Post-operative blood salvage with autologous retransfusion in primary total hip replacement

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Clinical, haematological or economic benefits of post-operative blood salvage with autologous blood re-transfusion have yet to be clearly demonstrated for primary total hip replacement. We performed a prospective randomised study to analyse differences in post-operative haemoglobin levels and homologous blood requirements in two groups of patients undergoing primary total hip replacement.

A series of 158 patients was studied. In one group two vacuum drains were used and in the other the ABTrans autologous retransfusion system. A total of 58 patients (76%) in the re-transfusion group received autologous blood. There was no significant difference in the mean post-operative haemoglobin levels in the two groups. There were, however, significantly fewer patients with post-operative haemoglobin values less than 9.0 g/dl and significantly fewer patients who required transfusion of homologous blood in the re-transfusion group. There was also a small overall cost saving in this group.

There were approximately 45 000 primary total hip replacements (THRs) undertaken in NHS Trusts in England and Wales in 2004. The rate of homologous blood transfusion after primary THR can be as high as 30% to 40%, with the mean volume of transfused blood being 1.5 units per case. Pre-operative haemoglobin (Hb) levels below 13.0 g/dl, 12.0 g/dl, and 11.0 g/dl have been shown to increase the use of homologous blood transfusion. Other factors include age of over 75 years, body mass index (BMI) greater than 27 kg/m², male gender and hypertension, especially if more than two of these coexist.

Homologous blood transfusion is not without risk. Although standards have improved, complications from administrative error, bacterial contamination, immunosuppression and possible viral contamination remain. The greatest risk of death is clerical error, and estimates of mortality from bacterial contamination of platelet components range between one in 20 000 and one in 85 000. Risks of viral contamination per unit of blood transfused vary with the country concerned, with reports from the USA of one in 2 135 000 for human immunodeficiency virus, one in 1 935 000 for hepatitis C virus, one in 205 000 for hepatitis B virus and one in 2 993 000 for human T-lymphocyte viruses. Also, there are increasing reports of other transfusion-related conditions, such as acute lung injury.

Various techniques have been developed to minimise the need for homologous blood transfusion, including pre-operative donation, intra-operative salvage and post-operative salvage. Pre-operative donation can present logistical problems, can be time-consuming, and is not always cost-effective. Wastage of donated blood can be as high as 45%. Some studies conclude that pre-operative donation is not indicated in non-anaemic patients, not cost-effective, and may increase the likelihood of autologous transfusion without lowering the risk of homologous blood transfusion.

Intra-operative salvage has only been shown to be effective in patients where pre-donated blood is unavailable or when excessive blood loss is expected, and is not routinely recommended in simple primary THR. However, this technique is useful in complex revision cases or when major blood loss is anticipated.

Although post-operative salvage is a safe technique with relatively few reported complications, its value in THR is controversial. Previous studies have included patients who had pre-donated blood and in whom autologous blood was salvaged either intra- or post-operatively. Some showed that patients receiving post-operative salvage have a lower incidence of homologous blood transfusion and...
higher post-operative Hb levels. Others question the clinical and economic benefit of post-operative salvage in primary THR. Another conclusion that although the risk of homologous blood transfusion is reduced in revision arthroplasty and in patients who have not pre-donated blood, there is no benefit in those primary THR patients able to pre-donate their blood. The introduction of minimal-incision techniques has been shown to reduce intra-operative loss of blood, but the rate of post-operative transfusion is not significantly reduced when compared to conventional surgery. From these studies it is difficult to determine whether post-operative salvage is beneficial for primary THR patients. Indeed, it is suggested that drains are unnecessary in such cases, with one prospective randomised study quoting the rate of homologous blood transfusion as 33% in patients with drains and 26.4% in those without. In our unit, pre-donation is not available and intra-operative salvage not implemented. We have used the ABTrans autologous retransfusion system (Surgical Innovations Ltd, Leeds, United Kingdom) for primary and revision hip and knee replacements since January 2000. A recent audit examined our use of this system in primary THR and showed a significant reduction in homologous blood transfusion as well as a reduced fall in the post-operative Hb value. The higher costs of the retransfusion system were offset by savings in homologous transfusion expense.

We undertook a randomised prospective study to determine whether post-operative salvage provides any clinical, haematological or economic benefit in primary THR. The aim was to determine whether post-operative salvage affects post-operative Hb values and reduces the need for homologous blood transfusion.

Patients and Methods

The study was approved by the local research ethics committee and was designed to compare two groups of patients undergoing primary THR with different types of drainage system. It was determined that 72 patients would be required in each group to detect a significant difference of 0.7 g/dl in post-operative Hb level (80% power, α value of 0.05) assuming a standard deviation (SD) of 1.5 g/dl obtained from the previous retrospective audit. A target of 190 participants was chosen to allow for patient loss during the study period.

Between December 2003 and December 2005, 190 consecutive patients undergoing elective primary THR for arthritis at Weston General Hospital were enrolled. Exclusion criteria included a history of coagulation disorder or unusual antibodies detected pre-operatively.

At pre-operative assessment, participants were instructed to discontinue aspirin and anti-inflammatory medication from ten days before surgery. Pre-operative Hb and haematocrit values were recorded. Six orthopaedic consultants and one orthopaedic specialist (including VGL) performed the operations. Some patients were given a pre-operative dose of 3500 units of tinzaparin (low molecular weight heparin) according to anaesthetic instructions but most received it on the evening of surgery. A dose of 1.5 g of cefuroxime was given routinely at induction and a lateral approach used by all but one surgeon, who used a posterior approach. The cemented prostheses comprised a V40 Exeter stem (Stryker Howmedica UK, Newbury, United Kingdom) and a Senator cup (Corin Medical, Cirencester, United Kingdom). The hybrid prostheses combined a cemented Exeter stem or CPS-PLUS stem (Plus Orthopedics, Swindon, United Kingdom) with an uncemented EP-FIT PLUS cup (Plus Orthopedics). The uncemented prostheses combined an EP-FIT PLUS cup with an SL-PLUS stem (Plus Orthopedics).

The patients were block randomised (computer generated) to one of two groups from sealed envelopes opened by a nurse after reduction of the prosthesis. Group A received two size 12 Medinorm vacuum drains (Van Straten, Querchied, Germany) and group B an ABTrans autologous retransfusion system. All drains have an external diameter of 4 mm and were inserted during closure of the wound deep to the tensor fascia lata. The autologous closed circuit system includes two drains with a Y connector and a 125 µm filter through which the blood passes before entering the 1200 ml reservoir. The pressure in the collection reservoir was 20 kPa in the Medinorm drain and 13 kPa in the ABTrans system.

Autologous retransfusion was given at four-hourly intervals from the opening of the drain, or when 400 ml had collected in the reservoir. The maximum time between collection and completion of each transfusion was six hours. The system was used for 24 hours or up to a total of 1600 ml. The protocol was derived from the manufacturer’s recommendations which were constructed according to American Association of Blood Banks guidelines. The Medinorm vacuum drains (Van Straten) were removed 48 hours after surgery.

The two groups were given identical routine post-operative care, which included two further doses of cefuroxime (750 mg) at eight-hour intervals and anti-embolism stockings. All were assisted to stand on the first post-operative day, and progressed to walking with a frame on the second day.

The individual orthopaedic team decided whether to give homologous blood transfusion. Local practice was to give two units if the post-operative Hb was less than 8.0 g/dl or if patients were symptomatic with Hb in the range of 8.0 g/dl to 10.0 g/dl. All were monitored for transfusion reactions, post-operative pyrexia, and wound or other complications. Post-operatively, the Hb and haematocrit values and the number of homologous units required were recorded. The effect of performance bias on the decision to transfuse (as a result of loss of blinding post-operatively) was analysed statistically.

The patients attended for follow-up at six to eight weeks; Hb and haematocrit values were recorded and the patients...
completed a questionnaire on satisfaction with the outcome, which was qualified by a questionnaire rating vigour. The costs of the drains and blood-giving sets were obtained from the hospital supplies department, and the hospital liaison nurse from the National Blood Service supplied the cost of a unit of packed red blood cells. Statistical analysis was performed using the Statistical Package for Social Sciences version 11 (SPSS Inc., Chicago, Illinois). The Mann-Whitney U test (non-parametric data) was used for the comparison of univariate means and the chi-squared test for comparison of categorical variables.

Results
From the 190 patients who agreed to participate, 158 sets of complete data were obtained. There were 22 incomplete Hb values, and ten patients did not fulfil the inclusion criteria.

There were 82 patients in group A and 76 in group B. Their demographics, the American Society of Anesthesiologists (ASA) grades, types of anaesthetic and prostheses are shown in Table I. The mean duration of the operation was the same for both groups at 1.6 hours (0.75 to 3.0). Pre-operative chemical prophylaxis for deep-vein thrombosis (DVT) was given to 17 patients (21%) in group A and 14 (18%) in group B. There was no association between pre-operative administration of tinzaparin and post-operative Hb value or requirement for homologous transfusion. Post-operative pyrexia was recorded in 29 patients (35%) in group A and 25 patients (33%) in group B. There was no statistically significant difference between the groups for length of stay. The mean for group A was 6.98 days (4 to 17) and the mean for group B was 6.40 days (4 to 11). The mean time to follow-up assessment was seven weeks (4 to 12).

Wound complications were recorded in five patients (6%) in group A and in 3 (4%) from group B (not significant). They included two possible superficial wound infections in each group, two haematomas in group A, one in group B, and one washout for possible infection three weeks post-operatively in group A, with no long-term sequelae to date.

### Table I. Patient demographics, American Society of Anesthesiologists (ASA) grade, anaesthetic type and type of prosthesis

<table>
<thead>
<tr>
<th></th>
<th>Group A (vacuum drain) (n = 82)</th>
<th>Group B (post-operative salvage) (n = 76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male:female</td>
<td>40:42</td>
<td>36:40</td>
</tr>
<tr>
<td>Age (years) mean (range)</td>
<td>75.5 (46 to 91)</td>
<td>73.5 (52 to 87)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (range)</td>
<td>27 (17 to 36)</td>
<td>29 (17 to 51)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>82</td>
<td>75</td>
</tr>
<tr>
<td>Orientation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right:left</td>
<td>43:39</td>
<td>46:30</td>
</tr>
<tr>
<td>ASA grade (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>13 (16)</td>
<td>16 (21)</td>
</tr>
<tr>
<td>II</td>
<td>61 (74)</td>
<td>50 (66)</td>
</tr>
<tr>
<td>III</td>
<td>8 (10)</td>
<td>9 (12)</td>
</tr>
<tr>
<td>IV</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Type of anaesthetic (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>9 (11)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Spinal</td>
<td>72 (88)</td>
<td>71 (89)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>Prosthesis (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cemented</td>
<td>43 (52)</td>
<td>33 (43)</td>
</tr>
<tr>
<td>Hybrid</td>
<td>32 (39)</td>
<td>41 (54)</td>
</tr>
<tr>
<td>Uncemented</td>
<td>7 (9)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

### Table II. Pre-operative, post-operative and follow-up haemoglobin and haematocrit values (mean values and range)

<table>
<thead>
<tr>
<th></th>
<th>Group A (vacuum drain) (n = 82)</th>
<th>Group B (post-operative salvage) (n = 76)</th>
<th>Mann-Whitney U test (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin (g/dl)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>13.59 (10.3 to 16.5)</td>
<td>13.61 (9.3 to 17.1)</td>
<td>0.859</td>
</tr>
<tr>
<td>Post-operative</td>
<td>10.61 (7.0 to 15.5)</td>
<td>10.77 (7.3 to 13.9)</td>
<td>0.324</td>
</tr>
<tr>
<td>Follow-up Hb</td>
<td>12.71 (9.9 to 15.6)</td>
<td>12.58 (9.9 to 16.4)</td>
<td>0.375</td>
</tr>
<tr>
<td>Haematocrit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>0.400 (0.290 to 0.540)</td>
<td>0.401 (0.270 to 0.500)</td>
<td>0.712</td>
</tr>
<tr>
<td>Post-operative</td>
<td>0.311 (0.210 to 0.440)</td>
<td>0.314 (0.210 to 0.400)</td>
<td>0.434</td>
</tr>
<tr>
<td>Follow-up Hct</td>
<td>0.378 (0.300 to 0.470)</td>
<td>0.374 (0.300 to 0.480)</td>
<td>0.430</td>
</tr>
</tbody>
</table>
The Hb and hematocrit values are shown in Table II. There were no significant differences between the groups in the mean values of pre-operative, immediate post-operative and follow-up Hb and hematocrit levels. However, 16 patients (20%) in group A had a post-operative Hb level below 9.0 g/dl, compared to six patients (8%) in group B (chi-squared test, \( p = 0.035 \)).

The volume of fluid collected post-operatively, the volume of blood re-transfused and number of units of homologous blood required are shown in Table III. Statistical analysis of the proportion of patients in each group who received homologous blood showed that group A was more strongly associated with the use of homologous blood than group B (chi-squared test, \( p = 0.182 \) for prosthesis type; \( p = 0.077 \) for BMI).

There were ten patients (6.3%) older than 75 years (six group A, four group B) with pre-operative Hb less than 13.0 g/dl. This subgroup was not associated with a greater use of homologous blood (chi-squared test, \( p = 0.899 \)). There was no association of increased need for homologous blood with type of prosthesis or BMI (chi-squared test, \( p = 0.182 \) for prosthesis type; \( p = 0.077 \) for BMI).

Patient satisfaction was recorded on a Likert scale of 1 to 5, least to most satisfied. The median (5, 1 to 5) was the same for both groups. Similarly, patient vigour was recorded on a Likert scale of 1 to 5, least to most tired, and both groups had a median of 2 (1 to 5).

The final analysis was to compare the cost to the hospital per patient. As there was no difference in the length of stay between the groups and all other parameters were comparable, the only factors to be considered were the costs of the drains and red cells transfused. These results are shown in Table IV.

### Discussion

In this study, the groups were comparable and there were no significant differences between them in pre-operative status, operative details, clinical outcomes, patient satisfaction or length of hospital stay. Post-operative salvage was not associated with an increased risk of early complications. The association between homologous blood transfusion and infection is controversial. Some studies report an increased infection risk following homologous transfusion, and this is reduced if autologous transfusion is used. Long-term follow-up of our cases will continue to determine whether this is the case.

In the post-operative salvage group, 58 patients (76%) were re-transfused a mean blood volume of 252 ml (0 to 800); blood was discarded in 18 (24%) of this group because of insufficient volume. This is comparable with other studies which reported mean re-transfusion volumes of 264 ml and positive re-transfusion rates of 75.6%.

There were no differences in Hb or hematocrit levels between the two groups throughout the study period. Other studies, which included patients for whom pre-operative donation and intra-operative salvage were
available, concluded that post-operative salvage had no haematological benefit. However, we found a significantly higher percentage of patients in the vacuum drain group whose post-operative Hb fell to 0.9 g/dl or less (20% compared to 8%). The significance or clinical relevance of this difference is unknown, as no obvious pre-operative or operative predisposing factors were identified. Statistical analysis did not demonstrate any association of homologous transfusion with advanced age (> 75 years) or pre-operative Hb below 13.0 g/dl, factors that have been shown to increase the likelihood of homologous transfusion. This may be a result of the relatively small number of patients in this group (10 of 158, 6.3%).

The most important finding in our study was a significant reduction in the number of patients requiring homologous transfusion in the post-operative salvage group. A total of 17 patients (21%) with vacuum drains required homologous transfusion, compared to six (8%) in those where post-operative salvage was available. Comparison with other studies is difficult because some included primary and revision cases as well as patients for whom pre-operative donation or intra-operative salvage was available. A reduction in homologous transfusion has been reported in primary arthroplasty when post-operative salvage is used. Nevertheless, other studies have indicated that post-operative salvage does not result in significant haematological, transfusion or clinical benefit in uncomplicated primary THR. The inclusion of a group in which no drain was used may have provided additional information, although figures from one study showed a higher rate of homologous transfusion for patients with no drains (26.4%) than our rates of homologous transfusion, compared to six (8%) in those with a vacuum drain and 8% in those with an autologous system.

The analysis of cost concluded that the use of vacuum drains alone was associated with a cost increase of 8% compared to post-operative salvage. This is calculated on the basis of cost per unit of packed red blood cells during surgery. Although the current price of a unit of blood is not anticipated to change, future costing may have to include additional screening tests. In our hospital, there has been a requirement to reduce the use of blood by 10%. Both these considerations favour the continued use of autologous retransfusion systems on economic grounds.

There are weaknesses in our study, which ideally should have included a group where no drainage was used, but we felt that such a group would be difficult to ‘blind’. No attempt was made to calculate the intra-operative loss of blood. Although we are aware of techniques to calculate this, it was felt that consistent and accurate intra-operative data could not be guaranteed. The size of the study sample was determined principally to test the hypothesis that post-operative salvage reduces the necessity for homologous blood transfusion in THR. As a result, the groups were too small to subdivide for the purpose of analysing smaller variables with statistical accuracy.

This study confirms that post-operative salvage significantly reduces the necessity for homologous blood transfusion in primary THR in a small, busy district general hospital. We found the ABTrans autologous re-transfusion system easy to use, safe and cost-effective. The only obvious clinical or haematological benefit was that the post-operative Hb was less likely to drop below 9.0 g/dl. As a result, our unit uses autologous re-transfusion for all primary THRs.

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References


