Effects of cell saver autologous blood transfusion on blood loss and homologous blood transfusion requirements in patients undergoing cardiac surgery on- versus off-cardiopulmonary bypass: a randomised trial

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Abstract

Objective: Off-pump CABG is potentially associated with reduced intraoperative blood loss and homologous blood transfusion in comparison to on-pump CABG. In this randomised controlled study we investigated the effects of autologous cell saver blood transfusion on blood loss and homologous blood transfusion requirements in patients undergoing CABG on- versus off-CPB. Methods: Eighty patients were randomised into one of four groups: (A) on-CPB with cell saver blood transfusion (CSBT), (B) on-CPB without CSBT, (C) off-pump with CSBT and (D) off-pump without CSBT. Volume of intraoperative autologous blood transfusion, postoperative mediastinal blood loss and homologous blood transfusion requirements were measured. Homologous blood was transfused when haemoglobin concentration fell below 8 g/dl postoperatively. Pre- and postoperatively prothrombin time and partial thromboplastin time were measured. Results: Preoperative patient characteristics were well matched among the four groups. The amount of salvaged mediastinal blood available for autologous transfusion was significantly higher in the on-pump group (A) compared to the off-CPB group (C) (433 ± 155 ml vs 271 ± 144 ml, P = 0.001). Volume of homologous blood transfusion was significantly higher in group B vs groups A, C and D (595 ± 438 ml vs 179 ± 214, 141 ± 183 and 230 ± 240 ml, respectively, P < 0.005). The cell saver groups (A and C) received significantly less homologous blood than the groups without cell saver (160 ± 197 ml vs 413 ± 394 ml, respectively, P < 0.005). Patients undergoing off-CPB surgery received significantly less homologous blood than those undergoing on-CPB CABG irrespective of cell saver blood transfusion (184 ± 214 ml vs 382 ± 397 ml, P < 0.05). Postoperative blood loss was similar in the four groups (842 ± 276, 1023 ± 291, 869 ± 286 and 903 ± 315 ml in groups A to D, respectively, P > 0.05). Clotting test results revealed no significant difference between the groups. There was no significant difference in postoperative morbidity between groups. Conclusion: Off-pump CABG is associated with significant reduction in intraoperative mediastinal blood loss and homologous transfusion requirements. Autologous transfusion of salvaged washed mediastinal blood reduced homologous transfusion significantly in the on-CPB group. Cell saver caused no significant adverse impact on coagulation parameters in on- or off-CPB CABG. Postoperative morbidity and blood loss were not affected by the use of CPB or autologous blood transfusion. We recommend the use of autologous blood transfusion in both on- and off-pump CABG surgery.

Keywords: Coronary artery bypass grafting (CABG); Cardiopulmonary bypass (CPB); Off-pump coronary artery bypass; Autologous blood transfusion; Cell saver; Homologous blood transfusion

1. Introduction

Cardiac surgical procedures account for approximately 10% of all blood supplied by the National Blood Service in the United Kingdom with at least three out of four patients requiring at least one unit of homologous transfusion [1]. In the present era of declining blood donation and the increasing cost of blood and its products alternatives to and/or the ability to reduce homologous transfusion requirements is becoming evermore imperative.

The use of CPB has been associated with increased coagulation abnormalities and marked inflammatory response [2,3]. Off-pump surgery is now a well-established alternative technique for CABG with several potential advantages including reduced morbidity and mortality in high risk patients [4,5]. Today, approximately 20% of all CABG cases in the UK are done on a beating heart [6].

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Cell saver autologous blood transfusion (autotransfusion) is defined as the collection of a patient's own blood at operation or from the surgical wound to allow its re-infusion into the patient [7]. In the 1970s Milles, Langston and D’Alessandro reported their experience with the use of predonated autologous blood and autotransfusion as an alternative to allogenic (homologous) transfusion [8].

Over the years the stimulus for autologous blood salvage was to alleviate the requirement for homologous blood transfusion and expedite resuscitation following massive haemorrhage [9]. Increasing concern over transmission of viral diseases, especially hepatitis and human immunodeficiency virus, has generated even greater interest in autologous blood salvage [10].

The devices used to provide autologous blood transfusion are known as cell savers. Many prototypes of these devices have been around since the early fifties but it was the Haemonetics Corporation in the early 1970s that first devised a differential centrifugation bowl coupled with a collection reservoir containing anticoagulant that created a suitable way of salvaging shed blood.

These devices are increasingly being used in major surgical procedures both acutely and in elective procedures. The major concerns regarding their use include: (1) possible up regulation of the systemic inflammatory response following re-transfusion [9,11], (2) coagulopathy postoperatively [12], (3) an increased risk of fat and air emboli [13], and (4) organ failure [14,15].

The aims of this study were to investigate the potential additive effects of autologous cell saver blood transfusion and CPB on blood loss, homologous blood transfusion requirements and clotting parameters in patients undergoing first time CABG. These effects were compared with patients undergoing CABG without CPB, with and without the cell saver.

2. Methods

2.1. Patient groups

The protocol of the study was approved by our Hospital Ethical Committee and informed consent was obtained from all patients. Eighty patients, undergoing first-time isolated CABG, were randomised into four groups: (A) on-CPB with cell saver blood transfusion (CSBT), (B) on-CPB without CSBT, (C) off-CPB with CSBT, and (D) off-CPB without CSBT. Randomisation was achieved by mixing non-transparent envelopes containing cards marked with the code of each group. Randomisation was done the day before surgery.

Consecutive patients meeting the criteria of first time CABG requiring at least three bypass grafts with moderate-to-good left ventricular function attending the Cardiothoracic Department at our institution were invited to participate in the trial. Exclusion criteria for patients were: known inflammatory diseases, existing infections, emergent surgery, use of long-term corticosteroids and non-steroidal anti-inflammatory drugs, anti-platelet agents in the week prior to surgery, known coagulopathy/long term anticoagulation with warfarin or heparin, severe pre-existing renal dysfunction (creatinine >200 μmol/l) or lung dysfunction (forced vital capacity (FVC) or forced expiratory volume in 1s (FEV1) <80% of predicted), LVEF <40%. Patients who met the criteria and accepted to take part were then randomised for the trial.

2.2. Anaesthetic and operative techniques

The detailed anaesthetic and operative techniques were standardised for all patients and has been reported previously [16].

In the on-CPB patient group the operation was performed through a median sternotomy. A 300 IU/kg heparin was administered to achieve an activated clotting time (ACT) of over 480 s prior to aortic and venous cannulation. Non-pulsatile extracorporeal circulation at moderate hypothermia of 32 °C and cold blood antegrade cardioplegia for myocardial protection was administered for all patients. Protamine sulphate was used at the end of the procedure to reverse heparinisation and to achieve the preoperative activated clotting time.

In the off-CPB group, anticoagulation was achieved using 150 IU/kg of heparin to achieve an activated clotting time above 300 s. The operation was performed through median sternotomy using the Guidant Acrobat SUV (Guidant, IN, USA) stabilisation device. Mean arterial blood pressure was maintained between 50 and 70 mmHg during the procedure by means of adequate filling, repositioning the heart and selective use of vasoconstrictors. Protamine sulphate was used at the end of the procedure to reverse heparinisation.

2.3. Cell-salvage protocols

Patients in the cell saver groups underwent intraoperative cell salvage, with autotransfusion of washed, salvaged red blood cells at the conclusion of the procedure. The cell saver was used to collect blood lost from skin incision to skin closure in the off-CPB group and from skin incision to commencement of CPB and then again after administration of protamine to skin closure in the on-CPB group. The blood lost from the commencement of CPB to the administration of protamine was suctioned by the CPB machine cardiotomy suckers and returned to the venous reservoir. Any remaining blood in the CPB circuit after discontinuation from bypass was retransfused via the aortic cannula before decannulation. No blood from the bypass circuit was reassigned to the cell saver. The blood was salvaged using a single lumen suction tube flushed with heparinised 0.9% normal saline (30 U/ml infused at 80 ml/h) and connected to the closed rigid collection chamber of a Dideco Electa autotransfuser device (Dideco, Gloucester, United Kingdom) at high pressure suction. Prior to autotransfusion, the salvaged blood was washed and centrifuged with resuspension of the red blood cells in saline, to a haematocrit of approximately 0.6. This blood was then transferred to a sterile collecting bag and retransfused into the patient via a standard blood-giving set at an average rate of 300 ml/min.

In the on-CPB patient group without cell saver all blood lost from skin incision to skin incision to commencement of CPB and protamine reversal to skin closure was aspirated into a waste sucker. During CPB blood was collected as described above.
2.4. Measurement of clinical parameters

Preoperatively patients had a full blood count which included haemoglobin concentration and haematocrit and a clotting screen comprising prothrombin time (expressed as international normalised ratio (PT ratio), a measure of the intrinsic and common clotting pathways) and partial thromboplastin time (expressed as PTT ratio to a normalised control value, a measure of the intrinsic and common clotting pathways). These tests were repeated on the first and fifth postoperative day.

Intraoperatively routine cardiovascular and pulmonary monitoring was undertaken. Arterial blood gas (ABG) analysis was undertaken as appropriate by the anaesthetist and perfusionist. Patients randomised to the cell saver groups had the quantity of collected mediastinal blood available for transfusion following processing recorded. The duration of cardiopulmonary bypass, aortic cross clamp time, number of grafts per patient, vessels grafted and conduits used were recorded.

Postoperatively, the amount of chest tube drainage in the first twenty-four hours was recorded as well as the total amount of homologous blood transfusion (HBT) in this same period of time. Homologous blood was only transfused if the haemoglobin concentration was less than 8 g/dl.

Data were prospectively collected on the length of intubation and length of intensive care stay. Postoperative complications including atrial fibrillation, renal complications, pulmonary problems (chest infection, pneumo- or haemorrhax and atelectasis) and cerebrovascular accidents were all recorded until the patient was discharged home. The total postoperative hospital stay was also recorded.

2.5. Statistical analysis

Results were expected to follow a normal distribution. Data were expressed as mean ± standard deviation (SD). For demographic data, the Student t-test was used to compare continuous variables and the χ²-test was used to compare nominal data between groups. A mixed model analysis of variance techniques was used to look for effects over time and between treatment groups. Bonferroni corrections were applied to the P-values to allow for the multiple comparisons that were made with pre-operative values. Significance was assumed for P < 0.05. All data analysis was performed with SPSS for windows, Version 9.0 (SPSS Inc., Chicago, IL).

### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>On-CPB with CSBT (N = 20)</th>
<th>On-CPB without CSBT (N = 20)</th>
<th>Off-CPB with CSBT (N = 20)</th>
<th>Off-CPB without CSBT (N = 20)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>66.3 ± 7.3</td>
<td>66.1 ± 10.8</td>
<td>67.25 ± 11.2</td>
<td>67.9 ± 9.5</td>
<td>&gt;0.5</td>
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<tr>
<td>Gender (male)</td>
<td>N = 16 (80%)</td>
<td>N = 16 (80%)</td>
<td>N = 15 (75%)</td>
<td>N = 19 (95%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>EF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good (&gt;50%)</td>
<td>N = 16 (80%)</td>
<td>N = 19 (95%)</td>
<td>N = 16 (80%)</td>
<td>N = 16 (80%)</td>
<td>&gt;0.05</td>
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<td>Moderate (40–50%)</td>
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<td>N = 1 (5%)</td>
<td>N = 4 (20%)</td>
<td>N = 4 (20%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Three-vessel disease</td>
<td>N = 19 (95%)</td>
<td>N = 18 (90%)</td>
<td>N = 18 (90%)</td>
<td>N = 19 (95%)</td>
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<tr>
<td>Angina class</td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>I</td>
<td>N = 3 (15%)</td>
<td>N = 4 (20%)</td>
<td>N = 4 (20%)</td>
<td>N = 6 (30%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>II</td>
<td>N = 12 (60%)</td>
<td>N = 13 (55%)</td>
<td>N = 11 (55%)</td>
<td>N = 9 (45%)</td>
<td>&gt;0.05</td>
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<tr>
<td>III</td>
<td>N = 4 (20%)</td>
<td>N = 3 (15%)</td>
<td>N = 4 (20%)</td>
<td>N = 5 (25%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>IV</td>
<td>N = 1 (5%)</td>
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<td>N = 1 (5%)</td>
<td>N = 0 (0%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Diabetes</td>
<td>N = 4 (20%)</td>
<td>N = 3 (15%)</td>
<td>N = 2 (10%)</td>
<td>N = 2 (10%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Hypertension</td>
<td>N = 16 (80%)</td>
<td>N = 14 (70%)</td>
<td>N = 14 (70%)</td>
<td>N = 12 (60%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Smoking history</td>
<td>N = 11 (55%)</td>
<td>N = 7 (20%)</td>
<td>N = 8 (40%)</td>
<td>N = 6 (30%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Renal dysfunction *</td>
<td>N = 0 (0%)</td>
<td>N = 1 (5%)</td>
<td>N = 3 (15%)</td>
<td>N = 1 (5%)</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Data are presented as percentage or mean ± standard deviation. BMI: body mass index; CPB: cardiopulmonary bypass; EF: ejection fraction.

* Creatinine >120 and <200 μmol/l.
compared to those undergoing on-CPB CABG (groups A and B), 184 ± 214 ml vs 382 ± 397 ml, respectively, \( P < 0.01 \).

There was a significant rise in prothrombin time (ratio) on the first postoperative day from preoperative levels (\( P < 0.0005 \)) in all groups with no statistical difference between groups (Fig. 3). At the fifth postoperative day the PT was still elevated compared to preoperative levels in all groups with no difference between groups.

The partial thromboplastin time (ratio) showed a significant increase on the first postoperative day in all patient groups (\( P < 0.001 \)) with no significant difference between groups (Fig. 4) and was still significantly raised on
ICU: intensive care unit; CVA: cerebrovascular accident; ARF: acute renal failure. Respiratory complications included chest infection, lung collapse and pneumothoraces. 

<table>
<thead>
<tr>
<th>Variable</th>
<th>On-CPB with CSBT (N = 20)</th>
<th>On-CPB without CSBT (N = 20)</th>
<th>Off-CPB with CSBT (N = 20)</th>
<th>Off-CPB without CSBT (N = 20)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation time (h)</td>
<td>9.25 ± 6.2</td>
<td>10.2 ± 5.2</td>
<td>9.4 ± 3.2</td>
<td>10.2 ± 3.6</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>ICU stay (h)</td>
<td>22.1 ± 9.2</td>
<td>23 ± 8.9</td>
<td>23 ± 8.4</td>
<td>21.7 ± 5.8</td>
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</tr>
<tr>
<td>Complications</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>N = 7 (35%)</td>
<td>N = 5 (25%)</td>
<td>N = 5 (25%)</td>
<td>N = 4 (20%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>N = 4 (20%)</td>
<td>N = 3 (15%)</td>
<td>N = 2 (10%)</td>
<td>N = 1 (5%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Renal</td>
<td>N = 2 (10%)</td>
<td>N = 1 (5%)</td>
<td>N = 1 (5%)</td>
<td>N = 0 (0%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>CVA</td>
<td>N = 0 (0%)</td>
<td>N = 1 (5%)</td>
<td>N = 1 (5%)</td>
<td>N = 0 (0%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>8.1 ± 2</td>
<td>8.3 ± 3.1</td>
<td>7.2 ± 2.3</td>
<td>7.4 ± 2.1</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Table 3: Postoperative outcomes

The strengths of the study were that it was able to look at both on- and off-pump patients undergoing CABG with and without the cell saver. The patient groups were well matched demographically and intraoperatively there was a high grafts per patient ratio with no discrepancy between the on- and off-pump groups. Postoperatively there was a low complication rate.

There was one death during the study in the on-CPB without cell saver group that was sudden on the pre-discharge day and attributed to an arrhythmia with no obvious cause of death found at post-mortem. The occurrence of postoperative complications was not significantly different between the groups (Table 3). Intubation time and CTICU stay were no significantly different between the groups but total hospital stay was significantly shorter in the off-pump groups compared to the on-pump group.

4. Discussion

In this study we investigated the effects of cell saver autologous blood transfusion on blood loss and homologous transfusion as well as trying to ascertain if autologous transfusion with the cell saver led to clotting derangements. To our knowledge this study is the first randomised trial to investigate the outcomes of intraoperative cell salvage in both on- and off-CPB CABG patients simultaneously.

The results demonstrate that patients undergoing CABG off-pump had significantly decreased homologous blood transfusion. There was a reduction in homologous transfusion in the cell saver blood transfusion group compared to the group that did not have intraoperative cell salvage and autotransfusion but this was not significant. In patients undergoing CABG on-CPB, use of intraoperative cell salvage and autotransfusion led to a significant reduction in homologous blood requirements in contrast to those patients who had their surgery with no intraoperative cell salvage and autotransfusion. The increase in homologous transfusion in the no cell salvage group was three-fold. The amount of homologous transfusion between the two cell saver groups was not significantly different.

Haemoglobin concentration fell significantly in all groups on the first postoperative day from preoperative values with no difference between groups. The coagulation markers increased significantly on the first postoperative day but revealed no difference between the groups.

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The efficacy of the cell saver in reducing homologous transfusion has been of some debate over the years. The disparity can be partly put down to differing transfusion protocols [1]. It has been noted that the indication for homologous transfusion has varied considerably in different trials with haemoglobin concentration for transfusion varying from 7.5 g/dl [17] to 10 g/dl [1,18].

Prospective studies looking at the efficacy of cell saver have been going on since the late seventies.

Cosgrove et al. [19] in 1978 looked at 50 consecutive patients undergoing CABG on-CPB. A cell saver was used to collect blood intra- and postoperatively as well as blood being removed from the patient preoperatively for later transfusion with normovolaemia anaemia being accepted in stable patients. They reported that 94% of patients received no bank blood products during their hospital stay, with no patients receiving homologous intraoperatively or during the first 24 h following surgery. They concluded that elective CABG could be performed without the need for homologous transfusion in the presence of intraoperative autologous blood collection and transfusion.

Winton et al. [20] in 1981 randomised forty patients undergoing routine cardiac surgery on-CPB to either receiving cell saver blood or not. They only collected shed mediastinal blood that was lost prior to heparinisation and following reversal with protamine sulphate. Their results showed that they only salvaged 105 ml per patient in the cell saver group and when taking into consideration the expense of the cell saver and its consumables that it was not cost-effective to use the device.

Kochamba et al. [21] combined an autotransfusion protocol with intraoperative haemodilution and found that this group of patients had 45% reduction in homologous transfusion and also a 28% reduction in chest tube drainage at 8 h post-surgery compared with a control group that had no autologous blood transfusion.

Dalrymple et al. [18] in 1999 randomised 112 on-CPB elective cardiac patients into cell saver and no cell saver groups. The trigger for homologous transfusion was an Hb concentration less than 10 g/dl. The number of patients requiring homologous transfusion (28 in the cell saver vs 46 in no cell saver group) and the total homologous blood

the fifth postoperative day but again there was no difference between groups.

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transfused (298 ± 49 vs 508 ± 49) was significantly less in the group where there was autologous transfusion using the cell saver.

The same group undertook another randomised trial of 166 patients in 2001 [1] this time looking at a third group which received cell saver blood as well as all blood processed from the cardiopulmonary circuit following separation from CPB. The transfusion trigger was once again 10 g/dl. The results showed that there was a significant reduction in homologous blood transfusion in the two cell saver groups compared to the no cell saver group but with no added benefit of using the blood from the CPB circuit.

Mcgill et al. [22] randomised patients undergoing elective CABG on-CPB into one of three groups: intraoperative cell salvage, intraoperative cell salvage with acute normovolaemic haemodilution and a group with no mechanical blood conservation. Patients were transfused if there haemoglobin concentration < 90 g/l. There was a significant reduction in the number of patients receiving homologous blood in the two cell saver groups: 26 out of 89 and 29 out of 88, respectively, as opposed to 43 out of 88 in the control group. The amount of homologous blood received was also significantly decreased. There was however no difference between the cell salvage groups.

Murphy et al. [23] randomised elective on-CPB CABG patients into those receiving intraoperative cell salvage and postoperative mediastinal fluid cell salvage with those receiving no autotransfusion. The transfusion trigger was haemoglobin concentration < 7 g/dl. There was significantly fewer patients receiving homologous transfusion in the cell salvage group with the amount of homologous transfusion being significantly lower in this group as well (0.43 ± 1.5 U vs 0.9 ± 2.0 U, P = 0.02 in the cell saver and no cell saver group, respectively).

In 2005, Murphy et al. [24] performed a randomised trial looking at the safety and efficacy of intraoperative cell salvage and autotransfusion in patients undergoing first time CABG off-CPB. The transfusion trigger was haemoglobin concentration below 8 g/dl. They reported that the cell saver group had a 20% reduction in numbers of patients requiring homologous transfusion but this was not significant. The 24-hour postoperative haemoglobin was significantly higher in the autotransfusion group (11.9 ± 1.41 g/dl vs 10.5 ± 137 g/dl, in the cell saver vs no cell saver groups, respectively).

In the last two papers clotting was assessed to see if there was a coagulopathy associated with autologous transfusion of cell-salvaged blood with a cell saver. No statistical difference was noted with respect of thromboelastograph values or laboratory measures of clotting pathway function (prothrombin time, activated partial thromboplastin time and fibrinogen levels).

With regard to the literature our study confirmed the positive effect of intraoperative cell salvage and autotransfusion in significantly reducing homologous transfusion in patients undergoing CABG on-CPB. We were also able to demonstrate and corroborate that off-pump surgery resulted in a significant reduction in homologous requirements independently of the cell saver use and that off-pump CABG without cell saver resulted in significantly less homologous blood compared to patients undergoing on-CPB CABG without cell saver. Our trigger for homologous transfusion was 8 g/dl which we believed to be the acceptable level, but in some of the papers reviewed this trigger was a much higher haemoglobin concentration.

The use of cell saver blood was not associated with any clotting derangement in our study which was in keeping with the more recent papers written on this matter.

Some papers report a significantly better haemoglobin concentration on the first postoperative day in the cell saver groups, but we were unable to confirm this when we compared postoperative levels with preoperative values and calculated the percentage change in haemoglobin concentration.

The limitations of our study were the lack of power for detection of clinical differences between groups. Furthermore our clotting analysis only involved standard laboratory tests without inclusion of parameters such as D-dimers or fibrinogen.

Further concerns regarding the cell saver such as its effects on systemic inflammatory response will be addressed in future trials that we are undertaking.

In conclusion we believe that autologous cell saver blood transfusion is safe and results in a significant reduction in homologous transfusion whilst not causing a clinically significant coagulopathy. The maximum reduction in homologous blood transfusion is achieved in combination with off-pump surgery. We strongly recommend the use of intraoperative cell salvage and autotransfusion in all forms of cardiac surgery.

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We would like to thank the British Heart Foundation (BHF) for their project grant which contributed to the funding of this work.

We are also grateful to the perfusion department for their assistance in conducting this trial.

Funding: British Heart Foundation for their project grant.

References


Dr M. Sousa Uva (Lisbon, Portugal): I appreciated your presentation very much, and I agree 100% with what you said.

I just wanted to have some comments from you regarding the problem of antiplatelet therapy. More and more of our patients have at least aspirin, and some of them dual therapy with clopidogrel, and I think this data would be even more statistically significant if you had included patients without interrupting antiplatelet therapy. I would like to have your comments on that.

Another thing, the percentage of transfused patients, you gave us the volume. I just wanted to have the percentage of transfused patients in each group.

I think another issue is, with the aim of reducing costs nowadays in surgery, I think with off-pump surgery we could even go a step further and say that we don’t use the cell-saver systematically and we use it only when the amount you recover in a sterile bag and if for instance the volume is above 500 ml, then you can concentrate and give that blood.

Dr Niranjan: I do agree with you regarding the use of antiplatelet drugs and not stopping them prior to surgery. When they are not operating this trial, we wanted to make everything as equal as possible, so that’s why we wanted all patients to have stopped all their antiplatelets 5 days preoperatively.

Your second question about the percentage of patients requiring transfusion, yes, I gave you volumes. In the off-pump group, the percentage is roughly 30%, but this was much higher in the on-pump group where we’re talking in between 50 and 60% of patients.

Regarding your comments on off-pump surgery and the use of the cell-saver, we found that between the two off-pump groups there wasn’t a clinical significance between those who used the cell-saver and those who did not use the cell-saver, but if there is any device we could use to prevent patients requiring homologous transfusion, then I think it’s favorable to use it, and there was a study done by Murphy et al., from the Bristol group this year and published in the JTCVS that said that even in off-pump surgery you should use the cell-saver.

Dr F. Sellke (Boston, Massachusetts, USA): I thought it curious that while there was no difference in blood loss between the groups, one of the groups, and I think it was one of the bypass groups, had more transfusion. How do you reconcile that? Was the preoperative hematocrit less in one of the groups?

Dr Niranjan: That group was actually the on-cardiopulmonary bypass group that did not have any autologous transfusion. We actually saw that those patients who had that surgery on cardiopulmonary bypass who had autologous blood transfusion had significantly reduced homologous transfusion requirements. The autologous hemoglobin and hematocrit were the same in all groups.

Dr Sellke: When you consider antiplatelet therapy, would aspirin be in that group?

Dr Niranjan: Yes, it would.

Dr Sellke: Because there is fairly credible evidence that patients who are on aspirin perioperatively have better outcomes.

Dr Niranjan: I’m not disputing that at all. I think for the purposes of this study, to assess actually the blood loss and the blood transfusion requirements, we wanted an even playing field.

Dr R. Stanbridge (London, UK): I think this study shows, like most of the studies before we have shown, that off-pump surgery does result in less blood transfusion, and it confirms that. In your group of off-pump surgery you didn’t have much difference between the two with the cell-saver and without. I would like to ask you whether you have routine intracoronary shunting during this procedure, because this can make quite a difference in the amount of blood loss shed in off-pump surgery, and whether there were any differences in the variability of people in one group and the other. Finally, I think the number of 20 is quite small to make any major comments about statistics.

Dr Niranjan: We don’t routinely use intracoronary shunting. Obviously it depends at the time of surgery if we feel we require other devices to help us, but it’s not a routine practice for the surgeon who does most of these procedures.

Regarding the number of patients, we weren’t trying to show statistical significance for clinical outcomes but for more laboratory-based data, and from previous studies done by some of the co-authors of this study, we found that 20 patients would give us significant data.