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Favourable results of a new intraoperative and postoperative filtered autologous blood re-transfusion system in total hip arthroplasty: a randomised controlled trial

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Abstract

Purpose A new intraoperative filtered salvaged blood re-transfusion system has been developed for primary total hip arthroplasty (THA) that filters and re-transfuses the blood that is lost during THA. This system is intended to increase postoperative haemoglobin (Hb) levels, reduce perioperative net blood loss and reduce the need for allogeneic transfusions. It supposedly does not have the disadvantages of intraoperative cell-washing/separating re-transfusion systems, such as extensive procedure, high costs and need for specialised personnel. To re-transfuse as much as blood as possible, postoperatively drained blood was also re-transfused.

Methods A randomised, controlled, blinded, single-centre trial was conducted in which 118 THA patients were randomised to an intraoperative autologous blood re-transfusion (ABT) filter system combined with a postoperative ABT filter unit or high-vacuum closed-suction drainage.

Results On average, 577 ml of blood was re-transfused in the ABT group: 323 ml collected intraoperatively and 254 ml collected postoperatively. Hb level was higher in the ABT vs the high-vacuum drainage group: 11.4 vs. 10.8 g/dl, $p = 0.02$ on day one (primary endpoint) and 11.0 vs. 10.4 g/dl, $p = 0.007$ on day three. Total blood loss was less in the autotransfusion group: 1472 vs. 1678 ml, $p = 0.03$. Allogeneic transfusions were needed in 3.6 % of patients in the ABT group and 6.5 % in the drainage group, $p = 0.68$.

Conclusion The use of a new intraoperative ABT filter system combined with a postoperative ABT unit resulted in higher postoperative Hb levels and less total blood loss compared with a high-vacuum drain following THA.

Introduction

Total hip arthroplasty (THA) is associated with a mean total blood loss of 1,500 ml and a postoperative decline in haemoglobin (Hb) levels of 3.0 g/dl [1]. It is important in THA to reduce perioperative net blood loss, to maintain higher postoperative Hb levels and to avoid the use of allogeneic blood transfusions as much as possible [2, 3]. One measure by which to try to achieve these goals is to implement autologous re-transfusion of blood lost during and after surgery. An advantage of intra- and postoperative autologous blood re-transfusion (ABT) is the good quality and direct contribution of the re-transfused red blood cells to oxygen transport and consumption and reduction of allogeneic blood transfusion requirement [4–9]. Postoperative ABT filter systems for re-transfusion of filtered drained blood are often used in primary THA. However, intraoperative cell-saver devices currently used in revision hip surgery are not used in primary THA because it is an extensive procedure with high costs. With these cell-saver devices, the blood is filtered and consecutively washed, the different cell types are separated and

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the red blood cells are subsequently re-transfused. Consequently, the 500 ml of blood, and thus suitable red blood cells that are directly available for autotransfusion, is lost during THA [4, 6–9]. Therefore, a new system has been developed for use during primary THA that filters the intraoperatively collected blood in the same manner as commonly used for postoperative blood loss. Subsequently, intraoperative filtered blood can be re-transfused. This system is intended to increase postoperative Hb levels, reduce the need for allogeneic blood transfusions and be less expensive and easier to handle than intraoperative cell-washing/separating devices and therefore suitable for general use in primary THA.

Combined intra- and postoperative re-transfusion delivers the maximum re-transfusion of autologous red blood cells lost during THA. We therefore conducted a prospective randomised controlled trial to evaluate the effects of this new intraoperative autologous filtered salvaged blood re-transfusion system combined with a postoperative ABT filter unit and compare it with a closed-suction high-vacuum drainage system following primary THA.

Materials and methods

This is an open, double-blind, randomised controlled single-centre study. Approval of our institutional medical ethics committee was obtained for this study in which 118 patients scheduled for primary THA were randomised to either the intraoperative and postoperative autologous transfusion group (Sangvia, intraoperative and postoperative autologous blood-salvage unit, low vacuum, 100–150 mmHg, Astratech, Mölndal, Sweden) or to the high-vacuum closed-suction drainage group (Redon, Medinorm AG, Quierschied, Germany). In the ABT, intraoperatively suctioned blood and postoperatively drained blood was re-transfused after filtering through 200-, 80- and 40-µm filters consecutively. Patients were enrolled based on the following inclusion criteria: provision of written informed consent and undergoing primary THA. Exclusion criteria were coagulation disorders, including deep venous thrombosis and pulmonary embolism; malignancy; ongoing infections; untreated hypertension; unstable angina pectoris; myocardial infarction within the past 12 months; coronary bypass surgery within the past 12 months; renal dysfunction; anticoagulant intake or participation in other clinical trials dealing with any drugs that affect blood loss.

Formal randomisation and concealed allocation took place prior to the operation. Sealed and numbered opaque envelopes containing pre-randomised cards to either the autologous transfusion group or the drainage group were available in the operating room. Intraoperatively lost blood was suctioned and collected for all 118 patients. The surgeons were blinded to group allocation until the end of surgery, just before wound closure, at which time the envelope was opened and the patient's allocation group was disclosed.

In the ABT group, blood collected during the operation was subsequently re-transfused, and a drain with a postoperative re-transfusion unit was inserted. Postoperatively drained blood was re-transfused within six hours of surgery. A closed-suction high-vacuum drain was inserted in the control (drain) group; intraoperatively suctioned blood was not re-transfused in this group. In both groups, the drains were removed 24 hours postoperatively.

All patients were operated at Isala Clinics, Zwolle, The Netherlands. Cemented hip prostheses (SP-2 stem, Fal cup, Link, Hamburg, Germany), uncemented prostheses [Bimetric stem, Recap cup, Biomet, Warsaw (IN), USA] and hybrid prostheses of these components were used in the study. Surgeons used either the posterolateral or anterolateral approach.

Measurements were taken when patients attended the clinic preoperatively, during hospital stay and six weeks and three months postoperatively. The primary endpoint of this study was Hb level on the first postoperative day. Secondary endpoints were Hb levels on the second and third postoperative days, the lowest postoperative Hb level, blood loss during surgery, volume of intraoperatively suctioned and re-transfused blood, volume of re-transfused drained wound blood, allogeneic blood transfusions, postoperative pain, hospital stay, adverse events and total blood loss. Total blood loss was calculated according to Gross based on the maximum perioperative decrease in Hb level and the patient's preoperative blood volume: blood loss=preoperative blood volume x (Hb preoperative – Hb lowest)/Hb average. Preoperative blood volume was calculated as 65 ml/kg. Hb average is average of preoperative Hb level and lowest postoperative Hb level [10].

Operation time, surgical approach, type of anaesthesia and patient's temperature at the end of surgery were assessed because of their potential effects on blood loss. Creatinine levels and estimated glomerular filtration rate (eGFR) according to the Modification of Diet in Renal Disease (MDRD) formula were recorded because of the possible negative effect on kidney function of free Hb in high concentrations. A preoperative creatinine level greater than 125 µmol/L was the exclusion criterion for renal dysfunction. Pain at rest and during exercise was scored on a visual analogue scale (VAS). Adverse events were registered during hospital stay and the first three months postoperatively. The physicians who performed postoperative examinations at the outpatient clinic were blinded to group allocation. A standardised blood management protocol was implemented for this study, as follows:

- Venous thromboembolism prophylaxis was carried out using fondaparinux (Arixtra®, 2.5 mg/0.5 ml) subcutaneously once daily. The first dose was administered on the evening of the day of surgery and was continued for five weeks.

- Administration of nonselective nonsteroidal anti-inflammatory drugs (NSAID)s was stopped one day before surgery. The COX-2-selective NSAID meloxicam 15 mg once daily was used in all patients.
- Additional allogeneic blood transfusions were given based on the Dutch allogeneic blood transfusion guidelines [11]. The trigger for allogeneic transfusions was an Hb level of 6.4 g/dl in patients with American Society of Anaesthesiologists (ASA) physical classification 1, 8.0 g/dl in ASA classifications 2 and 3, and 9.6 g/dl in ASA classification 4, as well as in those whose cardiac output failed to increase to compensate for dilution [11].

Statistical analysis

Based on a clinically relevant difference in Hb level on the first postoperative day of 0.8 g/dl [10.2 g/dl vs. 11.0 g/dl, standard deviation (SD)] 1.4 [12], alpha of 0.05 and power of 80.8 %, a sample size of 115 patients (50 per group plus 15 %) was required for this study. Study data were collected using customised case report forms and entered into a computerised database that allowed unbiased and reliable data management. Categorical data were expressed as percentages. Continuous data were expressed as means and SD. Based on an intention-to-treat analysis, differences were analysed using chi-squared tests for categorical data and Student's t tests for continuous data. The Levene test was used to check for test assumptions. A two-sided $p < 0.05$ was considered statistically significant.

Results

Patients were operated upon between August 2008 and May 2009. The study had an enrolment of 118 patients: 56 in the ABT group and 62 in the drain group without re-transfusion. The groups were statistically homogeneous with respect to gender, age, body mass index, medical history, Charnley osteoarthritis classification and indication for operation (Table 1). With the exception of operation time, which was six minutes longer in the drain group ($p = 0.04$), there were no significant differences between groups regarding anaesthetic or surgical parameters that could affect blood loss, such as type of anaesthesia, body temperature, surgeon, surgical approach or prosthetic fixation.

Perioperative blood loss, autologous transfusion, Hb levels

Total intraoperatively suctioned blood loss was similar in both groups: 537 ml in the ABT group and 555 ml in the drain group (Table 1). Of this blood loss, approximately 415 ml was collected with the re-transfusion suction unit and approximately 130 ml with a different suction unit. On average, 323 ml of the 415 ml intraoperatively collected blood in the ABT group was re-transfused. In one patient in the ABT group, intraoperatively collected blood was not re-transfused. In the ABT group, on average, 254 ml of postoperatively drained blood was re-transfused within six hours of surgery and was re-transfused in 46 patients (82 %). In eight patients, only a small volume of wound blood was collected, which was not sufficient to be re-transfused. In two patients, a technical failure of the system occurred. In the ATB group, a mean of 577 ml of intraoperatively and postoperatively lost blood was re-transfused. The

Table 1 Patient characteristics, surgical factors affecting blood loss, perioperative blood loss and re-transfusion

Characteristics	ABT group ($n=56$)	Drain group ($n=62$)
Mean age, years	67.6 (9.1)	69.3 (9.5)
Sex, F/M	36/20	42/20
BMI, kg/m^2	27.8 (4.4)	28.1 (4.4)
Charnley class A/B/C	40/11/5	38/11/13
Primary osteoarthritis/post-traumatic/osteonecrosis	53/1/2	61/0/1
Surgery		
Anaesthesia, spinal/general	38/18	47/15
Body temperature at end of operation, °C	36.2 (0.5)	36.0 (0.6)
Consultant orthopaedic surgeon/trainee	40/16	42/20
Approach, posterolateral/anterolateral	37/19	47/15
THA cemented/uncemented/hybrid	31/23/2	38/22/2
Operation time, min	63 (16)	69 (16)*
Perioperative blood loss and re-transfusion		
Total intraoperative suctioned blood loss, ml	537 (191)	555 (244)
Re-transfusion intraoperative blood loss	323 (150)	-
Re-transfusion postoperative collected drained blood<6 h	254 (198)	-
Total re-transfused blood loss	577 (261)	-

ABT autologous blood re-transfusion, *Drain* high-vacuum closed-suction drainage

Means (standard deviation), observed frequency distribution not significantly different, except *$p=0.04$

maximum re-transfusion of intraoperatively collected blood was 850 ml, the maximum re-transfusion of postoperatively collected blood was 960 ml and the maximum total re-transfused blood in a patient was 1,260 ml.

The Hb level on the first postoperative day, primary end-point of the study, was significantly higher in the ABT than in the drain group, as it was also on the third postoperative day (Table 2). The mean lowest postoperative Hb level was also significantly different. The decline in Hb level from preoperatively to the first and third postoperative days was also less in the ABT group, i.e. −2.8±0.9 vs. −3.3±0.9 (p =0.007) and −3.2±1.2 vs. −3.7±1.1 (p =0.01). Allogeneic blood transfusions were needed in 3.6 % (two patients) in the ABT group and 6.5 % (four patients) in the drain group (p =0.68.) In the ABT group, the four allogeneic transfusions were given on the second postoperative day. In the drain group, seven allogeneic transfusions were given in three patients postoperatively on the day of surgery, and two were given in one patient on the second postoperative day. Total blood loss was less in the ABT group compared with the drain group (Table 2).

Pain scores, hospital stay

Pain scores were similar for both groups preoperatively, during hospital stay, and six weeks and three months postoperatively (Table 2). Length of hospital stay was also similar in both groups: 4.5±1.2 days in the ABT group and 4.3±1.0 days in the drain group, p =0.48. Most patients were discharged on a predetermined discharge date.

Adverse events

Adverse events during hospital stay and afterwards up to three months postoperatively were similar between groups (Table 3). One patient with a preoperative high creatinine level, 164 µmol/L, was included. Moreover, 17 patients with suboptimal GFR, MDRD <60, were included: six in the ABT group and 11 in the drain group. No statistically significant differences were noted in creatinine levels, or GFR MDRD preoperatively or during hospital stay.

Discussion

In this study, the use of a new intraoperative ABT filter system combined with a postoperative ABT filter unit resulted in higher Hb levels on both the first (primary endpoint) and third postoperative days and in less total blood loss compared with the commonly used high-vacuum drainage system following primary THA. Higher pre- and postoperative Hb levels are correlated with better early functional recovery, higher patient satisfaction and shorter hospital stay following THA [2, 3]—although not substantiated in every study [13]—and with a reduced allogeneic blood transfusion rate [2, 3, 13, 14]. Allogeneic blood transfusions are related with poorer outcomes following THA, such as a higher postoperative infection rate, delayed wound healing and prolonged hospital stay. An advantage of autologous re-transfusion is the direct contribution of the re-transfused red blood cells to oxygen consumption in the patient [4, 6–9]. This is in contrast to red blood cells in allogeneic transfusions from a blood bank in which optimal contribution to oxygen consumption may take several hours because of so-called storage lesions [15, 16] .

Many surgeons prefer to use a drain following THA to reduce the risk of haematoma. In THA, the use of a postoperative ABT system only significantly reduced allogeneic blood transfusions in one study when compared with a closed-suction drainage system, but this was not so in another study,

Table 2 Perioperative haemoglobin levels, net total blood loss and visual analogue scale (VAS) pain scores

	ABT	Drain	P valuemm
Hemoglobin level (g/dl)			
Day −1	14.2 (1.3)	14.1 (0.9)	0.66
Day 1	11.4 (1.4)	10.8 (1.2)	0.02
Day 2	11.1 (1.4)	10.7 (1.2)	0.07
Day 3	11.0 (1.2)	10.4 (1.2)	0.007
Lowest	10.7 (1.4)	10.1 (1.2)	0.02
Total blood loss (ml)	1472 (531)	1678 (503)	0.03
Pain (VAS)			
Preoperative rest/exercise	3.7 (2.8)/6.4 (2.2)	3.8 (2.4)/6.7 (2.1)	ns
Day 1 postoperatively rest/exercise	3.1 (2.2)/5.0 (2.2)	2.9 (1.8)/4.8 (2.2)	ns
Day 3 postoperatively rest/exercise	2.2 (1.8)/4.3 (2.1)	2.1 (1.9)/3.6 (2.0)	ns
Discharge rest/exercise	1.6 (1.5)/3.1 (1.6)	1.8 (1.8)/3.1 (2.0)	ns
6 weeks postoperatively rest/exercise	0.5 (1.3)/2.0 (2.0)	0.8 (1.4)/2.1 (2.0)	ns
3 months postoperatively rest/exercise	0.3 (1.0)/1.2 (2.1)	0.5 (1.0)/1.6 (2.0)	ns

Means (standard deviation)

ABT autologous blood re-transfusion, *Drain* high-vacuum closed-suction drainage

Table 3 Adverse events, creatinine levels, glomerular filtration rate

Adverse events during hospital stay (n)	ABT ($n=56$)	Drain ($n=62$)
Body temperature >37.5	25	16
Shivering	10	10
Hypotension (RR sys <90 or RR dias <50)	8	12
Bradycardia (heart rate<50/min)	0	2
Chest pain	0	1
Atrial fluttering	2	0
Dyspepsia	25	28
Clots in drain fluid	2	0
Technical failures ABT	2	0
Dislocation THP	1	0
Adverse events (n) from discharge up to 3 months postoperatively		
Deep infection THP, reoperation, irrigation	1	0
Haematoma, suspected deep infection THP (not proven), reoperation, irrigation	0	1
Dislocation THP	1	1
Pneumonia	1	0
Death, not related to operation	1	0
Renal function during hospital stay		
Creatinine level (μmol/L)		
Preoperative	73 (14)	77 (19)
Day 1 postoperatively	63 (14)	66 (17)
Day 2 postoperatively	65 (13)	70 (21)
Day 3 postoperatively	67 (17)	71 (23)
GFR, MDRD<60 ml/min/1.73 m^2		
Preoperative (n)	6	11
Day 1 postoperatively	2	3
Day 2 postoperatively	3	7
Day 3 postoperatively	4	7

Good renal function when creatinine level<125 μmol/L and glomerular filtration rate according to the Modification of Diet in Renal Disease (GFR/MDRD)≥60 ml/min/1.73 m^2. Means (standard deviation), observed frequency distribution not significantly different

ABT autologous blood re-transfusion, *Drain* high-vacuum closed-suction drainage, *THP* total hip prosthesis. *sys* systolic, *dias* diastolic

and not when compared with no drainage system [12, 17, 18]. One randomised controlled trial was published on the comparison of the same intra- and postoperative ABT system used in this study compared with no drain after primary THA. The study showed less perioperative blood loss and less decrease in maximum postoperative Hb but no significant difference in Hb levels on days one, two and three [19].

Studies on intraoperative cell salvage with intraoperative cell-washing/separating ABT show that this system is not cost effective in primary THA [20, 21]. Moreover, it is an extensive procedure that needs personnel from the anaesthesia department. Therefore, these intraoperative cell-washing/separating devices are currently not used in primary THA despite the 500-ml blood with red blood cells of good quality that is suitable for autotransfusion. To re-transfuse as much of the perioperatively lost blood as possible in THA, intraoperatively and postoperatively collected blood was re-transfused in our study. The intraoperative filter system used in this study is assumed to be less expensive and can be used without an extensive training programme. Costs of the combined intra- and postoperative ABT filter system used in this study were around $180: approximately $140 for the intraoperative unit and approximately $40 for the postoperative unit. The ABT system comprises disposable components; there is no need to purchase a cell-saver machine, and there are no maintenance costs. However, this study was not set up as a cost-effectiveness analysis.

In this study, approximately 550 ml of blood was lost and collected during surgery. Not all available intraoperatively lost blood was suctioned with the re-transfusion system and autotransfused. This was partly due to unfamiliarity with the re-transfusion system and partly on purpose: e.g. a different suction unit was used while cementing the prosthesis. In the autotransfusion group, a mean of 323 ml of intraoperative blood loss and 254 ml of postoperative blood loss, totalling 577 ml, was re-transfused, resulting in less net total blood loss and higher postoperative Hb levels. There was no significant difference in allogeneic blood transfusions that may be affected by the strict Dutch transfusion trigger. Restrictive transfusion triggers seem to be safe for most surgical patients when appropriately implemented [22]. The introduction of a strict transfusion trigger, such as the Dutch allogeneic blood transfusion guidelines, has decreased the postoperative allogeneic blood transfusion rate by 20–50 % [11, 23–26]. Other larger studies powered on allogeneic transfusion rate are needed. Moreover, functional scores might be addressed in these studies.

Adverse events during hospital stay and during the first three months postoperatively were similar in both groups. Free Hb, which is released into the wound during surgery, may be harmful to the kidneys in high concentrations. Special attention was therefore paid to renal function, and patients with a history of renal dysfunction were not included in the study. One patient with a preoperatively high creatinine level was unintentionally included. Moreover, 17 patients with suboptimal kidney clearance were included. Despite this, kidney clearance did not deteriorate after surgery in either group. This study showed no statistically significant differences in creatinine levels, or GFR between groups. However, the study was not powered to detect differences in adverse events.

The strength of the study is its prospective randomised controlled design. Furthermore, surgeons were blinded to patient group allocation until the end of surgery, as were the research physicians during follow-up. Moreover, the primary endpoint was based on blinded laboratory analysis. Other perioperative factors that might affect blood loss were

examined also, and no differences were seen in these factors between groups. The limitation of the study is that not all available intraoperatively suctioned blood suitable for re-transfusion was autotransfused.

In conclusion, the use of a new intraoperative autologous filtered salvaged blood re-transfusion system combined with a postoperative ABT unit resulted in higher postoperative Hb levels and less total blood loss compared with a high-vacuum closed-suction drain following primary THA.

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