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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 (Transvascular 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 cross-sectional image supported by colour-flow imaging the true lumen is punctured with an integrated 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 multiple puncture 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.

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Patent Foramen Ovale Closure Using a Blind Transeptal Technique Is Safe

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Background: Percutaneous closure of patent foramen ovale (PFO) is an alternative to surgical treatment of this defect. Transesophageal 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 CardioSEAL using transeptal 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 CardioSEAL placement using the transeptal approach. Previous data from 33 consecutive patients using TEE or ICE guidance for PFO closure was used as a control group. The CardioSEAL device was used in all patients. Procedural success was defined as successful placement of the device. Follow-up transthoracic echocardiography (TTE) with bubble study at 3 month was performed in all but one patient.

Results: Twenty-eight patients in the transeptal group presented with a cerebral embolic event and 3 patients experienced extracranial embolic events. The CardioSEAL 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 transeptal technique without use of general anesthesia, TEE, or ICE guidance is a safe procedure without additional risks and cost. A large randomized trial and longer follow-up is needed to determine if a blind transeptal technique is comparable to echo guided techniques.

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Percutaneous Left Atrial Appendage 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 PLAATO™ Multicenter Trial so far (average age=71 yrs, 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 PLAATO™ Multicenter Trial was calculated according to the CHAD2 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 ischemia.

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 CHAD2 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 PLAATO™ 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 PLAATO™ device is not only a safe method, but seems to reduce the risk of stroke in patients with AF.

POSTER SESSION

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New Imaging Modalities for Coronary Artery Disease

Sunday, March 07, 2004, 9:00 a.m.-11:00 a.m.

Morial Convention Center, Hall G

Presentation Hour: 9:00 a.m.-10:00 a.m.

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In Vivo Macrophage Imaging of Acute Coronary Syndromes With Intracoronary Optical Coherence Tomography

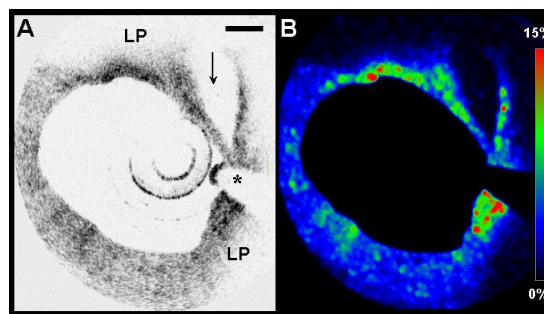
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Background: Atherosclerotic macrophage infiltration is a hallmark of coronary plaque instability. Optical coherence tomography (OCT) is capable of imaging macrophages within atherosclerotic plaque allowing quantitative and qualitative evaluation of coronary inflammation.

Aim: To establish the pattern of macrophage infiltration in ST elevation myocardial infarction (STEMI) and other forms of acute coronary syndromes (ACS).

Methods & Results: We performed OCT at culprit sites and remote lesions in 38 patients (19 STEMI, 19 ACS). A total of 95 lipid-rich plaques were analyzed. Macrophage density was calculated as the normalized standard deviation (NSD) of the optical signal within the superficial 50 microns of the fibrous cap. Macrophage heterogeneity was calculated as the variance of the NSD. There was no significant difference in the macrophage density for STEMI and ACS groups (5.59 ± 1.70 %, 5.95 ± 1.88 %, P = NS). However, macrophage heterogeneity was higher in the ACS group compared to the STEMI group (1.68 ± 0.61 %, 2.1 ± 0.75 %, P = 0.007). **Conclusion:** Although the superficial macrophage density is similar for both STEMI and ACS, the pattern of macrophage infiltration varies significantly with a greater heterogeneity found in the ACS group.

Figure (A) OCT image of a lipid-rich plaque (LP) adjacent to a site of intimal disruption (arrow). Scale bar = 500 µm; * represents guide wire shadow. **(B)** NSD image corresponding to (A) demonstrating sites of high macrophage density (green to red).



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

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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 539±317mm³, lumen was 256±159mm³, plaque&media was 283±176mm³, and %obstruction was 51±9%; 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