neurologic events and/or lesions on diffusion-weighted magnetic resonance imaging (DW-MRI) compared to CAS with a distal EPD alone.

BACKGROUND Despite reducing neurologic events, clinically successful CAS with distal EPD's may still result in increased lesions on DW-MRI. A small study revealed that routine aspiration during CAS w/ distal EPDs consistently recovered atherothrombotic debris (*Tex Heart Inst J* 2009; 36(5):404-8).

METHODS 31 patients with symptomatic, severe carotid stenosis at two different medical centers were randomized to either CAS w/ distal EPD with aspiration vs CAS with distal EPD alone. A Xact Rapid Exchange Carotid Stent System along with an Emboshield NAV[6] Embolic Protection System (Abbott Vascular) was used, and aspiration was performed with an Export catheter (Medtronic). A NIHSS neurologic assessment was done pre-procedure, post-procedure prior to discharge, and at 30 day follow up. Pre-procedure and post-procedure DW-MRIs were performed and interpreted by an experienced, blinded observer.