Clinical Analysis of Suction Drainage in Cementless Hip Replacement: A Prospective Randomised Study

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Abstract

Background: Several studies have suggested that the use of drains did not improve surgical outcomes after hip replacement. There is still a lack of strict recommendations for drainage use.

Methods: Prospective, randomised study was performed. The analysis included 100 patients. Inclusion criteria: idiopathic hip osteoarthritis. Exclusion criteria: secondary coxarthrosis, autoimmune disease, coagulopathy, venous/arterial thrombosis, hepatic/renal insufficiency, cement, or hybrid endoprostheses.

Results: We found smaller haematomas in the no-drainage group (9.76 mm vs. 10.33 mm, p = 0.653). The visual analogue scale score was lower in the no-drainage group (5 vs. 6). Less bloodloss in the no-drainage group (1,124 ml vs 1,224 ml, p = 0.59). Two patients had a deep joint infection in the no-drainage group, none in the drainage group.

Conclusion: It is noteworthy that two cases of early infections were observed in the no-drainage group, whereas there were no such complications in the drainage group. Further research is warranted to validate our findings.

Trial registration: The study was successfully retrospectively registered in Clinicaltrial.gov with identification number: NCT04333264 (03/04/2020). https://clinicaltrials.gov/ct2/show/NCT04333264?term=NCT04333264&draw=2&rank=1

Background

Hip replacement surgery has been called the most effective procedure of the century [1]. It is an orthopaedic procedure that necessarily entails soft tissue and bone damage. Intraoperative blood loss can be limited by haemostasis at several stages and by using anatomical, non-aggressive surgical techniques. The use of fibrinolysis inhibitors such as tranexamic acid, as well as topical use of vasoconstrictors, reduces both intra- and postoperative bleeding [2].

Significant intraoperative blood loss can affect haemostasis, leading to increased postoperative bleeding [3]. Suction drainage is used to drain the blood from the hip joint. It also serves to assess bleeding activity that may be an indication for urgent surgical intervention and repeated haemostasis. An excessive haematoma might also serve as a nidus for bacterial growth. Unfortunately, the drainage tube is also a significant point of access for infections in the hip. Several publications documented the risk of infection in the context of prolonged suction drainage [4, 5].

Postoperative blood loss is difficult to assess. The basic diagnostic method used is physical examination supported by diagnostic imaging. An ultrasound is a method of choice to assess fluid collection in soft tissues [6].

According to the literature, the reduction of postoperative haematomas might be affected by the proper use of thromboembolic prophylaxis, including low-molecular-weight heparin (LMWH) [7]. According to
recommendations, in Poland, LMWH is administered 12 hours before surgery, and the therapy is continued for 35 days after the intervention [8].

Until recently, we did not have strict recommendations for suction drainage after primary total hip replacement. Therefore, we sought to assess a homogenous group of patients with extended thromboprophylaxis to determine whether forgoing the drain in this cohort was safe. The objective of our study was to measure joint fluid collection, blood loss, and complications in patients undergoing hip replacement with and without drain placement.

Methods

The study was planned and conducted using a prospective randomised design. We performed simple randomisation using closed envelopes designating group allocation. The study was successfully retrospectively registered in Clinicaltrial.gov with identification number: NCT04333264 (03/04/2020).

The study began on 9 March 2016, after obtaining approval from our Bioethical Review Board. All methods provided in these study was carried out in accordance to approval from Bioethical Committee of Centre of Postgraduate Medical Education in Warsaw with approval number 13/PB/2016. Patients successively admitted to the ward for hip replacement were eligible for inclusion. All patients signed informed consent. Patients were prepared for surgery in a typical manner. LMWH was used for thromboprophylaxis in doses adjusted for body weight and risk factors. The first heparin dose was administered in the evening of the day before surgery. Thromboprophylaxis was continued for 35 days after surgery. All patients received tranexamic acid (Exacyl) intravenously, at a dose of 15 mg per kilogram of body weight, 10 minutes before skin incision. Experienced surgeons performed surgeries through a posterolateral approach with cementless hip replacement implantation. In all patients, wound healing was monitored during the postoperative period.

Over the 72 hours after surgery, all patients underwent ultrasound scans of their hip joints and the post-surgical wound using the aseptic technique. The scans were performed with patients in the supine position. The ultrasound scan assessed the fluid level at the level of the endoprosthesis neck and detected fluid accumulation in the soft tissues.

Blood loss volume, along with the occult bleeding, was analysed using the Gross formula:

\[
EBV_x (H_{t(0)} - \frac{H_{t(1)}}{H_{t_{av}}})
\]

EBV represented the estimated patient’s blood volume, \(H_{t(0)}\) represented haematocrit before surgery, \(H_{t(1)}\) represented haematocrit 24 hours after surgery, and \(H_{t_{av}}\) represented estimated pre- and postoperative haematocrit value. Despite limitations such as intraoperative fluid transfusion or renal insufficiency, the Gross formula is thought to estimate interoperative blood loss credibly [9].
Before surgery and within 72 hours afterwards, the range of hip joint motion was assessed for flexion, abduction, adduction, and flexion contracture. Pain levels were assessed using the visual analogue scale (VAS) in all patients. Physical examination and ultrasound scans were conducted 72 hours after surgery by the same physician. Patients were discharged depending on their general condition and progress in rehabilitation, usually from the third to seventh day after surgery. The follow-up period was 30 days.

A total of 134 patients were successively operated on from 14 March 2016 to 16 May 2018, meeting the study inclusion and exclusion criteria.

The inclusion criteria were primary hip osteoarthritis and age between 30 and 80 years. The exclusion criteria were secondary degenerative hip joint disease, autoimmune disease, congenital/secondary coagulopathy, history of venous/arterial thrombosis, hepatic/renal insufficiency, cement or hybrid endoprosthesis, and lack of patient consent.

Patients were allocated to two groups depending on the presence or absence of drains; 100 patients qualified for the final analysis, of which 20 patients later withdrew consent for participation in the study. In eight patients, the surgeon decided to use suction drainage, regardless of randomisation results; and in six, a cemented implant was used because of intraoperative conditions.

The allocation process was performed with simple randomisation use. Closed envelopes, with information on drainage usage, was opened in the operating theatre at the end of surgery. If the surgeon, considering the procedure and local conditions, decided that suction drainage was necessary, the patient was excluded from the study.

The investigated group included 55 females (55%) and 45 males (45%). The mean age was 62.8 years (range, 30–82 years)—64 years for women (range, 34–76 years) and 61.4 years for men (range, 30–82 years). The mean body mass index (BMI) was 28.95 kg.m$^2$ (men: 29.28 kg.m$^2$; women: 28.68). All patients were assessed for the severity of hip osteoarthritis using the Kellgren–Lawrence scale (Figure 1).

Calculations were made using Statistical Analysis System (version 9.4) software. Quantitative data were examined using the Student’s t-test, and distribution was assessed using the Shapiro-Wilk test. To examine qualitative characteristics, contingency analysis was used; for these analyses, X2 with Yates’s correction and Fisher’s F-tests were applied.

**Results**

At the final follow up was assessed 100 patients, 50 drainage group and 50 no-drainage group. The statistical analysis did not reveal any statistically significant differences between groups in terms of age, sex, body weight, degenerative disease severity on the Kellgren–Lawrence scale, and blood clotting factors (activated partial thromboplastin time [APTT], prothrombin time [PT], and international normalised ratio [INR]) (Table 1).
Table 1
The distribution of basic parameters in both groups.

|                          | Drainage               | No-drainage            | p-value |
|--------------------------|------------------------|------------------------|---------|
| Age (years)              | 63.12 (39–80)          | 62.48 (30–80)          | 0.75    |
| Gender (M/F)             | 24/26                  | 21/29                  | 0.69    |
| Body weight (kg)         | 83.5 (52–124)          | 81.7 (56–110)          | 0.54    |
| APTT (s)                 | 26.5 (16.1–37.2)       | 26.4 (18.1–40.8)       | 0.93    |
| PT (s)                   | 12.38 (8.8–15.1)       | 12.45 (9.1–15.1)       | 0.84    |
| INR                      | 1.03 (0.8–1.3)         | 1.03 (0.8–1.3)         | 0.89    |

M/F, male/female; kg, kilograms; APTT, activated partial thromboplastin time; s, second; PT, prothrombin time; INR, international normalised ratio.

The mean thickness of the fluid at the level of the endoprosthesis neck in the drainage group was 10.33 mm (range 0–24.6 mm), and that in the no-drainage group was 9.76 mm (range 1.9–33.4 mm) (p = 0.653).

The presence of haematomas in postoperative wound soft tissues, both suprafascial and subfascial, was assessed. Haematomas were detected in seven patients in the no-drainage group and eight patients in the drainage group (p = 0.78). BMI had no impact on the size of haematoma in the joint (p = 0.503).

Overall mean perioperative blood loss was 1,126 ml (range, 370–2,384 ml). In the no-drainage group, mean blood loss was 1,124 ml (400–2,281 ml), and in the drainage group, it was 1,224 ml (370–2,384 ml) (p = 0.59). Overall, the need for blood transfusion was rare (the median was 0). In both groups, blood transfusion was necessary for five patients (p = 0.247).

The risk of deep vein thrombosis during the 30 days after hip replacement surgery was also assessed. No patient in either group experienced postoperative deep vein thrombosis.

There were no significant differences between groups in terms of wound exudation on the third day after surgery (p = 1). In the no-drainage group, an early infection was observed in two patients. Infection was detected as a result of prolonged wound leakage (over 5 days) and was confirmed intraoperatively with two positive bacteriological cultures. These patients were subjected to the Debridement, Antibiotics, Implant Retention (DAIR) procedure with good outcomes. There were no significant differences between groups regarding the incidence of infection (p = 0.47).

Clinical status was assessed using the VAS, evaluating pain before surgery and 72 hours after surgery. In the no-drainage group, the median VAS score before surgery in the no-drainage group was 6; in the
After surgery, the median in the no-drainage group was 5, and it was 6 in the drainage group ($p = 0.71$) (Table 2).

**Table 2**

| Clinical Parameters | Drainage | No-drainage |
|---------------------|----------|-------------|
| Flexion before      | 85.8 (40–130) | 84 (20–120) |
| Flexion 3rd day     | 74.9 (45–110) | 78.5 (45–100) |
| Abduction before    | 20.7 (0–40) | 18.4 (0–40) |
| Abduction 3rd day   | 19.8 (5–30) | 19.3 (5–40) |
| Adduction before    | 9.7 (0–25) | 9.1 (0–25) |
| Adduction 3rd day   | 7.1 (0–20) | 7.8 (0–20) |
| Flexion contracture before | 6.9 (0–30) | 7.3 (0–30) |
| Flexion contracture 3rd day | 5 (0–20) | 3.6 (0–20) |
| VAS before          | 6.2 (2–10) | 5.6 (1–9) |
| VAS 3rd day         | 5.3 (1–10) | 4.9 (1–9) |

VAS, visual analogue scale.

The second clinical indicator was the evaluation of the hip range of motion 72 hours after surgery. Because of varying levels of degenerative disease, we considered differences in the range of motion before surgery and 72 hours after surgery. There were no significant differences between the groups in flexion, abduction, adduction, or flexion contracture ($p = 0.25$) (Figure 2)

In both groups, haemoglobin and C-reactive protein (CRP) values were measured preoperatively, and 24 and 72 hours postoperatively. At 72 hours after surgery, there were higher haemoglobin values in the no-drainage group: 11.05 vs. 10.85 g/dl ($p = 0.53$). The mean difference between haemoglobin 24 hours postoperatively and haemoglobin 72 hours postoperatively amounted to 0.82 in the no-drainage group, and 0.75 in the drainage group, $p = 0.49$. The decrease in CRP values between 24 hours preoperatively and 72 hours postoperatively was also analysed. There was no statistically significant difference between the groups ($p = 0.92$).

The mean hospitalisation duration in both groups was 7 days: 4–21 days without drainage vs. 4–19 days with drainage ($p = 0.60$). Because of prolonged wound leakage, two patients were readmitted 30 days after the surgery and qualified for the DAIR procedure. These patients were diagnosed with early infection ($p = 0.49$).
Discussion

We assessed a homogenous group of patients undergoing hip replacement. For legal reasons, all patients received extended thromboprophylaxis. The safety of suction drainage was not evaluated in this group of patients. The objective parameter that might provide information about the impact of preoperative heparin dose was the amount of blood in the hip postoperatively. In our analysis, we checked fluid levels above the endoprosthesis neck using ultrasonography in the supine position. We found lower fluid levels in the no-drainage group (9.76 vs. 10.33 mm, \( p = 0.653 \)); from this, we conclude that refraining from placing suction drainage has no effect on patients with extended thromboembolic prophylaxis who undergo a primary cementless hip replacement.

In the no-drainage group, we observed two patients with deep infections, whereas, in the drainage group, there were no infections. We did not recognise surgical site infections (SSIs). Only two patients had prolonged wound leakage (above 5 days); however, in these cases, we recognised deep infections. Zimmerli questioned the diagnosis of SSI in patients with implants because it cannot be reliably clinically differentiated from deep infections [10]. Despite the absence of statistically significant differences, this raised our doubts about the wisdom of not using suction drainage.

Historically, suction drainage was justified by the need to reduce hip joint haematoma and was consequently used to reduce the risk of periprosthetic infection. The first papers to question the use of suction drainage were published in the 1990s [11, 12]. Hou et al., based on 27 randomised studies, did not demonstrate a higher incidence of infections in no-drainage patients [13]. Similar conclusions were drawn by Chen et al., based on 16 papers [14]. Fagotti et al. reported two SSIs in the drainage group but no deep periprosthetic infections; in the no-drainage group, there were no SSIs, but one patient was diagnosed with a deep infection. However, there were no significant differences between groups [15]. Walmsley et al., in a study of 552 patients (577 hip joints), reported a higher incidence of SSIs (48% vs 2.9%) and deep infections (0.7% vs 0.4%) in no-drainage patients [16].

Kelly et al., in their meta-analysis, demonstrated that patients from the suction drainage group required blood transfusion significantly more frequently and had greater postoperative blood loss [17]. Hou et al., in their meta-analysis, also demonstrated significantly more frequent blood transfusions in the drainage group. Blood loss volume in our paper was insignificantly smaller in the no-drainage group; however, there was no difference between groups in blood transfusion rates.

Because of the short patient observation period, the VAS pain scale and the range of hip motion were used. The VAS scale is commonly used to assess pain experienced by patients undergoing hip replacement surgery [18]. In their meta-analysis, Hou et al. did not demonstrate any differences between groups in the VAS score. Fagotti et al. found significantly higher VAS scores among patients without suction drainage than among those with drainage. In our study, 72 hours postoperatively, a non-significant difference between groups in favour of the no-drainage group was identified.
A hip joint haematoma can reduce the range of motion [19]. Zeng et al. demonstrated a reduced range of hip joint mobility following surgery in patients who did not have suction drainage [20]. Nevertheless, Chen et al., in their meta-analysis, did not find any differences in ROM between the drainage and no-drainage groups, as was confirmed in our paper.

In most relevant publications, the majority of parameters did not differ significantly between groups [15–17, 21]. All these studies included heterogeneous groups; patients with primary and secondary osteoarthritis, coxarthrosis in the course of rheumatoid arthritis, and others. Some of these conditions could affect perioperative blood loss and the need for blood transfusion [22]. These conditions illustrate why we need more well-prepared multi-centre prospective studies.

There are several limitations to this study. First, it was a single-centre study and therefore may be subject to selection bias. For this reason, we instituted strict inclusion and exclusion criteria. Multi-centre studies are needed to validate our findings. A short observation period was appropriate for the intervention we investigated. For this reason, we used proper scales to assess short-term clinical outcomes. A large number of patients were excluded from the primary cohort, possibly influencing outcomes; however, all exclusions occurred before we opened the sealed envelopes, which ultimately did not impact the randomisation process significantly.

**Conclusions**

Hip replacement without suction drainage after surgery is a recognised therapeutic method. No superiority of either method was demonstrated; nevertheless, it is worth noticing that there were two cases of early infection in the no-drainage group compared to none in the drainage group. This suggests the need for further research in this respect.

**Abbreviations**

LMWH - low-molecular-weight heparin,

EBV - estimated patient’s blood volume,

Ht(0) - haematocrit before surgery,

Ht(1) - haematocrit 24 hours after surgery,

Ht_av - estimated pre- and postoperative haematocrit value,

VAS - visual analogue scale,

APTT - activated partial thromboplastin time,

PT - prothrombin time,
INR - international normalised ratio,

BMI – body mass index,

DAIR - Debridement, Antibiotics, Implant Retention procedure,

CRP - C-reactive protein,

SSIs - surgical site infections,

ROM – range of motion,

**Declarations**

*Ethics approval and consent to participate*

Study obtained approval from Bioethical Review Board, The Centre of Postgraduate Medical Education in Warsaw, with approval number: 13/PB/2016.

*Consent for publication*

Not applicable.

*Availability of data and materials*

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

*Competing interests*

The authors declare no competing interests.

*Funding*

Not applicable.

*Author contributions*

PB – study preparation, paper preparation, data collection; WM – paper preparation, critical review; MP – data collection, paper preparation; MK - data collection, paper preparation, JB – critical review, study conception. All authors reviewed and accepted final paper.

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References

1. Learmonth, I.D., Young, C., Rorabeck, C., The operation of the century: total hip replacement. Lancet 370:1508–1519. (2007)
2. Chen, S., et. al., The efficacy of topical tranexamic acid in total hip arthroplasty: a meta-analysis. BMC Musculoskelet Disord 17:8. (2016)
3. Ghadimi, K., Levy, J.H., Welsby, I.J., Perioperative management of the bleeding patient. Br J Anaesth 117:iii18–iii30. (2016)
4. Saleh, K., et. al., Predictors of wound infection in hip and knee joint replacement: results from a 20-year surveillance program. J Orthop Res 20:506–515. (2002)
5. Lee, G.W., et. al., New strategy of closed suction drainage after primary total hip arthroplasty. Acta Orthop Traumatol Turc 51:223–226. (2017)
6. Bialecki, J., Bartosz, P., Marczynski, W., Zajac, J. Usefulness of ultrasonography in the diagnosis of hematoma after primary hip arthroplasty. J Ultrason 17:149–153. (2017)
7. Mortazavi, S.M., et. al., Hematoma following primary total hip arthroplasty: a grave complication. J Arthroplasty 28:498–503. (2013)
8. Chmielewski, D., et. al., Principles of prevention of venous thromboembolism in orthopedics and traumatology]. Ortop Traumatol Rehabil 16:227–239 (2014) (in Polish)
9. Gibon, E., Courpied, J.P., Hamadouche, M., Total joint replacement and blood loss: what is the best equation? Int Orthop 37:735–739. (2013)
10. Zimmerli, W., Clinical presentation and treatment of orthopaedic implant-associated infection. J Intern Med. 276(2):111-119. (2014)
11. Murphy, J.P., Scott, J.E., The effectiveness of suction drainage in total hip arthroplasty. J R Soc Med 86:388–389. (1993)
12. Hadden, W.A., McFarlane, A.G., A comparative study of closed-wound suction drainage vs. no drainage in total hip arthroplasty. J Arthroplasty 1990;5 Suppl:S21–S4. (1990)
13. Hou, N., et. al., [Meta analysis of the efficacy and safety of drainage after total hip arthroplasty]. Zhonghua Yi Xue Za Zhi 97:1668–1672 (2017) (in Chinese)
14. Chen, Z.Y., et. al., Is wound drainage necessary in hip arthroplasty? A meta-analysis of randomized controlled trials. Eur J Orthop Surg Traumatol 24:939–946. (2014)
15. Fagotti, L., et. al., Use of closed suction drainage after primary total hip arthroplasty: a prospective randomized controlled trial. Rev Bras Ortop 53:236–243. (2018)
16. Walmsley, P.J., Kelly, M.B., Hill, R.M., Brenkel, I., A prospective, randomised, controlled trial of the use of drains in total hip arthroplasty. J Bone Joint Surg Br 87:1397–1401. (2005)
17. Kelly, E.G., Cashman, J.P., Imran, F.H., Conroy, R., O'Byrne, J., Systematic review and meta-analysis of closed suction drainage versus non-drainage in primary hip arthroplasty. Surg Technol Int. 224:295–301. (2014)
18. Brismar, B.H., Hallert, O., Tedhamre, A., Lindgren, J.U., Early gain in pain reduction and hip function, but more complications following the direct anterior minimally invasive approach for total hip arthroplasty: a randomized trial of 100 patients with 5 years of follow up. Acta Orthop 89:484–489. (2018)

19. Yumoto, T., et. al., Subperiosteal Hematoma of the Iliac Bone: An Unusual Cause of Acute Hip Pain after a Fall. Am J Case Rep 19:1083–1086. (2018)

20. Zeng, W., Zhou, K., Zhou, Z., Comparison between drainage and no-drainage after total hip replacement in Chinese subjects. Orthop Surg 6:28–32. (2014)

21. Suarez, J.C., et. al., Closed Suction Drainage Has No Benefits in Anterior Hip Arthroplasty: A Prospective, Randomized Trial. J Arthroplasty 31:1954–1958. (2016)

22. Salt, E., Wiggins, A.T., Rayens, M.K., Risk Factors for Transfusions Following Total Joint Arthroplasty in Patients with Rheumatoid Arthritis. J Clin Rheumatol 24(8):422–426. (2018)

**Figures**

**Figure 1**

Percentage distribution of patients with degenerative lesions on the Kellgren–Lawrence scale.
Figure 2

The difference in the hip range of motion (flexion, abduction, adduction, flexion contracture checked summary) before and after surgery in both groups

Supplementary Files

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- CONSORT2010Checklist.doc