# Autologous re-transfusion drain compared with no drain in total knee arthroplasty: a randomised controlled trial

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**Background.** Post-operative anaemia following total knee arthroplasty is reported to impede functional mobility in the early period following surgery, whereas allogeneic blood transfusions, used to correct low post-operative haemoglobin levels, have concomitant disadvantages. The use of a post-operative autologous blood re-transfusion drainage system as well as no drainage system following total knee arthroplasty have been shown to reduce peri-operative blood loss and allogeneic blood transfusions, compared to the regularly used closed-suction drains. No randomised studies have been performed, to the best of our knowledge, that indicate the superiority of either method.

**Materials and methods.** An open, randomised controlled study was conducted in 115 patients undergoing total knee arthroplasty who were randomly allocated to an autotransfusion drain or no drainage system. The primary end-point was haemoglobin level on the first post-operative day.

**Results.** In the autotransfusion group 515 mL (0-1,500 mL) of drained blood was re-transfused within the first 6 hours after surgery. Haemoglobin levels on the first (11.6 *vs* 11.0 g/dL), second (11.0 *vs* 10.3 g/dL) and third (10.5 *vs* 9.8 g/dL) days after surgery were significantly higher in the autotransfusion group. Total peri-operative net blood loss (1,576 mL *vs* 1,837 mL; P =0.03) and allogeneic transfusion rates (10.2% *vs* 19.6%; P =0.15) were lower in the autotransfusion group. There were no differences in pain scores, range of motion or adverse events during hospital stay and the first 3 months after surgery.

**Discussion.** Compared with no drainage, the use of a post-operative autologous blood re-transfusion drainage system following total knee arthroplasty results in higher post-operative haemoglobin levels and less total blood loss.

**Keywords:** knee arthroplasty, autologous blood transfusion, blood loss, haemoglobin, drain.



## Introduction

Total knee arthroplasty (TKA) often results in a large amount of total blood loss (on average 1,500 mL) and a mean post-operative decline in haemoglobin levels of 3.0 g/dL[1]. Blood saving measures are needed to reduce blood loss, to establish higher post-operative haemoglobin (Hb) levels and to reduce the requirement for allogeneic blood transfusions.

The use of a post-operative autologous blood transfusion (ABT) system in TKA as well as no drainage following TKA have been shown to reduce peri-operative blood loss and requirements for allogeneic blood transfusions, compared to the regularly used closed-suction drains[2-7]. As stated in a Cochrane review on autologous re-transfusion and another Cochrane review on drainage *vs* no drainage, it is now relevant to know which regimen is superior at maintaining higher post-operative haemoglobin levels and reducing net blood loss and transfusion requirements[3,7]. To the best of our knowledge, no randomised controlled trial has been published comparing the use of post-operative ABT with no drainage following TKA. Our hypothesis was that the use of post-operative ABT would reduce peri-operative blood loss and the allogeneic transfusion rate, and would decrease the reduction in post-operative Hb levels, compared with those occurring with no drainage following TKA. We, therefore, conducted an open, prospective, randomised controlled trial to compare the effects of a post-operative low-vacuum drainage autologous blood re-transfusion system with those of no drainage following TKA. The primary end-point of this study was the Hb level on the first post-operative day.

## Materials and methods

This was an open, randomised controlled study carried out in two centres. The study was approved by the institutional local ethics committees. In total 115 patients scheduled for primary total knee surgery were randomly allocated to either the post-operative autologous blood re-transfusion group (Bellovac ABT, autologous blood

salvage, low vacuum, 60-90 mmHg; Astratech, Mölndal, Sweden) or the no drainage group. Sixty-five patients underwent surgery at the Isala Clinics, Zwolle and 50 patients at the Kennemer Gasthuis, Haarlem, both located in the Netherlands.

Patients were enrolled if they were to undergo primary TKA, provided written informed consent and did not meet 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 "autotransfusion group" or "no drainage group" were available in the operating room. The surgeons were blinded to the group allocation until the end of surgery, just before closure, at which time the envelope was opened and the patient's group allocation was disclosed to the surgeon.

Standard surgical procedures were performed including a midline skin incision and median parapatellar quadriceps splitting approach. The hole drilled in the femoral canal was plugged. Surgery was performed using a pneumatic tourniquet to create a bloodless field. The tourniquet was deflated after the wound dressing and bandage had been applied. A cemented total knee prosthesis (Genesis-2, Smith and Nephew, Memphis, Tennessee, USA), cruciate-retaining or posterior-stabilised, was implanted in all patients. In the autotransfusion group a drain was inserted in the knee joint at the end of the operative procedure. Low suction drainage was started 30 minutes after the operation and the drained blood was re-transfused within 6 hours of surgery. In accordance with the manufacturer's guidelines, no more than 1,500 mL of blood could be re-transfused. Drains were removed 24 hours after surgery.

Patients attended the out-patient clinic pre-operatively and were followed during their stay in hospital and at 6 weeks and 3 months post-operatively. The primary end-point of this study was the Hb level on the first day after surgery. Secondary end-points included Hb levels on the second and third days after surgery, the lowest post-operative Hb level, intra-operative blood loss, post-operatively drained blood loss, amount of re-transfused drained blood, allogeneic blood transfusions, incidence of haematomas, wound-healing problems, post-operative pain, duration of hospital admission, adverse events and total blood loss.

Total blood loss was calculated according to Gross[8], based on the maximum peri-operative decrease in haemoglobin level and the patients' pre-operative blood volume:

$$\text{blood loss} = \frac{\text{pre-op. blood volume} \times (\text{pre-op. Hb} - \text{lowest Hb})}{\text{average Hb}}$$

Pre-operative blood volume was calculated as 65 mL/kg. Average Hb is the mean of the pre-operative Hb level and the lowest post-operative 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, as were disturbed wound healing, defined as redness of the skin more than 1 cm from the incision wound. Wound leakage was scored when any leakage of wound fluid was seen. Pain at rest and during exercise was scored on a visual analogue scale (VAS) and range of motion was assessed. Adverse events were registered during the hospital admission and for the first 3 months after surgery. The physicians who performed the post-operative examinations in the out-patient clinic were blinded to the patients' group allocation. A standardised blood management protocol was implemented for this study:

- venous thromboembolism prophylaxis consisted of fondaparinux (Arixtra®, 2.5 mg/0.5 mL) subcutaneously once daily. The first dose was administered in the evening of the day of surgery and the treatment was continued for 5 weeks;
- administration of non-selective non-steroidal anti-inflammatory drugs was stopped 1 day before surgery. The COX-2-selective non-steroidal anti-inflammatory drug meloxicam was used for all patients at a dose of 15 mg once daily;
- additional allogeneic blood transfusions were given based on the strict Dutch allogeneic blood transfusion guidelines[9]. The transfusion trigger for allogeneic transfusions was a haemoglobin level of 6.4 g/dL in ASA-1 patients, 8.0 g/dL in ASA 2/3 patients, and 9.6 g/dL in ASA 4 patients (and in patients who failed to increase their cardiac output to compensate for dilution)[9].

**Statistical methods**

Based on a clinically relevant difference in Hb levels on the first post-operative day of 0.8 g/dL (10.2 g/dL *vs* 11.0 g/dL, SD 1.4[5]), an alpha of 0.05 and a power of 80.8%, for this study a sample size of 50 patients per group was calculated which, with the addition of 15%, made a total of 115 patients. Effectiveness analysis was performed considering all patients in the autotransfusion group, regardless

of whether an autotransfusion was or was not given, based on the intention-to-treat principle. 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 in mean ± standard deviation (SD). 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 to be statistically significant.

## Results

Patients were enrolled between February 2007 and February 2009. In total 115 patients were included, 59 in the autotransfusion (ABT) group and 56 in the no-drain group (Kennemer Gasthuis 26 *vs* 24, Isala Clinics 33 *vs* 32). Nineteen surgeons performed the operations with the distribution over the ABT group and no-drain group being as follows: 5-2, 4-5, 4-4, 8-7, 5-6, 2-1, 3-3, 0-2, 0-2, 1-2, 0-1, 5-3, 3-5, 1-1, 4-2, 8-3, 1-2, 2-2, 3-3. The groups were statistically homogeneous with respect to gender, age, body mass index, medical history, Charnley osteoarthritis classification and indication for surgery (Table I). There were no significant differences between the two groups regarding anaesthesiological and surgical parameters that could affect blood loss.

### Peri-operative blood loss, autologous transfusion and haemoglobin levels

Because of the intra-operative use of a tourniquet, intra-operative blood loss was negligible in both groups (Table I). In the autotransfusion group, 702 mL (range 50-1,800 mL) was drained in the first 24 hours after surgery. In the first 6 hours postoperatively, 531 mL was collected of which, on average, 515 mL was re-transfused (0-1,500 mL). In seven of the 59 ABT patients, the collected drain fluid was not re-transfused because of the small volumes of drained wound blood (5 patients), cardiac problems before re-transfusion (1 patient) and technical problems (1 patient).

The Hb level was significantly higher in the autotransfusion group than in the no-drainage group on the first post-operative day, the primary end-point of the study, as well as on the consecutive days (Table II). The fall in Hb levels from pre-operative values to those on days 1, 2 and 3 post-operatively was significantly less in the ABT group than in the no-drainage group. Allogeneic blood transfusions were needed in 10.2% of patients (6/59 patients, 13 allogeneic transfusions) in the ABT group and in 19.6% (11/56 patients, 25 allogeneic transfusions) in the no-drainage group (P =0.15). The transfusion trigger in the ABT group was 8.1±0.7 g/dL (range, 7.5-9.3) whereas that in the no-drainage group was 8.1±0.8 g/dL (range, 6.6-9.4). All except four allogeneic transfusions in both groups were given after the Hb level measurement on the

**Table I -** Patients' characteristics, surgical factors affecting blood loss, peri-operative blood loss and post-operative re-transfusion.

| Characteristic | Autotransfusion (n =59) | No drainage (n =56) |
|---|---|---|
| Mean age, years | 68 (9) | 69 (8) |
| Sex, female/male | 42/17 | 39/17 |
| Body mass index kg/m$^2$ | 28.8 (5.1) | 29.3 (5.2) |
| Charnley class A/B/C | 32/24/3 | 32/17/7 |
| Primary osteoarthritis, HTO/FO/RA | 53/3/0/3 | 50/4/1/1 |
| **Surgical factors affecting blood loss** | | |
| Anaesthesia, spinal/general | 47/12 | 47/9 |
| Body temperature at end of operation, °C | 36.0 (0.6) | 36.0 (0.6) |
| Consultant orthopaedic surgeon/trainee | 45/14 | 41/15 |
| Operation time, min | 78 (18) | 75 (14) |
| **Peri-operative blood loss and re-transfusion** | | |
| Intra-operative blood loss, mL | 10 (26) | 15 (37) |
| Drainage 0-6 hours post-operative, mL | 531 (294) | - |
| Drainage 0-24 hours post-operative, mL | 702 (377) | - |
| Patients re-transfused, n/n | 52/59 | 0/56 |
| Re-transfusion post-operative, average 59 pt | 515 (325) | - |

Means (SD), observed frequency distribution not significantly different. HTO: history of high tibial osteotomy; FO: history of femoral supracondylar osteotomy; RA: rheumatoid arthritis.

**Table II -** Peri-operative haemoglobin levels.

| Haemoglobin level, g/dL | Day –1 | Day 1 | Day 2 | Day 3 | Lowest |
|---|---|---|---|---|---|
| Autotransfusion | 14.0 (1.4) | 11.6 (1.1) | 11.0 (1.0) | 10.5 (1.3) | 10.4 (1.1) |
| No drain | 13.8 (0.9) | 11.0 (1.0) | 10.3 (1.1) | 9.8 (1.2) | 9.8 (1.2) |
| p value | 0.3 | 0.003 | 0.001 | 0.002 | 0.002 |

Means (SD)

3rd day after surgery. The calculated net total blood loss was less in the autotransfusion group than in the no-drainage group (1,576±635 mL *vs* 1,837±624 mL, respectively; P =0.03). The estimated preoperative blood volumes were 5,370±970 mL and 5,380±1,056 mL, respectively (P =NS).

### Range of motion, pain, wound healing and hospital stay

There were no differences in peri-operative range of motion, VAS pain scores or wound healing between groups. There was no difference in the duration of hospital admission (day of surgery until day of discharge), which was 6.7 days in the ABT group and 6.6 days in the no-drainage group (P =NS). Most patients were discharged on a predetermined discharge date.

## Adverse events

Adverse events during the time in hospital and afterwards up to 3 months postoperatively were equally frequent in both groups (Table III). There were no deep infections of the knee prostheses. In the no-drainage group, two patients reported persistent wound leakage and haemarthrosis, 2 weeks after surgery, which did not require re-admission to hospital. Despite thromboprophylaxis, one patient was diagnosed with pulmonary embolism, which was treated with anticoagulant therapy. Clinical deep venous thrombosis was not diagnosed during either the hospital stay or in the subsequent 3 months.

## Discussion

In this study, the use of a post-operative low-vacuum drainage autotransfusion system following primary TKA resulted in higher Hb levels on the first day after surgery (the primary end-point of the study) than when no drainage system was used.

In TKA, higher pre-operative and post-operative Hb levels are related to higher functional scores, a shorter hospital stay[10,11], although not shown in every study[12], and a reduction of allogeneic blood transfusions[10-12].

An advantage of post-operative autologous re-transfusion is the good quality and direct contribution of the re-transfused red blood cells to oxygen transport and delivery in the patient[13-15]. A recent Cochrane review reported that the use of peri-operative autotransfusion

**Table III -** Adverse events.

| Adverse events during hospital stay (n) | Autotransfusion | No drainage |
|---|---|---|
| Body temperature (>37.5 °C) | 37 | 42 |
| Shivers | 5 | 1 |
| Hypotension (systolic <90, diastolic <50 mmHg) | 10 | 14 |
| Bradycardia (heart rate <50 bpm) | 4 | 3 |
| Myocardial infarction | 1 | 0 |
| Angina pectoris/cardiac ischaemia | 0 | 1 |
| Atrial flutter | 2 | 2 |
| Transient ischaemic attack | 1 | 0 |
| Pneumonia | 1 | 0 |
| Dyspepsia | 18 | 23 |
| Urinary tract | 3 | 3 |
| Limited range of motion, manipulation under anaesthesia | 2 | 0 |
| Peroneal nerve paresis | 2 | 1 |
| **Adverse events from discharge up to 3 months after surgery (n)** | | |
| Limited range of motion, manipulation under anaesthesia | 2 | 2 |
| Haemarthrosis, no readmission | 0 | 2 |
| Pulmonary embolism | 1 | 0 |

Observed frequency distribution not significantly different.

in orthopaedic surgery reduced the allogeneic blood transfusions rate by a relative 54%, compared with the use of regular drains[3]. Randomised controlled trials in TKA show that the use of a post-operative ABT system results in significantly less requirement for allogeneic blood transfusions compared to the use of a closed suction drain. The allogeneic transfusion rate in the ABT groups was 2-7% against 16-28 % in the drain groups[2,4-6].

The use of any drain is subject to debate. Pooled results in a Cochrane review showed that not using a drain after TKA decreased the number of patients who required a allogeneic transfusion from 50%, when using a closed-suction drain, to 31%[7]. In our randomised controlled trial comparing the use of a post-operative ABT system with no drainage following TKA, the ABT group had significantly higher post-operative Hb levels on the first and consecutive days, and less perioperative blood loss. Allogeneic blood transfusions were needed in 10% of patients in the ABT group and in 20% in the no-drainage group, with the difference not reaching statistical significance. However, the present study was not powered to detect a difference in allogeneic transfusion rate. Future TKA studies on autotransfusion versus no drainage that are powered to investigate differences in allogeneic blood transfusion rate are needed to clarify this issue.

Concerning costs, the question is whether savings from reducing allogeneic blood transfusion requirements outweigh the extra costs of the ABT system. The cost of an autologous blood re-transfusion system is around $75 while the costs of allogeneic blood transfusion, including cross-matching, delivery and refrigerated storage, is stated to be between $522 and $1,183, with a mean of $761[16]. In the present study, 25 allogeneic transfusions were given in the no-drainage group, while 13 allogeneic transfusions were given in the ABT group. For this study, the savings in the reduction of allogeneic transfusions (12 × $761 = $9,132) outweighed the additional costs of the ABT system (59 patients × $75 = $4,425), resulting in a total saving of $4,707 for the ABT group, which means approximately $80 per patient. A recent study on patients undergoing TKA found net savings in different cost scenarios of €5 to €106 per patient for the use of the same ABT system as used in this study and €–52 to €50 per patient for another ABT system[17]. A cost-effectiveness review on blood-saving measures stated that cell salvage had lower costs compared with all of the alternative blood-saving strategies except acute normovolemic dilution and concluded that autotransfusion may be a cost-effective method to reduce allogeneic transfusions[18].

Adverse events were equal in both groups. However, the study was not powered to show differences. Furthermore, range of motion, pain, wound healing and hospital stay were not significantly different, although the results concerning the duration of the hospital admission might have been affected by the predetermined discharge date.

Some study limitations and strengths are acknowledged. The study was not powered to detect significant differences in either allogeneic transfusion rate or incidence of post-operative complications and this is regarded as a limitation. One of its strengths is its prospective, randomised design. Moreover, the surgeons were blinded to the group allocation until the end of surgery, as were the research physicians during follow-up. Another strength is that other perioperative factors that might affect blood loss were examined too and no differences were seen in these factors between the two groups.

In conclusion, in this prospective, randomised blinded study on 115 patients, the use of an autologous blood re-transfusion drainage system resulted in higher post-operative Hb levels and less total blood loss, compared with no drainage following TKA.

*The Authors declare no conflicts of interest.*

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