



# Cell Saver AAA Bypass



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## Abstract

**Objective:** Using the cell saver (CS) in all elective open repairs for abdominal aortic aneurysms (AAA) is not recommended. We sought to define the group of patients in whom the use of the CS would be most beneficial.

**Methods:** We retrospectively studied all patients undergoing elective open repair (OR) for AAA. Using data from the centre's clinical database, we analysed demographic and analytic variables, the anatomy and size of the aneurysm, and surgical and postoperative data. We separated patients into those who required transfusion of 0 or 1 blood unit and those who required 2 blood units or more. Secondary outcomes were risk factors for blood loss during surgery and surgical complications.

**Result:** Between March 2010 and February 2014, 105 patients (93.4% males) underwent OR for an AAA. Mean values for data collected included age of 71 years, body mass index (BMI) of 27.5 (95% CI:26.6-28.3), preoperative haemoglobin (Hb) of 13.9 g/dL (95% CI:13.5-14.2), and aneurysm diameter of 62.9 mm (95% CI:59.8-66.1). Thirty-nine patients (37.1%) required a transfusion of 2 or more blood units. Predictive factors for needing at least 2 BUs were BMI  $\geq$  27.5 (RR:1.96), a preoperative Hb  $\leq$  13mg/dL (RR:2.46) and an aneurysm size  $\geq$  66.5 mm (RR:3.89).

**Conclusion:** High BMI, low Hb and large aneurysms are risk factors of substantial blood loss during AAA surgery and allow us to select patients in whom the cell saver is more beneficial.

## Introduction

Abdominal aortic aneurysm (AAA) repair [1] is associated with cardiac morbidity, respiratory complications, and renal failure related to surgical bleeding. Blood loss during surgery can be replaced through homologous blood transfusion (HBT) or through auto transfusion using a cell saver (CS). However, it is not clear under which circumstances the use of the Cell Saver device is appropriate. The use of a CS device is therefore a question of surgeon's choice and availability of a CS device. The use of the CS has proven to be safer than HBT in preventing transfusion reactions such as systemic inflammatory response syndrome, transfusion infections and immune modulation [2]. However, several studies have shown that using the CS without clearly defined criteria may not result in any significant differences in clinical outcome [3-5]. Other studies have reported no benefits in occlusive disease and no reduction in HBT, recommending that the use of the CS device should be reserved for a selected group of patients undergoing aortic reconstructions.

The group of patients who would benefit most from the use of the CS when undergoing AAA surgery has not yet been defined. We aimed to determine in which patients the use of the CS should be recommended and to identify blood loss and transfusion needs risk factors and differences in clinical outcomes associated with substantial blood loss.

## Methods

### Study population

Data were retrospectively collected from a clinical database of patients undergoing elective surgery for AAA repair at a tertiary university hospital (Hospital de la Santa Creu i Sant Pau, Barcelona Spain). At our centre, patients undergo elective AAA surgery when they have aneurysms larger than 55mm in diameter or are rapidly growing (5mm in 6 months or 10mm in 1 year). Surgery is also performed for AAAs of less than 55mm if they are associated with iliac aneurysms of 30mm or more. We included patients with juxtarenal, pararenal and inflammatory aneurysms to evaluate the influence of these anatomic characteristics on a hypothetically increased risk of bleeding. Patients undergoing surgery for ruptured aneurysms and AAAs in the emergency surgical room were excluded. Elderly patients with a notably increased surgical risk were treated primarily with endovascular aneurysm repair (EVAR) when presenting a favourable infrarenal aortic neck.

The variables analysed were sex, age, smoking habits (active smoker, ex smoker or non-smoker), hypertension, diabetes mellitus, chronic renal failure (glomerular filtration rate below 60 mL/min/1.73m<sup>2</sup>) and antiplatelet treatment (usually with aspirin). We collected data concerning any previous abdominal

interventions, separating laparoscopic and minor ambulatory operations from major abdominal surgeries. We also examined whether the AAA were infrarenal, pararenal, juxtarenal or suprarenal, regardless of whether clamping was infrarenal or suprarenal. We checked the clinical data to see whether the AAA was associated with aorto-iliac occlusive disease or whether it was inflammatory. We also checked the leading surgeon who performed the surgery.

Preoperative and postoperative haemoglobin (Hb) levels (from blood analysis 24 hours after surgery) were recorded. We also noted creatinine and platelet levels from the preoperative blood analysis. The surgical data collected were the chosen surgical approach, the usage or not of the CS, the amount of blood loss (measured in mL), the volume of liquids administered and the total amount of transfusion (measured in mL). Transfusions could be from the CS or from BU (each of 250 mL approximately). We assessed the need for vaso active drugs for over 24 hours and recorded the following complications: hemodynamic instability that needed vasoactive drugs, myocardial ischemia (defined as compatible chest pain and electrocardiographic changes or enzyme elevation), acute respiratory distress syndrome (ARDS) (compatible clinic symptoms and requiring invasive ventilation), acute inferior limb ischemia (requiring urgent surgical intervention), acute renal failure with typical acute tubular necrosis signs, acute mesenteric ischemia (assumed by clinic and enzymatic changes) and surgical mortality (in the 30 days following from surgery).

### Angio-CT

Radiologic images were reviewed using the IMPAX 6.4 Agfa Healthcare N.V.®. We measured aneurysm diameter and neck diameter and length, and assessed the patency of collateral vessels of the abdominal aorta (inferior mesenteric artery, sacra media artery and at least two lumbar arteries). Co-existing iliac aneurysms were also recorded.

### Surgery

Patients underwent AAA repair under general anaesthesia. All patients received intravenous antibiotic prophylaxis with cephazolin 2g and were heparinized with 1mg/kg of weight before aortic cross-clamping. The XX ratio time was used for the monitoring the anticoagulation during surgery and the reversion of heparin at the end of it. We used three surgical approaches: 1) the retroperitoneal approach in AAA with a short infrarenal neck, in obese patients and in patients with previous medial laparotomy; 2) medial laparotomy in cases requiring an aortobifemoral bypass; and 3) minilap for small aneurysms with a wide infrarenal neck.

### Equipment

Shed blood was collected and processed using BRAT2, from Cobe Cardiovascular®, Inc., Arvada, CO. An experienced perfusionist supervised the BRAT2 system.

### Transfusion triggers

All patients received initially intra operative fluids support with crystalloids. Colloids were avoided because they may affect the acute-phase response. Heterologous blood transfusions were administered when the Hb concentration was lower than 8mg/dL, or when it was lower than 10 mg/dL in patients with ischaemic cardiomyopathy or hemodynamic instability, unless salvaged red cells were available. In the cases that the surgeon, previously to the operation, suspected substantial bleeding would occur during surgery, the CS have been prepared (which includes the assembling of the CS device and the participation of the CS dedicated nurse).

### Group selection

Patients were divided into two groups according to whether they received 0-1 BU or 2 or more BU. It is worth noting that numerous authors [6] suggest 2 or more BU as a sufficient transfusion threshold to justify the use of a CS during surgery.

### Statistical analysis

A descriptive statistical analysis was performed to determine summary statistics (mean or median for quantitative variables and frequencies for qualitative variables) and scattering (confidence interval of 95%). Analytical statistics using T-Student test and Chi-square were performed to assess quantitative and qualitative data, respectively. For each indicator, we obtained the risk for the need to transfuse two or more BU using a linear regression. We constructed ROC curves for each significant indicator. A multivariable logistic regression analysis was also conducted. Analysis was performed using SPSS 15.0 statistics package.

### Result

One hundred and five patients underwent OR for AAA between January 2010 and December 2013. Shows their demographic and clinical variables and shows qualitative variables. Two patients were excluded from the statistical analysis due to lack of reliable data. Statistical analysis was therefore performed in 103 patients. Transfusion of 2 or more BU was needed in 37.9% (39/103) of patients. Among the 62.1% (64/103) patients remaining, 84.4% (54/64 patients) did not receive a transfusion and 15.6% (10/64 patients) received one BU.

Preoperative risk factors for the need to receive 2 or more BU were body mass index (BMI) ( $p:0.009$ ), preoperative Hb ( $p:<0.001$ ), aneurysm diameter ( $p<0.001$ ), age, ( $p:0.02$ ) and serum creatinine ( $p:0.046$ ). We did not consider age and creatinine levels for further analysis because the differences observed were clinically insignificant. When substantial blood loss was suspected and the CS was therefore used, the use of the CS was not beneficial in 75% of the cases because the patient did not need more than one BU during surgery. However, in 41.8% of the cases in which the CS was not used, it would have been beneficial because these patients

required 2 or more BU during surgery. We found differences in the number of postoperative complications when comparing patients who needed transfusion of 2 or more BU with those who needed 0 or 1 BU the incidence of complications in both groups of patients.

The ROC curves obtained from the linear regression of each indicator for transfusing 2 or more BU during surgery. We obtained the risk for each factor from the multivariable logistic regression analysis. The risk of needing 2 or more BU was 27% for a preoperative Hb lower than 130 mg/dL (sensitivity: 53.8%, specificity: 81.2%), 64.1% for having a BMI higher than 27.5 (sensitivity: 64.1%, specificity: 62.5%), and 72.3% for having an aneurysm larger than 66.5 mm (sensitivity: 69.4%, specificity: 81.7%). The presence of all three factors together implied a risk for requiring 2 or more BU of 73.7%, while the absence of all three implied a risk of 0% (specificity 100%).

## 5. Discussion

Our findings suggest that a preoperative Hb below 130, a high BMI and a large aneurysm diameter define a group of patients who have a higher risk of requiring BU transfusion and in whom the use of the CS should be recommended when undergoing open AAA surgery. In a previous study, Julian et al. [7] also observed that preoperative Hb was a predictor of transfusion, but they did not mention a threshold value for Hb.

Many solid reasons have been given to support the use of CS in open AAA surgery. To begin with, Takagi et al. [4] found that the median blood requirements per patient were 2 units lower when using the CS and they reported a greater risk reduction of HBT (RR: 0,63). In addition, the blood recovered from the CS is functionally superior to that used in HBT [7]. In another study, Spark et al. [8] observed that the use of CS reduced both the hospital stay and the postoperative infection rates. It has also been shown that use of the CS can reduce haemolysis [9], the risk of systemic inflammatory response syndrome (SIRS), and the risk of chest infection due to the consequent immune suppression of HBT [2,10]. Gharehbaghian et al. [10] described another advantage of the use of the CS when suggesting that blood from the CS might contain natural killer cells, thus enhancing the immunologic response. In view of all these advantages, it is crucial to determine which patients have an increased risk of bleeding and improving clinical outcomes since some HBT complications could be avoided with the use of the CS. These benefits, however, are negligible in patients who do not present any substantial blood loss during open AAA repair [9,11,12]. Our results showed that the use of CS without any specific criteria was non-beneficial in 75% of the cases in which it was used, and that it could be beneficial in 48.1% of the cases in which it was not used. In other words, the mild clinical improve of transfusing the recovered blood from the CS in patients in whom without the mentioned criteria does not justify the use of the CS, neither its costs. On the other hand, in the 48.1% in which the CS was not used blood loss and subsequent complications could be minimized.

During preoperative AAA surgery patient care, the risk of requiring any transfusion during surgery can be reduced by raising Hb levels over 13mg/dL and promoting patient weight loss to lower BMI levels below 27.5. Since these measures are not always feasible, the Hb levels, the BMI and the AAA diameter should be considered as risk factors for OR of AAA. Thus, in those increased surgical risk patients, EVAR could be better justified. Costs related to blood transfusion during AAA repair are another important issue. In our region, using the CS has a cost of 178.95€ per intervention. According to the Tissue and Blood Bank at our center, each BU in our region costs 111.86€ [13]. Thus, to economically justify the use of the CS, a patient should require at least 2 BU during the intervention. A similar comparison of costs has been made by other authors. Reddy et al. [14] & Tawes RL et al. [9] calculated that the costs of auto transfusion at their institution were retrieved when 2 BU were Salvaged et al. [15] estimated a break-even point at 2.7 units.

Our work has three main limitations, the first of which was its retrospective nature. Second, we could not clearly distinguish the functional differences between BU from HBT and BU from the CS because we counted both as BU, but this was not related to the main aim of the study. The last limitation to be considered is about the fact that the preoperative use of the cell saver was dictated by the surgeon's impression that there may be substantial blood loss. Further prospective study should be checking the validation of the criteria for use of the CS and considering its cost-efficacy.

## Conclusion

Preoperative Hb, BMI and the size of the aneurysm in patients undergoing elective AAA repair can help us determine those with a higher risk of blood loss during surgery. These indicators may identify patients with a higher risk of bleeding-related complications and help to optimize the use of the CS.

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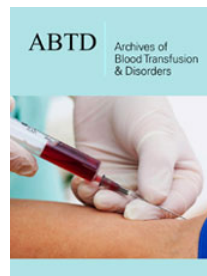
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