Hg (20-140 mm Hg). Immediate post-stent gradient was 15 mm Hg (0-60 mm Hg, p<.001). Median follow-up was 39 months (12-78 months). Seven patients had repeat study. Additional stents were implanted in 2 patients and 5 underwent stent re-dilation. At re-study, median gradient was 37 mm Hg (10-55 mm Hg), with post-dilation gradient of 12 mm Hg (0-40 mm Hg). Two procedure-related complications were noted. One stent was deployed in the femoral artery after dislodging during implantation. At restudy, one patient was found to have developed multiple aneurysms adjacent to stents implanted in the thoracic aorta and brachiocephalic vessels. **Conclusions:** Stent implantation is effective in providing gradient relief in SAA. Early procedure related complications are uncommon and gradient relief persists or is amenable to re-dilation. Uncomplicated stent implantation does not preclude aneurysm formation, however. This complication may be related to histopathologic and vessel wall-specific issues, making prediction of which patients are at risk difficult.

1190-98 Transcatheter Aortic Valvuloplasty Assisted by Right Ventricular Pacing

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Background: Transcatheter aortic valvuloplasty (TAV) is a well-established treatment modality for congenital 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 balloon 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 stroke 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 8/01. Results: Thirteen patients underwent TAV assisted by RV pacing (31 inflations). Mean age and weight were 9.9 years and 31.7 kg respectively. The aortic valve gradient decreased from 67.8 ± 18.6 to 19.4 ± 9.1 mmHg (75%). The average balloon to annulus ratio was 0.92 ± 0.08. RV pacing increased the heart rate by an average of 80 ± 29% and decreased LV systolic pressure by 36 ± 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+ in 1 and 2+ in 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.

1190-99 Intracardiac Echocardiography During Interventional Catheterization for Congenital Heart Defects

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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 10Fr 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 foramen ovale (PFO) closure, two patients atrial 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 PFO/ASD closure and degree of valvar regurgitation during BAV. There were no procedure related adverse events. The median fluoroscopy time for PFO/ASD closure was 17 minutes (range 11 to 36) and for BAV procedures was 30 minutes (range 21 to 68). 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 <24 hours following the catheterization. With a median follow-up of 2.4 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 general anesthesia and TEE may be significant to the patients overall procedural experience and be more cost effective. These data support continued utilization of this type of technology.

1190-100 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 using general anesthesia with 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 10yrs (range 0.4 to 55), proceeded to the catheterization laboratory. Static balloon-stretched ASD diameter was 7.1→26mm (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 (uneventful 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 22/47 (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 trivial/small 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 nosebleed and 1-pt with rectal bleeding. Both resolved with a decrease in the standard aspirin anticoagulation regimen. Although no pt has had new onset documented arrhythmia, 2-pts have had complaints of palpitations and 2-pts have had return of atrial arrhythmia after implantation. With a median follow-up of 210 days (range 27 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.

1190-101 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 feasiblity of a new Amplatzer device, to maintain patency of Fontan Fenestration and atrial level communication, after closure of the atrial septal defect. ***Methods:*** Amplatzer Septal Occluder® was modified 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, underwent placement of the device. A fenestration was created in the Goretex patch of the lateral tunnel with the help of transseptal needle. The fenestration was dilated with 8-mm balloon, and the 4-mm Fenestration device (8-mm disc) was deployed under transesophageal echocardiographic guidance. The fourth patient, who had ventricular dysfunction, had the device placed in the atrial septal defect. ***Results:*** The procedure was successful 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 fenestrations. ***Conclusions:*** This limited experience suggest that the Amplatzer Fenestration device can be a valuable tool in keeping Fontan Fenestrations patent. It can also maintain a communication at the atrial level in patients with pulmonary hypertension or ventricular dysfunction after atrial septal defect closure.

1190-102 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.

Methods: 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 defined and the cross-sectional area and mean contrast density in each region of interest was quantitated. The ratio of right pulmonary artery flow to total lung flow was determined by AD, expressed as a percent (Qp_{AD}), and was compared to the ratio of right pulmonary flow as determined by LPS (Qp_{LPS}). Observers blinded to the LPS data performed the AD measurements, and intraobserver and interobserver variability was determined.

Results: The Qp_{AD} ranged from 15-100% (mean +/- SD = 52 +/- 26), and the Qp_{LPS} ranged from 17-97% (57+/- 26). There was a significant linear relation between Qp_{AD}