

**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 - Revascularisation**

## **Invasive therapies**

### **Revascularisation**

#### **Experimental studies**

Paper	Baker, D. W., Jones, R., Hodges, J., Massie, B. M., Konstam, M. A., & Rose, E. A. 1994, "Management of heart failure. III. The role of revascularization in the treatment of patients with moderate or severe left ventricular systolic dysfunction", <i>JAMA</i> , vol. 272, no. 19, pp. 1528-1534.
Description	Systematic review
N=	n=8 cohort studies, with controls, for CABG, n=17 cohort studies on performance status, n=5 cohort studies on ejection fraction, n=3000 patients for CABG mortality analysis Ages 51-63 years, Male 84–100%, All LV ejection fraction <0.4, some clinical heart failure and some angina
Intervention	Coronary artery bypass grafts (some techniques more recent than others) Vs medically treated cohorts where available
Outcomes	Total mortality, Operative mortality, LV Ejection fraction, Functional class. All at between 1 and 6 years.
Results	<ul style="list-style-type: none"> <li>• Total mortality at follow up in CABG studies 16-70%.</li> <li>• Benefit over medical treatment 16% Vs 36% to 50% Vs 31% (i.e. higher mortality in CABG).</li> <li>• The studies with the better design when assessed showed benefit of surgery over medical treatment RR 0.5 (95% CI ~ 0.35 – 0.65).</li> <li>• All case series studies that evaluated LV ejection fraction and NYHA class have shown a postoperative improvement in these measures. LVEF from 0.26 before Vs 0.34 after, to 0.31 before Vs 0.40 after (p&lt;0.001 for a benefit). In 3 papers with NYHA class studies decreases were as much as 3.5 before Vs 2.3 after (P&lt;0.001 for a benefit).</li> <li>• The studies indicate mortality rates in excellent centres range from 5% in patients under 60 yrs, to more than 30% in patients 70+ years with severe ventricular dysfunction comorbid conditions.</li> </ul>
Comments	No hand searching The sub group with moderate to severe heart failure is applicable
Reference	179
Studies included	Alderman (1983), Bedard (1975), Blakeman (1990), Bounous (1988), Brockman (1987), Coles (1981), Cuckingham (1982), Faulkner (1977), Fox (1975), Hammermeister (1982), Hung (1980), Jones (1982), Lawrie (1991), Manley (1976), Mitchel (1975), Mochtar (1985), Pigott (1985), Solignac (1973), Spencer (1971), Stearn (1986), Urtzky (1986), Vliestra (1977), Yatteau (1974).

<b>Paper</b>	Bax, J. J., Wijns, W., Cornel, J. H., Visser, F. C., Boersma, E., & Fioretti, P. M. 1997, "Accuracy of currently available techniques for prediction of functional recovery after revascularization in patients with left ventricular dysfunction due to chronic coronary artery disease: comparison of pooled data", <i>Journal of the American College of Cardiology</i> , vol. 30, no. 6, pp. 1451-1460.
<b>Description</b>	Systematic review
<b>N=</b>	n=37 diagnostic studies fulfilling inclusion criteria from 396 identified covering 5 predictive techniques. Age range of 52-67 years, and all with chronic stable LV dysfunction
<b>Intervention</b>	Among the available tests the following were considered and compared:- Fluorine-18 fluorodeoxyglucose positron emission tomography (F18 FDG PET), Thallium-201 reinjection imaging (TI-201 reinjection), Thallium-201 rest-redistribution (TI-201 rest-redistribution), Technetium-99m sestamibic scintigraphy (Tc-99m MIBI), and Low dose dobutamine echocardiography (LDDE)
<b>Outcomes</b>	Sensitivity and specificity to predict improved contractile function after revascularisation
<b>Results</b>	<ul style="list-style-type: none"> <li>• F-18 FDG PET: n=12 studies, 332 patients, Sensitivity: 88% (95% CI: 84-91%), Specificity: 73% (69-77%)</li> <li>• TI-201 reinjection: n=7 studies, 209 patients, Sensitivity: 86% (95% CI: 83-88%), Specificity: 47% (43-51%)</li> <li>• Ti-201 rest-redistribution: n=8 studies, 145 patients, Sensitivity: 90% (95% CI: 87-93%), Specificity: 54% (49-60%)</li> <li>• Tc-99m MIBI: n=10 studies, 201 patients, Sensitivity 83% (95 % CI: 78-87%), Specificity 69% (62-74%)</li> <li>• LDDE: n=16 studies, 448 patients, Sensitivity: 84% (95% CI: 82-86%), Specificity: 81% (79-84%)</li> <li>• Overall the LDDE technique had the highest specificity than the other tests (sensitivity being largely similar) (p&lt;0.01), also the Ti-201 tests had significantly less specificity than LDDE, and F-18 FDG PET (p&lt;0.01) and also Tc-99m MIBI (p&lt;0.05)</li> </ul>
<b>Comments</b>	<p>Subgroup that are considered for revascularisation are applicable.</p> <p>Sensitivity and specificity were used to combine analysis as the proportion of segments showing functional recovery varies greatly between studies and are less dependant than predictive values on the prevalence of recovery of not from rest function</p> <p>There were not enough studies available in each group to analyse prediction of global improvement in rest function</p> <p>Information on loss to follow up rarely given, and different criteria for defining an positive or negative result may make comparisons difficult</p> <p>The current analysis favours the use of LDDE due to its higher specificity, although expertise in application is vital to maintain good predictability.</p>
<b>Studies included</b>	Alfieri (1993), Afridi (1995), Alfieri (1993), Arnese (1995), Arnese (1995), Baer (1996), Bax (1996), Bax (1996), Bisi (1994), Bisi (1995), Carrel (1992), Charney (1994), Charney (1994), Dilsizian (1990), Gerber (1996), Gerber (1996), Gonzalez (1996), Gropler (1993), Haque (1995), Knuuti (1994), Lucigniani (1992), Maes (1997), Maes (1997), Marwick (1992), Marzullo (1992), Marzullo (1993), Marzullo (1993), Marzullo (1993), Marzullo (1995), Maublant (1995), Maurea (1995), Mori (1991), Ohtani (1990), Perrone-Filardi (1995), Perrone-Filardi (1996), Perrone-Filardi (1996), Qureshi (1997), Qureshi (1997), Ragosta (1993), Senior (1995), Tamaki (1991), Tamaki (1991), Tamaki (1989), Tamaki (1995), Tillisch (1986), Udelson (1994), Udelson (1994), Vanoverschelde (1996), Vanoverschelde (1996),

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

<b>Paper</b>	Ellis, S. G., Da, S., Spaulding, C. M., Nobuyoshi, M., Weiner, B., & Talley, J. D. 2000, "Review of immediate angioplasty after fibrinolytic therapy for acute myocardial infarction: insights from the RESCUE I, RESCUE II, and other contemporary clinical experiences", <i>American Heart Journal</i> , vol. 139, no. 6, pp. 1046-1053.
<b>Description</b>	Systematic review
<b>N=</b>	n=9 RCTs, 1502 patients Age of patients varies between studies. 55-60 years
<b>Intervention</b>	Rescue Percutaneous Transluminal Coronary Angioplasty (PTCA) Vs conservative therapy in patients grouped to Occluded, TIMI grade 2, or grade 3 flow, and infarct arteries
<b>Outcomes</b>	Mortality at up to 1 year and LV ejection fraction at 30 days (2 trials)
<b>Results</b>	<ul style="list-style-type: none"> <li>• In patients with occluded coronary arteries in-hospital death and 30 day death showed a disadvantage of PTCA at 9.4% Vs 6.7% medical treatment, to a benefit of 6.3% Vs 33.3% respectively. In aggregate these trials show a significant reduction in early severe CHF 3.8% (PTCA) Vs 11.7% (Medical) (p=0.04)</li> <li>• 1 of the studies dealing with LVEF showed a modest improvement. The other showed an improvement from 44% to 53% in PCI group, and decrease from 45% to 41% in the conservative treatment group (p=0.027) at 6 months.</li> <li>• The benefit for patients with smaller infarcts remains unproven.</li> </ul>
<b>Comments</b>	No literature search was described and no quality assessment made of the studies. Not directly applicable but has consequences for development of Heart Failure
<b>Studies included</b>	Belenkie (1992), Ellis (1994), European Co-operative Study Group, Rescue 2, TIMI 1 (1985), TIMI 2, Topol (1987), Vermeer (1998), Widmisky (1998).

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

<b>Paper</b>	Hochman, J. S., Sleeper, L. A., White, H. D., Dzavik, V., Wong, S. C., Menon, V., Webb, J. G., Steingart, R., Picard, M. H., Menegus, M. A., Boland, J., Sanborn, T., Buller, C. E., Modur, S., Forman, R., Desvigne-Nickens, P., Jacobs, A. K., Slater, J. N., LeJemtel, T. H., & SHOCK Investigators. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock 2001, "One-year survival following early revascularization for cardiogenic shock.", <i>JAMA</i> , vol. 285, no. 2, pp. 190-192.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	n=301, Early group =152, medical stabilisation =149 Age =66yrs, Male =68%, History of MI =33%, diabetes =31%, hypertension =46%, LV ejection fraction =29%
<b>Intervention</b>	Patients in whom cardiogenic shock developed due to LV failure at 36 hours or less with ST elevation or Q waves, posterior infarction, or new left bundle branch block were treated either by PCTA or CABG within 6 hours of assessment and randomisation Vs medical stabilisation with thrombolysis and intra-aortic balloon counter-pulsation and subsequent revascularisation
<b>Outcomes</b>	Survival times without regard to transplantation to 1 year
<b>Results</b>	<ul style="list-style-type: none"> <li>• 55% and 38% of the early treatment group underwent PTCA and CABG respectively</li> <li>• Of predefined subgroup analysis the only significant interaction was with age p=0.03 (no significant difference was found between the trial arms in over 75 yrs)</li> <li>• Similar rates of hospitalisation between arms, and NYHA class I or II frequency post intervention only slightly higher (85% Vs 80%) in early treatment group at 1 year</li> <li>• This small subgroup of elderly patients (n=56) should not be viewed in isolation to the contrasting results from the larger unrandomised SHOCK registry</li> </ul>
<b>Comments</b>	

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

<b>Paper</b>	Kaul, U., Sahay, S., Bahl, V. K., Sharma, S., Wasir, H. S., & Venugopal, P. 1995, "Coronary angioplasty in high risk patients: comparison of elective intraaortic balloon pump and percutaneous cardiopulmonary bypass support--a randomized study", <i>Journal of Interventional Cardiology</i> , vol. 8, no. 2, pp. 199-205.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	n=40, IABP =20, PCPB =20 Age =55yrs, Male =98%, LV ejection fraction =21%
<b>Intervention</b>	Intraaortic balloon (40mm) catheter in left femoral artery Vs cannula lead portable cardiopulmonary bypass machine weaned off over 3-5 mins during PTCA treatment
<b>Outcomes</b>	Cardiac function post intervention and mortality at discharge and up to 17.5 months
<b>Results</b>	<ul style="list-style-type: none"> <li>• PTCA success in 38/40 patients in total</li> <li>• 71% of patients alive and angina free at 17.5 months</li> <li>• PA pressure during support lower in PCPB group 12.2 Vs 32.6 mmHg (p&lt;0.01)</li> <li>• Higher incidence of complications with PCPB 10% requiring surgery and 28% blood transfusion (p&lt;0.05, and p&lt;0.01 respectively) compared to Balloon counter-pulsation</li> <li>• Case selection was rigid.</li> <li>• Single centre study gave small sample with insufficient power</li> <li>• No patients within either arm developed a malignant ventricular tachyarrhythmia.</li> <li>• Does not apply to patients with haemodynamic collapse in the catheterisation lab which require a more efficient support system</li> </ul>
<b>Comments</b>	

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

Paper	Kjoller-Hansen, L., Steffensen, R., & Grande, P. 2000, "The Angiotensin-converting Enzyme Inhibition Post Revascularization Study (APRES)", <i>Journal of the American College of Cardiology</i> , vol. 35, no. 4, pp. 881-888.
Description	Randomised controlled trial
N=	n=159, ramipril =80, placebo =79 Age =61 yrs, Male =89%, LV ejection fraction ~43%, History of MI =76%
Intervention	Ramipril up to target dose of 10mg/day Vs placebo
Outcomes	Primary endpoints were quadruple composite of cardiac death / AMI / developing HF / recurrent angina pectoris; or triple composite without angina. Follow up median of 33 months
Results	<ul style="list-style-type: none"> <li>• Combining effectiveness of intervention on two revascularisation methods (no subgroup analysis)</li> <li>• Forcing age, gender, history of diabetes, or hypertension, and LVEF into a multivariate model with the primary endpoints gave similar results</li> <li>• LVEF in this study was higher than many other studies in the region of 40% compared to 25 – 30% in many other studies.</li> </ul>
Comments	

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

<b>Paper</b>	Urban, P., Stauffer, J. C., Bleed, D., Khatchatrian, N., Amann, W., Bertel, O., van den, B. M., Danchin, N., Kaufmann, U., Meier, B., Machecourt, J., & Pfisterer, M. 1999, "A randomized evaluation of early revascularization to treat shock complicating acute myocardial infarction. The (Swiss) Multicenter Trial of Angioplasty for Shock-(S)MASH.", <i>European Heart Journal</i> , vol. 20, no. 14, pp. 1030-1038.
<b>Description</b>	Randomised controlled trial
<b>N=</b>	n=55, invasive group =32, conservative =23 Age =65yrs, Male =67%, prior MI =25% Study conducted in 3 European countries
<b>Intervention</b>	Invasive treatment with angiography Vs conservative treatment in MI patients with shock due to primary pump failure within 48hrs of MI
<b>Outcomes</b>	Mortality at 30 days, and functional status and cardiac events to 1 year follow-up
<b>Results</b>	<ul style="list-style-type: none"> <li>Invasive group saw 31% survival to 30 days Vs 22% in conservative group RR 0.88 (95% CI 0.6 – 1.2) NS</li> </ul>
<b>Comments</b>	<p>Only a subgroup of MI patients with Shock promoting LV dysfunction are applicable</p> <p>No blinding stated</p> <p>Small sample</p> <p>Revascularisation successful in 85% of operations</p> <p>A trend in favour, but benefit of revascularisation perhaps not as has been estimated in recent years</p> <p>Often unable to reverse profound ventricular dysfunction</p> <p>Study had to be terminated early due to difficulties in patient recruitment, many patients not randomised because physicians considered</p>

**Non-experimental studies**

Paper	Malenka, D. J., O'Rourke, D., Miller, M. A., Hearne, M. J., Shubrooks, S., Kellett, M. A. J., Robb, J. F., O'Meara, J. R., VerLee, P., Bradley, W. A., Wennberg, D., Ryan, T. J., Vaitkus, P. T., Hettleman, B., Watkins, M. W., McGrath, P. D., & O'Connor, G. T. 1999, "Cause of in-hospital death in 12,232 consecutive patients undergoing percutaneous transluminal coronary angioplasty. The Northern New England Cardiovascular Disease Study Group.", <i>American Heart Journal</i> , vol. 137, no. 4 Pt 1, pp. 632-638.
Description	Case series (retrospective)
N=	
Intervention	
Outcomes	
Results	<ul style="list-style-type: none"> <li>• From 12,232 interventions there were n=122 deaths</li> <li>• 6 revascularisation centres in Northern New England, USA</li> <li>• In-hospital death was reported in 122 cases (mortality rate 1%) with 1 case lost 121 were available for review</li> <li>• The death mode most common, for 66.1% of patients was low-output failure, whereas ventricular arrhythmias accounted for 10.7% of deaths</li> <li>• The circumstance of death was deemed to be a complication of the procedure in 53.7% of cases, with a further 33.9% being attributable to pre-existing acute cardiac disease.</li> <li>• Patients dying of complications of procedure tended to have better LV function, more likely to have unstable angina, and a mid-left anterior descending or proximal circumflex coronary artery PTCA</li> <li>• Risk factors Associated with dying of a procedural complication included Age 70-79 yrs OR 2.71 (95% CI 1.32 – 5.58) (p&lt;0.01) or 80+ yrs OR 4.15 (1.69 – 10.15) (p&lt;0.01), female OR 3.41 (1.93 – 6.04), and receiving an intra-aortic balloon pump before the procedure OR 5.95 (1.49 – 23.81) (p=0.01)</li> <li>• Given that only half of deaths of patients undergoing PTCA are due to complications of procedure and the other half consequences of patients being critically ill then the risk for a average patient is lower than the 1% mortality commonly reported</li> <li>• Women may be at increased risk of death due to smaller vessel size, but more work is required to understanding the mechanisms mediating this increased risk.</li> <li>• Establishing mode of death is difficult in retrospective case audit</li> <li>• The data precedes the introduction of stents.</li> </ul>

<b>Comments</b>	<p>Study to describe the epidemiological causes of death after PTCA in a review of all such deaths within a region, by case note review</p> <p>A standardised extraction tool developed to classify the circumstances of death into 1 of 5 occurrences 1) complication of procedure 2) pre-existing acute cardiac disease 3) progression of chronic cardiac disease 4) acute or chronic non-cardiac conditions 5) unable to determine</p> <p>Further analysis was undertaken into the mode of death which was described as:- low-output failure, ventricular arrhythmia, primary respiratory failure, bleeding, infection, neurological event, or other</p> <p>One external 'control' auditor duplicated assessment in 50 cases and provided agreement with initial auditor at 70% for the mode of death (<math>k = 0.47</math>), and the consequence of death 79% (<math>k = 0.63</math>)</p> <p>Independent variables associated with outcome below <math>p=0.1</math> in univariate analysis were used in a multivariate regression model</p> <p>A liberal definition of procedural complication was used, as unless it could be proved otherwise a complication was assumed</p>
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