Intermediate Follow-Up for Atrial Septal Defect Closure With the HELEX \textsuperscript{TM} Septal Occluder Device: The FDA Phase I Feasibility Trial

John F. Rhodes, Jr., Geoffrey K. Lane, David Nykanen, Penny A. Radvansky, Evan M. Zahn, Larry A. Latson, The Cleveland Clinic Foundation, Cleveland, Ohio, Miami Children's Hospital, Miami, Florida.

Background: The HELEX \textsuperscript{TM} device has recently been used for transcatheter secundum atrial septal defect (ASD) closure. We report the intermediate follow-up data regarding device safety and performance. Methods: Between 4/00-12/00, pts with an ASD in two centers were enrolled in a prospective, non-randomized FDA phase-I feasibility trial. Catheterization procedures were performed under general anesthesia with transeosophageal echocardiographic guidance. Procedural success was defined as accurate placement of a device. Evaluations were scheduled for 1-3 month, 6-months and 1-year follow-up after closure. Results: Fifty-five pts with an ASD, median age 10yrs (range 0.4-84), procedures to the catheterization laboratory; 40 pts had balloon closure, 13 pts had standalone closure. Median fluoroscopy time was 17.1-26min (17.4±4). Device balloon waist ratio was 1.3-4.2 (1.8±0.5). The procedure was successful in 50 pts. There were 7 procedure-related adverse events with device embolization (unrelated referral) in 2 pts, transient asst regurgitation in 3 pts and transient ST depression in 2 pts. Median fluoroscopy time was 23 minutes. No adverse event prolonged the hospitalization. No pt had a clinically significant residual leak around the device. The incidence of trivial/small leaks has decreased from 27/54% (1 day) to 2/24% (47%) at 1-month and 9/30% (30%) at 6 months. At this time, 1-year follow-up is available in 15 pts with 2 (13%) having a minimal leak around the device and one having a small residual shunt through a second ASD. The only adverse events reported during follow-up have been 1 pt with noisebleed and 1 pt with rectal bleeding. Both were resolved with a change in the standard anticoagulation regimen. Although no pt has had a new onset documented arrhythmia, 2 pts had complaints of palpitations and 3 pts had returned to their baseline arrhythmia after implantation. With a median follow-up of 210 days (range 37 to 358) there have been no device fractures. Conclusion: These intermediate data indicate that the HELEX \textsuperscript{TM} device is safe and effective for secundum ASD closure. At follow-up no pt has a clinically significant residual leak and the incidence of clinically insignificant leak appears to decrease.

Amplatzer Fenestration Device: Application in Humans to Maintain Patency of Fontan Fenestration and Shunt Through the Atrial Septum

Zahid Arooh, David A. Danfot, Carlos A. Pedra, Univ. of Nebraska/Creighton Univ, Children's Hospital, Omaha, Nebraska, Instituto Dante Pazzanese de Cardiologias, Sao Paulo, Brazil.

Background: Patients who develop systemic venous failure and protein-losing enteropathy after lateral tunnel or extracardiac Fontan, may benefit from fenestration created between the systemic and pulmonary venous channels. Some fenestrations, whether created surgically or in the catheterization laboratory, tend to close spontaneously. In addition, patients with pulmonary hypertension or ventricular dysfunction and atrial septal defect may benefit from a small communication at the atrial level, if the defect is closed. The objective of this study was to assess the feasibility of a new Amplatzer device, to maintain patency of Fontan Fenestration and shunt level communication, after closure of the atrial septal defect. Methods: The Amplatzer Septal Occluder device is a 4-mm fenestrated disk designed to create a 4-mm fenestration through the discs and the waist of the device. The basic design, loading, delivery, deployment and release mechanism were similar Amplatzer Septal Occluder. Three patients with protein-losing enteropathy after Fontan operation, undiagnosed at presentation of the device, underwent placement of the device. Results: The device was deployed without complications and 2-pts have had return of atrial arrhythmia after implantation. With a median follow-up of 190 days (range 37 to 358) there have been no device fractures. Conclusion: These limited experience suggest that the Amplatzer Fenestration device can be a valuable tool in keeping Fontan Fenestration patent. It can also maintain a communication at the atrial level in patients with pulmonary hypertension or ventricular dysfunction after atrial septal defect closure.

Quantitative Angiographic Assessment of Pulmonary Blood Flow in Children With Congenital Heart Defects

Daniele G. Govenstein, Robert H. Beekman, III, Robert L. Sporn, Children's Hospital Medical Center, Cincinnati, Ohio.

Background: This study was performed to validate a new method of quantifying relative pulmonary blood flow by angiography. Method: Pulmonary angiograms and radionuclide lung perfusion scintigraphy (LPS) of 12 pts with various congenital heart malformations were compared. Relative blood flow to the left and right lung was measured by pulmonary angiographic densitometry (AD) using a new image analysis protocol. Perfusion regions of the left and right lung were delineated in the cross-sectional area with mean density contrast in each region obtained. The ratio of right to left cardiac output to total lung flow was determined by AD, expressed as a percent (QldR), and was compared to the ratio of right pulmonary flow as determined by LPS (QldR). Observers blinded to the LPS data performed the AD measurements, and interobserver and intraobserver variability was determined. Results: The QldR ranged from 15-100% (mean ± SD = 52 ± 26) and the QldR ranged from 17-97% (57±17). There was a significant linear relation between QldR and QldR with r=0.85. Conclusion: This novel method of quantifying relative pulmonary blood flow by angiography is feasible and correlates well with LPS.