ORAL CONTRIBUTIONS

868 Stroke Prevention: Newer Devices in Intervention Stenting for Peripheral Vascular Disease

Wednesday, April 02, 2003, 8:30 a.m.-10:00 a.m.
McCormick Place, Room S105

8:30 a.m.

868-1 Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) to Prevent Stroke in Patients With Atrial Fibrillation: Initial Results of the Multicenter Feasibility Trial

Horst Sievert, Michael D. Lesh, Stefan Ostermayer, Kai Billinger, Thomas Trepels, Heyder Omran, Antonio L. Bartorelli, Paolo Della Bella, Toshiko Nakai, Mark Reisman, William Gray, Carlo DiMario, Peter C. Block, Paul Kramer, David O. Williams, Athena Poppas, Allan Skanes, Ulrike Krumsdorf, Detlef Scherer, Cardiovascular Center Bethanien, Frankfurt, Germany, Univ. of California, San Francisco, CA

Background: Thromboembolism due to atrial fibrillation (AF) is a frequent cause of stroke. More than 90 % of thrombi in AF form in the LAA. Catheter closure of the LAA might prevent stroke in AF. In this multicenter trial 52 pts with AF (age=70 ± 7 yrs; M/F=32/20) and additional risk factors for stroke who were sub-optimal candidates for warfarin were enrolled.
Methods: The PLAATO system consists of a self-expanding cage covered with ePTFE delivered through a 12Fr transseptal sheath specially designed to access the LAA. It is retrievable before release and can be replaced with an alternate size to optimize sealing.
Results: Device implantation (diameters 18-32mm) was successful in all pts, in one during a second procedure. Angiography and transesophageal echocardiography during the procedure showed that the device was well-seated in all patients. Hemopericardium occurred in 3 (pericardiocentesis performed without sequelae) but all had successful implantation, esophageal bleeding due to TEE in 1. No migration, mobile thrombus or interference with cardiac structures was noted on TEE performed 1 and 6 mos post procedure. In 1 pt, a laminar echogenic layer representing possible thrombus was noted on the implant surface at 1 and 6 mos. No clinical events have occurred in this pt. During follow up (median 4.5 mo) one pt died 7 mo post implant. He had a history of diffuse atherosclerotic vascular disease and multiple prior strokes. TEE performed 2 weeks prior to death showed the device well positioned with no thrombus.
Conclusions: Transcatheter closure of the LAA with a novel implanted device is feasible, and safe during short term follow up. Longer term studies will be needed to show that this technology reduces stroke in pts with AF who are sub-optimal candidates for anticoagulation.

8:45 a.m.

868-2 Outcomes From Carotid Artery Stenting in Over 1,000 Cases From a Single Group of Operators

Gishel New, Gary S. Roubin, Sriram S. Iyer, George Dangas, Roxana Mehran, Yuliya G. Adamyan, Thosaphol Limpijankit, Christina Brennan, Palawi Kumar, Jiri J. Vitek, Lenox Hill Heart and Vascular Institute, Cardiovascular Research Foundation, New York, NY

Background: We report the 8year experience of a single group of operators in over 1000 carotid stenting (CS) procedures.
Methods: Patients were enrolled and prospectively followed from September 1994 until August 2002. Neuroprotection devices were introduced in January 2000. Patient demographics, procedural details, 30-day events and long-term follow up data were collected. Results were also annualized to determine if there was an improvement over time in periprocedural results.
Results: 1068 patients underwent CS of 1202 arteries. The mean age of the patients was 71 ± 10 years. 34% were female with 15% of patients were >80 years of age. 60% of patients had concomitant CAD. 10% had contralateral occlusions and 17% had a history of prior carotid endarterectomy. Procedural success was achieved in 99% of cases. 33% of patients had their procedure performed using a neuroprotection device. Data annualized in the table below shows a significant reduction in stroke over the 8-year time-period (Chi-Square for Trend Analysis). The only multivariate predictors of stroke were hypertension ($p < 0.05$), age > 80 yrs ($p < 0.05$) and symptomatic status ($p < 0.05$).
Thirty-Day Events

	9/94-9/95	9/95-9/96	9/96-9/97	9/97-9/98	9/98-9/99	9/99-9/00	9/00-9/01	9/01-9/02	Overall	P value
Arteries (n)	100	124	126	94	159	207	214	178	1202	NA
Minor Stroke	7 (7.0%)	7 (5.6%)	7 (5.5%)	3 (3.1%)	5 (3.1%)	2 (1.0%)	3 (1.4%)	1 (0.6%)	37 (3.1%)	< 0.01
Major Stroke	1 (1%)	2 (1.6%)	1 (0.8%)	0	2 (1.2%)	2 (1%)	1 (0.5%)	0	9 (0.7%)	NS
Fatal Stroke	0	0	3 (2.4%)	0	0	1 (0.5%)	1 (0.5%)	0	5 (0.4%)	< 0.05
All Strokes	8 (8.8%)	9 (7.9%)	11 (9.1%)	3 (3.4%)	7 (4.4%)	7 (3.5%)	5 (2.3%)	1 (0.6%)	51 (4.4%)	< 0.01

Conclusion: Improvements in technique, equipment, pharmacotherapy and the use of neuroprotection have contributed to the dramatic decline in event rates in the more recent years of this study. Stroke rates from carotid stenting have declined to levels comparable or better than randomized surgical trials.

9:00 a.m.

868-3 Transcatheter Closure of Post-Infarct Ventricular Septal Defects: Immediate and Mid-Term Results of U.S. Registry Using the Amplatzer Post-Infarct Ventricular Septal Defect Occluder

Ziyad M. Hijazi, David Balzer, Carlos Ruiz, Michael Vance, John Bass, Mary Heitschmidt, University of Chicago, Chicago, IL, Washington University School of Medicine, St. Louis, MO

Background: Post infarction rupture of the ventricular septum carries a grave prognosis. Surgical closure of such defects is associated with very high mortality and morbidity. Recent advances in device technology may potentially replace surgical closure in these patients. We report the initial and mid-term results of a US registry using the Amplatzer post-infarct VSD occluder.
Methods: Ten patients (7female) with post infarct ventricular septal defects (PIVSD) underwent an attempt of closure of their defects at a median age of 73 yr. (range 52-86 yr.). The median size of VSD as measured by echocardiography/angiography was 13.5 mm (range 6-18 mm). Six patients had prior unsuccessful surgical intervention for the VSD. The procedure was performed under general endotracheal anesthesia in 7.
Results: All patients tolerated the catheterization procedure. Devices were deployed from the right internal jugular vein in 8 patients and from femoral vein in two. The sizes of devices deployed ranged from 12-22 mm. In 9 patients the attempt was successful in deploying the devices and in one the device could not be secured across the VSD. The median fluoroscopy time was 36 minutes (15-63 minutes) and the median total procedure time was 131 minutes (range 76-229 minutes). Immediately after the procedure, the shunt disappeared completely in 1; 3 had trivial shunt and in 4 the shunt was small. Complications encountered during or after the procedure included hematoma requiring transfusion in one; pacemaker for pre-existent sinus node dysfunction in one and tracheaostomy for ventilator dependence in one. At a follow-up interval of 6-months, five patients are alive and doing well. Conclusion: Catheter closure of PIVSD using the Amplatzer device is safe and effective. Further clinical trials are underway.

9:15 a.m.

868-4 Nitinol Stent Fractures in the Superficial Femoral Artery: Incidence and Clinical Significance

Krishna J. Rocha-Singh, Karen Scheer, Janiece Rutherford, Prairie Heart Institution, Springfield, IL

Background: Nitinol stents combine the advantages of excellent radial strength and scaffolding with non-compressibility and minimal foreshortening. Originally designed for use in the carotid artery, nitinol stents are increasingly being used to treat suboptimal/failed percutaneous transluminal angioplasty (PTA) results in the superficial femoral artery (SFA). However, preliminary six month angiographic follow-up in a small cohort of SFA nitinol stent patients has recently revealed the unexcepted and previously unreported finding of stent strut fractures. The incidence and clinical significance of nitinol stent fractures in the SFA is unknown.
Methods: We retrospectively identified 78 patients (84 limbs, 92 lesions) in which 105 nitinol stents were implanted between January 1999 and November 2001 after suboptimal/failed PTA for severe claudication (93%) or critical limb ischemia. To date, 14 patients have returned for fluoroscopic assessment of the nitinol stent skeleton: 10 patients received 15 SMART™ stents, five received six DynaLink™ stents, and one received one Memotherm™ stent. All 14 patients had SFA color duplex-doppler assessment at the time of fluoroscopic follow-up to assess stent patency. The mean follow-up was 18.4 ± 9.8 mos. post-procedure (range 5mos. to 43 mos).
Results: All stent procedures were successful; no patient experienced abrupt or subacute stent closure. No patient required percutaneous or surgical revascularization of the index extremity at follow-up. Three of the 22 stents evaluated (13.6%) had fluoroscopic evidence of stent strut fractures resulting in stent deformation; one of the three stents met duplex doppler criteria for restenosis.The overall stent restenosis rate in the 14