aetiology (P < 0.0014) were significant risk factors for 30 day mortality on multiple logistic regression. Survival for all groups (±SEM) including in hospital mortality at 1, 5, and 10 years was 87.28% (± 1.28), 70.7% (± 2.09) and 47.52% (± 3.45) respectively. Factors associated with a significantly worse prognosis on Cox's proportional hazards model included higher preoperative NYHA status (P < 0.0034), LV dysfunction: (P < 0.0012), increasing age at operation (P < 0.0001), aetiology of regurgitation (ischaemic worst (P < 0.01) and valve replacement rather than repair (P < 0.034).

Conclusion: Mitral valve surgery for degenerative MR is associated with low mortality, especially when repair is possible. Ischaemic MR, traditionally thought to carry a worse surgical prognosis, had a low mortality similar to rheumatic disease.

1068-43 Age, Coronary Disease, and Thromboembolism Risk After St. Jude Mechanical Valve Replacement

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Background: Reported thromboembolism (TE) rates vary widely between institutions for the same prosthetic valves. We hypothesized patient age was an important factor explaining variations in TE rates.

Methods: We analyzed TE data in 978 consecutive patients undergoing St. Jude valve replacement (4,319 patient-years). Patient groups were aortic (AVR), mitral (MVR), and double valve (DVR).

Results: Elderly patients (≥65 years) had more diabetes (DM), hypertension (HTN), coronary disease (CAD), and underwent coronary bypass surgery (CABG) more often. TE rates were significantly higher in the elderly (P = 0.02). Univariate risk factors for TE were age, presence of CAD, concurrent CABG, DM, and HTN. In multivariate analysis, only CABG (P = 0.01) was a significant risk factor for TE.

Linearized TE rates (Events/100 pt years):

		MVR	AVR	DVR	Total
Age	<65	2.3	1.7	2.5	2.1
	≥65	2.6	3.1	3.8	3.0
CABG	N	1.7	1.9	2.8	1.9
	Y	3.6	3.3	4.0	3.6

Conclusions: Although TE rates are higher in the elderly they are also associated with other coronary risk factors. Multivariate analysis suggests coronary atherosclerosis is a strong underlying risk factor for long term TE risk. The mechanisms of the association of CAD with future TE risk in prosthetic valve patients are not clear.

1068-44 Long-term Follow-up of Atrial Contraction Following the Maze Procedure in Patients With Mitral Valvular Disease

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Background: Although the Maze procedure for atrial fibrillation (Af) has been effective to restore sinus rhythm (SR) with mitral valvular disease, the long-term results of this procedure has not been determined.

Methods: We echocardiographically studied 94 consecutive patients with mitral valvular disease (age, ± 9 years) before, early (3.1 ± 3.3 months) and late (2.2 ± 0.9 years) after the Maze procedure. The mean follow-up period was 2.4 ± 0.9 years (range, 0.9–4.5 years). Measurements included left atrial diameter (LAD), left ventricular diastolic diameter (LVD) and the peak velocity (Av, cm/s) and time-velocity integral (Ai, cm) of late diastolic filling wave (A-wave) obtained from transmittal flow recordings. Atrial filling fraction (AFF, %) was calculated as a fraction of Ai to time velocity integral of total diastolic filling.

Results: Left atrial and ventricular diameters significantly decreased after the procedure (from ± 12 to ± 7 mm, p < 0.01 for LAD, from 54 ± 9 to 47 ± 6 mm, p < 0.01 for LVD) and did not show significant changes during the follow-up period.

	SR	Af	A-wave	Av	Ai	AFF
Early	70 (75%)	24 (25%)	41 (44%)	46 ± 17	4 ± 1	17 ± 6
Late	65 (69%)	29 (31%)	32 (34%)	45 ± 14	4 ± 1	17 ± 6
p value	NS	NS	NS	NS	NS	NS

Conclusions: 1) Sinus rhythm and atrial contraction recovered early after the Maze procedure in most patients, and they were maintained for more than 2 years. 2) Once active atrial contraction was resumed, the degree of contraction did not change thereafter. 3) These results demonstrate that the Maze procedure is effective for a long period in patients with mitral valvular disease.

1068-45 Indexed Effective Orifice Area at Rest Predicts Increase in Gradient During Maximal Exercise in Patients With an Aortic Valve Bioprosthesis

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Patients with aortic bioprostheses do well despite relatively small effective orifice areas (EOA) and high transprosthetic gradients (TPG) at rest. However, few data have been collected in these patients during exercise. In this study, 19 patients with a normally functioning Medtronic Intact bioprosthesis and preserved left ventricular function were submitted to a maximal ramp upright bicycle exercise test using workload increments of 10 Watts/min. EOA and mean TPG were measured at rest and during exercise using Doppler echocardiography. EOA was measured by the continuity equation and mean TPG by the Bernoulli equation with inclusion of prevalvular velocities. At peak exercise (mean maximal workload: 114 ± 58 Watts), cardiac index increased by 3.29 ± 0.75 L/min/m^2 (122 ± 29%; p < 0.0001) whereas mean TPG increased by 11 ± 7 mmHg (84 ± 50%; p = 0.0001) and EOA by 0.19 ± 0.18 cm^2 (12 ± 11%; p = 0.007). A strong correlation was found between the increase in mean TPG during maximal exercise and the EOA at rest indexed for body surface area (r = 0.86, SEE = ± 4.0 mmHg; p = 0.0008) and the increase in EOA with exercise also correlated with the indexed EOA at rest (r = 0.63, SEE ±0.15 cm^2, p = 0.05). Due to the increase in EOA, the increase in TPG was less (−12.2 ± 5.9 mm Hg; p = 0.002) than predicted theoretically, had the EOA remained fixed. Thus, in these patients, the increase in mean TPG with maximal exercise could be predicted accurately from the indexed EOA at rest. The actual increase in TPG was however less than expected due to the potential of EOA to increase during exercise. Further studies are necessary to determine how these relations apply to other types of prostheses.

1068-46 Long Term Maintenance of Sinus Rhythm by Combined Valve and Arrhythmia Surgery in Patients With Mitral Valve Disease and Atrial Fibrillation

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Background: Atrial arrhythmia surgery in addition to valve surgery in pts. with atrial fibrillation [AF] is advised because serial cardioversion therapy of AF after valve surgery generally fails. We investigated rhythm outcome in pts. with a history of AF who underwent mitral valve surgery in combination with a left atrial isolation [LAI] procedure.

Methods: 14 pts. with significant mitral valve disease (1 mitral stenosis [MS], 11 mitral regurgitation [MR], 2 MS/MR) of different etiology underwent the combined procedure. NYHA class was 2.9 ± 0.5. Chronic AF was present in 11 pts (in 2 pts. >5 years), 3 pts. had previous AF. Mitral valve repair was possible in 9 pts., 5 pts. received a valve prosthesis. LAI procedure took an additional 30 to 40 minutes and consisted of atrial incisions, cryoablation and resection of both appendages.

Results: All pts. were in sinus rhythm [SR] immediately after surgery. Relapse of AF occurred in 10 pts. and within 7 days (peak incidence on day 3). At hospital discharge 7 pts. were still in AF, but 2 months later all had spontaneously converted to SR. During follow up (median 6 months, range 3–17 months) no new relapses of AF occurred.

Conclusion: Combined mitral valve surgery and left atrial isolation provide long term SR in pts. with a history of AF. As the procedure time of left atrial isolation is shorter than of the Cox-maze operation, left atrial isolation seems preferable for combined surgery.

1069 Pediatric Interventional Cardiology

Monday, March 30, 1998, 3:00 p.m.–5:00 p.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: 3:00 p.m.–4:00 p.m.

1069 154 Closure of Muscular Ventricular Septal Defects With Modified Amplatz Device in a Canine Model

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Background: Repair of multiple ventricular septal defects (MVSD) has always been challenging to the surgeon. The long term morbidity and mortality is significantly increased if the defects are closed via left ventriculotomy or

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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.