Involving a bifurcation site, restenotic lesions (including in-stent restenosis), two-vessel disease (a maximum of 2 lesions located in 2 different epicardial vessels), long lesions (≥ 25 mm).

Methods: The primary endpoint of the study is the Target Lesion Revascularization (TLR) rate at 180 days after stent implantation. Secondary endpoints are Target Vessel Failure (TVF) at 180 days, Major Adverse Cardiac Events (MACE) at 30 days and 180 days, and MACE at 1 year, 2 years, and 3 years in a subset of 500 patients, device success, procedure success and resource utilization.

Results: As of abstract submission, data about 1262 patients enrolled are at 30 days for analysis, for a total of 1435 lesions treated. Among these, 374 (34%) were restenotic lesions.

Conclusions: The patient recruitment in the DELIVER II study was completed on 9th of September 2002. Thirty-day safety results from the restenotic lesions subgroup will be available for presentation and will be compared with the outcome of other lesion subgroups. Multivariate analysis combining restenosis with other complicating factors will be presented as well.

* Manufactured by Cook Incorporated. DELIVER II is conducted by Guidant Corporation on behalf of Cook Incorporated.
Results: ISR was seen in 83 of 212 (39%) stented lesions. Of predictive value were presence of diabetes mellitus (P=0.014) as well as cumulative time of inflations (P=0.01) as procedural angiographic parameters. Notably, 9 of 11 (82%) patients with progression presented with acute coronary syndromes at follow-up.

Conclusion: The findings of the present pilot study show that restenosis of a target stenosis following stent implantation is associated with progression of other untreated lesions, and thereby suggest that both arteriosclerosis forms share common systemic pathogenic mechanisms. With presence of ISR, angiography of primarily untreated coronaries should be performed, especially in case of preexisting plaques.

Angiography & Interventional Cardiology

POSTER SESSION

1199 Newer Devices for Percutaneous Interventions: Renal and Ilio Femoral Angioplasty

Tuesday, April 01, 2003, 3:00 p.m.-5:00 p.m.
McCormick Place, Hall A
Presentation Hour: 3:00 p.m.-4:00 p.m.

Results of U.S. Phase I Clinical Trial of Closure of Patent Foramen Ovale Associated With Stroke/ Transient Ischemic Attack or Peripheral Embolism Using the Amplatzr Patent Foramen Ovale Device

Tom Honig, Ziyad M. Hijazi, Conrad J. Hagler, Hilendra Patel, John P. Cheatham, Lowell Schiller, Richard Gentleman, University of Chicago, Chicago, IL; Mayo Clinic, Rochester, MN.

Background: Patients with a patent foramen ovale (PFO) and paradoxical embolism are at risk for recurrent thromboembolic events. We report the results of Phase I US clinical trial of patients who underwent transcatheter PFO closure for secondary prevention of paradoxical embolism using the Amplatzer® PFO occluder (APC).

Methods: From March 2000 through May 2002, 50 patients (28 males and 22 females) with PFO and at least 1 paradoxical embolic event were referred for transcatheter PFO closure using the APC. The median age was 41 yr. (range 15 – 61 yr) and the median weight was 81 kg (range 45 – 118). Thirty-six patients had cryptogenic stroke, 10 patients had transient ischemic attack and 4 patients had peripheral embolism. Seventeen patients had both a PFO and an atrial septal aneurysm.

Results: Of 50 patients referred for closure, 49 underwent attempted closure of their PFO using the APC; one patient did not have a PFO. Fifty devices were successfully deployed in all 49 patients (one patient received two devices for two separate fenestrations). Immediate complete closure as documented by transesophageal echocardiography (TEE) was achieved in 28/49 (58%) and at 24 hours, by thromboaspheric echocardiography (TEE) was achieved in 31/49 (65%) patients. The median fluorosity time was 10.5 minutes (range 2.8 – 40) and the median procedure time was 65.5 minutes (range 16 – 300). Complications encountered during and within the follow-up period included one patient who developed a hematoma and an AV fistula requiring surgery and two patients who developed atrial fibrillation. At 3 month follow up, 44 patients had a TEE with contrast bubble study, 39 (89%) had complete closure. At a median follow-up interval of one year (range one month–569 days), there have been no recurrent embolic events.

Conclusion: Transcatheter closure of PFO using the APC seems to be a safe and effective therapy in the prevention of thromboembolic events in patients with a history of presumed paradoxical embolism.

Results of U.S. Phase I and II Clinical Trials of Transcatheter Closure of Patent Ductus Arteriosus in Adult Patients Using the Amplatzer Duct Occluder

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Background: Surgical closure of patent ductus arteriosis (PDA) in adult patients may be problematic. Recently, transcatheter closure of PDA using the Amplatzer duct occluder (ADO) has been shown to be safe and efficacious. We present our experience with this device in the adult population.

Methods: Between January 2000 and January 2002, forty one adult patients (31 females and 10 males) with a PDA were referred for closure with the ADO. The median age was 35.6 years (range 18 – 70). The median Qp/Qs was 1.4 (range 0.6 – 3.5). The median diamater of the pulmonary artery and main artery (extramural diameter) was 9.4 mm (range 5.6 – 12) and the median diameter of the ampulla was 17.1 mm (range 6.0 – 32) and the median length was 8.8 mm (range 1.6 – 35). According to the Toronto classification, there were 33 Type A PDAs/ 1 Type B/ 1 Type C: 2 Type D and 4 Type E.

Results: Of forty-one patients, thirty-seven underwent attempted closure of their PDA using the ADO. In the remaining four patients, the PDA was small, and was closed using Gianturco coils. The device was successfully deployed in all but one patient (the ductus could not be crossed) and the patient ultimately had successful PDA closure using a Gianturco coil. Moderate sized devices were used more frequently (1 patient received the 5/4 device; 2 the 6/4; 22 the 6/6; 7 the 10/6; 8 the 12/10; 1 the 14/12 and 1 patient received the 15/14 mm device). Complete angiographic closure was seen immediately after device deployment in 29 of 36 (81%) patients. At 24 hours, complete closure as evidenced by color Doppler echocardiography was demonstrated in 34 of 36 (94%) patients. The remaining two patients had small residual shunt. At 6 month and 1 year follow-up, complete closure was demonstrated in 35 of 36 (97%) patients. In the two patients with small residual shunts at 24 hours post-procedure, one patient demonstrated complete closure by echocardiography at 6-months post-procedure. The other patient had no available follow-up. No complications related to device implantation occurred in any patient.

Conclusion: Closure of PDA using the ADO is safe and effective in adult patients.