Closed suction surgical wound drainage after hip fracture surgery: a systematic review and meta-analysis of randomised controlled trials

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Received: 5 May 2007 / Accepted: 5 June 2007 / Published online: 9 August 2007
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Abstract There is still debate over the use of drains following hip fracture surgery. We have performed a systematic review and meta-analysis of the literature for randomised trials that related to the use of closed suction drains following hip fracture surgery. Six studies involving 664 patients were identified. There was no statistically significant difference in the occurrence of wound healing complications, re-operations or requirement for blood transfusion between drained and un-drained wounds. All other outcomes reported failed to show any benefit from the use of drains. Further randomised trials are required and until they have been undertaken the efficacy of closed surgical drainage systems in hip fracture surgery is unknown.

Résumé Il existe toujours un débat sur l'utilisation de drains après traitement chirurgical d'une fracture de la hanche. Nous avons réalisé une méta analyse de la littérature à partir d'essais randomisés relatant l'usage de drains aspiratifs après fracture de la hanche opérée. Six études regroupant 664 patients ont été analysées. Il n'y a pas de différences significatives sur le taux de complications (hématome). Le nombre des réinterventions, ni la nécessité de transfusions entre les plaies drainées et non drainées. De nouveaux essais randomisés seront utiles pour

déterminer l'efficacité du drainage chirurgical après fracture de la hanche.

Introduction

Drains have been used with varying success in orthopaedic surgery for many years. There are different opinions on the exact risks and benefits that closed suction drainage provides for a surgical wound and this is seen in everyday clinical practice, where some surgeons use drains and others do not. However, despite widespread use of closed suction drainage in hip fracture surgery, there are few randomised controlled trials evaluating scientifically the advantages and disadvantages of placing a drain in a surgical wound following hip fracture surgery. This meta-analysis aims to bring the reader up to date with current type Ia and Ib evidence on the use of closed suction drainage in hip fracture surgery.

Patients and methods

We identified all randomised controlled trials which compared closed suction drainage in hip fracture surgery with no drainage. Quasi-randomised trials (where the method of allocating participants to a treatment are not strictly random, e.g., date of birth, hospital record number and alternation) and trials in which the treatment allocation was inadequately concealed were considered for inclusion. Outcome measures recorded including wound infection, wound haematoma, complications directly relating to drains and transfusion rate.

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register to March 2006, the

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Cochrane Central Register of Controlled Trials (Issue 1, 2006), MEDLINE (1966 to March 2006), MEDLINE Pending, EMBASE (1988 to March 2006) and CINAHL (1982 to March 2006). The reference lists of identified articles were studied and in addition trialists were contacted as necessary. Articles in all languages were included and translated if necessary.

Each trial was independently assessed and data extracted without masking of the study names by two reviewers. The methodology of each study was evaluated using the method shown in Table 1. This is similar to that described by Detsky and colleagues [2]. Differences were resolved by discussion.

For each study, relative risks and 95 per cent confidence limits were calculated for dichotomous outcomes, and mean differences and 95 per cent confidence limits were used for continuous outcomes. Where appropriate, results of comparable groups of trials were pooled using a fixed effect model assuming there was no significant heterogeneity between studies. Heterogeneity between trials was tested using a standard chi-squared test with additional consideration of the I-squared statistic [4]. Heterogeneity was considered to be present if the p value from the chi-squared test was <0.10 or the I squared test was $>50\%$.

Results

Despite extensive searching of the literature only six randomised studies were identified [1, 3, 5, 6, 8, 10]. Varley was reported in two full reports [9, 10]. The study of Nicolajsen et al. [6] was only reported as a conference abstract with limited presentation of results, such that no data were available for meta-analysis. Details of the included studies are given in the Table 2. The studies involved a total of 664 patients. For the purpose of this review the unit of analysis was the number of surgical wounds and not the number of patients randomised. All patients had unilateral surgery.

Cobb et al. [1] randomised 35 patients to have their wounds closed over two suction drains, one deep to the fascia lata alongside the metal implant and the other in the superficial fat. The other 35 patients had their wounds closed in an identical manner except no drains were used. Wounds were assessed on the seventh postoperative day and any wound complications recorded during follow-up. Duranthon et al. [3] studied 86 patients with hip fracture treated with a bipolar hemiarthroplasty via a postero-lateral Moore approach. Outcomes recorded included the number of patients returning to theatre, haemoglobin fall, number of patients receiving a transfusion and temperature. Lautenbach et al. [5]

Table 1 Methodology scoring system

1. Was there clear concealment of allocation?	Score 3 if allocation clearly concealed (e.g., numbered sealed opaque envelopes drawn consecutively). Score 2 if there was a possible chance of disclosure before allocation Score 1 if the method of allocation concealment or randomisation was not stated or was unclear. Score 0 if allocation concealment was clearly not concealed such as those using quasi-randomisation (e.g., even or odd date of birth)
2. Were the inclusion and exclusion criteria clearly defined?	Score 1 if text clearly states the types of operations involved and the types of patients included and excluded. Otherwise score 0
3. Were the outcomes of patients who withdrew or excluded after allocation described and included in an intention to treat analysis?	Score 1 if yes or text states that no withdrawals occurred or data are presented clearly showing 'participant flow' which allows this to be inferred. Otherwise score 0
4. Were the treatment and control groups adequately described at entry and, if so, were the groups well matched for co-morbidity, or appropriate co-variate adjustment made?	Score 1 if at least four admission details given (e.g., age, sex, mobility, function score, mental test score) with either no important difference between groups or appropriate adjustment made. Otherwise score 0
5. Were the care programmes other than the trial options identical?	Score 1 if text states they were or if this can be inferred. Otherwise score 0
6. Were all the outcome measures, particularly the definition of wound sepsis, clearly defined in the text with a definition of any ambiguous terms encountered?	Score 1 if yes. Otherwise score 0
7. Were the outcome assessors blind to assignment status?	Score 2 if assessors of wound healing were blinded to study groups Score 1 if probably blinded. Otherwise score 0
8. Was there active follow-up of patients (review at scheduled times), as opposed to passive (simple reporting of incidents as they occurred) with a minimum follow-up of 3 months?	Score 1 if yes. Otherwise score 0
9. Was loss to follow-up reported with a minimum follow-up and was follow-up of a minimum of 3 months? If so, were less than 5% of patients lost to follow-up?	Score 1 if yes. Otherwise score 0

Table 2 Characteristics of included studies

Study	Year	Country	Number of cases	Type of fractures	Length of follow-up	Number lost to follow-up	Type of randomisation	Total methodology score
Cobb	1990	UK	70	All proximal femur	7 days	0	Even or odd hospital number	3
Duranthon	2000	France	86	Intracapsular (bipolar hemiarthroplasty)	10 days	0	Envelopes opened in theatre	8
Lautenbach	2000	South Africa	51	All proximal femur	14 days	0	Not stated	2
Nicolajsen	1996	Denmark	80	All proximal Femur	Unknown	Unknown	Unknown	1
Tjeenk	2005	Holland	200	All proximal femur	Hospital stay	0	Envelopes opened in theatre	9
Varley	1995	UK	177	All proximal femur	6 months	46 at 6 months (deaths)	Envelopes opened in theatre	7

randomly divided patients into five groups according to the drainage used. Nine patients received no drain, ten patients a 3-mm drain, 12 patients a 6-mm drain, 12 patients a double lumen drain with a bolus of streptokinase and 8 patients a double lumen drain with 4-hourly streptokinase. Blood loss during surgery and the volume of blood transfused were recorded along with leg swelling, volume of haematoma by ultrasound and wound seepage. Tjeenk et al. [8] studied 200 patients undergoing surgery for an intra- or extra-capsular femoral fracture treated with a hemi-arthroplasty or dynamic hip screw. Patients allocated to receive closed suction drainage had the end of the drain placed deeply beneath the fascia lata. The drain was removed at 24 h and wounds were covered with a surgical dressing only. All wounds were assessed on the 1st and 7th post-operative day and at discharge by an independent person. Wound healing was evaluated along with haematoma formation, wound dehiscence or wound infection. Varley et al. [9, 10] studied 177 patients undergoing dynamic hip screw or hemiarthroplasty for proximal femur fracture. Wound drains were removed 48 h post-operatively and the patient mobilised. The wound was inspected on the 2nd, 5th and 8th post-operative day and given a wound score. Wound drain tips were sent for microbiology and the amount of drainage was noted. On the 5th post-operative day patients underwent an ultrasound examination of the wound to determine the presence and size of any haematomas. Pre- and post-operative haemoglobin estimations and any transfusions given were recorded.

Wound infection

For the study of Cobb et al. [1], wounds were inspected at 7 days after surgery and assessed for signs of inflammation (heat, tenderness, redness and swelling). There was a tendency to more signs of inflammation in the drained group, but the difference was not statistically significant and the total number of patients showing signs of inflammation was similar (21/35 versus 20/35). Varley et al. [10] used the ASEPSIS scoring system. This is a grading of wound erythema, exudates, isolation or bacteria and need for further treatment. A higher score represented impaired wound healing. Wounds were assessed at 2, 5 and 8 days after surgery. Mean scores for the drained versus un-drained group were 1.02 versus 1.26 at day 2, 1.05 versus 1.13 at day 5 and 1.33 versus 2.05 at day 8. The difference between the two groups was statistically significant at day 8 ($P=0.018$ t-test). Lautenbach et al. [5] noted two overt deep infections and two superficial infections, all occurring in patients whose wounds were drained. Tjeenk et al. [8] found no significant difference in the wound infection rate between the drainage and non-drainage groups ($P=0.36$). The summation of the total number of reported wound infections for all studies that reported on this outcome are listed in Table 3 and Fig. 1 details the Forest plot for all wound infections. Nicolajsen et al. [6] reported without data no difference in the signs of wound infection between groups.

Table 3 Table of key outcomes

	Number of studies with data	Drained wounds	Undrained wounds	Relative risk	95% confidence intervals
All wound infections	5	18/306 (5.9%)	25/278 (9.0%)	0.62	0.34–1.14
Deep sepsis	4	4/220 (1.8%)	3/187 (1.6%)	0.77	0.17–3.48
Haematoma	3	17/178 (9.6%)	24/178 (13.5%)	0.71	0.41–1.24
Re-operation	4	3/264 (1.1%)	2/269 (0.7%)	1.30	0.33–5.20
Patients transfused	3	104/229 (45.4%)	94/234 (40.2%)	1.12	0.92–1.38

Fig. 1 Forest plot for the data from those studies which reported on the occurrence of wound infection related to the use of drains

Wound haematoma

Lautenbach et al. [5] stated without statistical analysis that the volume of haematoma as measured by ultrasound was smaller in the un-drained group. Varley et al. [10] also used ultrasound assessment for 140 of the patients. The mean size of haematoma was 20 ml in both the drain and no drain groups. Tjeenk et al. [8] found no significant difference in the severity of wound haematoma between the drainage group and the non-drainage groups ($P=0.29$). Table 3 gives the reported numbers of haematomas for the three studies that reported on this outcome. Nicolajsen et al. [6] reported without data no difference in wound haematomas between groups.

Re-operations for wound healing complications

Cobb et al. [1] stated that two of the drained group required re-operation, one for a partial wound dehiscence and one for removal of a drain that was stitched in place. Varley and Milner [10] also reported that one drain was inadvertently stitched in and required surgery to remove. Seven other patients in this study also required re-operations, but none for wound healing complications. Tjeenk et al. [8] stated two patients both in the non-drainage group required re-operation for removal of hemi-arthroplasty, but the reason for this was not stated. Combining all studies showing a tendency to an increased re-operation rate for the drains wounds, but the difference was not statistically significant (Table 3).

Transfusion requirement

Varley and Milner 1995 [10], Duranthon et al. [3] and Tjeenk et al. 2005 [8], all found that the use of drains gave an increased need for transfusion. Combining the results for all three papers gives a trend towards increased transfusion requirements if wounds are drained, but the difference was not statistically significant (Table 3). Nicolajsen et al. [6]

reported without data no difference in the requirement for transfusion between groups.

Change in haemoglobin or haematocrit

Cobb [1] and Duranthon et al. [3] reported there was no significant difference between groups for the post-operative haemoglobin levels. Tjeenk et al. [8] reported on the fall in haemoglobin with no statistically significant difference between groups. Varley and Milner [10], reported a mean fall in the haemoglobin of 27 g/l for the drained group versus 24 g/l for the un-drained group. The difference was not reported to be statistically significant. Nicolajsen et al. [6] reported without data no difference in the change in haemoglobin between groups.

Other outcomes

Only one study reported on mortality [8], with 6/100 patients dying in each group. Only Lautenbach et al. [5] reported on deep vein thrombosis as a complication of hip fracture surgery. They had no thrombosis in either cohort of a total 51 patients. No study reported on pulmonary embolism. Duranthon et al. [3] reported on the patient's temperature at day 1, 2, 5 and 10 post-operatively. There was no significant difference between groups. Cobb and Milner [1] noted mean maximum post-operative temperature was little different between drained and undrained groups. Nicolajsen et al. [1] reported no difference in the patient's temperature, sedimentation reaction or leucocyte levels between groups.

Discussion

The methodology of the studies identified and included in the analysis varied considerably, although in some cases the low score may reflect a poor reporting of trial methods rather than poor trial methodology. In addition, because few

studies used a blinded assessment of outcome, there may be bias in the reporting of subjective outcome measures. The follow-up period for all but one study was short, often involving only the time the patient was in hospital, and this may have resulted in under-reporting of outcomes.

The primary outcome measures for an investigation of drains should be the incidence of wound infections. The results of this analysis indicate no statistically significant difference for infections, but care should be taken before making definite conclusions for these outcomes, as the overall number of infections was small. In order to make any conclusion for this outcome, a power calculation indicates that at least 4,000 participants with adequate follow-up need to be studied before any conclusion can be drawn. Blood transfusion requirements and the re-operation rate tended to be lower for those patients in the no drain group. However, because of the limited number of cases, again no definite conclusion can be drawn.

A previous systematic review of randomised trials on drains in all types of orthopaedic surgery identified 36 studies involving 5,464 participants [7]. Wound drains could not be shown to have any effect on wound healing complications, but did result in an increase in the requirement for blood transfusion. Analysis of those randomised trials identified by the Cochrane collaboration for other types of surgery also shows a failure of such studies to demonstrate any benefit for closed suction drainage systems for any type of surgery.

Despite the common occurrence of hip fractures, there are not many studies to date so the true value of drains still remains unknown. Based on the randomised trials undertaken to date, there is insufficient evidence to support the routine use of closed suction drainage in hip fracture surgery. More studies need to be undertaken with a larger number of patients and longer follow-up before definite conclusions on the use of drains in hip fracture surgery can be made.

Conflict of interest statement No authors had any financial or personal relationships with any other people or organisation that could have influenced this piece of work inappropriately.

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