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Postoperative autologous blood transfusion drain or no drain in primary total hip arthroplasty? A randomised controlled trial

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Abstract

Purpose Postoperative maintenance of high haemoglobin (Hb) levels and avoidance of homologous blood transfusions is important in total hip arthroplasty (THA). The introduction of a postoperative drainage autologous blood transfusion (ABT) system or no drainage following THA has resulted in reduction of homologous blood transfusion requirements compared with closed-suction drains. The purpose of this study was to examine which regimen is superior following THA.

Methods A randomised controlled blinded prospective single-centre study was conducted in which 100 THA patients were randomly allocated to ABT or no drainage. The primary endpoint was the Hb level on the first postoperative day.

Results The postoperative collected drained blood loss was 274 (\pm 154) ml in the ABT group, of which 129 (\pm 119) ml was retransfused (0–400). There was no statistical difference

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B. J. Kollen University Medical Center Groningen, Groningen, The Netherlands in Hb levels on the first postoperative day (ABT vs no drainage: Hb 11.0 vs 10.9 g/dl), on consecutive days (day 3: Hb 10.7 vs 10.2, p=0.08) or in total blood loss (1,506 vs 1,633 ml), homologous transfusions, pain scores, Harris Hip Score, SF-36 scores, length of hospital stay or adverse events.

Conclusions The use of a postoperative autologous blood retransfusion drain did not result in significantly higher postoperative Hb levels or in less total blood loss or fewer homologous blood transfusions compared with no drain.

Introduction

Total hip arthroplasty (THA) is associated with a large amount of blood loss, intraoperatively and postoperatively, including "hidden" blood loss, totalling 1,500 ml and a mean postoperative decline in haemoglobin (Hb) levels of 3.0 g/dl [1]. Higher pre- and postoperative Hb levels are correlated with better early functional recovery, higher SF-36 score, higher patient satisfaction and shorter hospital stay following THA [2, 3], although not substantiated in every study [4], and with a reduced homologous blood transfusion rate [2-5]. THA are frequently complicated by the need for homologous blood transfusions, with their concomitant disadvantages [6-9]. The introduction of postoperative autologous blood transfusion (ABT) systems has resulted in a reduction of perioperative net blood loss and homologous blood transfusion rates, compared with closed-suction drains [10–14]. The use of drains of any kind might however be questioned, as no drainage following total hip implantation has also been shown to result in reduced homologous transfusion rates when compared to regular closed-suction drains [15]. It was therefore stated in a Cochrane review on this subject that further studies were

needed comparing autotransfusion with no drainage, examining Hb levels, blood loss and homologous blood transfusion requirement [15]. This has never been tested in THA in a blinded randomised controlled trial. The purpose of this study was to conduct a blinded prospective randomised controlled trial evaluating the effects of a postoperative low-vacuum ABT system compared with no drainage following THA. The primary endpoint of our study was the Hb level on the first postoperative day.

Materials and methods

The study is an open double-blind randomised controlled prospective single-centre study with two parallel groups. Approval of our Institutional Medical Ethics Committee was obtained for this study, in which 100 patients scheduled for primary total hip surgery were randomised to either the postoperative autologous transfusion group (Bellovac ABT, autologous blood salvage, low vacuum, 60-90 mm Hg, Astra Tech, Mölndal, Sweden) or the no drainage group. Patients were enrolled based on the following inclusion criteria: provision of written informed consent, subjected to primary total hip surgery and if not meeting any of the exclusion criteria: 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 operation within the past 12 months, intake of anticoagulants 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. Numbered sealed opaque envelopes containing pre-randomised cards with either "autologous transfusion group" or "no drainage group" were available in the operating room. The surgeons were blinded for group allocation until the end of surgery, just before closure of the wound, at which time the envelope was opened and the patient's group allocation was disclosed to the surgeon.

All patients were operated upon at Isala Clinics, Zwolle, The Netherlands. Cemented hip prostheses (SP-2 stem, Fal cup, Link, Hamburg, Germany), uncemented prostheses (Bi-Metric stem, Recap cup, Biomet, Warsaw, IN, USA) and reversed hybrid prostheses (cemented cup, uncemented stem) of these components were included in the study. Cefazolin was used as routine prophylactic antibiotic treatment. Surgeons used either the posterolateral or anterolateral approach according to their preference. A drain was inserted in the autotransfusion group. Low suction was started and the drained blood was retransfused within 6 h of surgery. Retransfusion of more than 1,500 ml was not allowed. Drains were removed 24 h postoperatively.

Patients attended the outpatient clinic preoperatively and were reviewed during hospital stay and at 6 weeks and 3 months postoperatively. The primary endpoint of this study was the Hb level on the first postoperative day. Secondary endpoints included Hb levels on the second and third postoperative days, the lowest postoperative Hb level, blood loss during surgery, homologous blood transfusions, incidence of haematomas, amount of drained retransfused wound blood, wound healing disturbances, postoperative pain, length of hospital stay, adverse events, Harris Hip Scores (HHS) [16], physical and mental SF-36 [17] scores, and total blood loss. Total blood loss was calculated according to Gross [18], based on the maximum perioperative decrease in Hb level and the patients' preoperative blood volume: blood loss = preoperative blood volume \times (Hb preoperative - Hb lowest)/Hb average. Preoperative blood volume was calculated as 65 ml/kg. Hb average is the average of preoperative Hb level and lowest postoperative Hb level.

Operation time, type of anaesthesia and patients' body temperature at the end of surgery were also recorded because of their effect on blood loss. Haematomas were recorded. Wound healing disturbances were recorded when redness of the skin was observed at more than 1 cm from the incision wound. Other potential wound healing problems such as discharge from the wound were recorded. Wound discharge was scored when any discharge of wound fluid was seen. Deep infection, suspected on clinical grounds, was diagnosed based on a positive culture at reoperation. Pain at rest and during exercise was scored on a visual analogue scale (VAS). Adverse events were registered during hospital stay and at the first 3 months postoperative visit. The doctors who performed the postoperative examinations in the outpatient clinic were blinded for group allocation. A standardised blood management protocol was implemented for this study:

- 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 prophylaxis was continued for 5 weeks.
- Administration of non-selective non-steroidal antiinflammatory drugs (NSAIDs) was stopped 1 day before surgery. The COX-2 selective NSAID meloxicam 15 mg once daily was used in all patients.
- Administration of acenocoumarol was stopped 3 days before surgery and acetylsalicylates 7 days before surgery.
- Additional homologous blood transfusions were given based on the Dutch homologous blood transfusion guidelines [19]. The trigger for homologous transfusions was an Hb level of 6.4 g/dl in American Society of

Anesthesiologists (ASA) 1 patients, 8.0 g/dl in ASA 2/3 patients and 9.6 g/dl in ASA 4 patients and in patients that failed to increase their cardiac output to compensate for dilution [19].

Statistical analysis

Based on a clinically relevant difference in Hb levels on the first postoperative day of 0.8 g/dl (10.2 vs 11.0 g/dl, SD 1.4 [13]), alpha of 0.05 and a power of 80.8 %, a sample size of 50 patients per group was calculated 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. Statistical analysis was conducted with SPSS v. 17.0 (SPSS Inc., Chicago, IL, USA) statistical software. Categorical data were expressed as percentages. Continuous data were expressed as means and SD. Differences were analysed using chi-square tests for categorical data and Student's t tests for continuous data. The Levene test was used to check for test assumptions. A twosided p < 0.05 was considered to be statistically significant. All 50 patients in the autotransfusion group were subjected to the efficacy analysis, regardless of whether an autotransfusion was actually performed, because of the intention-totreat principle.

Results

Patients were enrolled between February 2007 and April 2008. In total, 100 patients were included, equally divided over the postoperative autotransfusion group and the no drainage group. The groups were statistically homogeneous with respect to gender, age, body mass index (BMI), medical history, Charnley osteoarthritis classification and indication for operative treatment (Table 1). There were no significant differences between the two groups regarding anaesthetic and surgical parameters that could affect blood loss, such as type of anaesthesia, body temperature, surgeon, surgical approach or fixation of the prosthesis, except for operation time, which was 9 min longer in the autotransfusion group, p=0.004 (Table 1).

Perioperative blood loss, autologous transfusion and Hb levels

The intraoperative blood loss, 529 (\pm 280) and 469 (\pm 163) ml, was not significantly different between the two groups. The collected drain fluid in the first 24 h amounted to 274 (\pm 154) ml in the low-vacuum drainage autotransfusion group. In the first 6 h postoperatively, 172 (\pm 98) ml was collected from which, on average, 129 (\pm 119) ml was

retransfused (0–400). In 17 of the 50 patients (34 %) in the autotransfusion group, in whom a low-vacuum retransfusion drain was inserted, the collected drain fluid was not retransfused due to small volumes of drained wound blood, substantial blood clot formation in the drained blood, technical failures or fever. The average retransfusion volume in 33 of the 50 patients on whom retransfusion was performed was 199 (\pm 88) ml.

There was no difference in the primary endpoint of the study, Hb levels on the first postoperative day, 11.0 and 10.9 g/dl, respectively, p=0.72. During hospital stay, Hb levels in the ABT group were not significantly higher than in the no drainage group, 10.7 vs 10.2 g/dl, p=0.08 at the third postoperative day. There was no significant difference in lowest postoperative Hb levels. Homologous blood transfusions were needed equally in both groups, in two patients in the retransfusion group and in four patients in the no drainage group, p=0.41. Two units of homologous blood were given to those patients. Preoperative blood volume was 5,161 (±866) ml in the ABT group and 5,139 (±943) ml in the no drainage group, NS. Calculated net total blood loss was not significantly different, 1,506 (±564) ml in the ABT group and 1,633 (±645) in the no drainage group, p=0.30.

Pain, HHS and SF-36 scores

Pain scores were similar between the groups preoperatively, during hospital stay, and 6 weeks and 3 months postoperatively, except for exercise pain scores at 6 weeks which were higher in the autotransfusion group (Table 2). The HHS was similar before surgery and 6 weeks and 3 months after surgery in the autotransfusion and no drainage groups. There was no statistical difference in the physical, mental and total SF-36 scores preoperatively and 6 weeks postoperatively between the two groups.

Wound healing

Wound healing disturbances occurred equally often in both groups during hospital stay (Table 3). There was no statistical difference in the number of haematomas. Wound leakage was seen more often in the group without drainage system than in the ABT group on the third postoperative day, 62 vs 32 %, p=0.003, and at discharge (day), 48 vs 20 %, p=0.003.

Adverse events

Adverse events on recovery, on the ward during the rest of hospital stay and afterwards until 3 months postoperatively were equally frequent in both groups (Table 3). One intraoperative complication was seen: a fissure of the femoral shaft in the autotransfusion group. There were four deep

Characteristic	Autotransfusion $(n=50)$	No drainage $(n=50)$
Mean age, years	68.6 (9.1)	69.0 (9.2)
Sex, F/M	37/13	36/14
BMI, kg/m ²	28.1 (4.5)	27.6 (3.8)
Charnley class A/B/C	33/10/7	37/9/4
Primary osteoarthritis/post-traumatic/dysplasia/osteonecrosis	49/1/0/0	45/1/3/1
Surgery		
Anaesthesia, spinal/general	41/9	42/8
Body temperature at end of operation, °C	35.9 (0.6)	35.8 (0.5)
Consultant orthopaedic surgeon/trainee	27/23	24/26
Approach, posterolateral/anterolateral	46/4	43/7
THA cemented/uncemented/reversed hybrid	36/10/4	33/15/2
Operation time, min	80 (16)	71 (14)*

Table 1 Patient characteristics and surgical factors affecting blood loss

Means (SD); observed frequency distribution not significantly different, except *p=0.004

infections of the hip prostheses, two in each group, all revised within 5 weeks (range 2-5 weeks) of the index operation. All patients had positive cultures on lavage and were treated with antibiotics postoperatively. At follow-up, no signs of infection were observed at about 10 months (range 5-19 months). In the no drainage group, three patients reported persistent wound discharge 2 weeks after surgery, one requiring readmission. Symptoms of venous thrombosis or pulmonary embolism were not diagnosed during hospital stay or 3 months postoperatively.

Table 2 Perioperative Hb levels, net total blood loss, VAS pain scores, HHS and SF-36 scores		Autotransfusion	No drainage
	Hb level (g/dl)		
	Day -1	13.9 (1.1)	13.9 (1.1)
	Day 1	11.0 (1.3)	10.9 (1.1)
	Day 2	10.8(1.3)	10.6 (1.1)
	Day 3	10.7 (1.2)	10.2 (1.3)
	Lowest	10.4 (1.3)	10.1 (1.3)
	Total blood loss (ml)	1,506 (564)	1,633 (645)
	Pain (VAS)		
	Preoperative	5.4 (1.9)	5.0 (1.9)
	Day 1 postop. rest/exercise	3.5 (1.6)/5.1 (1.7)	3.3 (1.5)/4.6 (1.7)
	Day 3 postop. rest/exercise	2.4 (1.8)/3.7 (1.7)	2.1 (1.1)/3.9 (1.4)
	Discharge rest/exercise	2.2 (1.8)/3.5 (1.8)	1.9 (0.9)/3.5 (1.2)
	6 weeks postop. rest/exercise	1.7 (1.4)/3.1(1.6)	1.2 (1.1)/1.6 (1.4)*
	3 months postop. rest/exercise	1.2 (1.6)/2.1 (2.0)	1.1 (1.3)/1.9 (2.0)
	HHS		
	Preoperative	55 (13)	58 (12)
	6 weeks postop.	75 (14)	77 (12)
	3 months postop.	81 (13)	84 (13)
	SF-36 score		
	Preoperative SF-36 total	56 (15)	58 (16)
	Preoperative SF-36 physical	47 (14)	49 (16)
	Preoperative SF-36 mental	70 (16)	70 (17)
	Postoperative 6 weeks SF-36 total	61 (15)	64 (15)
	Postoperative 6 weeks SF-36 physical	54 (16)	58 (15)
Means (SD) not significantly different, except $p<0.001$	Postoperative 6 weeks SF-36 mental	71 (15)	72 (16)

Means different, except *p<0.001

	Autotransfusion	No drainage
Wound healing during hospital stay		
Wound healing disturbance (%)		
Day 1	2	0
Day 3	4	4
Discharge	2	4
Haematoma (%)		
Day 1	2	0
Day 3	20	36
Discharge	20	32
Wound discharge (%)		
Day 1	76	86
Day 3	32	62*
Discharge	20	48*
Adverse events during hospital stay (n)		
Fever (≥38.5)	5	3
Shivering	4	0
Hypotension (systolic BP <90, diastolic BP <50)	16	13
Bradycardia (heart rate<50/min)	3	2
Atrial fluttering	2	1
TIA	0	1
Dyspepsia	13	15
Urinary tract	8	5
Clots in drain fluid	2	0
Adverse events (n) from discharge up to 3 months posto	peratively	
Deep infection THP	2	2
Readmission due to persistent leakage	0	1
Dislocation THP	1	2
Ulcus duodeni and anaemia	1	1
TIA	0	1

except **p*=0.003 BP blood pressure, *TIA* transient

Observed frequency distribution not significantly different,

ischaemic attack, THP total hip prosthesis

Hospital stay

Length of hospital stay was not significantly different, $4.3\pm$ 0.7 days in the retransfusion group and 4.6 ± 1.3 days in the no drainage group, p=0.16. Most patients were discharged on the predetermined discharge date.

Discussion

To the best of our knowledge, no blinded randomised controlled trial has been published comparing a postoperative drainage ABT system with no drainage following THA. In this study, the use of a postoperative drainage autotransfusion system (ABT) did not result in a difference in Hb levels on the first postoperative day, the primary endpoint of the study, compared to no drainage following primary THA. The postoperative maintenance of high Hb levels and the avoidance of homologous blood transfusions is important after surgery and are associated with a better early functional postoperative recovery following THA [2, 3].

A recent Cochrane review reported that the use of perioperative autotransfusion reduced the rate of exposure to homologous blood transfusions by 54 % in orthopaedic surgery, compared with closed-suction drainage [10]. One of the advantages of autologous retransfusion is the good quality and the direct contribution of the retransfused red blood cells to oxygen transport, delivery and consumption in the patient [20–24]. This is in contrast to red blood cells in homologous transfusions from a blood bank, in which optimal contribution to the oxygen consumption may take several hours because of so-called storage lesions [25, 26].

In THA, the use of a postoperative ABT system reduced homologous blood transfusions from 47 to 34 % and from

21 to 11 % when compared with a closed-suction drainage system [13, 14].

However, another Cochrane review showed that the use of no drainage in THA, compared with closed-suction drainage, decreased the number of patients who required transfusion following THA significantly from 40 to 31 % [15]. The authors stated there is now a need for studies comparing retransfusion with no drain.

Our study compared these two regimens that were superior to closed-suction drainage following THA, i.e. no drainage and the use of a postoperative ABT system. Our study showed no significant differences in postoperative Hb levels on the first, second or third days, or in total blood loss or homologous transfusions. Length of hospital stay was similar, although this is probably influenced by the fact that most patients were discharged on a predetermined date. One study found a positive correlation between Hb levels on discharge and change in SF-36 score from preoperatively to 2 months postoperatively in patients after primary hip arthroplasty [3]. In our study, with no difference in postoperative Hb levels detected, there was no difference in the HHS and SF-36 scores 6 weeks and 3 months postoperatively between the autotransfusion group and the no drainage group.

In surgery, drains are commonly used in order to reduce haematomas and wound leakage. Our study found no significant difference in haematomas. A meta-analysis on closed-suction drainage against no drainage in total hip and knee replacement reported that reinforcement of wound dressings was required significantly 60 % more often in the group managed without drains [15]. In our study there was a significant 50 % reduction of wound leakage on day 3 (32 vs 62 % of patients) and at discharge at approximately day 4 (20 vs 48 %) in the ABT drainage group compared with the no drainage group. Scoring wound discharge is clearly subjective though. Three patients in the no drainage group suffered from profound persistent wound leakage 2 weeks after surgery, one requiring rehospitalisation. Profound postoperative wound discharge might be an argument in favour of the use of drains following THA.

The strength of our study is its blinded prospective randomised setup. The surgeons were blinded to group allocation until the end of surgery, as were the researchers during follow-up. Other factors that could affect perioperative blood loss were examined and proven to be similar for both groups. The weakness of the study is the relatively limited number of patients who were retransfused. Because retransfusion was not performed in 34 % (17) of patients for various reasons, only 33 of 50 patients benefited from autotransfusion. In our opinion this reflects daily practice.

In conclusion, in this prospective randomised blinded study on 100 patients for primary hip arthroplasty the use of a postoperative autologous blood retransfusion drain did not result in significant differences in postoperative Hb levels, total blood loss or homologous blood transfusions compared with no drain.

Conflict of interest The authors declare that they have no conflict of interest.

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