

POSTER SESSION

1208 Mechanical Assist Devices for Ventricular Dysfunction

Tuesday, April 01, 2003, 3:00 p.m.-5:00 p.m.

McCormick Place, Hall A

Presentation Hour: 4:00 p.m.-5:00 p.m.

1208-65

Favorable Clinical Outcome in Patients With Cardiogenic Shock Due to Fulminant Myocarditis Supported by Extracorporeal Membrane Oxygenation: Comparison With Those With Acute (Nonfulminant) Myocarditis

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Background: The application of extracorporeal membrane oxygenation (ECMO) with percutaneous cardiopulmonary bypass has been recently extended to temporary circulatory support in patients with fulminant myocarditis. However, the survival and prognosis of patients who are particularly ill remain poorly understood. **Methods:** Patients with myocarditis were divided into the following two groups. Fourteen patients who required ECMO for cardiogenic shock were defined as having fulminant myocarditis (F group), whereas 13 patients who had acute onset of symptoms but did not have compromised hemodynamics were defined as having acute (nonfulminant) myocarditis (non-F group). **Results:** In F group, 10 patients were successfully weaned from ECMO. Therefore, the overall survival rate at the time of discharge was 71%. Between patients who died (D) and those survived (S) in F group, there were significant differences ($P < 0.05$) in left ventricular end-diastolic dimension (D: 36 ± 6 vs S: 50 ± 2 [mean \pm SEM] mm), end-systolic dimension (D: 34 ± 6 vs S: 45 ± 2 mm), wall thickness (D: 15 ± 1 vs S: 11 ± 1 mm), maxCPK-MB levels (D: 353 ± 145 vs S: 120 ± 35 U/L) and serum creatinine levels (D: 2.1 ± 0.5 vs S: 1.0 ± 0.1 mg/dl). Compared with the non-F group, the fractional shortening in the F group was more severely depressed in the acute phase (F: 10 ± 1 vs non-F: $23 \pm 3\%$, $P < 0.05$), but recovered in the chronic phase (F: 30 ± 2 vs non-F: $33 \pm 3\%$, $P = NS$). Rates for adverse clinical events were also similar between the F and non-F groups during the follow-up period of 38 months on average. **Conclusions:** In patients with fulminant myocarditis, a hemodynamic support using ECMO results in excellent survival. Once a patient recovers from inflammatory myocardial damage, the subsequent clinical outcome is favorable, similar to that observed in patients with acute (nonfulminant) myocarditis.

1208-66

In Vitro Evaluation of the Concept of Pericardial Pressure Augmentation in Isolated Pig Hearts

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Introduction: Acute right heart failure is an unsolved problem in cardiology and cardiovascular surgery. Mechanical circulatory support devices primarily focus on left ventricular failure. Assist devices supporting the right ventricle require major surgery for implant, and for its explant. Thus, we thought for a method of minimal invasive right ventricular support by pericardial pressure augmentation (PPA).

Methods: For evaluation of the concept of PPA we built a tulip shaped prototype of the device covering the apical two thirds of the heart. It consists of two elastic foils with a helium gas filled space in between which is inflated and deflated by the driving console of an intra-aortic balloon pump. The outer non-compliant foil stabilizes the sac. The inner sac transfers the pressure augmentation directly to the epicardium therefore to the heart. Due to differences in myocardial thickness this technique of pericardial compression mainly supports the right ventricle. For in-vitro evaluation of this novel technique of PPA we tested the concept of PPA in 8 isolated pig hearts.

Results: Under PPA with 80 l/minute we recorded average right ventricular pressures of 31.3 ± 4.42 mmHg during systole, and 1.4 ± 1.80 mmHg during diastole. Left ventricular pressures were 23.7 ± 5.08 mmHg, and 0.7 ± 1.25 mmHg respectively. An outflow of 200 ml/minute through the pulmonary artery was obtained in the artificial circulation.

Conclusion: This in-vitro evaluation demonstrates the feasibility of pericardial pressure augmentation for right ventricular support. The concept of PPA offers an option of minimal invasive implantation, and non-surgical removing of a pericardial device. However, animal experiments and technical improvements of the device are required for further evaluation of this novel technique in the future.

1208-67

New Impella Intracardiac Minipump Supports the Acutely Failing Left Heart Significantly More Effective Than Intraortic Balloon Pumping

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Background: The Impella intracardiac minipump (IMP) is a new, percutaneous LV unloading device recently introduced clinically. The IMP features a 6 mm diameter integrated cannula-pump assembly with a capacity of 4.5 l/min for use in trans aortic valve position. The efficacy of the IMP has yet to be established. We tested the hypothesis that this device can provide more effective left heart support than IABP in acute heart failure.

Methods: Reversible acute mitral regurgitation (AMR) was induced in calves ($n=8$) by stenting the mitral valve using a vena cava filter. In each animal full IMP assist was com-

pared with standard 1 to 1 IABP assist. The recorded data included LV pressure and volume (conductance catheter), aortic pressure, left atrial pressure, pulmonary artery flow, coronary flow and carotid artery flow (ultrasonic flow probes).

Results: See table. Means \pm SD; * $P < .05$; **Relative changes and significance versus baseline; ***Relative changes and significance versus baseline AMR; ^aAbsolute changes. In the AMR setting the IMP effectively restores cardiac output, coronary perfusion and systemic perfusion. The IMP suppresses pulmonary congestion by unloading the left atrium.

Hemodynamic effect of assist

	Baseline		AMR* (%)	IABP** (%)	IMP** (%)
Regurgitant fraction	0	%	+57*	-2	-16
CO	8.5 \pm 4.0	l/min	-25*	+4	+25*
PLV peak	76 \pm 24	mmHg	-24*	-5*	-16*
PAo	66 \pm 21	mmHg	-23*	+11*	+17*
LAP	5.9 \pm 2.6	mmHg	+3.7* ^a	-0.7* ^a	-2.3* ^a
Carotid flow	514 \pm 275	ml/min	-26*	+8	+47*
Coronary flow	73 \pm 35	ml/min	-15*	+31*	+35
LV stroke work	4.2 \pm 3.3	MPa.ml	+30	-5	-28
LVEDV	202 \pm 97	ml	+15*	-2	-8*

Conclusion: Compared to IABP the new catheter based intracardiac pump significantly improves cardiac and systemic hemodynamics during acute mitral regurgitation. This minipump may fill the gap in the range of cardiac assist devices between standard IABP and current LV assist device alternatives.

1208-68

Left Ventricular Diastolic Filling Pattern by Passive Ventricular Reshaping in Canine Heart Failure

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Background: End-stage heart failure is associated with significant alterations in left ventricular (LV) geometry leading to increases in wall stress and reduced LV contractility. CardioClasp™ is a passive restraint device designed to normalize LV geometry and reduce wall stress. Improvement in wall stress should be associated with improved diastolic filling parameters.

Methods: In dogs ($n=10$; 22-26 kg) rapid ventricular pacing (210 ppm, week one, to 240 ppm week 4) induced decompensated heart failure. Hemodynamic data were obtained before and after CardioClasp™ placement. Fractional area of contraction was measured by direct epicardial echocardiography at baseline and with CardioClasp™. Using transeptal echocardiography, pulse wave Doppler measurements of standard mitral inflow were obtained in a sub-set of animals ($n=5$). Data represented here are expressed as mean \pm SEM. **Results:** In-vivo overall, CardioClasp™, decreased end-diastolic LV anterior-posterior dimension by $21.2 \pm 3.9\%$. LV wall stress was significantly reduced by $28.8 \pm 2.1\%$ with CardioClasp™. In association with these changes in geometry, fractional area change increased from 21.8 ± 3.6 to 29.7 ± 6.0 ($p=0.04$). In the subset group, peak ϵ wave velocity (58.6 ± 8.2 vs. 63.9 ± 7.8 cm/sec; $p=0.20$) and ϵ/α ratio (2.0 ± 0.2 vs. 2.1 ± 0.3 ; $p=0.11$) remained unchanged with CardioClasp™ placement, however, deceleration time was increased from 89.4 ± 12.1 to 107.0 ± 14.3 msec; ($p=0.03$), suggesting changes in LV compliance with the device. **Conclusions:** CardioClasp™ was able to reshape the ventricle and reduce the wall stress. CardioClasp™ is associated with a more favorable geometry, improved systolic performance and LV compliance.

1208-69

First Clinical Experience With the Impella® Micropump in Patients With Cardiogenic Shock

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Objectives To assess safety, feasibility and efficacy of the Impella® pump in patients with cardiogenic shock. **Background** Animal experiments showed left ventricular unloading and improved haemodynamics with the Impella micro-axial blood pump. **Methods** From January 2001 through April 2002, 12 patients in cardiogenic shock (on maximal inotropic support and with IABP in 6 cases) underwent left ventricle unloading with the Impella® micro-axial pump. Four were placed via the femoral artery (PCI patients) and 8 directly through the aorta (postcardiotomy heart failure). Mean age was 60 years (range 43-75), 8 were male. Mean CPK_{max} level was 5442 U/L (195-17938). **Results** A stable pump flow of 3.6 ± 1.1 L/min. was reached. Mean blood pressure before Impella® support was 61.5 ± 12.7 mmHg and increased to 75 ± 28.3 after 6 hours and 75.7 ± 16.8 mmHg ($p=0.038$) after 24 hours. Cardiac output increased from 3.8 ± 1.2 L/min to 5.7 ± 1.5 ($p=0.004$) and 5.9 ± 2.0 L/min ($p=0.01$) at 6 and 24 hours. Mean pulmonary wedge pressure decreased from 20.7 ± 13.2 mmHg to 13.8 ± 7.3 and 18 ± 7.4 mmHg at 6 and 24 hours (NS). Blood lactate levels decreased significantly after 6 hours of support (from 4.1 ± 2.9 to 2.1 ± 1.7 mmol/L, $p=0.008$). Free plasma haemoglobin levels were initially high (107.7 ± 61.7 mg/dl at 6 hours) and decreased to 50 mg/dl afterwards. Eight patients