1208 Mechanical Assist Devices for Ventricular Dysfunction

Tuesday, April 01, 2003, 3:00 p.m.-5:00 p.m.
McCormick Place, Hall A
Presentation 1 hour: 4:00 p.m.-5:00 p.m.

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

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Background: The application of extracorporeal membrane oxygenation (ECMO) with veno-arterial cannulation bypass has been recently extended to temporary 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 the F group, LV volumetric parameters were successively worsened from 5.2±1.1 to 3.8±0.9, whereas 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 and diastolic diameter (D:36.6±6.0 vs. 31.0±4.8 mm, P=0.001), systolic (D:56.6±18.2 vs. 42.5±11.3 mm, P<0.01), wall thickness (D:15.1±5.6 vs. 11.5±1.8 mm, P=0.001), end-diastolic volumes (D:33.6±14.5 vs. S:23.9±14.9 ml, P=0.001), and ejection fraction (D:2.1±0.5 vs. S:1.0±0.4, P<0.05). Comparatively, the fractional shortening in the F group was more severely depressed in the acute phase (F:10±4 vs non-F:23±3, P<0.05), but recovered in the chronic phase (F:30±7 vs non-F:33±3, P=NS). Rates for adverse clinical events were similar between the F and non-F groups during the follow-up period of 36 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.

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 and, for its implant. Thus, we thought for a method of minimal invasive right ventricular support by pericardial pressure augmentation (PPA). Methods: For exploration of the concept of PPA, we built a tulip shaped prototype of the device covering the apex two thirds of the heart. It consists of two elastic foils with a holmium filter filled in space which is inflated and deformed by the driving console of an intra-aortic balloon pump. The outer non-compliant foil stabilizes the sac. The inner balloon re-covers 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-vivo evaluation of this novel technique of PPA we tested the concept of PPA in 8 isolated pig hearts. Results: Under PPA with 80 ml / minute we recorded average right ventricular pressures of 31.3±7.4/42.2 mmHg during systole, and 1.4±1.8 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-vivo evaluation demonstrates the feasibility of pericardial pressure augmentation for right ventricular support. The concept of PPA offers an option of minimal invasive implantation, and no-surgical removing of a pericardial device. However, animal experiments and clinical translations of the device are required for further evaluation of this novel technique in the future.

New Impella Intracardiac Micropump Supports the Acutely Failing Left Heart Significantly More Effective Than Intraceliac Balloon Pumping

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Background: The intracardiac micropump (IMP) is a new, percutaneous LV unloading device recently introduced clinically. The IMP features a 6 mm diameter integral cannula-pump-assembly with a capacity of 4.5 l/min for use in trans aortic valve position. The efficacy of this device 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 compared 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. Conclusions: Compared to IABP the new catheter based intracardiac pump significantly improves cardiac and systemic hemodynamics during acute mitral regurgitation. This micropump can thus fill the gap in the range of cardiac assist devices between standard IABP and current LV assist device alternatives.

1208-07 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±2 kg) rapid ventricular pacing (100 ppm, weak ones, to 4400 ppm week 4) induced decompensated heart failure. Hemodynamic data were obtained before and after CardioClasp™ placement. Fractional area of contraction was measured by direct ecocardial echocardiography at baseline and with CardioClasp™. Using transaortic 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±SEM. Results: In vivo overall, CardioClasp™ decreased end-diastolic LV anterior-posterior dimension by 21±2.3 mm. LV wall stress was significantly reduced by 28.8±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 e wave velocity (0.6±0.2 vs. 0.8±0.2 cm/s, p<0.05) and peak E wave velocity (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 fluid restriction. 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.

1208-09 First Clinical Experience With the Impella Micropump in Patients With Cardiogenic Shock

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Objectives: To assess safety, tolerance and efficacy of the Impella® micropump 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 ventricular unloading with the Impella micropump via the femoral approach. Four were resuscitated patients (ICU patients) and 8 directly through the aorta (postcardiotomy heart failure). Mean age was 60 years (range 43–75). 8 were male. Mean CVP, P(A)O2 level was 5644 U/L (195-71938). Results: A stable pump flow of 3.6±1 L/min was reached. Mean blood pressure before Impella® support was 61±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±12.2 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±2.0 to 2.1±1.7 mmol/L, p=0.006). Free plasma hagemoglobin levels were initially high (107.7 ± 61.7mg/dl at 6 hours) and decreased to 50 mg/dt after 8 days. Patients...
Exercise Testing in Heart Failure Patients

Methods: Two hundred and thirty five subjects with CHF underwent exercise testing between 3/18/93 to 10/11/99. The ability of peak VO, and the VENCOZ slope to predict cardiac-related mortality and hospitalization were examined.

Results: Mean follow-up time was 33.27 months, and the annual mortality rate was 5.0%. Univariate Cox regression analysis found peak VO, and the VENCOZ slope to be both significant predictors of cardiac-related mortality and hospitalization (p=0.001). Multivariable analysis revealed peak VO, added additional value to the VENCOZ slope in predicting cardiac-related hospitalization, but not mortality. Receiver operating characteristic curve analysis demonstrated the VO, peak was a better predictor of events than peak VO, in CHF.

Conclusion: The VENCOZ slope is an important predictor of outcomes in CHF. Risk stratification is optimized by combining peak VO, and the VENCOZ slope.

Correlation of Brain Natriuretic Peptide Release, Cardiopulmonary Exercise Testing, and Six-Minute Walking Test in Patients With Heart Failure and Cardiac Resynchronization Therapy

Background: Brain natriuretic peptide (BNP) levels are elevated in reduced left ventricular function. Cardiac resynchronization therapy (CRT) improves cardiac hemodynamics and functional status in heart failure patients (pts). We investigated the effects of CRT on BNP levels, cardiopulmonary exercise testing (CPX) and 6 min walking test (WT) in these pts.

Methods: 20 pts (16m, 65±19y) with a mean EF 24±5%, LBBB (QRS 167±25 ms) and CRT were investigated. CPX and 6 min walking test (WT) were performed before and after 6 months of CRT with BVP pacing. Maximum (VOPmax) and oxygen consumption at the anaerobic threshold (V02-AT) were measured. WT was performed on 45 m long plain floor. BNP levels were determined with the Triage BNP test (Biosite, Diagnostics, USA). Data were collected before pacemaker implantation (baseline) and after 15±8 weeks of CRT (V02 mode). As BNP levels are influenced by renal function, serum creatinine and blood urea nitrogen (BUN) levels were measured simultaneously. Results: The effects of CRT on BNP levels, CPX, WT and renal function are shown in the table. Correlation coefficient r was calculated as change of variables over time (LVEF, peak VO,). Conclusion: Chronic CRT leads to a significant decrease in BNP release and improvement of exercise capacity. As there is an inverse correlation between change in BNP levels and CPX parameters, decreasing BNP levels seem to be an indicator for improved functional status and therapeutic efficacy of CRT in patients with advanced heart failure and LVSB.

Effects of CRT (means±SD; *p<0.05 vs baseline; **p<0.001)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>6 months</th>
<th>WT</th>
<th>Creatinine</th>
<th>BUN</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNP (pg/ml)</td>
<td>525±311</td>
<td>12.5±2.3</td>
<td>12.9±3.2</td>
<td>357±45</td>
<td>1.5±0.5</td>
</tr>
<tr>
<td>V02max</td>
<td>105</td>
<td>104</td>
<td>109</td>
<td>9.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Exercise capacity</td>
<td>3.8</td>
<td>4.3</td>
<td>3.7</td>
<td>2.9</td>
<td>0.4</td>
</tr>
<tr>
<td>Heart rate, bpm</td>
<td>77±14</td>
<td>75±10</td>
<td>117±21</td>
<td>107±17</td>
<td></td>
</tr>
<tr>
<td>Stroke volume index, ml/beat</td>
<td>13±11</td>
<td>35±12</td>
<td>38±11</td>
<td>40±14</td>
<td></td>
</tr>
<tr>
<td>Heart rate, bpm</td>
<td>14±14</td>
<td>9±10</td>
<td>9±10</td>
<td>8±10</td>
<td></td>
</tr>
</tbody>
</table>

The change in the peak ex cardiac index (CI) correlated with that in peak V02 (r=0.49; p=0.04) and was the only variable predictive of its increase at multiple regression analysis.

Conclusions: DVT is associated with an improvement in resting LVEF, resting and peak ex stroke volume index and CI and of maximal ex capacity. The improvement in the LV systolic function, with an heightened peak ex CI, contributes to the increase of the ex capacity.

Physical Training-Induced Reduction of Peripheral Monocyte-Related Inflammatory Markers Is Associated With Improvement in Endothelial Function of Chronic Heart Failure Patients

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Aim: To investigate whether the effects of physical training (PT) on serum monocyte-related inflammatory markers such as tumor necrosis factor α (TNF-α), granulocyte-macrophage colony-stimulating factor (GM-CSF), macrophage chemoattractant protein-1 (MCP-1), soluble intercellular adhesion molecule-1 (sICAM-1) and soluble vascular cell adhesion molecule-1 (sVCAM-1), are associated with changes in cerebral blood flow and endothelial function of patients with chronic heart failure (CHF).

Methods: Serum levels of these markers were assessed by ELISA in 15 CHF patients (ischemic: 7, dilated: 8, NYHA III-IV, EF 23±3%) before and after a 12-week program of PT in a randomized crossover design. Peak oxygen uptake (VO2max) was used to estimate functional status of CHF patients and venous occlusion plethysmography to assess endothelial function through reactive hyperemia-induced vasodilatation.

Results: PT produced a significant reduction in TNF-α (7.2±1.1 vs 4.9±0.9 pg/ml, p<0.01), GM-CSF (28.5±1.9 vs 20.6±1.5 pg/ml, p<0.02), MCP-1 (191±5 vs 175±2 pg/ml, p<0.001), sICAM-1 (385±29 vs 332±26 ng/ml, p<0.005) and sVCAM-1 (1309±68 vs 119±89 ng/ml, p<0.001), as well as an increase in VO2max (14.6±1 vs 16.7±1 ml/kg/min, p<0.01). A significantly higher (64%, p<0.05) increase in forearm blood flow in response to reactive hyperemia was observed after PT (from 2.7±0.3 to 4.3±0.6 ml/100 ml tissue/min) compared with 16.7% after detraining (from 2.2±0.5 to 2.5±0.4 ml/100 ml tissue/min). Significant correlations were found between PT-induced changes in VO2max and molecules sICAM-1 (r=−0.65, p<0.02) and sVCAM-1 (r=0.6, p<0.05), as well as PT-induced changes in peripheral blood flow and molecules TNF-α (r=0.56, p<0.05), sICAM-1 (r=0.34, p<0.05) and sVCAM-1 (r=0.66, p<0.05). A good correlation was also found between PT-induced increase in peripheral blood flow and VO2max (r=0.7, p<0.05).

Conclusions: PT reduces peripheral monocyte-related inflammatory markers in CHF. These immunomodulatory effects of PT may be related with the improvement in exercise capacity of CHF patients, possibly by increasing peripheral blood flow and improving endothelial function.

Physical Resynchronization With Bi vectricular Pacing on the Symptoms, Left Ventricular Function, and Hemodynamic Data of the Patients With Heart Failure and Increased QRS Duration

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Background: Controlled clinical trials have shown the beneficial effects of biventricular pacing (BVP) in patients with heart failure (HF) and left bundle branch block. The impact of CRT on the hemodynamic response to exercise (ex) has not been studied yet.

Methods: Eighteen consecutive patients with chronic HF, QRS duration >150 msec and left ventricular ejection fraction (LVEF) < 35% were studied by MUGA and cardiopulmonary exercise test with simultaneous Swan-Ganz cath, before and after 6 months of CRT with BVP pacing. Results: After 6 months of BVP LVEF increased from 20±8% to 25±12% (p=0.03), peak VO2 from 136±3.3 to 149.3±4.1 ml/kg/min (p=0.017) and from 50±2±16 to 58±11% of maximal predicted values (p=0.16), VO2 at the anerobic threshold from 9.9±3.2 to 11.5±2.7 ml/kg/min (p=0.019) and the half-time of post-ex VO2 recovery shortened from 150±29 to 119±22 sec (p=0.030). The VE/VO2 slope declined from 44±13 to 39±12 (p=0.05).

Hemo data in table (*p<0.05; t<0.01)