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ORIGINAL STUDY

No drain, autologous transfusion drain or suction drain? A randomised prospective study in total hip replacement surgery of 168 patients

Graham CHEUNG, Michael R. CARMONT, Andrew J.F. BING ,
Jan-Herman KUIPER, Robert J. ALCOCK, Niall M. GRAHAM

From the Robert Jones and Agnes Hunt Orthopaedic and District Hospital, Oswestry, Shropshire, United Kingdom.

We performed a prospective, randomised controlled trial to assess the differences in the use of a conventional suction drain, an Autologous Blood Transfusion (ABT) drain and no drain, in 168 patients. There was no significant difference between the drainage from ABT drains (mean : 345 ml) and the suction drain (314 ml). Forty percent of patients receiving a suction drain had a haemoglobin level less than 10 g/dL at 24 hours, compared to 35% with no drain and 28% with an ABT drain. Patients that had no drains had wounds that were dry significantly sooner, mean 3.0 days compared to a mean of 3.9 days with an ABT drain and a mean of 4 days with a suction drain. Patients that did not have a drain inserted stayed in hospital a significantly shorter period of time, compared with drains. We feel the benefits of quicker drying wounds, shorter hospital stays and the economic savings justify the conclusion that no drain is required after hip replacement.

Keywords : hip replacement ; autologous transfusion ; drain.

INTRODUCTION

In 2008, orthopaedic surgeons working in NHS Trusts in England and Wales performed approximately 64 700 total hip replacements (THRs) (*9*). In the absence of blood saving measures, blood loss per uncomplicated THR has been estimated at 1550-2400 mls (*17*) and on average, 48% of patients receive an allogenic blood transfusion (*8,27*).

Allogeneic blood transfusion is considered to be safe but is not free of complications and carries a small degree of risk. In the United Kingdom, the estimated frequency of infectious donations entering the blood bank during 1996-2003 was 1.66, 0.80 and 0.14 per million for HBV, HCV and HIV respectively (*31*). Use of allogeneic blood gives an increased rate of post-operative infection (*11,14,22*) and has been shown to prolong hospital stay by 2 days (*22*). Use of allogeneic blood should therefore be avoided unless absolutely necessary.

Drains are used with the intent of preventing haematoma accumulation and decreasing the likelihood of prolonged wound drainage, healing, or infection (*2*). A meta-analysis has confirmed that the

■ Graham C. Cheung, Specialist Registrar.
■ Andrew J. F. Bing, Consultant Orthopaedic Surgeon.
■ Robert J. Alcock, Consultant Anaesthetist.
■ Niall M. Graham, Consultant Orthopaedic Surgeon.
The Robert Jones and Agnes Hunt Hospital.
■ Michael R. Carmont, Consultant Orthopaedic Surgeon.
Princess Royal Hospital, Telford, Shropshire, UK.
■ Jan Herman Kuiper, Lecturer in Biomechanics.
Keele University, Staffordshire, U.K.
Correspondence : Mr NM Graham, Consultant Orthopaedic Surgeon. The Hip Unit, The Robert Jones and Agnes Hunt Hospital, Oswestry, Shropshire, SY10 7AG, United Kingdom.
E-mail : sarah.sides@rjah.nhs.uk

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use of closed suction drains reduced the need for wound dressings but also found that suction drain use actually increased blood transfusion requirements (*24*).

More recently the use of autologous transfusion drains has been analysed, although the literature includes retrospective reviews of data (*12,32*) and the grouping of data for both hip and knee arthroplasty (*15,20,32,37*) or all orthopaedic surgery (*5*). Two recent randomized controlled trials have compared the use of autologous transfusion drains and suction drains after hip arthroplasty (*29,30*). One trial found no significant difference in mean post-operative haemoglobin (Hb) levels but did find a significantly lower allogeneic blood transfusion rate for patients with a reinfusion drain (*30*), whereas the other trial found significantly higher post-operative Hb levels in patients with a reinfusion drain but no difference in allogeneic blood transfusion rates (*29*).

To our knowledge, so far only one study has compared between the three alternatives, namely a suction drain, a reinfusion drain or no drain (*26*). That study found no significant differences in post-operative Hb levels or allogeneic transfusion rates between the groups. All patients in that study had donated at least two units of autologous blood before the operation, which was routinely reinfused, resulting in a very low allogeneic blood transfusion rate of 3.3%. Pre-operative autologous blood donation is however not common practice (*27*) and has not been found to be cost-effectve (*3,10*). We therefore performed a prospective, randomised controlled trial to assess the difference between the use of a conventional suction drain, an autologous transfusion drain and no drain, on the rate of allogeneic blood transfusion and Hb levels. Secondary outcome measures included time until the wound became dry, differences in length of hospital stay and wound infection rates.

PATIENTS AND METHODS

The trial was approved by our local ethics research committee. Power calculation for a χ^2-test suggested that 42 patients per group would be required to detect that patients in one group would have a 15% larger risk than the other two groups to require a blood transfusion, based on the transfusion risk after hip surgery of 11% in our hospital (effect size 0.28, power 80%, p-value of 0.05). We studied a minimum of 50 patients per group to allow for drop out and loss to follow-up.

Between July 2005 and August 2006, 168 patients having primary total hip replacements for osteoarthritis were recruited into the trial. Informed consent was obtained. These patients were under the care of three different consultants who used an identical posterior approach to the hip. The exclusion criteria included the presence of clotting disorders, current anticoagulation and a previous thromboembolic event.

All patients had their pre-operative haemoglobin checked. A dose of Cefuroxime 1.5 g was given at induction of anaesthesia and a second dose 8 hours following surgery. The choice of hip replacement components was independently made by the operating surgeon.

Patients were randomised pre-operatively into one of three groups using stratified randomisation software to balance the groups with respect to potentially confounding factors (StratOs, Cooked Bits, Oswestry, UK). This software used the Pocock and Simon implementation of the minimization method (*20*). We used four prognostic factors for the stratification : age, gender, Body Mass Index (BMI) and use of aspirin and non-steroidal anti-inflammatory drugs (NSAIDs).Patients were allocated into one of three groups : autologous blood transfusion (ABT), a standard suction drain and no drain. All drains used a single size 12 drain, placed deep to the fascia lata. The ABT group received a Bellovac ABT (Astra Tech ltd, Gloucestershire, UK) and the vacuum drains were High Vacuum Medinorm type, (Van Straten, Quiershield, Germany). If deemed necessary, patients in the ABT group received an autologous transfusion of their own drain blood within 6 hours of collection as per the manufacturer's instructions. All drains were removed at 24 hours post surgery.

All patients received identical post-operative care aiming for early mobilisation and discharge home. Thromboprophylaxis consisted of a once daily dose of 150 mg of Aspirin for 6 weeks and a proton pump inhibitor. Further mechanical throm-

boprophylaxis consisted of foot pumps and below knee thromboembolic deterrent stockings (Tyco Healthcare, Gosport, UK). Postoperative mobilisation was commenced as soon as tolerated and when any spinal anaesthesia had worn off.

The decision on whether or not to transfuse was made by the ward doctors or anaesthetist. No criteria were set to trigger a transfusion, although all doctors at the trust had attended a transfusion awareness lecture, outlining broad guidelines. Decisions were to be made on an individual basis according to symptoms, previous history of cardiovascular and cerebrovascular disease and haemoglobin level. Discharge was only permitted once the wound was dry and the patient was safe to mobilise.

The type of prosthesis, use of non-steroidal anti-inflammatory drugs, levels of haemoglobin (Hb) and haematocrit (HCT), length of hospital stay, the type of anaesthetic, and the number of days till the wound became dry, (including drain site), prior to discharge were recorded. At a six-week outpatient appointment investigation and treatment for thromboembolic events, positive wound swab cultures and the use of antibiotics in the community were noted.

The primary outcome measure for the trial was the transfusion rate (the proportion of patients that received blood transfusion) and the volume of blood administered. Secondary outcome measures were postoperative level of Hb, wound infection rate, time of wound to become dry and length of hospital stay. Categorical data were compared between the three groups using Fisher's exact test. Since most continuous variables had a non-normal distribution, all continuous variables were compared between the three groups using the Kruskal-Wallis test. However, to adjust for the influence of age, BMI and pre-operative levels, we used Analysis of Covariance (ANCOVA) to compare volumes of blood, Hb levels and haematocrit levels between the groups, Generalized Linear Modelling (GLM) with a log link function to analyze differences between the groups in volume of transfused blood and length of hospital stay, and logistic regression to compare the odds of requiring a transfusion between the groups. GLM is a statistical analysis method particularly suited to cope with data that has a non-normal distribution by using a link function that transforms the mean of outcome variable (*18*). The log-link function is the appropriate transformation to analyse count data (*18*). Although ANCOVA is robust against deviations from normality (*23*), a GLM with a log link function is more suited to analyze data that is extremely skewed, such as length of stay. Relative risks of requiring a transfusion, adjusted for covariates, were calculated from the odds ratios determined by logistic regression (*38*). For all analyses comparing three groups, Tukey's HSD was used as a post-hoc test. All analyses were based on the intention to treat principle. A p-value of 0.05 or less was assumed to denote significance. All statistical analyses were performed using R version 2.8.1 (R Foundation for Statistical Computing) and SYSTAT version 11 (SYSTAT Software Inc., Richmond, CA, USA).

RESULTS

Of the 168 patients consented for the trial and randomised, 153 patients were actually entered in the study after exclusion criteria were re-checked. There were 53 patients in the ABT group, 52 in the suction drain group and 48 in the no drain group. The three groups were comparable in terms of gender distribution, NSAID use, pre-operative levels of Hb and HCT, anaesthetic used and implant type inserted (table I). However, despite the use of stratified randomization to balance the groups, age and BMI differed significantly between them (table I). For this reason, we used these two variables as covariates in our further analyses.

Median intra-operative blood loss was identical among the three groups, and increased significantly with BMI (table II). Patients with an ABT drain had a 14% smaller median drain volume than those with a suction drain, a non-significant difference (table II). Thirty-one (58%) patients in the ABT group received an autologous reinfusion with a median volume of 250 ml. The median reinfusion volume averaged over all patients in the group was 150 ml (table II). In a logistic regression, drainage volume was the only significant variable predicting whether a patient would receive an autologous reinfusion

Table I. Pre-operative patient characteristics and details of anaesthetics and implant type for the three groups*

	Reinfusion drain (n = 53)	Suction Drain (n = 52)	No Drain (n = 48)	p-value
BMI	29 (26-33)	26.3 (24.3-29.5)	27 (25-29)	0.034
Age (Years)	65 (61-73)	70.5 (63-76)	69 (62.3-76)	0.054
Sex (M/F)	22/39	24/30	23/30	0.60
Pre-op use of Aspirin/NSAIDs				0.11
Aspirin	6	12	6	
NSAIDs	13	19	17	
Both	5	6	2	
None	29	15	23	
Pre-op Hb (g/dl)	13.6 (13.0-14.4)	13.7 (12.7-14.3)	14.0 (12.9-14.8)	0.55
Pre-op HCT (%)	39.6 (37.9-42.7)	39.2 (36.5-41.5)	40.7 (37.9-42.7)	0.16
Type of Anaesthetic				0.33
GA	11	15	14	
GA + regional	16	12	6	
GA + spinal	5	2	5	
GA + epidural	5	9	4	
Spinal	14	9	15	
Epidural	0	1	2	
Spinal + regional	1	2	1	
Femoral Component				0.78
Uncemented	11	8	8	
Cemented	42	44	40	
Acetabular component				0.42
Uncemented	27	36	35	
Cemented	21	17	17	

* Values of continuous variables are given as median (IQR). P-values for differences between the three groups were calculated using the Kruskal-Wallis test for continuous data or Fisher's exact test for categorical data.

($p = 0.01$). Patients who received a reinfusion had a significantly larger drainage volume than patients who did not (350 vs 200 ml, $p < 0.001$, Mann-Whitney test).

Five times more patients with a suction drain than those without drain needed an allogeneic transfusion within 24 hours, and they required four times more units of allogeneic blood, both significant differences (table II and III). The allogeneic transfusion requirements of the patients in the ABT group were between the other two groups (table I and III). Higher age and lower BMI were associated with increased transfusion requirements (table II). The haemoglobin levels 24 hours after the operation, adjusted for pre-operative levels, were similar for all three groups, and larger for patients with larger BMI (table II). Haematocrit levels adjusted for pre-op levels were also similar (table II). Allogenic transfusion requirements after 24 hours and haemoglobin levels at 72 hours were similar for the three groups (table II and III). Analyzed over the total period, patients with a suction drain were three times as likely to receive an allogeneic transfusion than those without a drain, a significant difference, with the allogeneic transfusion requirements for patients with a reinfusion drain between the two (table II and III).

Table II. - Intra-operative and post-operative outcomes for the three groups*

	Reinfusion drain (n = 53)	Suction drain (n = 52)	No drain (n = 48)	p-value
Intra-op blood loss (ml)[1]	300 (200-458)	300 (200-400)	300 (250-350)	0.40
Drained volume (ml)	300 (200-400)	350 (113-558)	-	0.22
Re-infused volume (ml)	150 (0-250)	-	-	-
Post-op transfusion within 24 hours[1,2]	5 ptnts (9%)[a,b] (10 units)[a,b]	15 ptnts (29%)[a] (22 units)[a]	3 ptnts (6%)[b] (5 units)[b]	0.01 0.02
Hb at 24 hours (g/dl)[1]	10.5 (9.5-11.5)	10.5 (9.3-11.4)	10.4 (9.5-11.5)	0.87
HCT at 24 hours (%)	30.6 (27.9-33.6)	30.0 (27.0-33.2)	30.0 (27.1-33.4)	0.98
Post-op transfusion after 24 hours	4 ptnts (8%) (8 units)	7 ptnts (13%) (14 units)	3 ptnts (6%) (6 units)	0.46 0.46
Hb at 72 hours (g/dl)	10.1 (9.2-12.0)	10.5 (9.2-11.2)	10.5 (9.4-11.3)	0.60
Overall transfusion[2]	9 ptnts (17%)[a,b] (18 units)	19 ptnts (37%)[a] (36 units)	6 ptnts (13%)[b] (11 units)	0.02 0.04
Wound drying (days)	3 (2-5)[a]	4 (2-5)[a]	3 (2-4)[a]	0.04
Hospital length of stay (days)[2]	6 (5-8)[a,b]	7 (5.3-9)[a]	6 (5-7)[b]	0.03

* Values for continuous variables are given as median (IQR). P-values for differences between the three groups were calculated using ANCOVA for volumes, Hb levels and HCT level, GLM with log link function for days and number of transfusion units, and logistic regression for number of patients requiring transfusion. ANCOVA, GLM and logistic regression used age, BMI and pre-operative levels of Hb or HCT as covariates.

1) Significantly associated with BMI.

2) Significantly associated with age.

a,b) Means with the same letter do not differ significantly according to the Tukey HSD follow-up test. Means with differing letters differ significantly ($p < 0.05$).

Because not all patients with a reinfusion drain received an autologous transfusion, we also compared the allogeneic transfusion risk between the 31 patients in this group who did and the 22 who did not receive an autologous transfusion. In all, 3 of the 31 patients who did and 6 of the 22 patients who did not receive an autologous transfusion needed an allogeneic transfusion, translating in a relative risk of 0.3 (0.06-1.1).

Patients who did not have a drain stayed on average a day less in hospital than those with a suction drain, a significant difference (table II). Although their wounds were also dry a day earlier, this difference was not significant according to the Tukey HSD test (table II). The length of stay and number of days for the wound to dry for patients in the ABT group was between those in the two other groups (table II). Using a generalized model, we found that age and having had an allogeneic transfusion were the strongest predictors of hospital stay ($p < 0.001$ for each). Older patients stayed in hospital significantly longer (table II).

Two patients in the suction drain group had a superficial wound infection. One patient was treated with oral antibiotics by the general practioner, and the second was admitted seven months post-operatively with cellulitis around the wound. None of the patients in the other groups had an infection. Due to the small number of infections no significant difference between the three groups of patients could be detected.

Four patients developed post-operative medical complications : One patient developed a pulmonary embolus, one a myocardial infarction and one developed pancreatitis. One patient in the suction drain group died of multi-organ dysfunction. No

Table III. — Relative risk of allogenic blood transfusion, with 95% CI, adjusted for BMI and age*.

Drainage Group	RR within 24 hrs	RR after 24 hrs	RR overall
Reinfusion vs No	2.5 (0.58-7.6)	1.3 (0.28-4.7)	1.8 (0.67-3.9)
Suction vs No	5.0 (1.6-10.4)	2.1 (0.57-6.2)	3.0 (1.4-5.1)
Suction vs Reinfusion	2.2 (0.77-4.9)	1.6 (0.49-4.3)	1.7 (0.79-3.1)

* Adjusted risks based on logistic regression and confidence limits based on Tukey HSD follow-up test

patients required re-operation and there has been no clinical or radiological evidence of deep infections at 12 months post-op.

DISCUSSION

In this prospective randomized controlled trial comparing two types of drainage and no drains, the immediate post-op allogeneic transfusion rate was three times higher in patients who had a suction drain compared to patients who had no drain. The median length of hospital stay of patients fitted with a suction drain was also significantly higher (1 day) than that of patients who had no drain. There was no significant difference in terms of allogeneic blood transfusion requirement or length of stay between patients who had a reinfusion drain fitted and the other two groups of patients. We found no significant difference in post-operative haemoglobin levels between the three groups, neither 24 nor 72 hours after the operation.

The finding in this study that patients with a suction drain were significantly more likely to receive an allogeneic blood transfusion than those without a drain echoes the findings of a meta-analysis (*24*). The relative risk found in the present study is about twice the average reported in that meta-analysis (3.0 vs 1.43). This difference is mainly due to the low risk of transfusion in the absence of a drain in our study (13%) compared to the average for that group in the meta-analysis (28%).

The relative risk of an allogeneic blood transfusion for patients with a reinfusion drain was between the other two groups and did not differ significantly from either. The relative transfusion risk of 1.7 for suction drains relative to reinfusion drains is comparable to the combined relative risk of 2.2 for orthopaedic procedures in a recent meta-analysis (*5*), and very close to the 1.6 in a recent trial of suction drains versus reinfusion drains in hip surgery (*29*). The lower transfusion risk for patients with an autologous transfusion drain was achieved despite the fact that only 58% of patients with an ABT drain received a reinfusion. Such a relatively low reinfusion rate is not uncommon. For instance, in a recent randomized trial comparing between suction drains and reinfusion drains, only 66% of patients randomized to the reinfusion arm actually received a reinfusion (*29*). The reason for the low reinfusion rate in our study was most likely the small volume of drained blood in some patients. An additional factor may have been time expiry of the drained blood. According to the manufacturer's instructions blood collected in an ABT drain must be re-infused within 6 hours of surgery. Unfortunately, we were unable to find out if any patients in our study did not receive a reinfusion due to the drained blood being time expired. Interestingly, in our study the risks of allogeneic blood transfusion were 0.097 in the reinfused patients and 0.27 in the non-reinfused patients (RR = 2.8). Although this difference was not significant, it would be useful to conduct a trial to find out if it were beneficial to always attempt reinfusion.

In addition to the increased transfusion requirements, we also found that patients with a suction drain had a significantly longer median length of hospital stay than patients with no drain (7 versus 6 days, respectively). However, a meta-analysis reported that none of the seven included studies that analysed length of hospital stay found a difference (*24*). Most likely, the significant difference in length of stay found in our study is simply a reflection of either, the large difference in transfusion rates between the groups we found or the greater amount of time it took for their wounds to become dry. In a large European survey, patients who required an allogeneic transfusion had a significantly larger

length of stay than those who required no or an autologous transfusion (*27*). In our study, having an allogeneic blood transfusion was also a significant predictor of length of stay. The longer stay of patients requiring allogeneic transfusions is thought to be related to disturbances in wound healing (*35*). In line with that study, we did indeed find that patients who required an allogeneic transfusion had longer wound drying times (data not shown). The longer hospitalization of patients with a suction drain may be related to the longer time taken for the wounds to dry in that group. Length of hospital stay is multifactorial and can be influenced by other factors including post-operative pain, social circumstances and the view of the surgeons and patients.

We found no difference in length of hospital stay between patients with a reinfusion drain and those with no drain. As mentioned above, this lack of a difference is most likely related to the smaller difference in allogeneic transfusion risk between these two groups, and the ensuing smaller difference in wound healing disturbances. Wound healing disturbances may be related to an allogeneic transfusion, and not to drain usage *per se*. Drains are used in hip surgery because they theoretically reduce the risk of wound haematomas and infection. However, a meta-analysis of 18 studies with 3495 patients failed to find evidence for this (*24*). Our finding that drainage from the wound increased with drain use may in part be related to continued drainage from the drain site, once the drain was removed. Our finding is otherwise somewhat counterintuitive and should be interpreted with caution, although not without precedent. Cobb found that the use of a drain after hip fracture surgery was associated with late wound leakage (*7*). Dora *et al* found that those patients that had a drain had persistent drainage for an average 1.5 days longer than those without (*8*). Since wound infection is such a rare event in hip surgery (in our study it was 1.3%), a very large clinical trial would be needed to find out if drain usage reduces infection rates. Based on the average infection rate of 4.5% in the meta-analysis, such a study would require 750 patients in each group to demonstrate a difference in risk of 3% (3% vs. 6%) between the two groups.

There is no clear evidence that wound drainage is associated with reduction of haematoma formation. Wildman *et al* found no statistical difference in haematoma size on nuclear medicine scanning in their total hip replacements (*36*). Significant surgery results in the formation of a dead space which is not decreased by suction drainage as the tissues are not mobile enough. This space, therefore, has to fill with blood until a tamponade effect is achieved. This potential space is of the same volume

whether drainage is used or not. The use of closed suction drainage merely serves to increase this potential dead space by the volume evacuated by the drain (*21*).

There was no significant difference in levels of haemoglobin (Hb) at 24 and 72 hours or haematocrit (HCT) at 24 hours between the three groups. The differences in transfusion rates are therefore not explained by differences in post-operative Hb or HCT levels.

One weakness of this study is the lack of a strict transfusion trigger. Although recommended algorithms are available (*13*), the hospital's peer review board felt it important to treat each patient and their requirement for allogeneic blood on an individual basis. That haemoglobin levels post-operatively were similar between groups would suggest that the decision to transfuse was not based on Hb alone, but on risk factors and symptoms. The greater rate of transfusion in the suction drain group may in part be explained by the visible cue provided by blood in the drain and the knowledge that this blood will not be given back to the patient. Transfusion rates in total knee replacement vary between 6 (*16*) and 95% (*19*). This illustrates the heterogeneity of policies or simply of behaviours of clinicians with respect to blood transfusion. The decision to transfuse has a subjective component which can never be completely erased, which may reduce the reliability of transfusion rate as an outcome measure.

A second weakness in our study design is the lack of blinding to drain use by the operating surgeon. This is a common weakness of studies comparing the use of suction drains and reinfusion drains (*5*). In our study, surgeons were informed of the patient's study group prior to commencing surgery. Although this may have influenced the degree

of diathermy haemostasis performed, surgeons were advised to use equal scrutiny for all three groups. The absence of a significant difference in intra-operative blood loss suggests that the absence of blinding will not have influenced the outcome of the study through its effect on haemostasis. For future research this bias may be minimised by having the surgeon leaving the operating room and have the wound closed by a surgical assistant and the drain inserted as per randomisation. At our unit surgeons wanted to close the wounds themselves and so this method could not be used.

The intermittent clamping of drains after total hip replacement has been suggested as a method of reducing transfusion rates by producing a tamponade, but allow prevention of haematoma formation. Brueggemann *et al* used clamping of the drain for 55 minutes every hour for 6 hours after hip replacement to reduce drainage. This reduced calculated blood loss and transfusion requirements (*4*). On the other hand, Clifton *et al* in their randomised trial, showed no benefit in clamping a drain for 1 hour rather than immediate release post-operatively (*6*). Clamping was not performed in our study to avoid the addition of a further variable and reducing the effective sample size for each population. Other suggested methods of reducing blood transfusion have previously been summarised elsewhere (*17*), which were not formally investigated for the purposes of this study, but should also be considered in practice.

To our knowledge, this is the first study to prospectively compare all three wound drainage options available to surgeons, namely a reinfusion drain, a standard suction drain and no drain, in a population of patients undergoing total hip replacement who have not donated autologous blood preoperatively. We found that using a suction drain significantly increased risk of allogeneic blood transfusion and length of hospital stay, compared to using no drain. We found no significant difference between using a reinfusion drain and using no drain in the rate of allogeneic blood transfusion or the length of hospital stay, and therefore feel that those reasons cannot justify the use of a drain. Whether the use of a reinfusion drain can reduce the occurrence of wound complications will require a much larger study than ours was. This study, together with other previously published data would suggest that there is no benefit in using a non-transfusion suction drain. A further much larger study is required to define if there is any benefit of an autologous transfusion drain over no drain at all.

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