

**Chronic heart failure: management of chronic heart failure in  
adults in primary and secondary care**  
A clinical guideline for the NHS in England and Wales

**APPENDIX J: EVIDENCE TABLES**

**Section 7.4: Invasive Procedures - Other Procedures**

**Others**

**Experimental studies**

Paper	Agostoni, P. G., Marenzi, G. C., Pepi, M., Doria, E., Salvioni, A., Perego, G., Lauri, G., Giraldi, F., Grazi, S., & Guazzi, M. D. 1993, "Isolated ultrafiltration in moderate congestive heart failure", <i>Journal of the American College of Cardiology</i> , vol. 21, no. 2, pp. 424-431.
Description	Randomised controlled trial
N=	n=36, Ultrafiltration =18, no ultrafiltration =18 Age = 57.6, Male =83.3%, LV ejection fraction =24%, furosemide =100%, digoxin =86%, Ischaemic heart disease =31%, primary dilated cardiomyopathy =56%
Intervention	Intervention= Ultrafiltration as a one off treatment during a temporary admission with a diafilter in a veno-venous bypass circuit regulated to generate 600ml/h of filtrate Vs no ultrafiltration in patients with NYHA class II and III
Outcomes	Many outcomes assessed mainly cardiac and pulmonary function as well as exercise performance all to 6 months
Results	<ul style="list-style-type: none"> <li>• In the ultrafiltration group the mean pulmonary wedge pressure and cardiac index were reduced from 18 to 10 mmHg (<math>p&lt;0.001</math>), and 2.8 to 2.3 litres/min per <math>m^2</math> (<math>p&lt;0.01</math>) respectively.</li> <li>• Mean blood pressure was unchanged.</li> <li>• Decreases were seen in extravascular lung water (by X-ray) from the day of filtration to 180 days (9.0 Vs 15.2 at baseline (<math>p&lt;0.01</math>)) and reduction in LV diastolic diameter was significant up to day 30.</li> <li>• No significant changes in LV ejection fraction</li> </ul>
Comments	<p>In the ultrafiltration group the mean pulmonary wedge pressure and cardiac index were reduced from 18 to 10 mmHg (<math>p&lt;0.001</math>), and 2.8 to 2.3 litres/min per <math>m^2</math> (<math>p&lt;0.01</math>) respectively.          Mean blood pressure was unchanged.          Decreases were seen in extravascular lung water (by X-ray) from the day of filtration to 180 days (9.0 Vs 15.2 at baseline (<math>p&lt;0.01</math>)) and reduction in LV diastolic diameter was significant up to day 30.          No significant changes in LV ejection fraction</p>

Heart Failure Guideline: Evidence tables  
Section 7.4: Invasive Procedures - Other Procedures

<b>Paper</b>	Agostoni, P., Marenzi, G., Lauri, G., Perego, G., Schianni, M., Sganzerla, P., & Guazzi, M. D. 1994, "Sustained improvement in functional capacity after removal of body fluid with isolated ultrafiltration in chronic cardiac insufficiency: failure of furosemide to provide the same result", <i>American Journal of Medicine</i> , vol. 96, no. 3, pp. 191-199.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	n=16, ultrafiltration =8, furosemide =8. Age =60yrs, Male =87.5%, All NYHA class II and III, Ischaemic myocardial disease =31%, non-ischaemic dilated cardiomyopathy =69%  Italy
<b>Intervention</b>	Ultrafiltration as a one off treatment during a temporary admission with a diafilter in a veno-veno bypass circuit regulated to generate 600ml/h of filtrate (group 1) Vs furosemide supplementation as a bolus of 160mg and continuous infusion at 1mg/min until right arterial pressure lowered by 50% (ave 248mg) (group 2) in patients with NYHA class II and III
<b>Outcomes</b>	Various neuro-hormonal, cardiac function, pulmonary function, chest x-ray, and exercise function at 1 to 4 days, 1 month and 3 months
<b>Results</b>	<ul style="list-style-type: none"> <li>• At 24 hours total fluid output was 2,410 ml in group 1 Vs 3,360 ml group 2</li> <li>• At 4 days functional capacity was improved in group 1 with a Vo2 max difference at (p&lt;0.01), equally significant changes were seen in exercise time, and time to anaerobic threshold.</li> <li>• At 3 months Body weight in group 1 had been lowered by 1.5Kg Vs increase of 1Kg in group 2 (p&lt;0.01)</li> </ul>
<b>Comments</b>	Peak Vo2 was determined by the highest value achieved during exercise Similar initial fluid loss between study arms ultrafiltrate =1710ml, and furosemide =1460 ml All parameters reflecting lung function and exercise capacity were similarly improved at months 1 and 3 Patients who had supplemental diuretic clearing of the lungs, if it had taken place, disappeared within 4 days

Heart Failure Guideline: Evidence tables  
Section 7.4: Invasive Procedures - Other Procedures

<b>Paper</b>	Christenson, J. T., Simonet, F., Badel, P., & Schmuziger, M. 1997, "The effect of preoperative intra-aortic balloon pump support in patients with coronary artery disease, poor left-ventricular function (LVEF &#60; 40%), and hypertensive LV hypertrophy", <i>Thoracic &amp; Cardiovascular Surgeon</i> , vol. 45, no. 2, pp. 60-64.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	N=33, IABP =19, no IABP =14 Age =65yrs, Male =90%, majority NYHA class IV, LV ejection fraction =32%, unstable angina =68% Switzerland
<b>Intervention</b>	The use of a IABP (40 mm balloon connected to a pump inserted percutaneously) for 2 hours prior to CABG operation (group 1), Vs no IABP (group 2) in patients with CAD, hypertension, and LV ejection fraction <40%
<b>Outcomes</b>	Cardiac index data, mortality, need for inotropic support, and recovery times at 5 min, 30 min and to discharge and 3 month follow up of mortality, LVEF and NYHA class
<b>Results</b>	<ul style="list-style-type: none"> <li>• Bypass operation time was significantly shorter in group 1 (88.1 min) than group 2 (105 min) (p&lt;0.05)</li> <li>• Cardiac index (l/min/m<sup>2</sup>) greater in group 1 prior to cardiopulmonary bypass 2.84 Vs 1.73 (p&lt;0.001), and at 5 min, and 30 min after CPB</li> <li>• Low cardiac output recorded in 11% of group 1 Vs 64% of group 2 (p&lt;0.01)</li> <li>• Postoperatively group 1 patients required significantly less pharmacological support (Dopamin dose, Dobutamine, and Adrenalin)</li> <li>• Intensive care stay was shorter for group 1 (2.4 days) Vs group 2 (3.4 days) (p&lt;0.01), although overall stay prior to discharge showed no difference.</li> <li>• 3 month follow up revealed no differences, as there was no mortality, LVEF had increased in patients to 49%, and most patients were in NYHA class 1.</li> </ul>
<b>Comments</b>	Small sample size Limited HF subgroup as population Outcomes for procedural efficiency rather than long term effects No IABP related mortality or complications reported

Heart Failure Guideline: Evidence tables  
 Section 7.4: Invasive Procedures - Other Procedures

<b>Paper</b>	O'Rourke, M. F., Norris, R. M., Campbell, T. J., Chang, V. P., & Sammel, N. L. 1981, "Randomized controlled trial of intraaortic balloon counterpulsation in early myocardial infarction with acute heart failure", <i>American Journal of Cardiology</i> , vol. 47, no. 4, pp. 815-820.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	N=30, Balloon counterpulsation =14, Control =16 Age =57 yrs, Male =80%, arterial blood pressure =112/73 mmHg New Zealand and Australia
<b>Intervention</b>	Intraaortic balloon pump or not implanted within 12 hours of symptoms of MI with HF evidence
<b>Outcomes</b>	Blood Creatine Kinase every 72 hours to discharge, and complications assessed. 15 month follow up of mortality and morbidity
<b>Results</b>	<ul style="list-style-type: none"> <li>• Great variation in release of Creatine Kinase, but no SD between the groups.</li> <li>• There was no significant difference for in hospital or long term mortality 8 deaths Vs 10 deaths control by follow up.</li> <li>• There was no difference in morbidity across the two study groups, sup group analysis into NYHA class was not feasible due to small numbers</li> </ul>
<b>Comments</b>	<p>Study terminated as no improvement was being found          Hospital survival was 92% when counterpulsation started while ischaemic pain persisted and 43% when commenced after pain had disappeared          Ischaemic myocardial damage may become irreversible well before the 12 hour intervention window used</p>

Heart Failure Guideline: Evidence tables  
 Section 7.4: Invasive Procedures - Other Procedures

<b>Paper</b>	Cohen, M., Dawson, M. S., Kopistansky, C., & McBride, R. 2000, "Sex and other predictors of intra-aortic balloon counterpulsation-related complications: prospective study of 1119 consecutive patients", <i>American Heart Journal</i> , vol. 139, no. 2:Pt 1, pp. 282-287.
<b>Description</b>	Case control study
<b>N=</b>	N=1110, Cases =126, Controls =993 Age =65 yrs, Male = 65%, Cardiac index (l/min/m <sup>2</sup> ) =2.8, history of Peripheral vascular disease =8%, diabetes =27%, hypertension =52% USA
<b>Intervention</b>	Prospective study to examine the complications associated with intraaortic balloon counterpulsation (IABC) and the role of sex and other risk factors
<b>Outcomes</b>	Pre specified major complications = cases
<b>Results</b>	<ul style="list-style-type: none"> <li>• The only independent predictors of a major complication were:</li> <li>• History of peripheral vascular disease RR 4.1 (95% CI 2.47-6.97) (p&lt;0.001)</li> <li>• Female sex RR 2.3 (1.45-3.72) (p0.0005)</li> <li>• Body surface area RR 0.26/m<sup>2</sup> (0.09-0.79) (p0.02)</li> <li>• Thus in a high risk cohort with these parameters the major complication rate was 15% compared with 3% in non-high risk patients (p&lt;0.0001)</li> </ul>
<b>Comments</b>	<p>Major complications occurred in 11% of all patients</p> <p>Female sex remained an independent predictor of risk even after correcting for height and body surface area</p> <p>Trial not randomised</p> <p>No evidence yet that catheter size below which there is a dramatic reduction in complications, or at least that has not yet been reached.</p>

Heart Failure Guideline: Evidence tables  
Section 7.4: Invasive Procedures - Other Procedures

Paper	Kontoyannis, D. A., Nanas, J. N., Kontoyannis, S. A., Stamatelopoulos, S. F., & Mouloupoulos, S. D. 1999, "Mechanical ventilation in conjunction with the intra-aortic balloon pump improves the outcome of patients in profound cardiogenic shock. [see comments.]", <i>Intensive Care Medicine</i> , vol. 25, no. 8, pp. 835-838.
Description	Cohort study
N=	N=28, Normal IABP =18, Additional MV =10 Patients taken from the same consecutive admissions with cardiogenic shock due to be given cardiac support by IABP. Age =61yrs, Male =82%, Cardiac index (l/min/m <sup>2</sup> )=1.94, pulmonary capillary wedge pressure=31 mmHg Greece
Intervention	To compare the outcome of patients presenting with profound cardiogenic shock after MI treated conventionally with inotropic agents and Intraaortic balloon pump (IABP) Vs the same treatment with the addition of mechanical ventilation with positive end-expiratory pressure (PEEP)
Outcomes	Outcomes predefined as reversal of shock, weaning from the IABP, and hospital discharge without further therapeutic intervention
Results	<ul style="list-style-type: none"> <li>• Cardiogenic shock was reversed in 72% of IABP and 100% with MV (NS)</li> <li>• Weaning from IABP was more successful with MV 90% Vs 44% IABP alone (p=0.04)</li> <li>• Ultimately discharge without further therapy was possible in 80% of MV group Vs 28% of IABP group (p=0.01)</li> </ul>
Comments	Other outcomes included reduced pulmonary capillary wedge pressure with the MV addition to therapy 16.1 Vs 20.6 mmHg (p=0.025) Treatment not randomised

**Non-experimental studies**

Paper	Acker, M. A. 1999, "Dynamic cardiomyoplasty: at the crossroads.", <i>Annals of Thoracic Surgery</i> , vol. 68, no. 2, pp. 750-755.
Description	Review
N=	
Intervention	
Outcomes	
Results	<ul style="list-style-type: none"> <li>• More than 600 patients implanted with cardiomyostimulators have shown a clinical improvement in 80-85% of hospital survivors, with NYHA class improving 1.2 classes with improvement from 6 months and sustained benefit.</li> <li>• Significant improvements in quality of life scores and depression benefits have been noted, as has a reduction in the number of hospital admissions for HF.</li> <li>• A phase II trial in NYHA class III patients found similar benefits with NYHA improvement significantly better than in reference group</li> <li>• Modest but significant improvements have been recorded in haemodynamic parameters, including LV ejection fraction and LV stroke work, however, no changes seen in cardiac index, pulmonary capillary wedge pressure, right ventricular ejection fraction or maximal oxygen consumption</li> <li>• Survival has improved over time from 31% hospital mortality in phase 1 trial to less than 3%. Recently survival has been found to be 78% at 1 yr and 70% at 2 years for class III patients</li> <li>• Predictors of mortality are peak oxygen consumption and LV ejection fraction for procedure related death. Long term survival affected by preoperative functional class, and pulmonary vascular resistance</li> <li>• Mechanisms for action may either be active systolic assistance or passive girdling effects, with laboratory and subgroup studies lending credence to both mechanisms. Additional benefits may include increased collateral blood flow to ischaemic areas in ischaemic cardiomyopathy, and even potential muscle nerve and neuro-hormonal interaction</li> <li>• The Phase III randomised trial C-SMART with a control arm of best medical management, and outcomes hospitalisation, objective exercise measures, QOL scores, NYHA class, and survival may determine the ultimate role of treatment therapy.</li> </ul>
Comments	<p>An update on all current clinical results and practice of dynamic cardiomyoplasty (DCMP)                  Remains a promising but still unproven treatment in end stage heart failure                  The immobilisation of the latissimus dorsi muscle which is wrapped around the circumference of the heart, and after a training period the muscles is stimulated to contract in synchrony with cardiac systole</p>
Reference	196

Paper	Athanasuleas, C. L., Stanley, A. W., Buckberg, G. D., Dor, V., Di Donato, M., & Siler, W. 2001, "Surgical anterior ventricular endocardial restoration (SAVER) for dilated ischemic cardiomyopathy", <i>Semin.Thorac.Cardiovasc.Surg.</i> , vol. 13, no. 4, pp. 448-458.
Description	Case series
N=	
Intervention	
Outcomes	
Results	<ul style="list-style-type: none"> <li>• Preoperative LVEF was 29% +/- 10.4 and increased post operatively to 39% +/- 12.4 (<math>p &lt; 0.0001</math>) but this measurement was not obtained in cases and not at the same post operative interval</li> <li>• No effect was seen with either type of myocardial protection during procedure</li> <li>• Few patients required mechanical support IABP (7.7%) LVAD (0.05%) and ECMO (1.3%)</li> <li>• Hospital mortality in 439 patients was 6.6%, but proportions were higher in those patients undergoing concomitant CABG or mitral valve replacement</li> <li>• No hospitalisation for congestive HF was required in 85% of patients to 18 months, and readmission was not related to postoperative LV ejection fraction until it was below 30%.</li> <li>• <u>No randomisation to medical therapy or CABG alone which will be required in further studies</u></li> </ul>
Comments	<p>To evaluate the safety and efficacy of the SAVER procedure, good description of operation given  n=439 patients in 11 centres, operations not necessarily standardised between centres  USA and European  Patients with post infarction dilated cardiomyopathy  Time to operation was mean 564 days  Age =63 yrs +/- 10.7  Akinesia seen in 64% of patients and dyskinesia in 33%  Concomitant procedures included CABG, Mitral valve replacement or repair.  Patients were subgrouped by myocardial protection during procedure (cardioplegia Vs open beating) and by mechanical support modalities (intraaortic balloon counterpulsation (IABP), Left ventricular assist device (LVAD), or extra corporeal membrane oxygenation.  Outcomes included efficacy, LVEF, NYHA class change and re-hospitalisation  Multivariate regression was undertaken with confounding factors relating to outcome</p>
Reference	195

Paper	Lavee, J. & Paz, Y. 2002, "Mechanical alternatives to the human heart: Paracorporeal assist systems", <i>Israel Medical Association Journal</i> , vol. 4, no. 2, pp. 125-130.
Description	Review
N=	
Intervention	
Outcomes	
Results	<ul style="list-style-type: none"> <li>• Centrifugal pumps are relatively simple to operate with no special training necessary, and are comparatively cheap as opposed to other devices. They work by blood being let into the pump from an inlet tube where it is caught up by vanes and paddled outward. Implantation can be simple however attention is needed to avoid complications of bleeding, and left and right support can be provided. The device requires anti-coagulation medication to avoid thromboembolisms. They have been designed for short term use but cases of 18 day assistance have been reported. Primary indications for use are post-cardiotomy ventricular failure.</li> <li>• The ABIOMED BVS 5000 is a para-corporeal pulsatile ventricular assist device, in the form of a dual chamber pump with the upper chamber passive as a reservoir filled by gravity, and the lower chamber the pump. Circulation is derived from systole with compressed air entering the lower chamber causing the bladder between the chambers to collapse and returning blood volume to the patient. The most common indication for use has been low cardiac output in post-cardiotomy, although it has also supported recovery from acute MI with cardiogenic shock, and acute myocarditis. The device severely limits mobility and support is seldom given for more than 8 days</li> <li>• An alternative system, which allows for left and or right heart support is the Thoratec assist device. This works by canulae being connected to the heart and the great vessels with a pneumatic drive-line to a console that can control and monitor the pump operation. A fixed stroke volume with a variable pump rate creates a variable output. The limitations to the device are the size of the console, which practicably requires the patient to remain admitted, and the inherent costs. It is currently used as a bridge to transplant, with the longest support being reported as 515 days. Complications include bleeding (42%) renal failure (36%) and infection (36%) from a multi centre review.</li> <li>• The Berlin Heart assist device is a similar but scaled version of the VAD with the blood pump being operated by a variety of electro-pneumatic drive units that can be worn externally. Implantation techniques are identical to those of the VAD. The device tends to be used as a bridge to transplant (59%) in addition for postcardiotomy heart failure (15%). Mean support has been 63days with extremes to 525 days</li> </ul>
Comments	To assess the functionality of available para-corporeal device Mechanical assistance used as (1) a bridge to myocardial or haemodynamic recovery (2) a bridge to transplant (3) an alternative to transplant 4 systems approved for use, each reviewed for efficacy, complications, use, and durability

Heart Failure Guideline: Evidence tables  
Section 7.4: Invasive Procedures - Other Procedures

Paper	Stevenson, L. W. 1996, "Selection and management of candidates for heart transplantation.", <i>Current Opinion in Cardiology</i> , vol. 11, no. 2, pp. 166-173.
Description	Review
N=	
Intervention	
Outcomes	

<p><b>Results</b></p>	<ul style="list-style-type: none"> <li>• Common reversible factors should be corrected where possible including Mitral valve replacement / repair, or restoration of sinus rhythm in HF patients with atrial fibrillation.</li> <li>• Optimisation of medical therapy should be achieved wherever possible</li> <li>• Survival rates after cardiac transplantation suggest an approximate 80% survival at 2 years, 60% at 6 years, compared to a 50% survival at 1-2 years without transplantation</li> <li>• Most transplanted patients report improved functional capacity and life satisfaction despite requiring an average of 10+ medication doses per day.</li> <li>• It is a greater challenge to identify ambulatory HF patients in whom transplantation will improve 2 year survival and QOL compared to those requiring preoperative inotropic support.</li> <li>• With improved HF therapies actuarial 1 year mortality is only 32% even inpatients with NYHA class IV HF and LVEF &lt;25%</li> <li>• In a study of 265 ambulatory patients with NYHA class IV HF and LVEF&lt;25%, transplantation can only be generally recommended when a significant improvement in QOL is expected to accompany prolonged survival, as 1 year mortality after transplantation is on average 15%</li> <li>• Recipients with a preoperative VO<sub>2</sub> less than 10mL/kg/min are likely to experience a significant functional improvement, whereas those with greater than 18mL/kg/min may not notice a major increase in exercise tolerance after transplantation</li> <li>• A six month reassessment of 68 patients who had been placed on a transplantation list due to a VO<sub>2</sub> less than 14mL/kg/min resulted in the removal of 31 patients from the list who had seen a 2mL/kg/min or more improvement due to optimisation of medical therapy</li> </ul> <p>Accepted indications for transplantation                  Peak VO<sub>2</sub> less than 10mL/kg/min with achievement of anaerobic metabolism                  Severe ischaemia consistently limiting routine activity not amenable to bypass surgery or angioplasty                  Recurrent symptomatic ventricular arrhythmias refractory to all accepted therapeutic modalities</p> <p>Probable indications for transplantation                  Peak VO<sub>2</sub> less than 14mL/kg/min and major limitation of the patient's daily activities                  Recurrent unstable ischaemia not amenable to bypass or angioplasty                  Instability of fluid balance and renal function not due to patients non compliance with regimen of weight monitoring. Flexible use of diuretic drugs, and salt restriction</p> <p>Inadequate indications for transplantation                  Ejection fraction =20%                  History of NYHA class III or IV symptoms of HF                  Previous ventricular arrhythmias                  Peak VO<sub>2</sub> greater than 15mL/kg/min without other indications</p>
<p><b>Comments</b></p>	<p>n=54 references with summaries and indication of special interest                  USA reviewer                  To define the characteristics of patients most suitable for heart transplant and highlight contraindications.                  Slightly date review prior to the routine use of B blockers in severe HF and wider evidence on pacing / defibrillation                  Good basis of comparison of expected outcomes with or without transplantation in terms of length of survival and quality of life</p>
<p><b>Reference</b></p>	<p>182</p>

Paper	Twidale, N., Manda, V., Nave, K., & Seal, A. 1998, "Predictors of outcome after radiofrequency catheter ablation of the atrioventricular node for atrial fibrillation and congestive heart failure", <i>American Heart Journal</i> , vol. 136, no. 4 (1), pp. 647-657.
Description	Case series
N=	
Intervention	
Outcomes	
Results	<ul style="list-style-type: none"> <li>• n=44 consecutive patient cohort 66% male, with mean age of 71 years</li> <li>• USA</li> <li>• Complete AV block achieved in all 44 patients</li> <li>• 1 month post ablation exercise duration had increased from 2.6mins to 4.0 mins (<math>p&lt;0.01</math>) and in 33 patients at 12 months increased to 4.4mins (<math>p&lt;0.05</math>)</li> <li>• Similarly LV ejection fraction increased from 34.6% to 43.8% at 1 month, and 43.0% at 12 months (<math>p&lt;0.01</math> and <math>p&lt;0.05</math> respectively)</li> <li>• Again QOL scores improved from 62.3 points at baseline to 35.6 points at 1 month and 35.0 points at 1 year (<math>p&lt;0.01</math> and <math>p&lt;0.05</math> respectively) (lower scores indicate good QOL)</li> <li>• During a mean follow up of 17.0 years the predictors of death significant in multivariate analysis were (1) failure to improve cardiac performance at 1 month <math>p=0.003</math> (2) significant mitral regurgitation at baseline <math>p=0.038</math> (3) baseline ejection fraction <math>&lt;30\%</math> <math>p=0.045</math></li> <li>• These parameters may warrant prophylactic ICD therapy to prevent sudden death or mitral valve surgery to avert LV dysfunction when found in post ablation subjects</li> <li>• Adverse events included deterioration within 24 hours with worsening heart failure (95) and sustained ventricular tachycardia (7%)</li> <li>• Potential errors in echocardiographic assessment given baseline was carried out in AV</li> <li>• A control arm was not included as patients were severely symptomatic despite conventional drug therapy</li> </ul>

<b>Comments</b>	<p>Study to determine factors that can help predict clinical outcome in patients with CHF undergoing atrioventricular (AV) node ablation for atrial fibrillation</p> <p>Inclusion criteria was LV ejection fraction &lt;45%</p> <p>Investigations at baseline at 1 and 12 months included cardiac performance in terms of exercise testing (Bruce or Norman protocol), Echocardiography (averaged over 3 to 5 cycles by 2 experienced technicians), and quality of life questionnaire (Minnesota)</p> <p>A priori measure of improved function was increase in ejection fraction greater than 1 SD of baseline</p> <p>Catheter ablation with a 4 mm tip electrode, with radio-frequency energy of 550 – 700 KHz, and block had to persist for at least 30 minutes</p> <p>A ventricular rate-adaptive pacemaker implanted with a range of 70 – 120 BMP</p> <p>Pre-specified factors for regression analysis with outcome included (1) age, sex, duration of AF, presence of CAD, treatment with calcium antagonist or B blocking drugs prior to ablation, baseline ejection fraction, exercise tolerance time, resting and peak heart rate, QOL score, significant (&gt;2+) mitral regurgitation (2) number of radio frequency applications for ablation, L or R ablation approach, presence or absence of escape rhythm post ablation (3) pacemaker sensor, ventricular lead site. Also finding of improved performance 1 month after ablation.</p> <p>Univariate variables with significance of &lt;0.1 were added into a stepwise multivariate analysis</p>
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