SOCIEDADE BRASILEIRA DE ORTOPEDIA E TRAUMATOLOGIA

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Original Article

Use of closed suction drainage after primary total hip arthroplasty: a prospective randomized controlled trial☆

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ARTICLE INFO

Article history:
Received 16 January 2017
Accepted 6 March 2017
Available online 18 January 2018

Keywords:
Arthroplasty replacement hip
Suction
Drainage
Blood loss surgical

ABSTRACT

Objective: This study aimed to investigate drain use in a controlled population of patients with hip osteoarthritis undergoing primary total hip arthroplasty.
Methods: This prospective controlled trial evaluated 93 patients randomized into two groups: a group that received drains and a group that did not. The patients who were randomized to the drain group used a 3.2 mm drain placed under the fascia that was kept in place for 24 h. Postoperative evaluations were performed after 24 h and then three, six, and 12 weeks after total hip arthroplasty. The primary outcome was perioperative blood loss in both groups 24 h after total hip arthroplasty. The other parameters that were evaluated included mid-thigh circumference, the rate of blood transfusion, hematocrit, inflammatory serum levels, and the Harris Hip Score.
Results: The clinical and laboratory data revealed no differences between the study groups with respect to blood loss and need for blood transfusion, duration of hospital stay, reoperation rate, complications, inflammatory serum markers, and the Harris Hip Score. Patients without closed suction drainage reported higher pain levels after 24 h (VAS score 1 vs. 2, $p < 0.01$).
Conclusion: Similar clinical and laboratory outcomes were found in both cohorts.

☆ Work performed in the Grupo de Quadril, Instituto de Ortopedia e Traumatologia, Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, São Paulo, SP, Brazil.

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https://doi.org/10.1016/j.rboe.2018.01.001

Uso de drenos de sucção fechada após artroplastia total de quadril primária: um estudo prospectivo, randomizado e controlado

Palavras-chave:
Artroplastia de quadril
Sucção
Drenagem
Perda sanguínea cirúrgica

RESUMO

Objetivo: Investigar o uso de drenos em uma população controlada de pacientes com osteoartrose do quadril submetidos a artroplastia total de quadril primária.
Métodos: Este estudo prospectivo controlado avaliou 93 pacientes randomizados em dois grupos: um grupo no qual se usou drenos e um grupo no qual não se usou drenos. Os pacientes que foram randomizados para o grupo com drenos utilizaram dreno de 3,2 mm, colocado sob a fáscia, e mantido no local por 24 horas. As avaliações pós-operatórias foram realizadas após 24 horas e três, seis e 12 semanas após a artroplastia total de quadril. O desfecho primário foi perda sanguínea perioperatória em ambos os grupos 24 horas após a artroplastia total de quadril. Os demais parâmetros avaliados foram circunferência do meio da coxa, taxa de transfusão de sangue, hematócrito, níveis séricos inflamatórios e Harris Hip Score.
Resultados: Os dados clínicos e laboratoriais não indicaram diferenças entre os grupos de estudo quanto à perda de sangue e necessidade de transfusão de sangue, tempo de internação hospitalar, taxa de reoperação, complicações, marcadores séricos inflamatórios e *Harris Hip Score*. Os pacientes que não usaram drenos de sucção fechada relataram maiores níveis de dor após 24 horas (EVA 1 *vs.* 2, $p < 0{,}01$).
Conclusão: Encontramos resultados clínicos e laboratoriais semelhantes em ambas as coortes.

Introduction

Closed suction drainage (CSD) after total hip replacement (THR) is a common practice among orthopedic surgeons. Waugh and Stinchfield focused their studies on wound hematomas and demonstrated a lower infection risk associated with the use of CSD.[1] Over the last decades, the advantages of CSD have been extensively debated, and the routine use of CSD after THR remains controversial.[2–6] Drainage may still be a risk factor for blood transfusion postoperatively[2,4] and wound complications.[3] A drainage period of 24 h is the most commonly accepted duration, and this period is when the maximal drainage volume occurs.[7–9] The analysis of clinical parameters such as hematocrit levels and thigh circumference may provide more objective information and improve the scientific evidence. The goals of this study were to (1) compare the blood loss of patients undergoing THA and (2) evaluate the clinical and laboratory results at 3, 6 and 12 weeks after the procedure between patients who received a CSD and patients who did not.

Methods

Trial design

The study design was a single-center, prospective, 1:1 randomized, parallel clinical trial. Both the patients and surgeons were blinded before the surgical procedure. This trial was registered and approved by the National Institutes of Health, and approval was obtained from the local Institutional Review Board.

Participants

We enrolled study participants who were undergoing a THA due to primary or secondary osteoarthritis. The patients who reported a previous surgery on the same limb, patients with hip arthrodesis and patients with coagulation disorders were not included. We excluded patients who had the following complications detected during surgery: intraoperative fractures, significant bleeding, or the need to increase the surgical incision to a length greater than 20 cm.

Surgical procedure

A non-cemented porous titanium alloy coated with hydroxyapatite THA (Lépine® and Depuy®) was implanted through a direct lateral Hardinge approach in all cases. Patients randomized to Group 1 had a single 3.2 mm diameter, 100 mm length suction drain placed under the fascia slightly anterior and distally from the surgical incision. Wound closure was performed in layers using absorbable sutures (Vicryl 1) for the reattachment of the gluteus medius muscle to the greater trochanter and closure of the fascia lata. The subcutaneous tissue was closed with Vicryl 2.0, and the skin was closed with mononylon 3.0. The procedure time was recorded in minutes from the time of the skin incision until skin closure. The routine dressing consisted of a 10 cm × 25 cm sponge taped to the skin using adhesive strips. All patients were assigned to the same ward and received care from the same nursing staff. Enoxaparin (40 mg) was administered 12 h after the procedure and was continued for four weeks for deep vein thrombosis prophylaxis. The hemostatic measures for intraoperative bleeding were biterminal electrocoagulation or manual compression.

No additional drugs (epinephrine or tranexamic acid) were used. Assisted passive mobilization of the lower limb was initiated as a mechanical anti-thrombotic prophylaxis. The prophylactic measures for infection were the application of chlorhexidine to the skin before the procedure and Cefuroxime 1.5 g given intravenously at induction and then every 12 h for 24 h. The skin incision length was kept between 10 and 20 cm. During the hospital stay, all the patients received the same analgesic protocol, which consisted of intravenous Dipyrone 1000 mg every 6 h, Ketoprofen 100 mg every 12 h and Tramadol 100 mg if necessary.

Outcomes

The primary outcome was the total blood loss (TBL) in both groups 24 h after the THA. The TBL was calculated from the hematocrit values (HCT) obtained preoperatively and on the first post-operative day. We assumed that a 1% fall in the hematocrit value corresponded to 170 ml of circulating blood.[10] To calculate the TBL, the following formula was used: $170 \times [\text{HCT preoperative} - \text{HCT first post-operative day}] + [\text{number of transfusions} \times 450])$.[10] The secondary outcomes included the rate of blood transfusion and its relationship with TBL, the presence of early complications and the Harris Hip Score. CRP and ESR curves were compared for both groups, as well as the weight of dressing and the presence of a hematoma.

A single surgeon helped by a nurse inspected the wounds 24 h after the procedure. The patient was positioned in lateral decubitus for full visualization of the thigh after the dressing was removed. The first dressing was analyzed according to the wet drainage area and weight, using a metric tape and a precision balance with a readability of one decimal place, respectively. Afterwards, the surgeon evaluated the presence of hematoma and tenderness on the operated limb. The presence of large hematomas were assessed and recorded. The tenderness was evaluated according to a scale from 1 to 5 (1 no tenderness, 2 mild tenderness, 3 moderate, 4 severe tenderness and 5 very severe tenderness). The drains were removed after 24 h, and the volume of the contents was recorded in milliliters. After the dressing change, the perimeter of the mid-thigh circumference was measured with the patient in supine position. For the assessment of thigh swelling, the metric tape was positioned perpendicular to the long thigh axis, halfway between the superior anterior iliac spine and the upper border of the patella.[6]

A blood sample was collected after 24 h to measure the hematocrit, and the data concerning blood transfusions were also assessed. Blood transfusion was indicated when Hb levels of patients were lower than 10 g/dL combined with clinical symptoms of anemia or whenever Hb levels were under 7 g/dL. A serum C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and complete blood count were assessed at 3, 6 and 12 weeks after discharge. Clinical data regarding infections were also recorded.

Randomization

A computed-generated sequence of numbers was used to assign the patients randomly into two groups. A physician who was not involved with the study allocated the results of the randomization in sealed opaque envelopes. Before wound closure, a nurse was asked to open the envelope containing the number of the group: 1 indicated drainage, and 2 indicated no drainage.

Blinding

The physician who performed the functional assessment through the Harris Hip Score, the physical therapists involved with the patient's rehabilitation program and the statistician were blinded to the patient's group assignment.

Statistical methods

The variables that were normally distributed were assessed with parametric tests. The comparisons between the groups were done using the two-tailed *t*-test. For the comparison of data without normal distribution, the two-tailed Mann–Whitney test was used. Qualitative data were assessed using the Chi-square test or the Fisher exact test. The significance level was established as $p < 0.05$. The statistical data analysis was performed using SPSS software version 20 for Mac (SPSS, Inc, Chicago, Illinois).

Results

A total of 146 patients were assessed by our service between May 2014 and May 2015 to determine their eligibility for the study. A total of 42 patients did not meet the inclusion criteria. Therefore, 104 patients underwent randomization. A total of 11 patients were excluded due to the following reasons: 4 patients presented with intraoperative fractures, and 2 patients needed cementation of the femoral canal. An additional 3 patients were lost to follow-up, and 2 patients abandoned treatment. The remaining 93 patients were included and analyzed, with 42 participants in Group 1 and 51 participants in Group 2. A flowchart representing the patients included in our study is shown in Fig. 1.

Baseline data

The baseline characteristics and perioperative variables of the participants in both groups were compared (Table 1). There were no significant differences between the investigated variables. A diagnosis of primary osteoarthritis accounted for 61% of the study patients, and osteonecrosis of the femoral head (30%) was the second most common diagnosis.

Clinical assessment

The preoperative mean HHS was 49 ± 18 for Group 1 and 44 ± 18 for Group 2. At the 3 month evaluation, the mean value for the HHS was 82 ± 8 for Group 1 and 84 ± 11 for Group 2. Neither of the assessments revealed a statistically significant difference between the groups ($p > 0.05$).

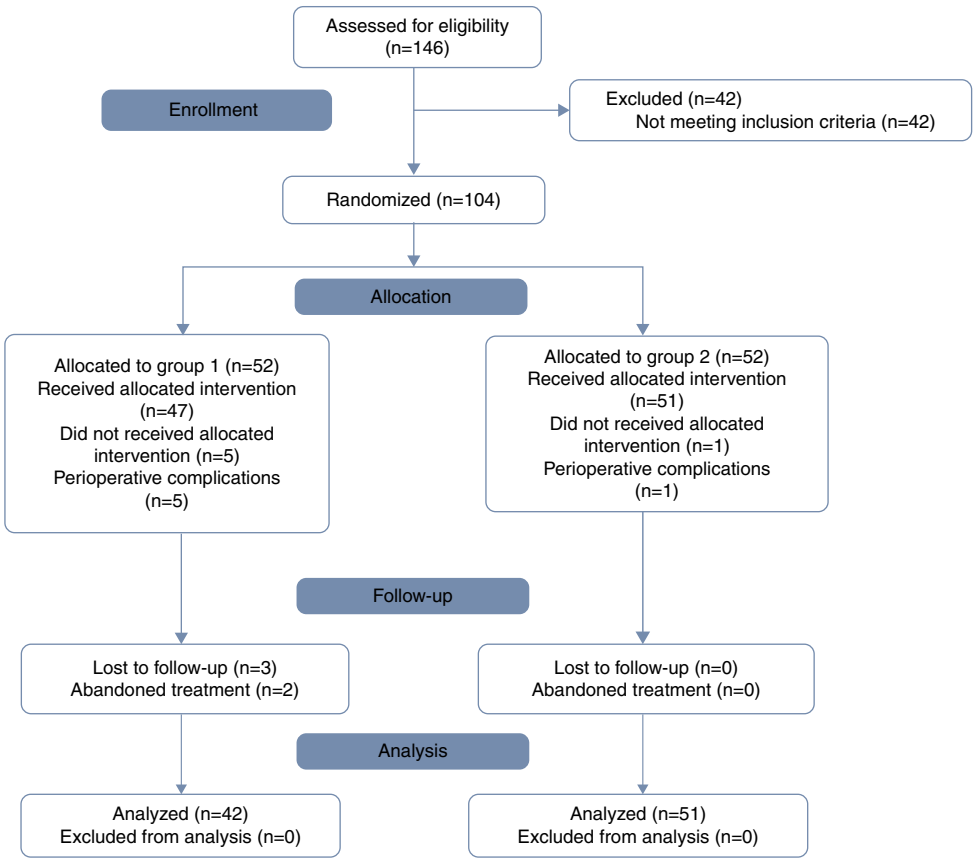

Fig. 1 – Flow chart showing the number of patients at each phase of the trial.

Table 1 – Baseline characteristics and preoperative and perioperative variables.

	Group 1 (drainage)	Group 2 (no drainage)	*p*
Age (y)	52 ± 13 (29–77)	57 ± 13 (30–83)	0.094
Female gender (*n*/%)	24/57	25/49	0.435
Body mass index (kg/m^2)	28 ± 5 (17–40)	27 ± 5 (19–39)	0.557
Preoperative Harris Hip Score (points)	49 ± 18 (18–76)	49 ± 18 (14–83)	0.974
ASA score (1:2:3) (*n*)	9:28:5	12:35:4	0.798
Length of incision (cm)	17 ± 2 (13–20)	16 ± 2 (12–20)	0.453
VAS for pain (1–10)	8 ± 2 (3–10)	8 ± 2 (1–10)	0.243
Duration of operation (min)	138 ± 23 (100–180)	131 ± 25 (90–195)	0.168

ASA, American Society of Anesthesiologists; VAS, Visual Analog Scale.

The mean drainage volume in Group 1 24 h after surgery was 315 ± 247 ml of serosanguinous fluid. The dressing parameters and clinical variables 24 h after surgery are presented in Table 2. The only parameter that presented statistical difference was the VAS (Group 1: 1 ± 0.2 vs. Group 2: 2 ± 1.3, $p = 0.009$). At 3 months, the mean value of the mid-thigh circumference increment was 1 cm ± 3 and 2 ± 3 for Group 1 and Group 2, respectively ($p > 0.05$). At 3 months, tenderness classified as absent, mild or moderate was present, respectively, in 89.5%, 5.3% and 5.3% of the patients in Group 1 and 90.9%, 6.8% and 2.3% of the patients in Group 2; there were no statistically significant differences between the groups ($p > 0.05$).

A hospital stay duration greater than 3 days was observed in 5 (11.9%) patients in Group 1 and 6 (11.8%) patients is Group 2, and this difference was not statistically significant ($p > 0.05$).

Laboratory assessment

The hematocrit levels 24 h after the procedure were 29 ± 5% in Group 1 and 29 ± 4% in Group 2, and this difference was not statistically significant ($p > 0.05$) (Table 3). Fig. 2 presents a comparison between the hematocrit levels for the 2 groups at 24 h and 3, 6 and 12 weeks after the procedure. The average perioperative blood loss was 2581 ± 1425 ml and 2224 ± 1077 ml ($p > 0.05$) for Group 1 and Group 2, respectively. A total of 10 patients in Group 1 and 7 patients in Group 2 required transfusion within 24 h after the procedure ($p > 0.05$). The mean volume of the red blood cell transfused was 331 ± 131 ml in Group 1 and 349 ± 143 ml in Group 2 ($p > 0.05$), with an average of 0.29 unit/patient in Group 1 and 0.20 unit/patient in Group 2 ($p > 0.05$). These variables exhibited no significant differences between the 2 groups.

Table 2 – Clinical variables 24 h after surgery.

	Group 1(drainage)	Group 2(no drainage)	p
Weight of dressings increase (g)	18 ± 40 (0 to 164)	34 ± 81 (0 to 461)	.892
Secretion area of dressings (cm^2)	52 ± 77 (0 to 250)	58 ± 82 (0 to 250)	.901
Mid-thigh circumference increment (cm)	2.6 ± 2.5 (−4 to 8)	3.5 ± 2.3 (−3 to 8.5)	.106
Need for reinforcement (*n*/%)	3/8.3	6/12.2	.562
Tenderness (1:2:3:4:5) (%)[a]	37:17:33:10:3	32:26:18:16:8	.502
VAS for pain (1–10)	1 ± 0.2 (1 to 2)	2 ± 1.3 (1 to 5)	.009

[a] 1, absent; 2, mild; 3, moderate; 4, severe; 5, very severe. Grades given by the same rater.

Table 3 – Laboratory findings during follow-up.

	24 h			3 weeks			6 weeks			12 weeks		
	Group 1	Group 2	p	Group 1	Group 2	p	Group 1	Group 2	p	Group 1	Group 2	p
Hematocrit	29 ± 5	29 ± 4	0.836	35 ± 5	36 ± 4	0.937	37 ± 4	38 ± 4	0.356	40 ± 4	40 ± 4	0.588
Leucogram ($\times 10^3$)	–	–	–	8 ± 2	7 ± 2	0.06	8 ± 3	7 ± 2	0.448	8 ± 2	7 ± 2	0.025
CRP	–	–	–	14 ± 18	20 ± 44	0.253	21 ± 35	12 ± 11	0.956	8 ± 10	6 ± 6	0.623
VHS	–	–	–	34 ± 22	34 ± 22	0.82	24 ± 24	25 ± 19	0.521	14 ± 13	14 ± 14	0.983

Group 1, drainage; Group 2, no drainage.

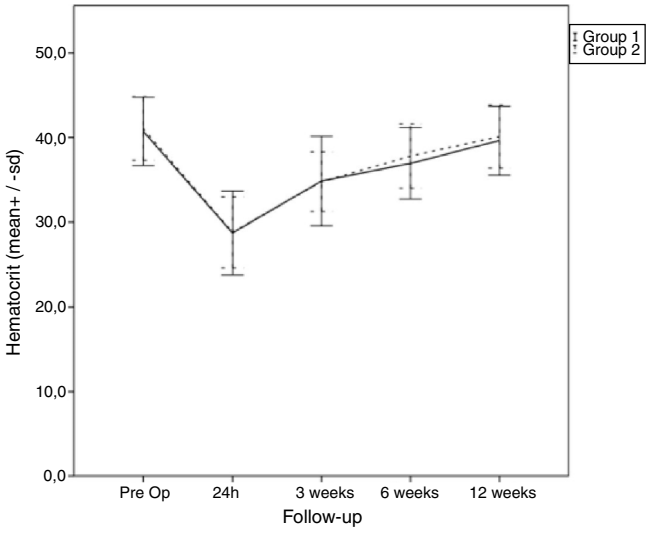

Fig. 2 – Hematocrit curves during follow-up. Group 1, drainage; Group 2, no drainage.

Figs. 3 and 4 display the results of the inflammatory marker tests at the 3 month follow-up. There were no differences between the cohorts regarding the follow-up measurements of the inflammatory blood markers ($p > 0.05$).

Complications

The clinical complications are depicted in Table 4. We observed complications in 7 cases; 5 occurred in Group 2, and 2 occurred in Group 1. There was no statistically significant difference between the groups ($p > 0.05$). Two patients in Group 2 underwent reoperation, and no patient in Group 1 underwent reoperation ($p > 0.05$). The first patient who required reoperation was a woman who was 83 years old with severe scoliosis and poor bone quality; she developed a hip dislocation two weeks after the initial procedure and was successfully treated with a constrained liner. The other patient who required reoperation was also from Group 2 and was a 65-year-old woman who had a deep wound infection that was treated with surgical debridement and intravenous antibiotic therapy. None of the 93 study patients experienced major bleeding complications.

Discussion

The current study focused on the comparison of the blood loss in THA patients who were managed with and without drainage. Objective data such as thigh circumference and inflammatory markers were also assessed. Most of the investigated parameters did not demonstrate any significant differences between the study groups.

The use of CSD may increase total blood loss after primary THA.[2–4,8,11] Consequently, a higher rate of blood transfusion might be expected.[2–4,8,11] In the current study, we observed similar rates of total blood loss, blood transfusion and postoperative hematocrit curves in both groups. Other authors have also reported no difference in the blood volume parameters related to drainage.[5,9,10,12–14] However, the drainage group in the current study exhibited a TBL of 250 ml, which was higher than the TBL of 175 ml described in a recent meta-analysis.[2]

A decrease in the duration of surgery is also expected when drains are not used.[9] The mean surgical time observed in Group 2 (no drainage) was 6 min shorter. This duration difference might be related to the time spent on drain insertion and fixation. Although the use of drains is associated with a prolonged surgical time, this small difference might not be clinically significant.

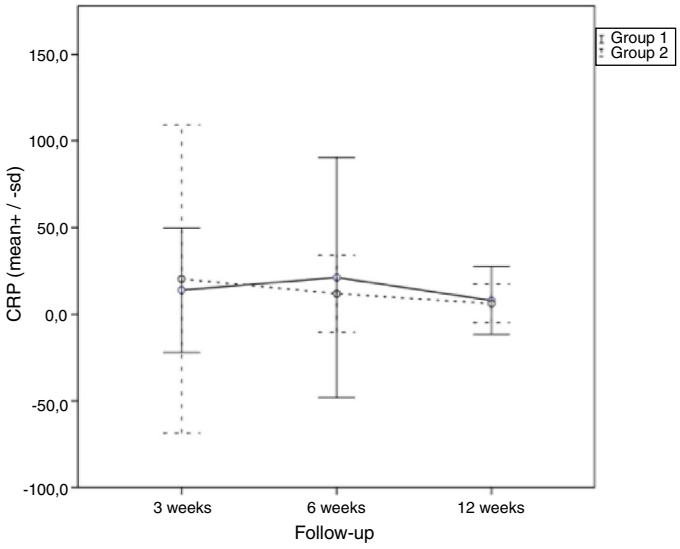

Fig. 3 – CRP curves during follow-up. Group 1, drainage; Group 2, no drainage.

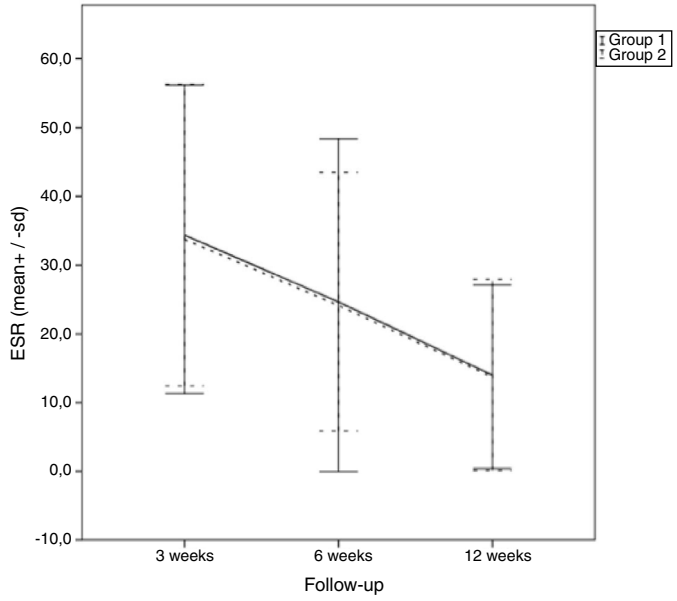

Fig. 4 – ESR curves during follow-up. Group 1, drainage; Group 2, no drainage.

The position where the drain tube is placed has been poorly reported.[7,8] Drains that are placed under the fascia instead of in contact with the prosthesis might produce a lower volume of drainage. Nevertheless, von Roth et al.[9] reported a lower volume by placing the tube intra-articularly. We recorded a volume of 315 ml, which was similar to the volume found in other studies.[3] Future studies should better elucidate the optimal location for drain placement.

A significant increase in the early postoperative pain score in the group without a CSD was noted ($p < 0.01$). However, at the 3 month follow-up, there was no difference in this variable between the groups. Drainage after THA may prevent swelling of the thigh and reduce early thigh pain.[6,14]

Our analysis showed no significant differences in the CRP and ESR values between the groups. Sidhu et al.[15] studied ESR and CRP values at the 3 month follow-up in patients presenting with active tuberculosis who underwent THA with drainage, and they reported similar values to our findings. Other authors who reported the ESR and CRP values of patients who underwent joint replacement without evidence of infection obtained similar values to the ones we reported in the present paper.[16,17] Although we have not identified any other studies that compared CRP and ESR values and the presence of a CSD in patients undergoing THA, we believe that the use of a drain does not affect the inflammatory state of the patients.

Wound hematomas and surgical site infections are possible complications after THA. Although some papers have related the severity of the hematoma to the absence of surgical drainage,[8–10] a recent meta-analysis reported no influence of drains on the incidence of hematomas.[4] Moreover, the lateral approach is associated with increased blood loss and postoperative pain when compared to other approaches.[18]

Table 4 – Complications.

	Group 1 (drainage)	Group 2 (no drainage)	Total	*p*
SWI	2	0	2	0.12
DWI	0	1	1	0.36
Hematoma	0	3	3	0.11
DVT	0	1	1	0.36
Total	2	5	7	0.36

SWI, superficial wound infection; DWI, deep wound infection; DVT, deep vein thrombosis.

Our reported rate of 3.2% cases of surgical site infection (SSI) was lower than the rate reported by the World Health Organization (8.7%).[19] Although the presence of suction tubes is associated with retrograde migration of microorganisms,[20,21] a positive drain culture usually does not increase the chance of an SSI.[22,23] The one case that involved a deep wound infection that required reoperation occurred in Group 2 (no drainage). The deep infection may have occurred due to an infection in the hematoma that developed in that case.

Previous studies on the necessity of drainage after THA included both cemented and non-cemented implants.[3,6,8] A strength of the current study is that we employed only one type of implant and one surgical approach. We believe that standardizing surgeries can produce more comparable data. Future studies could evaluate if there are differences in the clinical and biochemical results related to the use of drainage in cemented THA and in different surgical approaches.

Limitations

In spite of the fact that the surgeon and the patient were blinded to the randomization group until the moment of the drain tube insertion, the physician who assessed the wound parameters 24 h after the procedure was not blinded because of the obvious presence or absence of a drain. This limitation may have resulted in a biased evaluation of tenderness, mid-thigh circumference and wound hematoma. Furthermore, the current study was performed in a university setting, where fellows and residents perform surgeries under supervision, which might have resulted in a longer duration of the procedures and a higher incidence of complications.

Conclusion

In this study, we found similar clinical and laboratory findings between patients who underwent THA with and without a CSD. Patients without a CSD reported higher early pain levels. No differences were detected in the complication rates. Based on the findings of this study, the routine use of CSD after primary THA was stopped in our institution.

Conflicts of interest

The authors declare no conflicts of interest.

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