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Pre-operative intra aortic balloon pumps in patients undergoing coronary artery bypass grafting (Review)

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[Intervention Review]

Pre-operative intra aortic balloon pumps in patients undergoing coronary artery bypass grafting

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ABSTRACT

Background

The intra aortic balloon pump (IABP) is a mechanical assist device which improves cardiac function. The device has a well-established place in algorithms for managing low cardiac output following cardiac surgery. There is increasing evidence that certain cardiac surgery patients benefit from a period of preoperative augmentation with the intra aortic balloon pump.

Objectives

To determine the effect of the preoperative intra aortic balloon pump on mortality and morbidity in a number of different patients groups undergoing coronary artery bypass grafting.

Search methods

The Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library* (Issue 3, 2009), MEDLINE (2000 to August 2009), EMBASE (1998 to August 2009), BIOSIS previews (1969 to August 2009) and ISI Proceedings (1990 to August 2009) were searched. References and ongoing registers of studies were checked. No language restrictions were applied.

Selection criteria

Randomised controlled trials (RCTs) of any size or length were included.

Data collection and analysis

Papers were assessed for inclusion by two authors independently and differences were settled by consensus with a third author. Date are presented in the form of odds ratios (OR) and 95% confidence intervals (CI).

Main results

Six trials were included (five on-pump and one off-pump). This update adds the results of one further trial. Data from a total of 255 patients were included in the meta-analysis of mortality outcomes; all on-pump. Generally, the patients were considered as "high risk" and 132 were treated preoperatively with IABP and 123 served as controls. There were four hospital deaths in the intervention arm and 23 in the non-intervention arm (OR 0.18, 95% CI 0.08 to 0.41; P<0.0001). In a subgroup analysis, low cardiac index (<2.0 L/min/m^2) was noted in 21 out of 105 patients in the treatment arm and 59 patients out of 88 in the non-treatment arm (OR 0.14, 95% CI: 0.08 to 0.25; P<0.00001). An

off-pump versus on-pump analysis was not possible due to the limited number of off-pump studies. However a single well-conducted RCT suggested favourable effect of the preoperative IABP in off-pump patients.

Authors' conclusions

Evidence suggests that preoperative IABP may have a beneficial effect on mortality and morbidity in specific high risk patient groups undergoing coronary artery bypass grafting, however there are many problems with the quality, validity and generalisability of the trials. However, the available evidence is not robust enough to extend the use of IABP to truly elective, high risk patients. Defining more precisely which patient groups may benefit would be the challenge for the future.

PLAIN LANGUAGE SUMMARY

Preoperative intra aortic balloon pumps in patients undergoing coronary artery bypass grafting

Patients undergoing coronary artery bypass grafting may suffer from heart failure in the immediate hours following surgery due to stunning of the heart muscle. Drugs may be required to support the heart if this happens. Increasingly, a device called an intra aortic balloon pump is used as a mechanical assist device to help such patients. The device is a balloon which is positioned close to the heart in the main blood vessel called the aorta. By inflating and deflating with beats of the heart it acts to increase blood flow to the heart as well as reduce the amount of work the heart is doing. This is a temporary device which supports the heart during the immediate post operative period. Recent evidence suggests that certain patients may benefit from a period of support with the balloon pump before their operation in order to try and optimise heart function before the stress of surgery. This review suggests the intra aortic balloon pump may be beneficial in terms of survival from the operation however there are many problems with the validity of the trials used in this review and a categorical answer to this question requires further randomised controlled trials.

BACKGROUND

Within cardiac surgery, the intra aortic balloon pump (IABP) has a well established place in algorithms for managing low cardiac output following surgery and is described in any specialty textbook (Bojar 1999). The device acts to increase diastolic blood pressure and therefore coronary perfusion while reducing afterload, thus increasing stroke volume and cardiac output. The clinical aspects of this device are well described in "Perioperative Care in Cardiac Surgery" by Bojar 1999. The IABP is integral to current postoperative management and is of undeniable efficacy, so it is not surprising that there have been no RCTS in this setting as ethical permission would not be forthcoming. The analogy has been made that we don't need an RCT to determine whether a parachute is efficacious in preserving life. Within current clinical practice the IABP is deployed preoperatively in a number of circumstances including unstable angina refractory to medical treatment and cardiogenic shock following percutaneous coronary intervention (Gutfinger 1999). Further indications for deployment of the IABP preoperatively have emerged from retrospective (Dietl 1996; Holman 2000) and randomised controlled studies (Christenson 1997a; Christenson 1997b; Christenson 1997c; Christenson 1999; Christenson 2003; Oberhoffer 2006) including: age, poor left ventricular function, left main stem disease, diffuse coronary disease and redo surgery. The Benchmark Registry (Ferguson 2001) describing current practice in the use of the IABP suggests that of 16,909 uses between 1996 and 2000, 13% were in high risk patients undergoing surgical coronary revascularization. The Registry is USA based and collects clinical data retrospectively on patients receiving an IABP from a number of centres throughout the world. A further retrospective analysis from the Benchmark Registry, in which outcomes from US and non-US centres were compared, advocates the early deployment of the IABP (Cohen 2003). There is some evidence from randomised and non-randomised studies supporting the prophylactic use of the IABP in certain cardiac surgery patients. This review represents a formal assessment of the cumulative data with meta-analysis of all the evidence for and against the use of this device preoperatively in patients undergoing surgical coronary revascularisation. This review is an update of our previous Cochrane review (Field 2007).

OBJECTIVES

To determine the effect on mortality and morbidity of using the intra aortic balloon pump preoperatively in patients undergoing coronary artery bypass grafting.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) of any size or length allowing assessment of short, medium and long term outcomes.

Types of participants

Adult patients (≥ 18 years old) undergoing isolated, coronary artery bypass surgery, both on-pump (i.e. use of conventional mechanical circulation support) and off-pump. No restriction was placed on the case-mix, potentially allowing for stratification of effects by level of patient risk.

Types of interventions

A period of augmentation, of any length, with the intra-aortic balloon pump prior to median sternotomy incision.

Types of outcome measures

Primary outcomes: mortality within the commonly accepted definitions of either prior to discharge or within thirty days.

Secondary outcomes: inotropic requirements, haemofiltration requirements, ventilatory requirements, length of intensive care unit (ITU) stay, length of hospital stay, and cost effectiveness. Additional secondary outcomes were complications related to the IABP including limb ischaemia, bleeding and infection. Quality of life was not thought to be a meaningful outcome measure with respect to the IABP per se.

Search methods for identification of studies

Electronic searches

Searches were performed on the following databases: Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library* (Issue 3, 2009), MEDLINE (2000 to August 2009), EMBASE (1998 to August 2009), BIOSIS Previews (1969 to August 2009) and ISI Conference Proceedings Citations Index on Web of Knowledge (1990 to August 2009). MEDLINE and EMBASE searches were restricted to these years to take into account work already done in compiling CENTRAL. A randomised controlled trial filter was applied for MEDLINE (Dickersin 1994) and for EMBASE searches (Lefebvre 1996).

The search strategies are listed in Appendix 1 (original search February 2005) and Appendix 2 (updated search August 2009). The searches were not restricted by language.

Searching other resources

Reference lists of identified studies were checked for relevant studies. The meta-register of controlled trials (http://www.controlled-trials.com) and the Clinical Trials Search Portal of the World Health Organization (http://apps.who.int/trialsearch/) were searched.

Representatives of Datascope (IABP manufacturers) were questioned regarding further relevant data. Where data were not fully reported, attempts were made to obtain this through direct contact with the relevant authors. In particular, Dr Christenson was contacted as five RCTs identified were from his Department. He confirmed the independence of these studies, as well as providing additional outcome data, and his letter is registered with the Cochrane Heart Group. Attempts were made to contact Dr Oberhoffer for further information as his study, the sixth RCT appears in abstract form only.

Data collection and analysis

Having used the above search strategy to identify potentially relevant abstracts, papers were independently reviewed by two authors (MF & TT) to assess their suitability for data extraction according to our criteria. Differences in opinion were settled by consensus with a third author (MB). Data were extracted and stored within a pro forma and from there entered into Review Manager 5 (Review Manager 2008). Quality of papers were assessed by each author for adequacy of randomisation and

concealment, and labelled according to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). Meta-analysis was conducted on hospital mortality, two year mortality and post operative low cardiac output syndrome. Data were presented in the form of odds ratios (OR) and 95% confidence intervals (95% CI).
Assessment of heterogeneity within the data set was performed using Funnel Plots and chi-squared tests.

RESULTS

Description of studies

Results of the search

A total of 1124 references were identified by our search, after removal of duplicates 924 remained. From these 28 studies were thought to be of relevance and the full papers were sought. Of these five studies met the inclusion criteria. One further study was a randomised controlled trial registered with ClinicalTrials.Gov and is currently recruiting, see Characteristics of ongoing studies. One additional randomised controlled trial, published in abstract form, was identified by one of the review authors during the World Congress of the World Society of Cardio-Thoracic Surgeons, Ottawa, Canada. Four studies were identified through additional searches of reference lists (although none of these finally met the inclusion criteria). Finally six trials (285 participants) met our inclusion criteria. Five studies were on-pump (255 participants) and one study off-pump (30 participants).

Included studies

The characteristics of the included trials is described in detail within the Characteristics of included studies. In terms of the on-pump studies data from a total of 255 patients was included. One hundred and thirty two patients were treated preoperatively with a IABP and 123 patients were treated without preoperative IABP. Primary patient specific data were not available to perform a meta-analysis on other end-points including: inotropic requirement, ITU stay, hospital stay, ventilatory requirement, cost effectiveness and renal rescue. In addition, an off-pump versus on-pump analysis was not possible due to the limited number of off-pump studies.

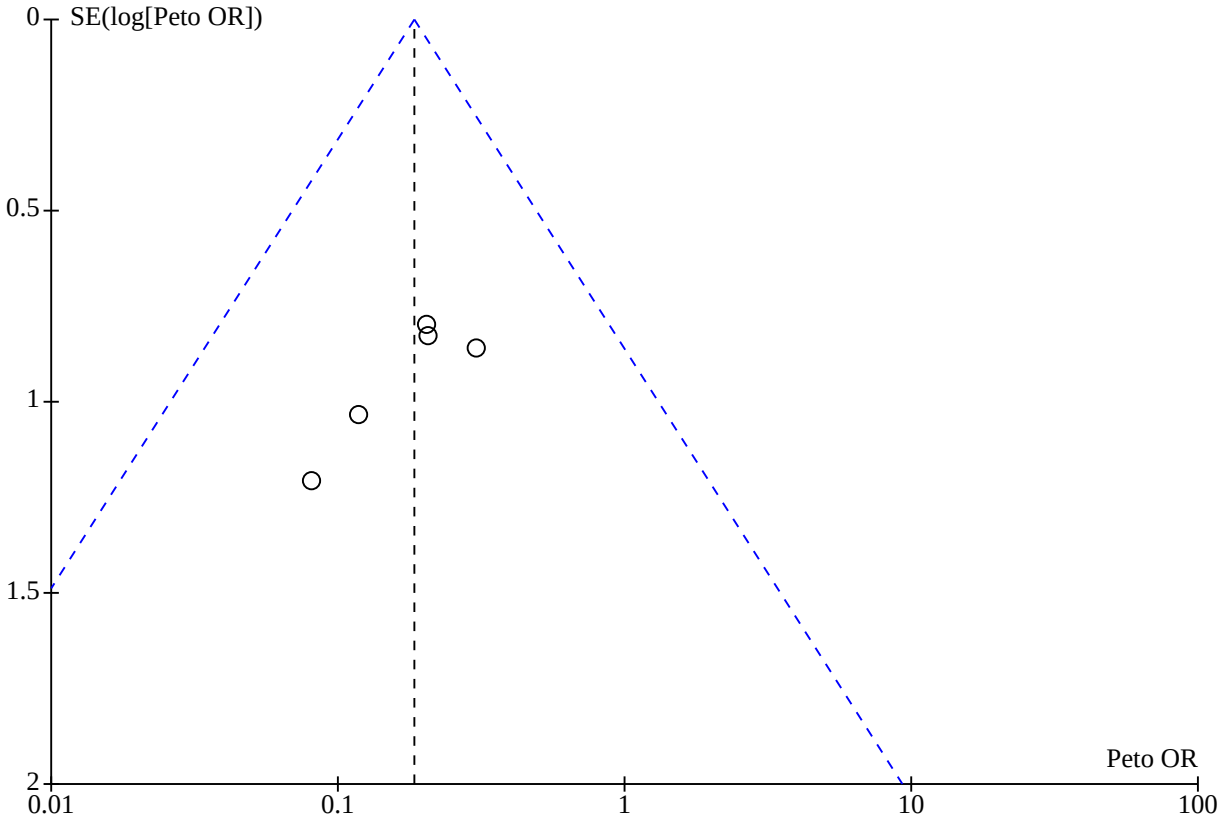
Excluded studies

For details of excluded studies see Characteristics of excluded studies.

Risk of bias in included studies

The six randomised trials included were all published in peer-reviewed journals apart from Oberhoffer 2006 which was accepted for presentation at the World Congress of World Society of Cardio-Thoracic Surgery and published in abstract form. Their characteristics are given in detail in the Table of Included Studies (Characteristics of included studies). All studies apart from Oberhoffer 2006 had the same principle investigator and this was of some concern. However the author was contacted and assurances sought, and obtained, that each study was entirely independent. Through this contact, additional data were also obtained on two year outcomes. These five papers acknowledge the support of either St Jude Medical or Datascope. Datascope are the manufacturers of the intra-aortic balloon pump. Attempts were made and some contact was had with Dr Oberhoffer via telephone however further information was not forthcoming. Please see Figure 1 for description of bias.

Figure 1. Funnel plot of comparison: 1 Preop CABG IABP versus no Preop CABG IABP, outcome: 1.1 In-hospital death.



General bias is bound to exist in terms of reporting of positive results in the literature however we are unaware of any data to that effect. Clearly the study is not blinded to either the patient or the surgeon. Follow-up in the studies are however complete. We believe the largest bias is against a positive result in that there is a high conversion rate from "no preoperative IABP" to post operative insertion caused by poor patient progression.

Effects of interventions

Each study characteristic is presented briefly in tabular form (see Table of Included Studies). Below is a more comprehensive assessment of each study.

Christenson 1997a randomised 33 patients into two groups between 1994 and 1996, a control group (14) and an intervention group (19). **The inclusion criteria were patients with a triad of three vessel artery disease, arterial hypertension and a LVEF <40%**. The intervention group had a two hour period of preoperative augmentation with an IABP. Myocardial revascularisation was performed using normothermic cardiopulmonary bypass (CPB) and myocardial protection included intermittent cold cardioplegia with topical hypothermia. Preoperative cardiac index was noted to rise significantly following preoperative IABP insertion (1.73+/- 0.57 versus 2.84+/-0.63, P<0.001) and 30 minutes following CPB (2.53+/-0.71 versus 3.74 +/1 0.85, P<0.001). Post operative low CI requiring pharmacological support was required in 11% of patients in the intervention group. Interestingly, 64% of patients in the control group required IABP insertion post operatively (P<0.01). The IABP was removed 1.2+/- 0.5 days post operatively in the intervention group and 3.1+/- 1.1 in the control group (P<0.001). There were no IABP complications. There were no hospital deaths in the intervention group and three deaths in the control group (21.4%, P<0.05). Intensive care requirement was 2.4+/-0.9 days in the intervention group and 3.4+/11.1 days in the control group (P<0.01).

Christenson 1997b randomised 48 patients into two groups between 1994 and 1996, a control group (24) and an intervention group (24). **The inclusion criteria were patients undergoing redo CABG with at least two of the following: poor LVEF (<0.4), unstable angina or left main stem stenosis>70%**. The intervention group had a two hour (2.1 +/- 0.6) period of augmentation with an IABP. Myocardial revascularisation was performed using a normothermic CPB and myocardial protection included cold cardioplegia with topical hypothermia. Preoperative cardiac index was noted to rise significantly following preoperative IABP insertion (1.8 +/-0.41 versus 2.76+/-0.52, P<0.0001) and 30 minutes following CPB (2.54+/-0.58 versus 3.87+/-0.72, P<0.0001). 69% of patients in the control group required IABP insertion postoperatively. The IABP was removed 1.2+/-0.5 days postoperatively in the intervention group and 4.1+/-1.7 in the control group. There were two IABP complications. There was no hospital mortality in the intervention group and four deaths in the control group (16.6%, P<0.049). Intensive care requirement was 2.4+/- 0.8 days in the intervention group and 4.5 +/- 2.2 days in the control group (P<0.007).

Christenson 1997c randomised 52 patients into three groups between 1994 and 1996, a control Group A (13), intervention Group B (19) and intervention Group C (20). **The inclusion criteria were patients with two or more of: LVEF<-.4, left main stem stenosis>07, REDO CABG or unstable angina**. The intervention groups consisted of either a one day period of preoperative IABP augmentation (group B) or a 1-2 hour period (group C). Myocardial revascularisation was performed using normothermic CPB and myocardial protection included intermittent cold cardioplegia with topical hypothermia. Preoperative cardiac index was noted to rise significantly following 1 hour or preoperative IABP insertion (1.68+/-0.49 versus 3.12+/-0.68, P<0.001) and 30 minutes following CPB (2.01+/-0.61 versus 4.17+/-0.64, P<0.001). Postoperative low CI requiring pharmacological support was required in 13% of patients in the intervention group. 60% of patients in the control group required IABP insertion postoperatively (P<0.05). The IABP was removed 1.3 +/- 0.5 days postoperatively in the intervention group and 3.1+/-1.0 in the control group (P<0.001). There were no IABP complications. There were two deaths in the two intervention groups (6%) and five deaths in the control group (25%, P<0.05). Intensive care requirement was 2.3+/- 0.9 days in the intervention groups and 3.5+/- 1.1 days in the control group (P<0.004).

Christenson 1999 randomised 60 patients into two groups between 1997 and 1998, a control group (30) and an intervention group (30). **The inclusion criteria were patients with two or more of: LVEF<0.3, unstable angina, reoperation or left main stem stenosis>70%.** The intervention group was randomised into either a two (10), twelve (10) or twenty four (10) hour period of preoperative augmentation with an IABP. Myocardial revascularisation was performed using normothermic CPB and myocardial protection included intermittent cold cardioplegia with topical hypothermia. Preoperative cardiac index was noted to rise significantly following preoperative IABP (1.82+/- 0.16 versus 2.69 +/- 0.66, P<0.0001) and 30 minutes following CPB (2.58 +/- 0.86 versus 3.52+/-0.71, P<0.0001). Postoperative low cardiac output was observed in 37% of patients in the intervention group. Twenty three of the 25 patients (83%) in the control group with low cardiac output required IABP insertion postoperatively. The IABP was removed 19.7 +/- 12.3 hours post operatively in the intervention group and 55.3+/- 32.1 hours in the control group (P<0.0002). There were five IABP complications. There was one hospital death in the intervention group (3.3%) and six deaths in the control group (20%). Intensive care requirement was 116.4 +/- 67.8 hours in the control group and 48.4 +/- 29.3 hours in the intervention group (P<0.0001).

Christenson 2003 randomised 30 patients designated for off-pump surgery into two groups, a control group of 15 (B) and an intervention group of 15 (A). **The inclusion criteria were patients with two of: ejection fraction <0.3, left main stem, unstable angina and redo surgery.** Study end-points were cardiac protection, inflammatory response and clinical outcome including mortality. Conversion to CPB was zero in Group A and 10 in Group B. There was a single death in Group B and none in Group A.

Oberhoffer 2006 randomised 62 "high risk" patients undergoing CABG. Group A (27) had an IABP inserted one hour before surgery while Group B (35) were operated without a IABP. **The inclusion criteria were patients with two of: left-ventricular ejection fraction less than 0.35, unstable angina, left main stem stenosis greater then 70% or reoperation**. Study end-points were inotropic support, length of ITU stay and mortality. Group B had 5 deaths while Group A had one death. Nine patients in group B converted to an IABP postoperatively.

Pooled analysis

Primary outcomes

All cause mortality in hospital: (Analysis 1.1)

In terms of mortality outcomes, meta-analysis was conducted on the five RCTs with on-pump patients. Data from a total of 255 patients were included. One hundred and five patients were treated preoperatively with a IABP and 88 patients were treated without an IABP. There were four hospital deaths in the intervention arm and 23 in the non-intervention arm (OR 0.18; 95% CI: 0.08 to 0.41; P<0.0001).

Further analysis beyond mortality excluded Oberhoffer data as the abstract did not provide sufficient information to allow inclusion.

All cause mortality at two year follow-up:(Analysis 1.2)

In terms of two year mortality (excluding early and perioperative mortality), (data provided by Dr Christenson), there were no deaths in the intervention arm (102 followed up) and a single death in the non-intervention arm (72 followed-up) (OR 0.11; 95% CI: 0.00 to 5.64; P<0.027).

Secondary outcomes

Cardiac output: (Analysis 1.3)

Low cardiac index (<2.0 L/min/m2) was noted in 21 of 105 patients in the treatment arm and 59 patients out of 88 in the non-treatment arm (OR 0.14; 95% CI: 0.08 to 0.25; P<0.00001). A large proportion of the control group had an IABP inserted postoperatively for low cardiac index (52 out of 88). Evidence suggests one hour of preoperative IABP augmentation is sufficient.

Limitations

We were unable to perform a meta-analysis on other secondary outcomes which included: inotropic requirement, ITU stay, hospital stay, ventilatory requirement, cost effectiveness and renal rescue due to limited available data

In addition, an off-pump versus on-pump analysis was not possible due to the limited number of off-pump studies, however a single, well conducted randomised controlled trial suggested a favourable effect of the preoperative IABP in off-pump patients (Christenson 2003).

DISCUSSION

Key findings

Data from a total of 255 patients was included in the mortality outcomes analysis. There were significantly fewer in-hospital deaths in the intervention compared to the control arm (OR 0.18; 95% CI: 0.08 to 0.41; P<0.0001). In the sub-group of Christianson papers, low cardiac index (<2.0 L/min/m2) was noted in fewer patients in the treatment arm compared to the control arm (OR 0.14; 95% CI: 0.08 to 0.25; P<0.00001). Evidence from RCT 4 suggests one hour of preoperative IABP augmentation is sufficient. There was no differences in long term mortality in the survivors of the

primary hospital episode. There was insufficient data to analyse off pump patients.

Limitations

The results of this meta-analysis are limited by a number of issues concerning the included randomised controlled trials:

a) In general terms all the studies identified and used in the meta-analysis were small. Five were from the same institution, with the same principle investigator, over a relatively short and overlapping period of time. The study independent of Christiansons group has only been published in abstract form. Each study design is broadly similar and therefore any bias can be expected to be propagated. Because of the nature of the trials there was no blinding in the methodology.

Discussion with Dr Jan Christenson has provided some reassurance that the data in each of his studies are independent, but this does not allow us to exclude other methodological problems. Another point for observation is that these studies were funded in part by Datascope who might be expected to benefit from positive results.

b) More specifically there are points of concern within each study. The randomised controlled trials included in this review are principally concerned with the efficacy of the preoperative IABP as a prophylactic intervention. However, as pointed out by Holman 2000 with regard to these studies, "these studies included many patients with on-going myocardial infarction and preoperative cardiogenic shock, which are generally accepted therapeutic rather than prophylactic indications for IABPs". In particular, all the studies had a variable number of patients with "unstable angina", 100% in Christenson 2003. This may account for two other issues of concern. Firstly there was a very high mortality in the control group (23/123) relative to the IABP group (4/132). It seems likely that this high mortality was a result of the unstable nature of the patient population recruited. A reflection of this is the observation that a large percentage of the control group had a low post operative cardiac index requiring insertion of an IABP (52/88 in Christiansons series). The same observation is made in the single off-pump study in which there was an unusually high conversion to on-pump in the control group (10/15) which did not have a preoperative IABP. In addition, seven patients in the control group required a postoperative IABP for low cardiac output. These facts may be attributable to the high risk nature of these patients, however because of a lack of information regarding their Euroscores (Nashef 1999) or Parsonnet (Parsonnet 1989) scores we are unable to judge this objectively. [For details of these scoring systems see additional Table 1 and Table 2.] Whatever the explanation, a mortality of around 20% in patients undergoing CABG would be regarded as unacceptably high by any standards (SCTS Blue Book 2008) .

c) The definition of "high risk" is problematic. Many of the definitions used in these studies are not conventionally accepted prognostic factors (Euroscore or Parsonnet score) for operative mortality. The definition of high risk in these studies is based on an "in-house" definition of a combination of left main stem disease, diffuse disease, redo-surgery, low ejection fraction, unstable angina, posterior vessel off-pump surgery and hypertension. Some of these parameters (diffuse disease, left main stem and posterior vessel off-pump surgery) are not commonly accepted prognostic factors.

A recent paper by Diez 2008 attempted to risk stratify patients. Unfortunately, the data presented suggests little progress on the issue of preoperative risk stratification. . Another retrospective study by Healy 2006 suggested that the correct identification of appropriate patients who would benefit from pre-emptive placement of IABP could be performed using the EuroSCORE. Patients with a preoperative score of >5 in their study benefited from preoperative IABP. Dunning 2003 performed a retrospective study and "derived and validated a clinical score that has a sensitivity of 50% and a specificity of 96.5% in the prediction of those patients requiring an IABP. The authors argued that it was more robust than using the Parsonnet score and that their validated clinical scoring system would be useful both to guide individual clinical decision making and to compare variation of IABP usage among institutions. Although retrospective studies are limited in the conclusions that can be drawn from them, we believe the only way forward in predicting which patients should have a preoperative intra-aortic balloon pump is based on the EuroSCORE which should be part of any future trial.

Additional Meta-analyses

The results of two recent meta-analysis concur with ours. However, we believe ours to be robust because Dyub 2008 included non-randomised data, data on patients undergoing off pump surgery, and data on patients where the IABP was inserted at the end of the operation (Marra 2002) and only two of the four on-pump randomised trials by Christianson were included (as Dyub 2008 et al believed there was duplication). We believe off-pump patients should be analysed separately as the conduct of the operation and the effects of a IABP are such as to not allow bulk analysis. The second systematic review by Dunning 2004 was incomplete and purely descriptive with no statistical analysis.

Other non-randomised studies

On-pump studies

Although there are clear concerns about the analysis presented in the paper, there is a large body of contributory non-randomised evidence concerning the use of the IABP preoperatively in a number of patient groups both on-pump (Dietl 1996; Gutfinger 1999; Holman 2000) and off-pump (Craver 2001; Kim 2001; Suzuki 2004). Dietl 1996 have published a retrospective analysis of 163 consecutive patients with severe left ventricular dysfunction (EF<0.25) and undergoing isolated CABG between January 1991 and December 1995. In group A, 37 patients had a preoperative IABP, while group B (126 patients) underwent operation without this early intervention. Interestingly, 28 patients in group B (22.2%) required a post operative IABP for haemodynamic support, 42.9% (12/28) of whom subsequently died. Overall 30 day mortality in group A was 2.7% (1/37) and in group B was 11.9% (15/126). Needless to say this resulted in a significant cost benefit. A significant number of the recruited population were diagnosed as having urgent or emergency operations and a proportion had unstable angina or a history of myocardial infarction within a week. Gutfinger 1999 retrospectively analysed 206 consecutive patients undergoing isolated CABG between January 1993 and September 1996. Group I (109) acted as controls and did not receive a preoperative IABP, while Group II (97) acted as the intervention arm. Patients in Group II had a higher number of unstable patients and this is reflected in the higher Parsonnet score (Group I, 15+/-6.4 and Group II, 21.4+/-7.3, P<0.001). The difference

in mortality between the two groups (Group I, 3(2.8%) and Group II, 6(6.2%)), NS) was taken as evidence of efficacy. However, the study lacked statistical power to exclude either substantial harm or benefit in the intervention compared to the comparison group.Holman 2000 took a different approach and suggested that previous studies had looked at using the preoperative IABP in high risk patients who were also "unstable" - now a commonly accepted therapeutic intervention. These authors distinguished this high risk unstable population from a truly elective high risk population. The propensity matched study consisted of a retrospective analysis of 7,581 patients registered with the Alabama CABG Cooperative Project between July 1995 and June 1996, 592 of whom received a prophylactic pre-incision IABP. No patients had current or recent instability. There was no survival advantage to using a prophylactic IABP in this patient population, however there was a significant reduction in hospital length of stay. Clearly, the efficacy of the preoperative IABP in truly elective, on-pump high risk patients requires further clarification, preferably with a randomised controlled trial. More recent studies in this updated review confirm our conclusions (Miceli 2009; Gong 2009; Kern 2009; Santarpino 2009) suggesting further studies are needed to define this population.

Off-pump studies

Three studies (Craver 2001; Kim 2001; Suzuki 2004) provide additional, non-randomised, retrospective data describing the preoperative IABP in high risk patients undergoing off-pump CABG. Kim 2001 published a retrospective analysis of 142 high risk patients who underwent off-pump CABG between April 1998 and July 2000. Their specific interest was in the efficacy of the preoperative and intraoperative IABP in aiding posterior vessel off-pump surgery. Despite the intervention arm of the study (with IABP, 57) having a higher number of high risk unstable patients than the control arm (without IABP, 85), there was no significant difference in mortality between the two groups (single death in without-IABP group), and this was taken as evidence in favour of the prophylactic IABP. Conversion rates to CPB were comparably low in both groups towards the end of the study. Suzuki 2004 reported on a series of 133 consecutive patients undergoing off-pump CABG between April 2000 and July 2003. Group I had 32 patients who were treated with a preoperative IABP and Group II served as controls (101). Despite Group I having a higher proportion of unstable high risk patients in it, mortality was not significantly different between the two groups (Group I, 0 and Group II, 1). There was no conversion to CPB in either group. This was taken as evidence of the preoperative IABP improving stability in high risk patients. Craver 2001 reported a favourable effect of the preoperative IABP in a limited series of 16 patients who underwent off-pump CABG. There was no control group in this study. Unfortunately, as with the on-pump studies, the patient population recruited were generally from a high risk unstable group and further work is required to understand which high risk elective patients might benefit from this intervention. A further study by Etienne 2007 concluded that the combined use of preoperative intra aortic counterpulsion and beating heart intervention allows complete revascularisation in high risk patients with an important reduction in operative mortality and excellent mid-term results. Group I (25 "emergencies" in which IABP was inserted one hour preoperatively) were compared with Group II (non-emergencies in which IABP was inserted 24 hours preoperatively) and EuroSCORE was utilised. They suggest that "compared with the EuroSCORE predictive model a dramatic decrease in mortality occurred in both groups. Group I predicted mortality was 36.8% and observed was 20% and in Group II the predicted mortality was 15.2% and the observed was 0%. Additional evidence for benefit in off-pump surgery and highlights the utility of Euroscore in this process.

Negative or indifferent studies

Baskett 2005 reported on a large retrospective study of preoperative intraaortic balloon pump in coronary bypass surgery and concluded that the use of preoperative IABPs was consistently associated with higher mortality. This study can be criticised for its methodology and despite the propensity matching employed, no evidence of benefit was identified.

AUTHORS' CONCLUSIONS

Implications for practice

The combined clinical experience of the authors suggests at present it is usual practice in the UK to deploy the IABP preoperatively in patients listed for isolated coronary surgery only when they are deemed unstable with rest pain or in heart failure i.e. so-called "in-house urgent" cases. We are however aware of no formal published UK based data to support this opinion (SCTS Blue Book 2008). This review found some evidence to support this practice of deploying the preoperative IABP in high risk unstable patients. However, the available randomised data is dependent on small statistically underpowered studies with unclear methodology. This update adds a further single RCT (abstract form) to the analysis, however the evidence remains insufficiently robust enough to extend the use of IABP to truly elective, high risk patients. The issue of elective patients may be addressed in the trial currently on-going in Italy.

Implications for research

Further RCT evidence is required. It would be helpful to perform an RCT looking at entirely elective, high risk patients. In particular, it would be interesting to design a trial with patients stratified by risk according to the recognised risk score for perioperative death (Euroscore). Such data would allow us to know if the efficacy of IABP depends on level of patient risk.

ACKNOWLEDGEMENTS

We would like to thank Dr Jan Christenson for his letter giving additional information about the included studies and for confirming that included RCTs 1-4 in this review are all individual randomised controlled trials, and that they are not sequential publications of the same trial(s).

We would like to acknowledge the Cochrane Heart Group without whose help this work would not have been completed.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Christenson 1997a

Study characteristics	
Methods	Study duration: June 1994 -March 1996. Parallel RCT of two groups (preoperative IABP versus no preoperative IABP). Measurements: Ejection fraction: LHC ventriculography and echocardiography. Cardiac index: Swan-Ganz catheter. Definition of hypertension: WHO criteria. Hypertrophy:
Participants	Group 1: +preop IABP (19) Group 2: -preop IABP (14) Group 2 cross-over to perioperative IABP: 9 Criteria for cross-over:CI<2.0 l/min/m2. Mean age: 65 (44-82) years. Sex: 90% men. Three vessel disease: 100%. Unstable angina: 69%. Hyperlipidaemia: 64%. Smokers: 60%. IDDM:18%. PVD: 8%. LVEF group I: 32.6+/-9.2 LVEF group II: 31.8+/-6.0 All distributed equally between the two groups.

Christenson 1997a *(Continued)*

Interventions	Primary treatment: coronary artery bypass surgery performed on cardiopulmonary bypass using normothermia and cold crystalloid cardioplegia. Average anastomosis: 4.6+/-1.6 per patient with 33% requiring endarterectomy; equally distributed between the two groups. Conduit use: Primary additional randomised intervention: Femoral percutaneous insertion of a 9F, 40ml Datascope IABP two hours prior to skin incision.
Outcomes	Mortality: Cardiac index: Pharmacological support: Hospital stay: Two year follow-up mortality and morbidity.
Notes	The effect of preoperative intra-aortic balloon pump support in patients with coronary artery disease, poor left-ventricular function (LVEF<40%) and hypertensive LV hypertrophy. Christenson JT, Simonet F, Schmuziger M (1997) Thoracic and Cardiovascular Surgeon 60-64. Main patient study group: hypertensive patients with ischaemic heart disease and poor left ventricular function.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation process not described
Allocation concealment (selection bias)	Unclear risk	Concealment method not described
Blinding (performance bias and detection bias) All outcomes	High risk	The nature of the study (presence of a IABP) precludes blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	There are many general issues as outlined in "Risk of bias in included studies". This study in particular has included a highly select group of patients who have been randomised within the study but no blinding exists. There was a high rate of transition in the control arm to having a IABP inserted postoperatively due to poor progress resulting in an underestimation of effect

Christenson 1997b

Study characteristics

Methods	Study duration: June 1994-October 1996. Parallel RCT of two high risk groups undergoing redo surgery (preoperative IABP versus no preoperative IABP). Measurements:

Christenson 1997b *(Continued)*

	Ejection fraction: LHC ventriculography and echocardiography. Cardiac index: Swan-Ganz catheter.
Participants	Group 1: +preop IABP (24) Group 2: -preop IABP (24) High risk: two additional factors from: poor LV (<0.4), unstable angina, LMS (>0.7). Group 2 cross-over to perioperative IABP: 9 Group 1 re-insertion of IABP:2 Criteria for cross-over:CI<2.0 l/min/m2. Mean age: group1; 65 (48-82) years; group 2; 62 (46-81). Sex: three women in group 1 and two women in group 2 LVEF <0.4group I: 87% LVEF <0.4 group II: 83% All high risk factors distributed equally between the two groups.
Interventions	Primary treatment: coronary artery bypass surgery performed on cardiopulmonary bypass using normothermia and cold crystalloid cardioplegia. A warm blood "hot shot" was employed. Average anastomosis:3.5+/-1.3 group 1 and 3.3+/-1.3 group 2 per patient. Conduit use: Primary additional randomised intervention: Femoral insertion of a 9F, 40ml Datascope IABP. Timing: Method:
Outcomes	Mortality: Cardiac index: Pharmacological support: Hospital stay: Two year follow-up mortality and morbidity.
Notes	Preoperative intraaortic balloon pump enhances cardiac performance and improves the outcome of redo CABG. Christenson JT, Badel P, Simonet F, Schmuziger M. Annals of Thoracic Surgery 1997; 64:1237-44.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"On admission to the hospital, the patients were randomised by lottery principle, drawing pre-prepared sealed envelopes containing the group assignment"
Allocation concealment (selection bias)	Unclear risk	"Sealed envelopes" - unsure if they were opaque
Blinding (performance bias and detection bias) All outcomes	High risk	The nature of the study (presence of IABP) precludes blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	There are many general issues as outlined in "Risk of bias in included studies". This study in particular has included a highly select group of patients who have been randomised within the study but no blinding exists. There was a high rate

Christenson 1997b *(Continued)*

	of transition in the control arm to having a IABP inserted postoperatively due to poor progress resulting in an underestimation of effect

Christenson 1997c

Study characteristics	
Methods	Study duration: June 1994-March 1996. Parallel RCT of two high risk groups undergoing CABG (preoperative IABP versus no preoperative IABP). Measurements: Ejection fraction: LHC ventriculography and echocardiography. Cardiac index: Swan-Ganz catheter.
Participants	Group 1: +preop IABP (13 at 24 hours and 19 at 2 hours) Group 2: -preop IABP (20) High risk: two additional factors from: poor LV (<0.4), unstable angina, LMS (>0.7) and redo surgery. Group 2 cross-over to perioperative IABP: 12 Group 1 continuation of IABP: 4 Criteria for cross-over:CI<2.0 l/min/m2. Mean age: group1; 64 +/-6. Sex: 87% men. All high risk factors distributed equally between the two groups.
Interventions	Primary treatment: coronary artery bypass surgery performed on cardiopulmonary bypass using normothermia and cold crystalloid cardioplegia. A warm blood "hot shot" was employed. Average anastomosis: 4.3+/-1.5. Conduit use: Primary additional randomised intervention: Femoral insertion of a 9F, 40ml Datascope IABP. Timing: Method:
Outcomes	Mortality: Cardiac index: Pharmacological support: Hospital stay: Two year follow-up mortality and morbidity.
Notes	Evaluation of preoperative intra-aortic balloon pump support in high risk coronary patients. Christenson JT, Simonet F, Badel P, Schmuziger M. European Journal of Cardiothoracic Surgery 1997; 11:1097-1103. Group 1 and group 2 were summated as there were no significant differences between them

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The patients fulfilling the above criteria were randomised into either of three groups by lottery (pre-prepared closed envelopes containing group assignment"
Allocation concealment (selection bias)	Unclear risk	"Sealed envelopes" - unsure if they were opaque
Blinding (performance bias and detection bias)	High risk	The nature of the study (IABP) precludes blinding

Christenson 1997c *(Continued)*
All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	There are many general issues as outlined in "Risk of bias in included studies". This study in particular has included a highly select group of patients who have been randomised within the study but no blinding exists. There was a high rate of transition in the control arm to having a IABP inserted postoperatively due to poor progress resulting in an underestimation of effect

Christenson 1999

Study characteristics	
Methods	Study duration: July 1997-June 1998. Parallel RCT of two high risk groups undergoing CABG (preoperative IABP versus no preoperative IABP). Three timing points for IABP insertion: 2, 12 and 24 hours. Measurements: Ejection fraction: LHC ventriculography and echocardiography. Cardiac index: Swan-Ganz catheter.
Participants	Group 2: +preop IABP (30; 10 into each timing point) Group 1: -preop IABP (30) High risk: two additional factors from: poor LV (<0.4), unstable angina, LMS (>0.7), reoperation and LMS (0.7). Group 1 cross-over to perioperative IABP: 23 Group 2 continuation of IABP: 1 Criteria for cross-over: CI<2.0 l/min/m2. Mean age: 63+/-9.8 Sex: 88% men All high risk factors distributed equally between the two groups.
Interventions	Primary treatment: coronary artery bypass surgery performed on cardiopulmonary bypass using normothermia and cold crystalloid cardioplegia. A warm blood "hot shot" was employed. Average anastomosis:4.4+/-1.3 group 1 and 4.1+/-1.4 group 2 per patient. Conduit use: Primary additional randomised intervention: Femoral insertion of a 9F, 40ml Datascope IABP. Timing: Method:
Outcomes	Mortality: Cardiac index: Pharmacological support: Hospital stay: 2 year follow-up mortality and morbidity.
Notes	Optimal timing of preoperative intraaortic balloon pump support in high risk coronary patients. Christenson JT, Simonet F, Badel P, Schmuziger M. Annals of Thoracic Surgery 1999; 68:934-9. The three timing points in the +IABP group were summated as there were no significant differences between these groups.

Christenson 1999 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"On admission to hospital the patients were randomly assigned to groups by lottery principle drawing pre-prepared sealed envelopes containing the group assignment"
Allocation concealment (selection bias)	Unclear risk	"Sealed envelopes" - unsure if they were opaque
Blinding (performance bias and detection bias) All outcomes	High risk	The study was not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	High risk	There are many general issues as outlined in "Risk of bias in included studies". This study in particular has included a highly select group of patients who have been randomised within the study but no blinding exists. There was a high rate of transition in the control arm to having a IABP inserted postoperatively due to poor progress resulting in an underestimation of effect

Christenson 2003

Study characteristics	
Methods	Parallel RCT of two high risk groups undergoing CABG, off -pump (preoperative IABP versus no preoperative IABP).
Participants	Group A: +preop IABP (15). Group B: -IABP (15). High risk: two factors from poor ejection fraction (<0.3), left main stem, unstable angina and redo surgery.
Interventions	Primary treatment: coronary artery bypass surgery performed off pump. Primary additional randomised intervention: IABP.
Outcomes	Mortality: Cardiac index: Hospital stay: Conversion rate: Myocardial protection: Inlammatory response: Conduit use:
Notes	The role of intra-aortic counterpulsion in high risk OPCAB surgery: A prospective randomised study. Christenson JT, Licker M, Kalangos A. Journal of Cardiac Surgery 2003; 18: 286-294.

Risk of bias

Christenson 2003 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated
Allocation concealment (selection bias)	Unclear risk	Concealment method not stated
Blinding (performance bias and detection bias) All outcomes	High risk	Study not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data
Selective reporting (reporting bias)	Unclear risk	All outcome data reported
Other bias	High risk	There are many general issues as outlined in "Risk of bias in included studies". This study in particular has included a highly select group of patients who have been randomised within the study but no blinding exists. There was an extremely high "bail out" incidence in the control arm with 10 out of 15 been converted from off-pump to on-pump surgery. This would be deemed unacceptable in current practice.

Oberhoffer 2006

Study characteristics	
Methods	Study period May 2003 to November 2004. Parallel RCT of two high risk groups undergoing CABG (preoperative IABP versus no preoperative IABP). Measurements included preoperative left-ventricular ejection fraction and post operative cardiac index.
Participants	Group A (27 patients) IABP inserted 1 hour preoperatively and Group B (35 patients) no preoperative IABP. All were high risk patients as defined by having two of the following criteria: ejection fraction less than 35%, unstable angina, left main stem stenosis (>70%) or reoperation.
Interventions	Primary treatment: Coronary artery bypass grafting on cardiopulmonary bypass. Primary additional randomised intervention: IABP.
Outcomes	Mortality: Cardiac index, Pharmacological support and Intensive Care stay were all measured however a lack of sufficient original unprocessed data excluded a meta-analysis.
Notes	PROSPECTIVE RANDOMIZED STUDY OF PREOPERATIVE INTRAAORTIC BALLOON COUNTERPULSATION IN HIGHRISK CORONARY ARTERY BYPASS GRAFTING PATIENTS Martin Oberhoffer, Marion Weis, Sandra Eifert, Darius Rassoulian, Bruno Meiser, Michael Schmoeckel, Bruno Reichart, Calin Vicol. 16th World Congress of World Society of Cardio-Thoracic Surgeons, Ottawa, Canada August 2006

Oberhoffer 2006 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Abstract only
Allocation concealment (selection bias)	Unclear risk	Abstract only
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Abstract only
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Abstract only
Selective reporting (reporting bias)	Unclear risk	Abstract only
Other bias	Unclear risk	Abstract only

Most of the included trials above have the same Principal Investigator, however correspondence with the authors confirms all studies are entirely independent.
All studies examine the role of the preoperative IABP in patients undergoing CABG, however each study looks at slightly different patient characteristics and outcomes.
Christenson 1997a: Main patient study group: hypertensive patients with ischaemic heart disease and poor left ventricular function.
Christenson 1997b: Main patient study group: high risk redo CABG surgery.
Christenson 1997c: Main patient study group: heterogeneous group of "high risk"patients with patient examining timing of preoperative IABP and cost effectiveness.
Christenson 1999: Main patient study group: heterogeneous group of "high risk"patients with patient examining timing of preoperative IABP.
Christenson 2003: Main patient study group: off-pump patients.
Correspondence with the Principal Investigator (Dr Christenson) has confirmed adequate allocation concealment. "For each trial, sealed envelopes containing group identity was prepared prior to the start of the trial, mixed and kept in a box. Once a patient fulfilled the study entry criteria set forth, a secretary drew one envelope, the envelope was opened and the patient was assigned to the group mentioned".
All studies demonstrate very high rates of post operative conversion to IABP in the control groups.
There was a rate of conversion to cardiopulmonary bypass in the control group of the off-pump study.
Oberhoffer 2006: This independent study was accepted in abstract form for the 16th World Congress of the World Society of Cardio-Thoracic Surgeons, Ottawa, Canada, August 2006. The work was not presented at the meeting. Telephone and e-mail contact has been made with Dr Oberhoffer who assures us of his intention to publish this work in a pier review journal however to date it has not been published in full form.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Babatasi 2003	Not RCT
Badel 1996	Not RCT
Baskett 2003	Not RCT
Baskett 2005	Not RCT

Study	Reason for exclusion
Christenson 1997d	Not RCT
Christenson 2000a	Not RCT
Christenson 2000b	Summary paper
Christenson 2001	Not RCT
Christenson 2002	Not RCT
Cohen 2003	Registry study
Cooper 1997	Not RCT.
Craver 2001	Not RCT
Dietl 1996	Not RCT
Diez 2008	Not RCT
Etienne 2007	Not RCT
Ferguson 2001	Not RCT
Gong 2009	Not RCT
Gutfinger 1999	Not RCT
Holman 2000	Not a RCT.
Kang 2001	Not a RCT
Kern 2009	Not a RCT
Kim 2001	Not a RCT
Lo 2001	Not RCT
Marra 2002	Not a relevant RCT (IABP not placed preoperatively)
Miceli 2009	Not RCT
Suzuki 2004	Not RCT

Characteristics of ongoing studies *[ordered by study ID]*

NCT00881192

Study name	Perioperative Intra-Aortic Balloon Pump (IABP) in Coronary Artery Bypass Grafting (CABG) Operations in Patients With Severely Depressed Left Ventricular Function
Methods	RCT

NCT00881192 *(Continued)*

Participants	Estimated Enrollment:160
Interventions	Control: No Intervention No preoperative IABP; if needed, postoperative IABP placement IABP: Active Comparator Preoperative IABP placement
Outcomes	Primary Outcome Measures: Major morbidity according to STS (mechanical ventilation > 48 hours, mediastinitis, surgical reexploration, stroke, acute renal failure) [Time Frame: 30 days after operation] [Designated as safety issue: No] Secondary Outcome Measures: Time on mechanical ventilation; ICU and hospital stay [Time-Frame: 30 days after the operation] [Designated as safety issue: No] IABP complications (lower limb ischaemia, mesenteric ischaemia, bleeding) [Time Frame: 30 days after the operation] [Designated as safety issue: Yes]
Starting date	Study Start Date: April 2009
Contact information	Policlinico S. Donato
Notes	RCT including patients scheduled for elective CABG surgery (with or without associated procedures) and having a left ventricular ejection fraction < 0.30. Exclusion criteria: age < 18 years, no patient's consent, contra-indications to the use of IABP (severe peripheral arteriopathy; endovascular abdominal aortic prostheses). Patients will be randomly allocated to either a control group or a treatment group. Patients in the control group will not receive an IABP preoperatively, and patients in the treatment arm will receive an IABP positioned immediately after the induction of anaesthesia and before beginning surgery. Randomization will be performed the day before the operation. Primary endpoint: reduction of major morbidity rate (defined as either prolonged (> 48 hours) mechanical ventilation, acute renal failure, mediastinitis, surgical revision, stroke). Secondary endpoint: reduction in inotropic drug use, shortening of mechanical ventilation and ICU stay. http://clinicaltrials.gov/ct2/show/NCT00881192

DATA AND ANALYSES

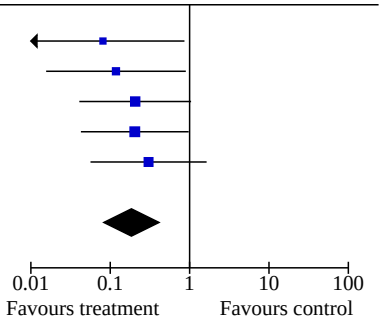
Comparison 1. Preop CABG IABP versus no Preop CABG IABP

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 In-hospital death	5	255	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.18 [0.08, 0.41]
1.2 Two year mortality following CABG (cardiac related)	4	174	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.11 [0.00, 5.64]
1.3 Low postop cardiac index (<2.0 L/min/m2)	4	193	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.08, 0.25]

Analysis 1.1. Comparison 1: Preop CABG IABP versus no Preop CABG IABP, Outcome 1: In-hospital death

Study or Subgroup	+ preop IABP Events	Total	- preop IABP Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Christenson 1997a	0	19	3	14	11.4%	0.08 [0.01 , 0.86]
Christenson 1997b	0	24	4	24	15.6%	0.12 [0.02 , 0.90]
Christenson 1997c	2	32	5	20	24.3%	0.21 [0.04 , 1.04]
Christenson 1999	1	30	6	30	26.2%	0.20 [0.04 , 0.97]
Oberhoffer 2006	1	27	5	35	22.5%	0.30 [0.06 , 1.64]
Total (95% CI)		**132**		**123**	**100.0%**	**0.18 [0.08 , 0.41]**
Total events:	4		23			

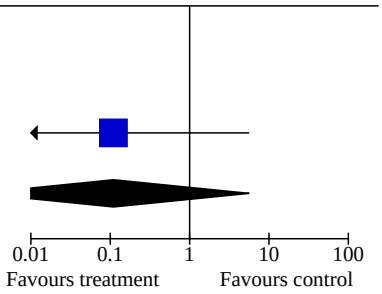
Heterogeneity: Chi² = 1.02, df = 4 (P = 0.91); I² = 0%
Test for overall effect: Z = 4.14 (P < 0.0001)
Test for subgroup differences: Not applicable



Analysis 1.2. Comparison 1: Preop CABG IABP versus no Preop CABG IABP, Outcome 2: Two year mortality following CABG (cardiac related)

Study or Subgroup	+preop IABP Events	Total	- preop IABP Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Christenson 1997a	0	19	0	11		Not estimable
Christenson 1997b	0	24	0	22		Not estimable
Christenson 1997c	0	30	0	15		Not estimable
Christenson 1999	0	29	1	24	100.0%	0.11 [0.00 , 5.64]
Total (95% CI)		**102**		**72**	**100.0%**	**0.11 [0.00 , 5.64]**
Total events:	0		1			

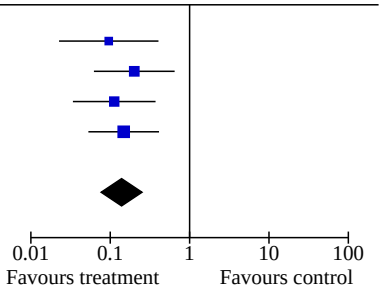
Heterogeneity: Not applicable
Test for overall effect: Z = 1.10 (P = 0.27)
Test for subgroup differences: Not applicable



Analysis 1.3. Comparison 1: Preop CABG IABP versus no Preop CABG IABP, Outcome 3: Low postop cardiac index (<2.0 L/min/m2)

Study or Subgroup	+preop IABP Events	Total	-preop IABP Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Christenson 1997a	2	19	9	14	16.8%	0.10 [0.02 , 0.41]
Christenson 1997b	4	24	13	24	25.5%	0.20 [0.06 , 0.65]
Christenson 1997c	4	32	12	20	24.3%	0.11 [0.03 , 0.37]
Christenson 1999	11	30	25	30	33.3%	0.15 [0.05 , 0.41]
Total (95% CI)		**105**		**88**	**100.0%**	**0.14 [0.08 , 0.25]**
Total events:	21		59			

Heterogeneity: Chi² = 0.77, df = 3 (P = 0.86); I² = 0%
Test for overall effect: Z = 6.54 (P < 0.00001)
Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. Details of the Euroscore scoring system

Risk	Score
Age	1 point per 5 years over 60
Female	1
Raised serum creatinine	2
Extracardiac arteriopathy	2
Pulmonary disease	1
Neurological dysfunction	2
Redo surgery	3
Active endocarditis	3
Critical preop state	3
Unstable angina	2
LVEF 30-50%	1
LVEF <30%	2
Recent infarction	2
PAP>60	2
Emergency	2
Ventricular septal rupture	4
Other than isolated CABG	2
Thoracic aortic surgery	3

Risk level	Total Score
Low Risk	0-2
Medium Risk	3-5
High Risk	6-24

Table 2. Details of the Parsonnet Scoring system

Risk	Score

Table 2. Details of the Parsonnet Scoring system *(Continued)*

Age	70-74	7
	75-79	12
	80	20
Female		1
Raised BMI		3
Diabetes		3
Hypertension		3
Ejection Fraction	30-49%	2
	<30%	4
Reoperation 1		5
Reoperation 2+		10
Catheter disaster		10
Congenital heart disease		10
Preop IABP		2
Mitral valve		5
Aortic Valve		7
PAP >60		8

Total Score	Risk
0-4	1%
5-9	5%
10-14	9%
15-19	17%
>20	30%

APPENDICES

Appendix 1. Search strategies 2005

CENTRAL on The Cochrane Library

#1INTRA-AORTIC-BALLOON-PUMPING*:ME
#2(ASSISTED next CIRCULATION)
#3(AORT* near BALLOON*)
#4IABP
#5(INTRA-AORT* near BALLOON)
#6(INTRAAORT* near BALLOON)
#7(((((#1 or #2) or #3) or #4) or #5) or #6)
#8CORONARY-ARTERY-BYPASS*:ME
#9(CORONARY near BYPASS)
#10CABG
#11(AORTOCORONARY next BYPASS)
#12MYOCARDIAL-REVASCULARISATION*:ME
#13(CORONARY near REVASCULARI*)
#14(MYOCARD* NEAR REVASCULARI*)
#15(HEART near REVASCULARI*)
#16(((((((#8 or #9) or #10) or #11) or #12) or #13) or #14) or #15)
#17(#7 and #16)

MEDLINE

1Intra-Aortic Balloon Pumping/
2Aortic balloon.tw
3Aort$ balloon$.tw
4Intra-aortic balloon.tw.
5Intraaortic balloon.tw.
6Iabp.tw.
7Assist$ circulation.tw.
8Assisted circulation/
9Or/1-8
10Exp coronary artery bypass/
11Aortocoronary bypass.tw.
12Cabg.tw.
13(coronary adj5 bypass).tw.
14myocardial revascularisation/ (
15((coronary or heart or myocard$) adj5 revasculari$).tw.
16or/10-15
179 and 16

EMBASE

1 Aorta Balloon/
2 aortic balloon.tw.
3 aort$ balloon$.tw.
4 intra-aortic balloon.tw.
5 intraaortic balloon.tw.
6 iabp.tw.
7 assist$ circulation.tw.
8 Assisted Circulation/
9 or/1-8
10 exp Coronary Artery Bypass Graft/
11 aortocoronary bypass.tw.
12 cabg.tw.
13 (coronary adj5 bypass).tw.
14 Heart Muscle Revascularization/
15 ((coronary or heart or myocard$) adj5 revasculari$).tw.
16 or/10-15
17 9 and 16
18 controlled study/

19 clinical trial/
20 major clinical study/
21 random$.tw.
22 randomized controlled trial/
23 trial$.tw.
24 compar$.tw.
25 control$.tw.
26 follow-up.tw.
27 blind$.tw.
28 double blind procedure/
29 placebo$.tw.
30 clinical article/
31 placebo/
32 doubl$.tw.
33 or/18-32
34 17 and 33

Appendix 2. Search strategies 2009

CENTRAL on The Cochrane Library

#1 MeSH descriptor Intra-Aortic Balloon Pumping this term only
#2 ASSISTED next CIRCULATION in All Text
#3 (AORT* in All Text near/6 BALLOON* in All Text)
#4 IABP in All Text
#5 (INTRA-AORT* in All Text near/6 BALLOON in All Text)
#6 (INTRAAORT* in All Text near/6 BALLOON in All Text)
#7 (#1 or #2 or #3 or #4 or #5 or #6)
#8 MeSH descriptor Coronary Artery Bypass explode all trees
#9 (CORONARY in All Text near/6 BYPASS in All Text)
#10 CABG in All Text
#11 AORTOCORONARY next BYPASS in All Text
#12 MeSH descriptor Myocardial Revascularization this term only
#13 (CORONARY in All Text near/6 REVASCULARI* in All Text)
#14 (MYOCARD* in All Text near/6 REVASCULARI* in All Text)
#15 (HEART in All Text near/6 REVASCULARI* in All Text)
#16 (#8 or #9 or #10 or #11 or #12 or #13 or #14 or #15)
#17 (#7 and #16)

MEDLINE on Ovid

1 Intra-Aortic Balloon Pumping/
2 aortic balloon.tw.
3 aort$ balloon$.tw.
4 intra-aortic balloon.tw.
5 intraaortic balloon.tw.
6 iabp.tw.
7 assist$ circulation.tw.
8 Assisted Circulation/
9 or/1-8
10 exp Coronary Artery Bypass/
11 aortocoronary bypass.tw.
12 cabg.tw.
13 (coronary adj5 bypass).tw.
14 Myocardial Revascularization/
15 ((coronary or heart or myocard$) adj5 revascular$).tw.
16 or/10-15
17 9 and 16
18 randomized controlled trial.pt.
19 controlled clinical trial.pt.
20 Randomized controlled trials/
21 random allocation/
22 double blind method/

23 single-blind method/
24 or/18-23
25 exp animal/ not humans/
26 24 not 25
27 clinical trial.pt.
28 exp Clinical Trials as Topic/
29 (clin$ adj25 trial$).ti,ab.
30 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).ti,ab.
31 placebos/
32 placebo$.ti,ab.
33 random$.ti,ab.
34 research design/
35 or/27-34
36 35 not 25
37 26 or 36
38 17 and 37
39 (2005$ or 2006$ or 2007$ or 2008$ or 2009$).em.
40 38 and 39

EMBASE on Ovid

1 Aorta Balloon/
2 aortic balloon.tw.
3 aort$ balloon$.tw.
4 intra-aortic balloon.tw.
5 intraaortic balloon.tw.
6 iabp.tw.
7 assist$ circulation.tw.
8 Assisted Circulation/
9 or/1-8
10 exp Coronary Artery Bypass Graft/
11 aortocoronary bypass.tw.
12 cabg.tw.
13 (coronary adj5 bypass).tw.
14 Heart Muscle Revascularization/
15 ((coronary or heart or myocard$) adj5 revascular$).tw.
16 or/10-15
17 9 and 16
18 controlled clinical trial/
19 random$.tw.
20 randomized controlled trial/
21 follow-up.tw.
22 double blind procedure/
23 placebo$.tw.
24 placebo/
25 factorial$.ti,ab.
26 (crossover$ or cross-over$).ti,ab.
27 (double$ adj blind$).ti,ab.
28 (singl$ adj blind$).ti,ab.
29 assign$.ti,ab.
30 allocat$.ti,ab.
31 volunteer$.ti,ab.
32 Crossover Procedure/
33 Single Blind Procedure/
34 or/18-33
35 (exp animals/ or nonhuman/) not human/
36 34 not 35
37 (2005$ or 2006$ or 2007$ or 2008$ or 2009$).em.
38 36 and 37 and 17

ISI Proceedings and Biosis Previews on Web of Knowledge

4 #1 and #2 and #3

3 TS=(random* or rct or trial)
2 TS=(CABG or (Coronary same bypass) or (aortocoronary same bypass) or (myocardial revasculari*) or (heart near revasculari*))
1 TS=((intra-aortic balloon pump) or (intraaortic balloon pump) or iapb)

WHAT'S NEW

Date	Event	Description
15 April 2021	Review declared as stable	A topic expert judged this research area to be inactive - no new or ongoing trials.

HISTORY

Protocol first published: Issue 4, 2003
Review first published: Issue 1, 2007

Date	Event	Description
9 December 2010	New citation required but conclusions have not changed	This update of the original 2007 Cochrane Review represents a significant reassessment of this literature as well as an extensive update of the non-randomised retrospective data. A new section is included describing two other meta-analyses on the same topic. New authors have joined the team.
9 December 2010	New search has been performed	The searches have been re-run to August 2009. One new study (abstract form) has been included with another having been registered and recruiting - this ongoing study will be further assessed in the next update version.
9 September 2008	Amended	Converted to new review format.
15 October 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Mark Field - conception, planning, study selection, writing and final approval of first and second versions
Arvind Rengarajan - developing, study selection, editing and final approval of first study

Thomas Theologou- planning, study selection and final approval of second version

Mohamad Bashir - study selection, discussion and preparation of second version
Omar Khan - developing, editing and final approval of first study
Tom Spyt - developing, editing and final approval of first study
David Richens - consultation and editing of first study

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- The Liverpool Heart and Chest Hospital, Liverpool, UK
- The Trent Cardiac Centre, Nottingham, UK

- Glenfield Hospital, Leicester, UK

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Coronary Artery Bypass [adverse effects] [mortality]; Coronary Artery Bypass, Off-Pump; Heart Failure [therapy]; *Intra-Aortic Balloon Pumping; Postoperative Complications [therapy]; Randomized Controlled Trials as Topic

MeSH check words

Humans