

Simplified wound care and earlier wound recovery without closed suction drainage in elective total hip arthroplasty. A prospective randomized trial in 100 operations

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Abstract

Introduction Evidence to support or refute closed suction drainage (CSD) in primary total hip replacement (THR) is not conclusive. Our anecdotal experience was that persistent ooze from the drainage hole often delayed wound recovery. We hypothesized that, without CSD, wound care would be simplified without short or long term disadvantage.

Materials and methods Hundred patients scheduled for primary THR were randomly assigned for CSD or non-drainage. Drains were withdrawn at day 2. Pain, wound hematoma, number of dressing changes, time of persistent discharge from the operation site (skin incision and drain hole), total blood loss and number of blood transfusions were prospectively recorded. Hip function, presence of heterotopic ossifications (HTO) and complications were recorded at a follow visit 1 year after surgery.

Results Wound sites managed without CSD needed significantly less wound dressings ($P < 0.001$) and were dry at an earlier time ($P < 0.001$). Despite a significant bigger subfascial hematoma in the non-drained group ($P < 0.05$), in terms of pain, thigh swelling, total blood loss, number of transfusions needed, hip function and

HTO no difference was recorded between the groups ($P = 0.2–0.82$).

Conclusion To omit CSD in primary THR results in simplified and more rapid wound management without any disadvantage at short and long term.

Keywords Total hip replacement · Drainage · Suction · Wound · Blood loss

Introduction

The use of a closed suction drain (CSD), consisting of a perforated plastic tube connected to a bottle with negative pressure, aims to reduce the formation of hematoma which is thought to impair wound healing by increasing wound tension and reducing tissue perfusion [3]. Furthermore, hematoma provides an excellent culture medium for infection [21] and may favor persistent oozing or bleeding from the wound.

A potential adverse effect of surgical drains is that they may become contaminated and act as a conduit for infection into the depths of the wound [9, 15, 19]. Furthermore, on rare occasions they may have been inadvertently misplaced or sutured to surrounding tissues requiring additional surgery to remove them [3].

Results of clinical trials on the use of drains are conflicting and most of them include different surgical procedures into the same study [3, 7, 20], have a short follow-up [4, 12, 18] or use small numbers [12, 17].

Total hip replacement (THR) is now a standardized highly successful procedure. In the context of reduced financial resources in our health care systems, one main effort in this field to day aim to reduce the time of nursing care dependence. Using drain on a routine

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base, our anecdotal experience was that prolonged discharge from the incision nearly never occurred in our patients, even if the total volume of drainage was very low. However, serous ooze from the drainage hole after drain removal often was present for several days requiring additional daily dressing changes and nursing care, provoking some distress to the patient and potentially increasing hospital stay.

We therefore hypothesized that in terms of wound care and duration of serous discharge from the operation site, wound management without CSD after hip arthroplasty would be simplified and would not be associated with short or long term disadvantage.

Materials and methods

Patients

Starting in July 2003, patients scheduled for elective primary THR were asked to participate in this study if they did not suffer from bleeding coagulopathy, did not receive medicine affecting the coagulation system up to 10 days before surgery or did not have pathological INR, aPTT or thrombocyte count on the occasion of the preoperative screening. Hundred patients were included if informed consent to participate was signed. The local ethics protection committee approved the study. For randomization into the group of no drain and the group of drain, closed envelopes opened by the anesthetist only at the end of surgery just before wound closure was used. No further vessel coagulation was allowed after assignment. From 146 patients undergoing primary THR till May 2004, 35 were not willing to participate, 2 suffered from coagulation disorders, 2 received medicine affecting the coagulation systems and 7 had pathological values on the preoperative screening. They were treated with closed suction drainage.

From the remaining 100 patients, 50 patients got a drained wound and 50 got no drain.

Surgical technique

Surgery was performed by three experienced staff members in the lateral position under spinal or general anesthesia in dedicated orthopedic theatres equipped with a vertical type of laminar airflow. Three doses of a third generation cephalosporin (Zinacef 1.5 g in intervals of 8 h) starting 30 min preoperatively were given to all patients. Subcutaneous injections of a low molecular weight heparin (Clexane®) starting the evening before surgery and continued during the whole period

of partial weight bearing was given according to the dosage recommendations of the producer. A transgluteal approach with release of the ventral portion of the vastus lateralis and gluteus medius from the greater trochanter was used for all hips. Blood vessels were electrocoagulated throughout the procedure. Uncemented pressfit cups (Fitmore, Centerpulse®) with modular polyethylene inlay (Protasul® or Durasul®) and cemented (Palacos®) femoral stems (Exafit®, Centerpulse®) as well as 28 chrome-cobalt head sizes were used in all patients. The ventral portion of vastus lateralis and gluteus medius was refixed to the greater trochanter using 4 transosseous sutures (Ethibond® 3, Ethicon) and a continuous suture (Vicryl® 2-0, Ethicon). In patients allocated to the drainage group, one 3.5 mm drain was placed under the fascia lata into the split of the gluteus medius muscle and led out through a stab wound 5 cm anterior to the incision with at least a 3 cm long subcutaneous channel. The wound was closed in layers with a continuous Everett suture (Maxon loop®, Tyco) for the fascia lata, a continuous monofil suture (Maxon®3-0, Tyco) for the subcutaneous layer, single cuticular stitches (Maxon®4-0, Tyco) and a continuous cutaneous suture (Ethicrin® 4-0). A hydrocolloid wound draping (Comfeel®, Coloplast AG.) aimed to be removed only 14 days after surgery was used. The drain was connected to a vacuumed (−900 mbar) drainage bottle (Redon®, B/Braun) and removed after 48 h.

Post-operative evaluation

Outcome assessors during the hospital stay were not blind to assignment status as the drain whole was visible. At the 12 months evaluation assessors were blind.

The amount of blood drained through the drainage was recorded on day 2 just before removal. The time of persistent discharge from the surgical incision and from the drain hole was recorded in days. The wound dressing applied immediately after surgery was aimed to be left in place until discharge from hospital and changed only if leakage was present. In this case it was exchanged by a conventional dressing. Conventional dressings of the surgical incision as well as of the drain hole were changed as soon as they were soaked. Dressing changes per patients were counted until discharge from hospital.

Pain was evaluated daily for the first 6 days using a Visual Analog Scale (0 [none]–10 [strong pain]). Swelling of the thigh was recorded on day 2 after drain removal by calculating the difference of thigh circumference 20 cm proximal to the upper patellar pole preoperatively and on day 2. The extent of subcutaneous

and subfascial wound hematoma were measured at the sixth post-operative day by a radiologist using sonography and the volumes calculated (volume (cm³) = [width (cm) × depth (cm) × cranio-caudal expansion (cm) × 314]/6). Total blood loss was calculated from hemoglobin concentrations and hematocrit values recorded preoperatively and on the sixth post-operative day. Making the assumption, that a 1% fall of the hematocrit value corresponds to 170 ml of circulating blood, the following formula was used: 170 × [Hct preoperative – Hct sixth post-operative day] + [number of transfusions × 450] [8]. The total number of blood transfusions (autologous or/and allogenic red cell concentrates) were recorded on day 6.

Any re-operations or wound healing complications during the first postoperative year were recorded. At the routine 1 year control examination patients had a complete history about any complications since surgery and a clinical examination according to the Harris Hip Score. On anteroposterior pelvic and cross-table lateral views of the hip, the presence of heterotopic ossification was graded according to Brooker et al [2].

Data analysis and statistics

Quantitative variables (number of wound dressings, time of wound discharge, thigh circumference, volume of hematoma, total blood loss, blood transfusions, pain, HHS) between the drained and non-drained wounds were analyzed using an unpaired two-tailed *T*-test. For comparison of categorical variables (general vs. regional anesthesia, grade of heterotopic ossification) a Chi-square test was used. Pearson correlation was used for correlation between quantitative variables. The level of statistical significance was set at 0.05, two-tailed.

Results

Sample demographics

Patients in the non-drained group were older than patients in the drained group. This was accepted as a

consequence of randomisation, estimated to be not relevant and therefore not adjusted for in the statistical analysis. In terms of BMI, gender and general versus regional anaesthesia both groups were similar (Table 1).

Post-operative evaluation

The mean quantity of blood collected in the drainage bottle was 97 ± 138 ml (0–810 ml). The time of persistent discharge from the surgical incision did not differ between the drained and non-drained group, but when persistent discharge from the drainage hole was taken into account, drainage from the wound site of the drainage group persisted significantly for a longer time ($P < 0.001$) (Table 2). Similarly, patients from the drainage group needed significantly more dressing changes than patients without drainage ($P < 0.001$). No correlation existed between the quantity of blood collected in the drainage bottle and time of persistent discharge from the surgical incision ($R = -0.76$, $P = 0.6$) or the drain hole ($R = 0.42$, $P = 0.775$).

With respect to postoperative pain, swelling of the thigh, subcutaneous hematoma, total blood loss and number of blood transfusion units given, differences between the drained and non-drained group were statistically not significant (Table 3). Only the volume of subfascial hematoma was significantly superior for non-drained wounds ($P < 0.05$). Swelling of the thigh and extent of wound hematoma did not correlate ($R = 0.253$, $P = 0.076$), nor did swelling of the thigh or extent of subfascial hematoma correlate with pain at

Table 1 Sample demographics

	Drained group ($n = 50$)	Non-drained group ($n = 50$)
Age, mean ± SD (range)	61 ± 13 (30–84)	66 ± 10 (51–86)
Gender, female/male	28/22	27/23
BMI, mean ± SD (range)	27 ± 5 (20–42)	28 ± 5 (20–38)
General anesthesia	11	11
Regional anesthesia	39	39

Table 2 Wound care parameters

	Drainage group	Non-drainage group	Difference
Wound discharge (days)			
Surgical incision, mean ± SD (range)	1.5 ± 1.1 (1–6)	1.6 ± 1.6 (1–6)	$P = 0.72$
Drainage hole, mean ± SD (range)	3.8 ± 1.8 (2–10)	none	–
Wound site, mean ± SD (range)	3.8 ± 1.8 (2–10)	1.6 ± 1.6 (1–6)	$P < 0.001$
Number of dressings per patient, mean ± SD (range)	2.9 ± 1.9 (1–9)	1.6 ± 1.6 (1–7)	$P < 0.001$

Table 3 Short-term variables during hospital stay

	Drainage group	Non-drainage group	Difference
Pain, VAS 0–10			
Day 2, mean \pm SD (range)	1.9 \pm 1.5 (0–6)	1.8 \pm 1.6 (0–5)	$P = 0.68$
Day 6, mean \pm SD (range)	1.8 \pm 1.6 (0–5)	2.0 \pm 1.5 (0–5)	$P = 0.57$
Swelling on day 2 (cm)			
20 cm above patella, mean \pm SD (range)	2.6 \pm 3.1 (–4 to 10)	2.5 \pm 3.4 (–5 to 10)	$P = 0.73$
10 cm above patella, mean \pm SD (range)	1.0 \pm 2.7 (–4 to 8)	0.6 \pm 2.4 (–4 to 8)	$P = 0.46$
Hematoma on day 6 (cm ³)			
Subcutaneous, mean \pm SD (range)	1.9 \pm 4.1 (0–19.1)	0.94 \pm 3.4 (0–21)	$P = 0.2$
Subfascial, mean \pm SD (range)	2.6 \pm 3.3 (0–15.8)	8.0 \pm 17.0 (0–81)	$P = 0.03$
Total blood loss (ml), mean \pm SD (range)	2,346 \pm 1,034 (170–5,130)	2,195 \pm 1,110 (50–5,130)	$P = 0.49$
Blood transfusions (units), mean \pm SD (range)	2.4 \pm 1.6 (0–5)	2.5 \pm 1.9 (0–5)	$P = 0.82$

any time ($R = -0.06$ to 0.12 , $P > 0.2$) or persistent discharge from the surgical incision ($R = -0.04$, $P = 0.6$). A weak correlation existed between the extent of subfascial hematoma and the time of persistent discharge from the drainage hole ($R = 0.279$, $P = 0.049$). Total blood loss did not correlate with the quantity of blood collected in the drainage bottle ($R = -0.131$, $P = 0.376$), nor did it with the extent of subfascial hematoma ($R = 0.186$, $P = 0.196$).

Wound complications making surgical revisions or medical treatments necessary did not occur in both groups. In two patients from the drainage group trochanteric fracture occurred postoperatively. One underwent surgical revision with open reduction and fixation 3 months later, the other was treated conservatively.

At the 1 year follow-up visit, patient's history revealed deep vein thrombosis occurring in two patients, one managed with, and one without drainage. Both were treated with low molecular weight heparin. No wound infections were encountered. Harris Hip Score and grading of heterotopic ossification did not differ significantly between the two groups at one year.

Discussion

To our knowledge, this is one of the largest full reported randomized clinical trials, which confines to primary total hip replacement and follows patients for one year after surgery. Ritter [18] randomized 140 THR and followed them during a maximum of one week postoperatively only. Della Valle [6] randomized 104 THR and followed them for 3 months. Other larger series are not confined to THR [4, 11, 13] or are not full reported. Confinement to primary total hip replacement reduces possible cofounders due to regional differences of operation sites. Other cofounders due to differences in the operation technique such

as cemented versus non-cemented implants or different surgical approaches were also kept to a minimum because all surgeries followed the same surgical approach and technique and used exactly the same implants. When interpreting the results of the present study, one should be aware of its confinement to a conventional transgluteal surgical approach and to hybrid fixation using a cemented stem. Therefore, the study's conclusions may not be transposed to minimally invasive approaches and non-cemented THR. In this latter setting evidence to support or refute CSD still has to be studied.

Nevertheless, in the setting of a conventional transgluteal approach using hybrid fixation, in terms of postoperative wound care and patient's comfort, wounds managed without drain needed significant less wound dressings and achieved a dry operation site (incision and drain whole) a mean of 1.5 days earlier. The main reason for this difference was persistent discharge from the drain hole exceeding 3 days in 56% of patients managed with a drain. This agrees with other reports mentioning but not measuring this disadvantage of drains [3, 11]. In our clinical practice a dry wound site is a prerequisite for discharge from hospital, thus managing patients without drain has a potential for reducing hospital stay. This agrees with Della Valle's [6] study finding a longer hospital stay in the drained group and delayed persistent serous drainage with delayed discharge in two.

In terms of short-term variables, the only advantage of wound drainage was a significant smaller subfascial hematoma. This agrees with Kim's [8] results measuring hematoma formation in drained and non drained hips but disagrees with Widman [22] results doing the same using scintigraphy. This short term difference was present on sonography only, but did not reach clinical relevance as no correlation could be detected between the extend of subfascial hematoma and pain, swelling of the thigh, time of discharge from the wound and

number of dressings used. This disagrees with a study by Magnussen [10], who demonstrated a significant correlation between the presence of a haematoma and the development of an unsatisfactory wound.

It is a limitation of the present study, that its statistical power would never be enough to detect a significant difference in terms of wound infections between the two groups of patients. Literature on this topic is still confusing. On one hand, a large prospective study of clean surgical wounds showed a lower infection rate (1.53%) for non-drained wounds when compared to drained wounds (1.8%) [5]. Acus [1] reported significantly more superficial infections in the drained group (8.9% vs. 1.8%, $P < 0.025$). Murphy [12] showed only one case of infection in the drained group (5%) whereas the non-drained group had no infection at all. On the other hand, Waugh [21] showed a 1% infection rate in the wounds treated with suction as compared with the 3% infection rate in the control group. Finally, Ravikumar [17] abruptly stopped his study after having a 54% infection rate for the non-drained group compared to 8% in the drained group. In the present study, no superficial and no deep infections were encountered. This is similar to the results of others [4, 11, 14, 18].

Interestingly, neither the use of CSD nor the amount of drained fluid nor the extent of hematoma correlated with the calculated total blood loss or with the need of blood transfusions, respectively. This agrees with the majority of other reports on this topic [4, 11, 13, 14, 16, 18]. We therefore conclude that the main blood loss occurred during surgery.

In terms of longer follow-up, managing wounds with or without drains did not influence functional outcome one year after surgery. Concerns about a potentially higher risk for heterotopic bone formation for patients with greater subfascial hematoma formation could not be confirmed.

In conclusion, in the setting of THR using a transgluteal approach and hybrid fixation, managing surgical wounds without drainage, while without negative clinical manifest effect on short and long term, was associated with simplified and easier wound care, quicker wound recovery and a potential for shorter hospital stay.

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