CLINICAL RESEARCH

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hors' Contribution: Study Design A Data Collection B titistical Analysis C a Interpretation D rript Preparation E iterature Search F Funds Collection G	CDEF 2 BF 1	Pengfei Zan Jie J. Yao Lin Fan Yong Yang Zifei Zhou Zhong Wu Chunyan Zhu Dong Yang	 Department of Orthopedic Surgery, The Tenth Peoples' Hospital, Affiliated to Tongji University, Shanghai, P.R. China Medical School, University of Texas Southwestern Medical Center, Dallas, TS U.S.A. Department of Orthopedic Surgery, General Hospital of Ningxia Medical University, Yinchuan, Ningxia, P.R. China Department of Orthopedic Surgery, Shanghai East Hospital, Affiliated to Ton University, Shanghai, P.R. China Department of Surgery, The Tenth Peoples' Hospital, Affiliated to Tongji University, Shanghai, P.R. China
Correspondin Source c	AG 1	Guodong Li Guodong Li, e-mail: litrue2004@163.com	cience Foundation of China (NSFC), grant number (81572632)
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Efficacy of a Four-Hour Drainage Clamping

Technique in the Reduction of Blood Loss



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Background

Total hip arthroplasty (THA) is a widely-used surgical procedure to relieve pain, correct deformity, and restore function and mobility [1]. However, because of the extensive soft tissue damage and bleeding associated with osteotomy, hemorrhage following THA is a major concern, which may be severe enough to cause anemia and necessitate blood transfusion [2,3]. Because a blood transfusion can be a difficult procedure if there is a shortage of blood products, there may be a risk of transfusion-transmitted infections, or cultural aversion to transfusion, there has been a steady push towards reducing the necessity of blood transfusion during and following THA [4].

Traditionally, postoperative closed suction drainage has been widely used during and following THA, based on a study published by Waugh [5], who showed a lower infection rate when drainage was used. However, some surgeons have challenged the routine use of postoperative closed suction drainage [5–13]. Drainage is believed to be effective in decreasing hematoma formation, which may reduce postsurgical pain, swelling, and the incidence of infection [6,14,15]. However, the reduction of hematoma formation can encourage postoperative hemorrhage by reducing the tamponade effect at the incision site, which then raises the risk of blood transfusion [16,17]. Therefore, drainage clamping might be an optimal compromise; reducing blood loss and also the complication of hematoma. Most blood loss occurs during the first few postoperative hours (37% in two hours and 55% in four hours) [18]. The intra-articular tamponade effect from hours of drainage clamping may reduce the blood loss in THA [19].

Previous studies of drainage clamping have focused primarily on total knee arthroplasty (TKA) rather than THA. Proposed methodologies vary greatly, with different continuous and intermittent clamping times during TKA [17,19–25]. A longer clamping period was associated with increased complications, such as delayed wound healing, hematoma, skin edge necrosis, and risk of infection [21,26,27]. There have been previous studies that have claimed that the four-hour drainage clamping technique could achieve an ideal result [23,25]. A meta-analysis has also confirmed that the four-hour drainage clamping technique can reduce blood loss effectively during TKA [28].

As far as we know, there have been only two studies that have previously evaluated drainage clamping in THA [29,30]. Brueggemann et al. [29] reported that two suction drains clamped intermittently for 55 minutes every hour for the first six hours postoperatively significantly reduced blood loss; this was a rather complicated method. More recently, Cao et al. [30] have shown that a six-hour drainage clamping technique in THA resulted in reduced blood loss, with a statistically significant reduction of postoperative drainage, which did not require a blood transfusion. Given the uncertainty surrounding this technique, the aim of this prospective cohort study was to determine the safety and efficacy of a four-hour drainage clamping technique in patients undergoing THA.

Material and Methods

Patient recruitment

The Consolidated Standards of Reporting Trials (CONSORT) statement was followed to conduct this prospective cohort study. All patients who were diagnosed with osteoarthritis and femoral head osteonecrosis treated with unilateral total hip arthroplasty (THA) were considered for inclusion in the study from March 2012 to December 2015.

Exclusion criteria included revision cases, simultaneous bilateral THA cases, cases of tuberculous osteoarthritis, traumatic osteoarthritis with a history of previous hip surgery, and patients with the following comorbidities: anemia, deep vein thrombosis (DVT), anticoagulation prior to surgery, coagulopathy, severe diabetes mellitus, and poorly controlled hypertension. The study was approved by the Human Research Ethics Committee of the Shanghai Tenth Peoples' Hospital Affiliated to Tongji University, and all the participants signed informed written consent forms.

Operative technique and interventions

All patients undergoing THA were provided with standardized perioperative care. All recruited participants underwent the operative procedure in the lateral decubitus position, with a standardized general anesthesia, using non-cemented femoral prostheses. A standardized THA procedure was then performed through a posterolateral approach and minimally invasive technique. After prosthesis implantation, the wound was closed after irrigation with a drainage tube insertion under the deep fascia. The operations were all performed by a senior surgeon in our hospital, who was the corresponding author of the present article. All procedures were conducted in a similar fashion except for postoperative drainage technique. The drainage tubes were initially all clamped after first insertion; the surgeons closed the wound and applied gauze and adhesive dressing. A nurse opened a previously prepared sealed, opaque envelope, in which an instruction on whether the drainage tube was to be continuously clamped for four hours or released immediately. All drainage was removed at 24 hours postoperatively for all patients.

An oral non-steroidal anti-inflammatory drug (celecoxib capsules, 200 mg, once daily) was prescribed for postoperative pain control regularly to all patients. Patients did not receive chemical thrombo-prophylaxis. Fluid supplementation was standardized in both groups. All patients were mobilized according to a standardized physical therapy protocol, under the guidance of doctors and nurses, from the first postoperative day after removing the drainage tube.

Criteria for blood transfusion were a hemoglobin (Hb) level <8 g/dL or <10 g/dL with symptomatic anemia (drop in blood pressure below 100 mm Hg, tachycardia >100 beats/min, urine output <30 mL/h) [31]. The wounds were assessed every two days for leakage and any wound-related complications. We conducted Hb and Hematocrit (Hct) measurements at 48 hours postoperatively for the calculation of blood loss, and 96 hours postoperatively to determine whether there was any necessity for transfusion, as the Hb at 96 hours postoperatively has been shown to be the lowest [32,33]. Sutures were removed on the tenth postoperative day. Patients were discharged from hospital in accordance with the routine practice in many Chinese hospitals.

Outcome measurements

The demographic baseline, intraoperative, and postoperative data were recorded for analysis. All patients underwent followup in the clinic or over the phone at one month, three months, six months and one year postoperatively. At the one-year follow-up, Harris Hip Scores were calculated.

The primary clinical outcome measurement in this study was blood loss, which included intraoperative blood loss, postoperative drainage volume, calculated blood loss, and subsequent transfusion requirements. Secondary outcomes were operation time, Visual Analogue Scale (VAS) score at one day and seven days, Harris Hip Score at one year and postoperative complications. The intraoperative blood loss was calculated by measuring the suction volume and change in surgical sponge weights. Postoperative drainage volume was recorded by the nursing staff. The calculated blood loss was obtained by the method proposed by Gross [34].

Randomization and blinding

A computerized random sequence was used to generate a randomization of the cohort with the sealed envelope method, as described above, and the sequence was concealed until the intervention was assigned after the insertion of the drainage tube in the operation room. The demographic baseline data and subsequent intraoperative and postoperative clinical outcome measurements were collected by two independent observers.

Power analysis

The sample size was calculated to detect a difference of 100 ml calculated blood loss in the 48 hours postoperatively, based

on the method from a previous study [30]. The standard deviation of blood loss at 48 hours postoperatively was 124.2 ml in the clamped drainage group. Thus, a total of 26 patients in each group were required to detect this difference with a 90% power and a single tail alpha value of 5%. As a drop out rate was estimated to be as high as 20%, we determined the recruitment goal of 32 patients per group.

Statistical methods

Data analysis was performed by using standard statistical software (SPSS, Inc. USA). Categorical variables were presented as absolute number and relative frequencies, of which the Chisquared test was used to test the differences. Continuous variables were presented as the mean and ranges, of which the Student's t-test was used to investigate parametric data. The results were considered as significant difference if the p value was less than 0.05.

Results

Patient flow

A total of 91 patients were initially enrolled and assessed, 27 patients were excluded from the cohort, of whom 18 patients did not meet the exclusive criteria, and nine patients declined to participate, leaving a final of 64 patients recruited for this study. The date of the final follow-up was December 7th, 2016. One patient in the clamping group and two patients in the non-clamping group were lost to follow-up, leaving 31 patients in the clamping group and 30 patients in the non-clamping group in the final analysis. A CONSORT flow diagram of the study is presented in Figure 1. The patient demographic data were matched equally, as presented in Table 1.

Clinical outcome measurements

All of the detailed perioperative data are presented in Tables 2 and 3. The intraoperative blood loss was 321.1 ± 85.6 ml in the clamping group, and 334.4 ± 68.8 ml in the non-clamping group; no significant difference was found (p=0.494). Postoperative drainage volume was 146.6 ± 45.9 ml in the clamping group, which was significantly less than that of 260.1 ± 59.5 ml in the non-clamping group (p<0.001).

The Gross formula [34] was used to calculate the authentic blood loss, 980.6 ± 199.1 ml in the clamping group and 1108.8 ± 252.8 ml in the non-clamping group, with a significant difference between groups (p=0.028). In order to show the differences in blood loss between the groups, according to the least to the greatest blood loss recorded, we arranged the patients into pairs regardless of the order of the operations

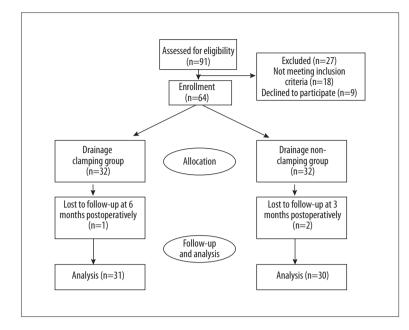


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram showing the flow of patients in the study protocol

Table 1. Preoperative baseline data.

Parameters	Clamping group (n=32)	Non-clamping group (n=32)	P value
Age	68.5±6.3	67.6±5.3	0.549
Diagnosis (osteoarthritis/osteonecrosis)	27/5	24/8	0.351
Left/right hip	18/14	16/16	0.616
Male/Female	11/21	13/19	0.606
BMI	25.3±1.5	25.5±1.4	0.645
HB (g/L)	132.8±7.4	133.7±7.2	0.633
VAS score	4.3±1.3	4.1±1.1	0.582
Harris score	51.4±10.4	50.3±9.6	0.682

BMI - body mass index; HB - hemoglobin; VAS - visual analogue scale.

Table 2. Follow-up outcomes.

Parameters	Clamping group	Non-clamping group	P value
Operation time (min)	79.6±7.7	80.5±8.2	0.639
Intraoperative blood loss (ml)	321.1 <u>±</u> 85.6	334.4 <u>±</u> 68.8	0.494
Postoperative drainage volume (ml)	146.6±45.9	260.1±59.5	<0.001*
Calculated blood loss (ml)	980.6±199.1	1108.8±252.8	0.028*
Blood transfusion patients	1	7	0.023*
Blood transfusion unit	2	18	0.001*
VAS score (POD1)	4.5±1.0	4.1±1.1	0.106
VAS score (POD7)	2.5 <u>±</u> 0.8	2.3±0.6	0.308
Harris score (PO1y)	84±5.2	85.2 <u>+</u> 4.2	0.325

VAS - visual analogue scale; POD - postoperative day; PO - postoperative; * indicates a significant difference.

Table 3. Complications.

Parameters	Clamping group(n=32)	Non-clamping group (n=32)	P value
Skin tension blister	5	2	0.230
DVT	1	0	0.314
Superficial infection	0	1	0.314
Total complications	6 (18.8%)	3 (9.4%)	0.281

DVT – deep vein thrombosis.

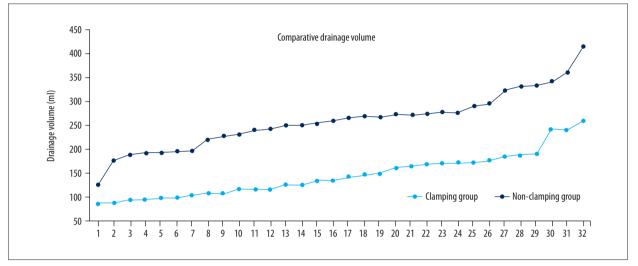


Figure 2. Comparative drainage volume among the groups (from least to greatest blood loss).

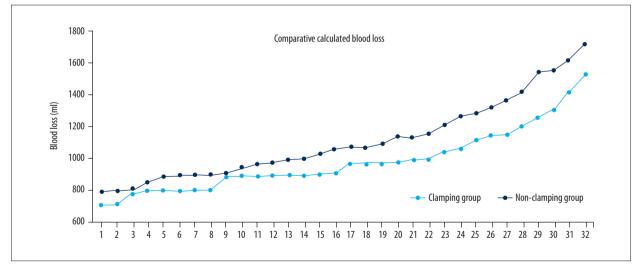


Figure 3. Comparative calculated blood loss among the groups (from least to greatest blood loss).

(Figures 2 and 3). Significantly fewer patients in the clamping group (one case) received blood transfusions than in the non-clamping group (seven cases) (p=0.023). Similarly, the total units of blood transfused was significantly different; 2 units in the clamping group and 18 units in the non-clamping group (p=0.001).

A total of six complications (18.8%) occurred in the clamping group; five cases of skin tension blister were treated with aspiration, and one case of deep venous thrombosis (DVT) was treated with continuous oral coagulant drug therapy. Three complications (9.4%) occurred in the non-clamping group, two cases of skin tension blister were treated in the same

way, and a superficial infection was treated with antibiotic therapy. This difference in the complication rate was not significant (p=0.281).

Discussion

To the best of our knowledge, this is the first study to investigate the clinical outcome of four hours of postoperative drainage clamping following total hip replacement (THA) compared with a non-clamping drainage technique. The most important finding of this study was that the four-hour drainage clamping technique was an effective strategy following THA. Compared with drainage non-clamping, four hours of drainage clamping reduced blood loss and blood transfusion requirements. Rates of adverse outcomes were similar between treatment groups. Therefore, the four-hour drainage clamping technique could potentially be a routine technique for use in THA.

As in total knee arthroplasty (TKA), although the effect of closed suction drainage on blood loss and postoperative complications has been controversial for THA, most surgeons commonly use the closed suction drainage during total joint arthroplasty (TJA) [6–13]. It has been claimed that in TKA, clamped suction drainage achieved good effects on reduction of blood loss and the need for blood transfusion [17,23]. THA differs from TKA because it is more difficult to apply a tourniquet and compressive dressing in THA. There have been many approaches for the control of blood loss following THA; some of these strategies include autologous blood transfusion, and pharmacolog-ic interventions such as the use of tranexamic acid [35,36], or fibrin tissue adhesive [37–39]. The drainage clamping method could be a more convenient way to achieve this goal, if its safety and effectiveness can be demonstrated.

Following surgery, most of the blood loss occurs during the first few hours [40], with 37% at two hours and 55% at four hours [18], and so improved control of blood loss during this four-hour period would seem to be most effective. However, the length of time for which the drainage should be clamped remains controversial. A period of drainage clamping for one hour to 24 hours has been proposed for TKA [17,19,21,23,25]; some intermittent drainage clamping methods have also been shown to be effective in controlling bleeding [20,24,29]. The clinical trials that have been conducted with two-hour, onehour and half-hour drainage clamping methods failed to show a reduction in true blood loss. Two previous studies on a fourhour drainage clamping technique achieved better results, and a subsequent meta-analysis found the ideal clamping period should be four hours or more. Brueggemann et al. [29] reported a method in which two suction drains were clamped intermittently for 55 minutes every hour for the first six postoperative hours, reducing blood loss significantly after THA. Cao et al. [30] have shown that a six-hour drainage clamping technique was effective with a statistically significant reduction in postoperative drainage amount; however, there was no difference in blood transfusion risk.

In this study, a four-hour drainage clamping technique reduced postoperative drainage volume and significantly reduced blood loss. This difference also translated to the number of patients requiring blood transfusion and the amount of transfused blood. These results all confirmed the efficacy of the four-hour drainage clamping technique on blood loss following THA.

In our trial cohort, we discovered a few more skin tension blisters in the drainage clamping group; we considered that the drainage clamping inevitably induced temporary hematoma accumulation which may increase the tension in the local wound area. Thromboembolism is an important complication after THA, because of the associated increases in the morbidity and mortality. In our present study, there was no difference in the cases of thromboembolism cases between the two groups.

There were several limitations of this study. First, the small study sample size may have been insufficient to allow analysis of clinical complications of the technique. Second, the patients and medical staff were totally blinded due to patient allocation, which may have introduced bias to the study. Though limitations exist, our present study provided evidence that the four-hour drainage clamping technique was a safe and effective strategy for use in THA. Further, large-scale controlled studies are recommended to evaluate this technique.

Conclusions

The four-hour drainage clamping technique was an effective strategy for patients undergoing THA. Compared with drainage non-clamping, four hours of drainage clamping has reduced blood loss and subsequent transfusion requirements. Furthermore, no additional risk for adverse outcomes was found. Therefore, a four-hour drainage clamping technique could potentially be routinely used in THA.

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Conflict of interest

None.

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