

Low- or high-vacuum drains in hip arthroplasty?

A randomized study of 73 patients

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We compared the effect of low-vacuum and high-vacuum drains on blood loss and blood transfusions in a randomized study of 73 patients undergoing primary hip arthroplasties.

During the first postoperative hour, the high-vacuum drains evacuated more blood than the low-vacuum ones, median 135 and 35 mL ($p < 0.001$). After that, the rate of blood loss into the drains was approximately the same. Median blood losses into the drains after 24 hours were 570 mL in the high-vacuum group and 480 mL in the low-vacuum group ($p = 0.03$). Corresponding values after 48 hours were

785 mL and 585 mL ($p = 0.002$). The hemoglobin concentration in the drain fluid during the second postoperative day was lower in the high-vacuum group, indicating a more serous discharge.

Our findings indicate that drains should be removed within 24 hours. High-vacuum drains evacuate more blood initially but may cause more damage to the tissues, especially if they are left for more than 24 hours. We found no significant difference in postoperative hemoglobin decrease or in the number of blood transfusions and wound complications in the 2 groups.

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The use of closed suction drains may decrease the risk of postoperative wound complications (Waugh and Stinchfield 1961, Surin et al. 1983, Magnussen et al. 1986); Moss (1981) found fewer wound infections and less wound margin necrosis in breast surgery. Drains can be constructed to produce a high (high-vacuum) or a low (low-vacuum) negative pressure relative to the atmospheric pressure (Rudberg 1988).

As we are interested in methods for reducing perioperative blood loss, we investigated whether the use of low-vacuum drains could reduce blood loss and blood transfusions in hip arthroplasty. A second aim of the study was to evaluate differences in wound complications.

Patients and methods

The high-vacuum drain investigated was the Medinorm 600 (Medinorm AG, Querschied, Germany). The bottle volume is 650 mL and the initial suction pressure is reported to be approximately 600 mmHg. Trials in the Department of Medical Technique at our hospital showed an initial negative pressure of approximately 670 mmHg relative to the atmospheric pressure, decreasing to 450 mmHg when the bottle was half-full (300 mL). The suction ceased when the bottle contained approximately 550 mL of fluid.

As the low-suction drain, we used the Handy-Vac (Lövens AS, Ballerup, Denmark). This drain has a manually compressed bellow that creates an initial suction of approximately 65 mmHg. As the bellow expands, the drain is converted to a passive drain with a suction of approximately 25 mmHg through a siphon mechanism. Blood from the bellow is drained into a plastic drain bag. For both drain types, a subfascial 18 gauge and a subcutaneous 16 gauge drain tube were used.

Control measurement of drain volumes in the two drain types, versus a graduated glass in 39 patients, showed that the high-vacuum drain (Medinorm) had an accuracy with a mean error of +1 mL, 95% confidence interval -4 to +6 mL. The mean error in the low-vacuum drain (Handyvac) was +36 mL, 95% confidence interval 4–67 mL.

All the patients in the study had a primary, cemented Charnley total hip replacement. Patients with rheumatoid arthritis or bleeding disorders or failed hip fractures with unremoved osteosynthesis material were excluded.

A power analysis applied to a previous study (Elawad et al. 1991) revealed that 80 patients would be required to discover a significant difference in postoperative blood loss of 300 mL, with a power of 80% and a significance level of 5%. This number was calculated to compensate for drop-outs. The randomiza-

Table 1. Basic patient data. Mean (SD)

	High-vacuum	Low-vacuum
No. of patients	38	35
Men/women	9/29	9/26
Age	75 (9)	73 (8)
Height	165 (7.5)	166 (8)
Weight	71 (13)	68 (12)
Left/right hip	19/19	18/17
Operation time, minutes	116 (30)	116 (17)
Use of cell-saver at operation	15 7	
Epidural/general anesthesia	37/1	32/3

tion between low- and high-suction drains was made by sealed envelopes from a random number table. The envelopes were opened towards the end of the operation, when closure of the wound started, and the drains were to be inserted. Due to randomization error or peroperative decision to use an uncemented prosthesis, 7 patients were excluded. These drop-outs occurred at random.

The diagnosis in the remaining 73 patients was primary coxarthrosis in 63 and secondary arthrosis in 10 (Table 1). 3 patients had previous hip fractures. Their osteosynthesis pins were removed more than 3 years before the hip arthroplasty. Drugs containing NSAID were discontinued at least 1 week before operation in all patients.

All operations were performed with the patients in the supine position, using a trochanteric osteotomy. Surgery was performed in a Charnley box with vertical laminar flow. 69 patients had epidural anesthesia and 4 had general anesthesia (Table 1). All patients received antibiotic prophylaxis. 2 patients in the high-vacuum group received tranexamic acid postoperatively because of profuse bleeding during operation, 1600 and 2600 mL. Blood losses into the drains were 1915 and 1160 mL, respectively. Another patient in the low-vacuum group, with per- and postoperative blood losses of 600 and 730 mL, was also given this drug.

15 patients in the high-vacuum and 7 in the low-vacuum group were operated on with a cell-saver (Electromedics AT-1000, Electromedics corp, USA) connected peroperatively (Table 1). The cell-saver was used as a routine procedure whenever it was available. 4 patients with high-vacuum drains and 1 with low-vacuum drains also had the machine connected during the first 4 hours after the operation.

1 of these patients, in the high-vacuum group, was 1 of the 3 who was given tranexamic acid. The suction pressure from the cell-saver was adjusted to 60–80 mmHg, i.e., about the same as the initial value in the low-vacuum drain.

Dextran was used for thrombosis prophylaxis. 1 L of dextran 70 (Macrodex®, Medisan, Uppsala, Sweden) was given during the day of operation. Another 0.5 L was given during postoperative days 1, 3, and 5. Graded compressive stockings were used during operation and the first postoperative week (Fredin et al. 1989).

Bleeding into the drains were recorded at 1, 4, 8, 12, 24, and 48 hours postoperatively. Blood hemoglobin concentration and hematocrit were measured on admission, immediately before operation, 1 hour after operation and on the 1st, 3rd, 7th, and 10th postoperative days and also at the first out-patient visit after approximately 6 weeks. Blood transfusions were recorded as the number of Sagman units used, 1 unit is approximately 330 mL of erythrocyte concentrate, produced from 450 mL of donor blood.

Complications, such as bleeding through the bandages, wound hematoma, discharge from the drain sites and signs of infection were also recorded at the regular change of dressings 5 days postoperatively or earlier if needed.

Hemoglobin concentrations in drainage fluid during the first and second postoperative days were checked in a separate study of another 18 hips in 17 patients (12 women), age 71 ± 10 years, not included in this study, who also were randomized to high-vacuum (n 10) or low-vacuum (n 8) drains.

Statistics

The Mann-Whitney rank sum test was used to test the difference between the data concerning blood loss and blood transfusions. To compare the blood hemoglobin levels, the Student's t-test was used. Results are expressed as median values (lower and upper quartiles), unless otherwise stated.

Results

Blood loss

Operative bleeding was the same in both groups, 800 mL, upper and lower quartiles 700–1100 mL in the high-vacuum group and 675–1250 mL in the low-vacuum group. The peroperative blood losses in the subgroup of patients with cell-saver connected during operation were a median of 950 (750–1100) mL and 900 (800–1300) mL, respectively. The median peroperative blood loss in the 5 cases who had the cell-saver connected also during the first postoperative hours was 1000 (900–2600) mL.

The greatest difference between volumes flowing into the drains occurred during the first postoperative hour, when blood losses into the high-vacuum drains

Table 2. Median (upper and lower quartiles) rate of blood loss into the drains (mL/hour)

Hours after operation	High-vacuum group	Low-vacuum group	P-value
0–1	135 (80–180)	35 (10–100)	< 0.001
1–4	48 (43–80)	43 (25–68)	
4–8	20 (12.5–27.5)	25 (15–37.5)	
8–12	12.5 (5–16)	12.5 (2.5–22.5)	
12–24	11 (8–15)	8 (2–13)	
24–48	4.5 (3–6.5)	4.5 (2–6.5)	

were 135 (80–180) mL and into the low-vacuum drains 35 (10–100) mL. After that, the drainage, expressed as mL/hour, was approximately the same (Table 2). Accumulated blood loss is shown in Table 3. The difference in blood loss was more pronounced in the subcutaneous than in the subfascial drains. In the subgroup of patients in whom a cell-saver was used, the final drain bleedings were 840 (615–1035) mL in the high-vacuum group and 700 (380–850) mL in patients with low-vacuum drains.

In the separate study on hemoglobin concentrations in the drain fluid, there was a tendency to lower values, 18 (11–27) and 21 (13–34) g/L in the subcutaneous and subfascial high-vacuum drains and 38 (28–46) and 51 (30–56) g/L in corresponding low-vacuum drains the second postoperative day. There was, however, a great variation in these values and the difference between the two drains was not significant.

Blood transfusions

The total amounts of blood transfused, including blood returned from the cell-saver, were 740 (500–985) mL in the high-vacuum group and 650 (510–1040) in the low-vacuum group ($p = 0.8$). The amounts of transfused homologous blood were the same in both groups, median value 2 Sagman units, range 0–7 in the high-vacuum group, 0–5 units in the low-vacuum group. Blood hemoglobin values were higher in the low-vacuum group, but the decline in blood hemoglobin levels was not significant from admission to the 7th postoperative day between the two groups (Table 4).

Complications

No patient was reoperated in the period studied. There was no delayed wound healing. 1 patient in the low-vacuum group bled through the dressing. 1 patient in the high-vacuum group and 2 in the low-vacuum group had wound hematomas that resolved spontaneously. In the high-vacuum group, 7 patients and in the low-vacuum group, 3 patients had secretion from the drain sites ($p = 0.4$). 9 of these patients had bacterio-

Table 3. Blood loss into the drains. Median (upper and lower quartiles) total drain volumes

Hours after operation	High-vacuum group	Low-vacuum group	P-value
1	135 (80–180)	35 (10–100)	< 0.001
4	300 (235–430)	180 (100–300)	
8	410 (300–500)	300 (225–400)	
12	440 (330–550)	405 (250–540)	
24	570 (465–705)	480 (385–595)	0.03
48	785 (570–1035)	585 (450–700)	0.002

logical cultures taken. The positive cultures demonstrated *Staphylococcus epidermidis* in 2 patients and *Enterococci* in 1. All these wounds healed without complications. 1 patient in the low-vacuum group without wound complications, developed signs of infectious loosening of the prosthesis, leading to revision 11 months later. Peroperative cultures showed scarce growth of diphtheroid rods.

Discussion

Our recordings concerning the vacuum characteristics in the 2 drain-types were similar to the findings of Rudberg and Tera (1988), except that we found a somewhat lower value (450 vs 525 mmHg) when the bottle was half-full in the Medinorm drains.

The accuracy of the volume-scaling in the two drains was, however, different. The lower accuracy of the Handy-Vac drains, in which the blood loss was systematically overestimated by a mean of 35 mL, tended to reduce the difference between the two drain types as the low-vacuum drains generally drained lower volumes than the high-vacuum type.

During the first postoperative hour, the blood loss into the high-vacuum drains was about 100 mL more than into the low-vacuum drains. This difference may be exaggerated by a greater difficulty in accurately reading small volumes in the low-vacuum drains.

Table 4. Mean (SD) hemoglobin levels at different points of times

Time	High-vacuum	Low-vacuum	P-value
On admission	133 (9)	136 (12)	
Immediately preop.	127 (12)	131 (17)	
1 hour postop.	104 (13)	112 (12)	0.009
Day 1	97 (11)	98 (10)	
Day 3	101 (11)	101 (14)	
Day 7	102 (10)	108 (10)	0.02
Day 10	107 (9)	112 (10)	0.05
6 weeks postop.	122 (11)	127 (12)	

This error would, however, decrease as the drained volumes increased. After the first hour, the rate of blood loss into the drains rapidly decreased and became approximately the same in the two drains. 12 hours after the operation and later, the rate of blood loss into the drains was about 10 mL/hour or less, suggesting that the drains may be removed by that time.

2 patients in the high-vacuum group received tranexamic acid because of high blood loss vs 1 patient in the low-vacuum group. This patient, however, had a moderate blood loss and the reason for tranexamic acid medication was not clear. Furthermore, 15 patients in the high-vacuum group had a cell-saver connected during the operation and in 4 patients the use of the cell-saver was extended to the first 4 postoperative hours. Corresponding numbers of patients in the low-vacuum group were 7 and 1. These patients may confound the results, as they had higher pre- and postoperative blood losses. On the other hand, the suction pressure in the cell-saver is approximately the same as the initial level in the low-vacuum drains, which tends to reduce the measured difference between the groups. If patients with tranexamic acid and cell-saver are excluded, total blood losses after 48 hours were 740 (500-970) mL into the high-vacuum drains vs 575 (475-655) mL into the low-vacuum drains ($p = 0.03$), i.e., the conclusion of the study is not changed.

Findings in previous studies concerning the efficacy of drains are contradictory. In 1961, Waugh and Stinchfield claimed that the use of closed suction drains was beneficial in various orthopedic operations. On the other hand, Lidwell (1961), Jepsen et al. (1969) and Simchen et al. (1984) reported that the use of drains was a risk factor for wound infection. These studies, not made at random, report a retrospective incidence of wound infections in various elective and emergency operations. That drains in these studies show a significant relation to postoperative infections can be due to the fact that surgeons probably tend to use drains more often when they suspect that the wounds are contaminated. Lidwell (1961) and Simchen et al. (1984) point out that a reoperation—for example, due to bleeding or the evacuation of a hematoma—is a significant risk factor for postoperative infection.

A drain could also damage tissue, especially if it exerts a high negative pressure (Woodforde Scott 1981, Cherry and McClatchey 1983, Kirschner et al. 1989). On the other hand, Britton et al. (1979) reported that high vacuum drains functioned better than low-vacuum ones after mastectomies, resulting in lower drain volumes and faster drain removal. Our study showed there was a discharge from the drain holes after drain removal in 7/38 patients in the high-

vacuum group, as opposed to 3/35 in the low-vacuum group. The hemoglobin concentration in the exudate was lower in the high-vacuum drains during the second postoperative day. Taken together, these two observations may mean that the high-vacuum drains have a more irritating effect in the wounds.

Closed-suction drains have resulted in less wound infection, less wound margin necrosis and a shorter hospital stay than passive drainage in breast surgery (Moss 1981). However, in elective orthopedic surgery, Acus et al. (1992) in a retrospective study and Cobb (1990), Beer et al. (1991) and Ritter et al. (1994) in randomized studies found no advantages using drains in knee and hip arthroplasty. As pointed out by Dust (1992), however, the risk of a type II statistical error is considerable with a small number of patients. In a recent study, Varley and Milner (1995) found that the use of drains resulted in better wound healing and a reduced infection rate in surgery for proximal femoral fractures. They used a scoring system (ASEPSIS) to assess wound complications which may give better discrimination of complications than a mere counting of wound hematomas and/or signs of infection.

Several authors have agreed that a draining hematoma represents an important route for early deep infection (Surin et al. 1983). Magnussen et al. (1986) showed that, after hip arthroplasty, 21 of 24 "poor wounds" had a significant wound hematoma on ultrasound examination. Of 64 patients with satisfactory wounds, 48 showed no evidence of hematoma. Andrews et al. (1981) also reported that deep hematoma occurred in 7 of 68 infected hip arthroplasties. The aim of using drains after hip arthroplasties is therefore to avoid excessive hematoma formation. In this regard, the high-vacuum drains evacuated a greater volume during the first postoperative hour. Whether this represents a more effective hematoma evacuation or an increased blood loss from the circulation cannot be ascertained from our study. Small deep hematomas are commonly found by ultrasound examination, even if drains are used (Parrini et al. 1988, Varley et al. 1994).

According to Willett et al. (1988), Willemen et al. (1991) and Drinkwater and Neil (1995), the spread of microorganisms into the wound is seen only if the drains are left in the wound for more than 24 hours. As in their studies, we also found that most (median 83-84%) of the total drained volume had been collected within 24 hours. After 24 hours, the fluid collected in the drains has a low hemoglobin concentration and therefore consists of wound secretion that could be maintained even by the presence of the drains. This indicates that drains should be removed

after no more than 24 hours or even earlier. Early removal of the drains will probably also aid mobilization of the patients.

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