associated with other complex congenital anomalies. The purpose of this study was to close MVSD's with modified Amplatz device which is retrievable, self centering, repositionable and low profile. It is constructed of 0.004 inch Nitinol wire mesh filled with polyester fibers.

Methods: MVSD was created in twelve dogs via right thoracotomy with the help of a sharp punch. The location was anterior muscular (3), midmuscular (4), apical (4) and atrioventricular canal type in one. The size of the defect ranged from 6 mm–14 mm. Three of these defects were closed intraoperatively with the help of the catheter through the right ventricular free wall. The remainder of the nine VSD's were closed three to six weeks post operatively in the cardiac Catheterization Laboratory. The devices were placed through a 7 French sheath percutaneously. Transesophageal echocardiography was utilized for optimal placement.

Results: Placement was successful in all twelve animals. The immediate closure rate was 100% when the device was placed intraoperatively. The percutaneous closure rate was 55% (5/9) immediately after placement of the device, 77% (7/9) after one month and 100% (9/9) after three months. One dog required a second device.

Conclusion: This device appears highly efficacious in closing muscular ventricular septal defects. Since it can be delivered with a small delivery sheath and is completely retrievable after deployment it will be highly suitable for small children.

1069-155 Interventional Closure of Atrial Septal Defects With the Amplatzer™ Device in Children and Adults

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Purpose: The early results from two different centers of percutaneous interventional closure of atrial septal defect (ASD) at the oval fossa with the Amplatzer™ device are presented.

Material and Method: The implantation of the Amplatzer™ device was started and performed in 34 patients with the age of 1.2–70 years mean 19.3 ± 22.1, median 8.1. The weight was 9.4–120 kg, mean 39.4 ± 29.8, median 23.8. The stretched ASD size was 6–20 mm, mean 12.3 ± 3.8, median 12 mm, the flow ratios from 0.9–3.0:1, mean 2.0 ± 0.53, median 1.8, calculated from oximetric measurements.

Results: A device could be implanted in all cases without problems. No complication occurred, except for one transient disc thrombus, which resolved uneventfully after additional heparin treatment. The fluoroscopy time was 10.7 ± 5.3 min., median 9.3. The longest time of 27.4 minutes occurred in the first patient. The interventional time was 45–180 min., mean 99.9 ± 30.3, median 95. On the morning following implantation, the devices were found to remain in correct position. A < 1 mm shunt was detected in one with color Doppler. Neither venous inflow nor valves were affected and normalization of the septal movement had already occurred. During up to one year's follow-up no adverse effect has been detected. The minimal shunt of less than 1 mm persists after 3 months.

Conclusion: Selected ASDs at the oval fossa can be closed easily, reliably and safely with the Amplatzer™ device in all age groups.

1069-156 Repeat Balloon Dilation of Congenital Valvar Aortic Stenosis: Immediate Results and Midterm Outcome

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Balloon dilation (BD) is the primary treatment for the initial management of congenital valvar aortic stenosis (CVAS) for pts of all ages at our institution. However, the preferred approach to restenosis following BD of CVAS remains unclear. In order to determine efficacy, we reviewed all available data on pts who underwent 2 or more BDs of CVAS between 1/85 and 12/96. Among 298 pts (70 neonates), 37 underwent repeat BD, 3 of whom had a prior surgical valvotomy and 4 with hypoplastic left heart syndrome (HLHS). A greater proportion of neonates had a repeat BD (26% vs 8%, $p < 0.001$). At BD2 (1 d–7.5 yrs post BD1), the peak systolic ejection gradient was reduced from 66 ± 23 to 35 ± 16 mmHg ($p < 0.001$). Aortic regurgitation (AR) increased in 11 pts (30%), and was moderate or more in 8 (22%). There was no procedure related mortality.

During a mean follow-up of 5 yrs (10 mo–11 yrs), there were 2 deaths, 1 surgically related and 1 following withdrawal of support in a pt with HLHS. Of the 35 survivors, 5 had operations for AS or AR and 2 pts had a Norwood procedure. Among the remaining 28 pts, 24 of 25 (96%) were asymptomatic, the maximum instantaneous Doppler gradient across the aortic valve was 50 ± 15 mmHg in 26 pts, and AR was moderate or more in 8 of 27 (30%) pts.

Conclusions: 1) Repeat BD is feasible, effective, and without mortality. 2) AR was at least moderate in 22% of pts after BD2. 3) Repeat BD was more common in those who had BD1 as neonates.

1069-157 A New Controlled Release System for Standard 0.052" and 0.038" Gianturco Coils

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Background: Coil embolization during PDA closure has stimulated the development of controlled release systems. This report describes the safety and effectiveness of a new controlled release system for 0.052" and 0.038" coils.

Methods: The release system was created from inexpensive materials consisting of a guide wire that was snapped onto the end of the Gianturco coil allowing retrieval of the coil through a long sheath. The coil was released by advancing a directional catheter over the guide wire thereby unsnapping the coil for delivery. The reliability of coil retrieval and release was tested in vitro. The 0.052" controlled release system was subsequently used in 6 patients to close large PDAs. Procedural results were compared with a cohort of 16 patients who had attempted large PDA closure using uncontrolled coil release.

Results: In vitro testing showed 100% successful retrieval and release of a fully deployed coil with the force required for release >3 times the force required for retrieval (5.4 ± 2.0 vs. 1.4 ± 0.4 N for 0.052" coils; 3.1 ± 0.8 vs. 1.0 ± 0.3 N for 0.038" coils). Six of 6 controlled coil release patients (100%), ages 16 months to 48 yrs with PDA diameter 4.1 ± 0.7 mm, had successful closure with no incidence of coil embolization. These results compare favorably to the 11 of 16 uncontrolled coil release patients (69%), ages 3 months to 43 yrs with PDA diameter 4.3 ± 0.6 mm, who had successful closure.

* $p < 0.05$

Release System	Embo/Mal Rate*	Procedure Time*	Fluoro Time*	Hosp Charges
Uncontrolled (11)	32%	269 ± 78	64 ± 44	11470 ± 3496
Controlled (6)	0%	186 ± 27	34 ± 16	9810 ± 831

Conclusion: The new 0.052-in coil release system is safe and effective for closing large PDAs. The 0.038-in release system may prove useful for controlled closure of smaller PDAs and technically difficult peripheral vascular anomalies. Further clinical trials are warranted.

1069-158 Transcatheter Occlusion Versus Surgery for Patent Ductus Arteriosus: A Five-Year Experience of Treatment Success, Hospital Course and Complications

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Background: Current treatments for patent ductus arteriosus (PDA) include surgical ligation/division and transcatheter occlusion. The purpose of this study was to compare treatment success, hospital course and complications following surgical versus transcatheter treatment of isolated PDA.

Methods: Hospital records from 1/93 to 3/97 were retrospectively reviewed. Complications were defined as post-procedure events which caused morbidity or prolonged hospitalization. Successful treatment was defined as no residual ductal shunting on follow up echocardiogram.

Results: Successful treatment in the surgery patients was 47/48 (97.9%) and 106/114 (93.0%) in the catheterization patients (p = NS). Catheterization devices implanted were Gianturco-Grifka Vascular Occlusion Devices (19 patients) and Gianturco Coils (95 patients). (PP-Post Procedure, ICU-Intensive Care Unit, CT-Chest Tube)

(Data = Means)	AGE YRS	WT KG	PP DAYS	ICU DAYS	CT DAYS	ETT HRS
Surgery	4.3	15.7	5.8	1.4	1.2	8.4
Cath	7.4	23.5	1.1	0.2	0.0	0.0
p-value	0.013	0.001	0.001	0.001	0.001	0.001

At least one complication was found in 19/48 (39.6%) surgical patients and 9/114 (7.9%) catheterization patients ($p < 0.001$).

Conclusions: Transcatheter occlusion and surgery are equally effective to treat PDA. When compared to surgical therapy, transcatheter occlusion is associated with significantly fewer complications, less morbidity and fewer post procedure hospital and ICU days.