Initial Clinical Experience With an Intravascular Ultrasound-Guided Transmembrane Puncture Device to Facilitate Recanalization of Total Femoral Artery Occlusions

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Purpose: Failure to recanalize chronic superficial femoral artery occlusions is caused in the majority of the cases by subintimal passage of the occlusion with inability to re-enter the true lumen with the guide-wire. The present study details our initial experience with the CrossPoint TransAccess crossing device (Transcatheter Inc.) to facilitate recanalization of total femoral artery occlusions.

Methods: 14 consecutive patients (11 male, mean age 63 years) who failed recanalization attempts of chronic superficial femoral artery occlusions (mean occlusion length 12.7 cm) with standard techniques were re-scheduled for a secondary recanalization procedure. The CrossPoint device is a 6.2F rapid exchange catheter, which tracks over a 0.014"-wire. A 20MHz phased array IVUS transducer is integrated into the tip of the catheter allowing visualization of the vessel morphology. Using the guidance of the IVUS crosssectional image supported by colour-flow imaging the true lumen is punctured with an alternated 24G needle allowing delivery of a second 0.014"-wire.

Results: Re-entry into the true lumen was successfully accomplished in all cases without complications. In 4 cases with severe calcification predilatation of the false channel was necessary to allow advancement of the CrossPoint device. Furthermore, in patients with severe calcification 2nd step attempts were necessary to penetrate the dissection membrane. A procedural success (>25% residual stenosis) could be achieved in all cases after predilatation and stenting of the occlusion with selfexpanding nitinol stents. Conclusion: The CrossPoint device is an effective and save tool to facilitate true lumen re-entry during recanalization of total superficial femoral artery occlusions.

Patent Foramen Ovale Closure Using a Blind Transseptal Technique Is Safe

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Background: Percutaneous closure of patent foramen ovale (PFO) is an alternative to surgical treatment of this defect. Transeptal echocardiography (TEE) or intracardiac echocardiography (ICE) guidance is used for percutaneous placement of closure devices. The use of general anesthesia during TEE or the use of ICE significantly increases the cost of this procedure. We report our experience of PFO closure with CardiSEAL using transseptal puncture without TEE or ICE guidance.

Methods: We report 29 consecutive patients (men 18, age 52±13, ejection fraction 60±3%) with cerebral embolic event and associated PFO treated with percutaneous CardiSEAL placement using the transseptal approach. Previous data from 33 consecutive patients using TEE or ICE guidance for PFO closure was used as a control group. The CardiSEAL device was used in all patients. Procedural success was defined as successful placement of the device. Follow-up transcranial Doppler echocardiography (TTE) with bubble study at 3 month was performed in all but one patient.

Results: Twenty-eight patients in the transseptal group presented to penetrate a cerebral embolic event and 3 patients experienced extracranial embolic events. The CardiSEAL device was successfully deployed in all 29 patients. There was no in-hospital mortality or thromboembolic event. All patients were discharged within 24 hours of the procedure. The average device size was 29±2 mm. There was no significant difference between the study group and the control in fluoroscopy time (9±5 vs 9.4±5 min, p=NS) and amount of contrast used (136±60 vs 139±68 ml, p=NS). At a mean follow up of 69±58 days one patient had atrial fibrillation, device associated thrombus, and a transient ischemic neurological event. Another patient committed suicide prior to follow-up. Four patients had intracardiac shunt detected by TTE with bubble contrast.

Conclusion: PFO closure using a blind transseptal technique without use of general anesthesia, TEE, or ICE guidance is a safe procedure without additional risks and cost. A large randomized trial and follow-up is needed to determine if a blind transseptal technique is compatible to echo guided techniques.

Percutaneous Left Atrial Ablation Transcatheter Occlusion (PLAATO™) to Prevent Stroke in Patients With Atrial Fibrillation: Interim Results of the Multicenter Feasibility Trial

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Background: In order to prevent stroke in patients with AF and additional risk factors who are suboptimal candidates for warfarin therapy, 103 persons have been enrolled in the PLAATOTM Multicenter Trial so far (average age=71 years, 43-90 yrs; M= F= 63/40). Transcatheter occlusion proved to be a safe procedure, nonetheless its benefit is still to be discussed.

Methods: The risk of stroke for every patient enrolled in the PLAATOTM Multicenter Trial was calculated according to the CHADS2 Risk Classification Scheme. Besides AF, this scheme considers other stroke risk factors such as congestive heart failure, hypertension (systolic >160 mm Hg), age greater than 75 years, diabetes and prior cerebral ischaemia. Results: Follow up tests have been performed in 101 patients that were enrolled in the study (68,26 patient years). Most of the patients having several additional risk factors besides AF, these were added to their personal CHADS2 Score, correlating with the annual risk of stroke. The expected annual stroke rate without treatment was calculated to be 5.3 % on the average (1.9%-18.2 %). Two patients whose LAA was occluded suffered from a stroke six month after implantation of the device. The annual stroke rate of PLAATOTM patients was therefore calculated to be 2.9 % on the average. In one case, there was no relation to the device or the implantation, in the other, the relation is unknown.

Conclusions: As far as the interim follow up results show, transcatheter occlusion of the LAA with the PLAATOTM device is not only a safe method, but seems to reduce the risk of stroke in patients with AF.

Virtual Histology of Intravascular Ultrasound Images: Feasibility and Clinical Correlations in Humans


Virtual histology (VH, Volcano Therapeutics) uses spectral analysis of backscattered intravascular ultrasound (IVUS) to classify plaque elements as calcium, fibrotic, fibrofatty, or lipid core. Algorithms have been derived and validated in vitro. We report the first in vivo studies (68 native arteries in 50 pts). ECG-gated, motorized pullback IVUS images are analyzed. External elastic membrane (EEM) and lumen borders are identified by automatic edge detection; plaque/media is “separated” into its components. Results: The length analyzed was 44±24mm (2.4±0.6 frames/mm). Total segment (lesion reference) EEM volume was 595±317mm3, lumen was 25±15mm3, plaque/media was 283±176mm3, and % obstruction was 51±3%; calcium was 2±3%, fibrotic plaque 31±14%, fibrofatty plaque 14±16%, and lipid core 12±8% of total plaque/media volume. When compared to pt characteristics, % total segment calcium was greater in stable patients.