Background: Transcatheter aortic valve replacement (TAV) is a well-established treatment option for patients with severe aortic valve stenosis. However, during dilation, inadvertent balloon movement (due to the contractile force of the left ventricle) can increase risk of unnecessary trauma to the aortic valve apparatus resulting in aortic insufficiency (AI). A new technique was developed to stabilize balloons position during dilation. Methods: Standard transfemoral retrograde techniques were used for TAV. A pacing catheter was inserted into the right ventricle (RV) apex and just prior to balloon inflation, the heart was paced at a faster rate in order to decrease the stroke volume and left ventricle (LV) systolic pressure. The lower LV systolic volume and systolic pressure result in a more stable balloon position. Balloon inflation was carried out in the usual manner and following balloon deflation, RV pacing was discontinued. Echocardiographic and cath lab data were reviewed in all patients who underwent TAV assisted by RV pacing between 9/99 and 6/01. All patients were under RV pacing (TAV) device. Mean age and weight were 9.9 years and 31.7 kg respectively. The aortic valve gradient decreased from 67.8 ± 18.5 to 19.4 ± 1.1 mmHg (75%). The average balloon to annulus ratio was 0.96 ± 0.06. RV pacing increased the heart rate by an average of 96 ± 29 bpm and decreased LV systolic pressure by 96 ± 12%. Balloon position remained stable during inflation in all except for one when there was loss of capture resulting in a premature ventricular contraction (PVC). Review of the fluoroscopic and hemodynamic recording of that inflation indicated the balloon “milked” forward during the PVC. Normal sinus rhythm returned in all cases immediately after RV pacing was discontinued. No change in AI or trace AI was seen in 10 pts. The development of mild AI was seen in 3 (1 + 1 + 1 in 2 and 2 pts). Conclusion: RV pacing during TAV is safe and stabilizes balloon position during aortic valve dilation. Larger series and longer follow-up are warranted to confirm that stable balloon position during TAV decreases the incidence of aortic insufficiency.

Intracardiac Echocardiography During Interventional Catheterization for Congenital Heart Defects

Background: Echocardiographic guidance is often used during transcatheter interventions for patients with congenital heart defects. Few data exist regarding intracardiac echocardiographic (ICE) guidance during transcatheter interventions. We report data from a single center regarding the efficacy and performance of ICE for this patient population. Methods: The 100th AcuNav™ ICE catheter provides a 2-dimensional image and Doppler color mapping using the Sequoia ultrasound system. Between 5/01 and 9/01, data were collected prospectively from patients undergoing interventional procedures using ICE and conscious sedation. The ICE catheter was positioned through an 11Fr sheath in the right atrium. Results: Seventeen patients, median age 48 years (range 12 to 77), underwent a transcatheter intervention for a congenital heart defect with ICE guidance. Twelve patients underwent patent ductus arteriosus (PDA) closure region 1 (PDA) closure and two patients aortic septal defect (ASD) closure and three patients balloon aortic valvuloplasty (BAV). ICE allowed the patients to avoid general anesthesia and transesophageal echocardiography (TEE). ICE provided accurate monitoring for placement of devices during PDA/ASD closure and degree of valve regurgitation during BAV. There were no procedurally related adverse events. The median fluoroscopy time for PDA/ASD closure was 17 minutes (range 11 to 36) and for BAV procedures was 30 minutes (range 21 to 88). Overall billable charges were less for the ICE group when compared to the potential charges of the procedure including general anesthesia and TEE. All patients were discharged within 24 hours following the catheterization. With a median follow-up of 24 months (range 0.7 to 3.8) there have been no adverse events. Conclusion: ICE is a safe and effective method for guidance during interventional procedures for patients with congenital heart defects. The avoidance of having developed multiple anesthetic dedicated staff may be significant to the patient overall procedural experience and be more cost effective. These data support continued utilization of this type of technology.

Intermediate Follow-Up for Atrial Septal Defect Closure With the HELEX™ Septal Occluder Device: The FDA Phase I Feasibility Trial
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Background: The HELEX™ 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. Catheterizations were performed under general anesthesia and transesophageal echocardiography guidance. Procedural success was defined as accurate placement of a device. Evaluations were scheduled for 1-day, 1-month, 6-months and 1-year following deployment. Results: Fifty-five pts with an ASD, median age 10 yrs (range 0.4 to 58), proceeded to the catheterization laboratory. Static balloon occlusion time 17.1 ± 26.8 min (17.4 ± 4.1 min). Device/ballooon 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 (unrelentful retrieval) in 2 pts, transient arrhythmia 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 27/50 (54%) at 1-day to 2/24 (8%) at 1-month and 2/20 (30%) at 6-months. At this time, 1-year follow-up is available in 15 pts with 2 (13%) having a residual 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 noise/bowel and 1 pt with rectal bleeding. Both resolved with a decrease in the standard atenolol/azolidone regimen. Although no pt has had new onset documented arrhythmias, 2 pts have had complaints of palpitations and 1 pt had return to sinus rhythm 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™ device is safe and effective for secundum-ASD closure. At latest 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
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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 atrial level communication, after closure of the atrial septal defect. Methods: We reviewed in all patients who underwent TAV assisted by RV pacing between 9/99 and 8/01. Device safety and performance. Results: Evaluations were scheduled for 1-day, 1-month, 6-months and 1-year following device placement. The incidence of clinically insignificant leak appears to decrease. Atrial level communication was present in all patients. There was immediate drop in systemic arterial saturations and systemic venous pressures after placement of the device. All patient showed dramatic hemodynamic improvement. Follow-up was available from 3 to 12 months. Echocardiographic evaluation at the last follow-up revealed low velocity flow through the fenestration. 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
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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 scans (LPS) of 12 children 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. Perfused regions of the left and right lung were delineated from the cross-sectional area and mean contrast density in each region of each slice. The ratio of right to left pulmonary artery flow to total lung flow was determined by AD, expressed as a percent (CQAD) and was compared to the ratio of right to left pulmonary flow as determined by LPS (CQPS). Observers blinded to the LPS data performed the AD measurements, and interobserver and interobserver variability was determined. Results: The CQAD ranged from 15-100% (mean ± SD= 52 ± 26) and the CQPS ranged from 17-97% (±7 ± 26). There was a significant linear relation between CQAD and CQPS.