To use closed suction drain or not after total hip arthroplasty; a randomized controlled trial?

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Aim
The aim of the study is to provide clinical evidence through an analysis of the pros and cons of using a closed-suction drain (CSD) system after primary total hip arthroplasty.

Patients and methods
We conducted a prospective, randomized, controlled trial in Assiut University Hospitals between February 2016 and July 2017. In all, 100 patients who underwent primary total hip arthroplasty (cemented and cementless) were enrolled and randomly allocated into two groups of 50 patients each: group A (patients had CSD) and group B (patients had no CSD). Patients with revision surgery, uncontrolled bleeding tendency, liver or renal impairment, and low preoperative hemoglobin (Hb) level less than 11 g/dl were excluded from the study. The primary outcomes were Hb reduction and the number of patients transfused and the volume of blood transfusion per patient. The secondary outcomes were evaluation of the wound [including early surgical site infection (SSI), wound discharge, need for dressing reinforcement, ecchymosis], time for operative procedure, and length of hospital stay.

Results
Hb reduction was more in the group of CSDs (group A: 3.01 g, group B: 2.57 g, $P < 0.04$*). The number of patients transfused was also more in the CSD group (group A: 37/50, group B: 26/50, $P < 0.03$*). The mean volume of blood transfused per patient was significantly higher in the CSD group (group A: 1.13 unit of blood, group B: 0.52 unit, $P < 0.02$*). Patients without CSDs show more wound discharge (group B: 36/50, group A: 33/50, $P = 0.038$*), more dressing reinforcements (group B: 2.02 dressing per patient, group A: 1.7, $P < 0.03$*), and more ecchymosis (group B: 30/50, group A: 23/50, $P < 0.04$*). No significant difference concerning time for surgical procedure, early SSI, or length of hospital stay.

Conclusion
CSD had a negative effect on Hb reduction and rate and volume of blood transfusion (more Hb reduction and subsequently more transfusion requirements), while it had a positive effect on wound condition (less wound discharge, less dressing reinforcements, less ecchymosis), and no effect regarding early SSI, time for surgical procedure, and length of hospital stay.

Keywords:
closed-suction drain, hemoglobin reduction, total hip arthroplasty

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Introduction

Closed-suction drains (CSDs) are commonly used by orthopedic surgeons in large joint arthroplasties to avoid the development of postoperative hematomas. This practice has been promoted since 1961 by Waugh and Stinchfield [1] and it was probably intended as a way to reduce the high risk of infection related to the use of open drainage.

The rationale for using CSD is to reduce the formation of wound hematoma that causes increased tension and decreased perfusion in the surrounding tissues, which could explain the final detrimental effect on wound healing and the likelihood of wound dehiscence and wound infection.

During the years this practice has become a standard of care in total joint replacement among orthopedic surgeons, despite the fact that many good-quality clinical studies failed to demonstrate any effect of CSD in preventing wound complications, thus questioning the indiscriminate use of CSD in total joint arthroplasties. On the other hand, some potential drawbacks have been associated with, which is considered a potential route for the entry of bacteria; as a prosthetic material it is able to compromise the natural host defenses and to

act as a support for developing infection. In addition, a suction drain may increase the perioperative blood loss, diminishing the tamponade effect on the joint.

Finally, pain and discomfort at removal of the drain have been reported as well as cases of blockage and breakage of the drain tube, leading to reoperation [2].

The routine use of CSD in orthopedic surgery has therefore aroused much controversy, with recent studies indicating that this practice may be of more harm than good, and at an additional cost [3].

A recent meta-analysis conducted in 2013 of 3186 patients undergoing primary total hip arthroplasty (THA) showed that the use of CSD increased the rate of blood transfusion and did not provide any benefits regarding the incidence of infection, functional recovery, or other complications [4].

Koyano [5] in Japan said 'Studies that evaluated the effects of CSD using more specific parameters such as range of movement of the hip joint showed no difference between groups with CSD and without CSD'.

So we conducted this clinical trial to evaluate the use of CSD in primary THA and to determine whether it is beneficial or not.

Patients and methods

Study design

This study is a prospective, double-blind, randomized controlled trial conducted in a single center in which 100 patients underwent primary THA who were randomly allocated to two parallel groups of 50 patients each (clinicaltrials.gov research protocol registration ID: NCT02845427).

Devices to be used

(CSD; closed-suction drainage system).

Patient selection

Inclusion criteria

Primary THA (cemented and cementless).

Exclusion criteria

Revision cases: uncontrolled bleeding tendency (prothrombin concentration <70%), liver impairment (liver failure), renal impairment (serum creatinine >3 mg/dl), and preoperative hemoglobin (Hb) level of less than 11 g/dl.

Study methods

Preoperative clinical and laboratory assessment

Obtaining detailed history and full clinical examination, preoperative laboratory investigations (complete blood count) to determine the Hb level and assessment of renal function, coagulation, and bleeding profile preoperatively.

Method and timing of randomization

Permuted block randomization blocks having equal numbers of A and B (A: drain, B: no drain) are used. A sealed opaque envelope, in which instruction on whether to use drainage or not, will be opened just before wound closure by a nurse in the operative room. Patients were divided equally into two groups according to the letter withdrawn randomly.

Method of calculation of intraoperative blood loss

Intraoperative blood loss was quantified by measuring the irrigation fluid and the number of surgical packs (towels) used to dry the field intraoperatively by the researcher plus the amount of blood in the intraoperative suction drain.

The surgical towel used measures 20 × 25 cm. It loads about 50 ml blood when it is partially soaked with blood and about 80 ml blood when fully soaked with blood.

Postoperative anticoagulant protocol

The use of anticoagulation (all patients will receive Enoxparin 'Clexane' (USA) subcutaneous injection/24 h for thrombosis prophylaxis, dose as follows: body weight >60 kg will receive 0.4 ml, 50–60 kg will receive 0.3, >50 kg will receive 0.2 ml) started 12 h postoperatively, and continued till discharge where it is shifted to oral anticoagulants.

Methods of evaluation of postoperative blood loss

A suction drain was placed in group A cases and the blood volume was recorded at 24 h when it was removed.

Methods of postoperative evaluation and follow-up

In all the patients included in this study, no intraoperative blood transfusion was done. If the anesthetist found that it was necessary (due to excessive bleeding), the patient was excluded from this study. All patients had Hb levels tested on the first and second postoperative days to evaluate the need for blood transfusion. Blood transfusion was given if the Hb level is less than 8 g/dl as recommended by Lee *et al.* [6]. The early reduction in Hb level was defined as the difference in Hb between the preoperative value and the postoperative sample taken 24 and 48 h after surgery.

Checking wound condition to detect any [discharge, ecchymosis, soaking of dressing, and need for reinforcement or any early surgical site infection (SSI)] at 24 h postoperatively (when the drain is removed), 48 h, 72 h, 15 days (when stitches are removed) and 30 days postoperatively.

Documentation of the amount of blood transfusion during the first 72 h postoperatively, any postoperative complications, and length of hospital stay.

Ethical approval

An approval for the study is obtained from the ethics committee in the Faculty of Medicine in Assiut University Hospitals, Assiut University. Informed consent was obtained from all patients included.

Statistical analysis

Expressed as mean, SD, number, and percentage. Data collected and analyzed by computer program SPSS 'version 23' (SPSS Inc., Chicago, Illinois, USA). *t*-Test (and Mann–Whitney if necessary) was used to determine significance for numeric variables. χ^2-Test and Fisher's exact test were used to determine significance for categorical variables.

Results

Demographic data of the study groups: there was mean value of age 48.25 years in group A versus 43.60 years in group B with nonsignificant difference. Also there was nonsignificant difference ($P > 0.05$) with sex and side (Table 1).

The preoperative and postoperative Hb level in the study groups: there was nonsignificant difference between the two groups in Hb levels preoperatively and 24 h postoperatively ($P > 0.05$). But there was significant difference between two groups in Hb level 48 h postoperatively ($P < 0.04$) (Table 2). Also, as regard the mean reduction in Hb level preoperatively and postoperatively in the study groups, there was nonsignificant difference at 24 h between the two groups, but there was significant difference at 48 h postoperatively ($P < 0.04$) [Table 2].

There was significant difference ($P < 0.05$) in blood transfusion between the two groups with higher in group A than in group B (Table 3).

There was significant difference ($P < 0.05$) between two groups regarding wound discharge (minimal or moderate compared with the total number of cases in each group) in study groups (Table 4). The wound discharge was considered minimal when there were just spots of discharge staining the dressing, while considered moderate if the dressing is partly soaked.

As regards dressing reinforcement in the study groups, there was significant difference ($P < 0.05$) between groups, with less need for dressing reinforcement in group A (treated with drain) than in group B (treated without drain), not only in the number of patients required dressing reinforcement but also in the number of changing dressings among those patients [Table 4]. Changing of dressing indicated if it is fully soaked with blood or discharge when inspected by the researcher.

Regarding ecchymosis in the study groups, there was significant difference ($P < 0.05$) between two groups with lower in the percentage of patients having

Table 1 Demographic data of the study groups

Items	Group A (*n*=50)	Group B (*n*=50)	*P*
Age (years)			
Mean±SD	48.25±15.06	43.60±14.41	0.191 (NS)
Minimum-maximum)	20.0-75.0)	20.0-80.0	
Sex [*n* (%)]			
Male	28 (56.0)	24 (48.0)	0.316 (NS)
Female	22 (44.0)	26 (52.0)	
Side [*n* (%)]			
Right	14 (28.0)	13 (26.0)	0.306 (NS)
Left	36 (72.0)	37 (74.0)	

Table 2 Hemoglobin level preoperatively postoperatively in the study groups

Items	Group A (*n*=50)	Group B (*n*=50)	*P*
Hb level preoperative	12.70±1.69	12.84±1.42	0.699 (NS)
Hb level 24 h postoperative	10.08±1.43*	10.27±1.39*	
Hb level 48 h postoperative	9.69±1.12**	10.27±1.38*	
Hb reduction 24 h postoperative			
In g/dl	2.62±0.26	2.57±0.03	0.385 (NS)
In %	20.62	20.01	
Hb reduction 48 h postoperative			
In g/dl	3.01±0.57	2.57±0.04	<0.04*
In %	23.70	20.01	

*Significant, **Highly significance, NS, non significance; Hb, hemoglobin.

Table 3 Blood transfusion in study groups

Items	Group A (*n*=50)	Group B (*n*=50)	*P*
Number of patients required transfusion [*n* (%)]	37 (74.0)	26 (52.0)	<0.03*
Total number. of blood transfusion units (mean±SD)	56.5±10.52	26±12.47	<0.001**
Mean blood transfusion			
Volume (ml) (mean±SD)	565±15	260±0.00	<0.02*
Volume (units)	1.13	0.52	

*Significant, **Highly significance, NS, non significance.

Table 4 Dressing reinforcement and ecchymosis in study groups

Items	Group A (*n*=50) [*n* (%)]	Group B (*n*=50) [*n* (%)]	*P*
Wound discharge			
No discharge	17 (34.0)	14 (28.0)	<0.04*
Wound discharge			
Minimal	32 (64.0)	34 (68.0)	**0.038***
Moderate	1 (2.0)	2 (4.0)	
Total	33 (66.0)	36 (72.0)	
Dressing reinforcement			
Number of patients required dressing reinforcement	40 (80)	46 (92)	<0.03*
Number of dressing reinforcements			
1 (once)	21 (42.0)	15 (30.0)	<0.001**
2 (twice)	11 (22.0)	18 (36.0)	
3 (three times)	7 (14.0)	10 (20.0)	
4 (four times)	1 (2.0)	3 (6.0)	
Mean number of changing dressings among patients required dressing reinforcement	1.7	2.02	
Total number of dressings	68	93	<0.03*
Ecchymosis			
No ecchymosis	27 (54.0)	20 (40.0)	<0.03*
Wound ecchymosis			
Minimal	23 (46.0)	28 (56.0)	<0.04*
Moderate	0.0	2 (4.0)	
Total	23 (46.0)	30 (60.0)	

*Significant, **Highly significance, NS, non significance.

ecchymosis in group A than in group B [Table 4]. Ecchymosis is considered minimal when skin discoloration is not dark, for distance within 5 cm from the surgical line, and considered moderate when darker or exceeds 5 cm from the surgical line.

SSI in the study groups shows nonsignificant difference ($P > 0.05$). In group A, two cases developed SSI at day 6 postoperatively; one of them required reoperation (debridement and wash at 10th day postoperatively), and the other case resolved by antimicrobial therapy for 2 weeks. In group B, only one case showed SSI at day 10 postoperatively and indicated antimicrobial therapy for 2 weeks. The surgical site is considered infected when there is purulent discharge with hyperemic edges of the wound. Late wound infection cannot be fully assessed because of the relatively short follow-up duration of the study (Table 5).

Concerning hospital stay in the study groups, there was nonsignificant difference between the two groups ($P > 0.05$) [Table 5].

Discussion

Wound hematomas are inevitable following orthopedic operations because complete hemostasis is difficult to achieve when the medullary canal has been exposed, subsequent effect of hematoma is increased tension over the wound resulting in decreased tissue perfusion, delaying healing process, and providing a rich medium for bacterial culture [1]. Thus, the use of suction drains after major operations seems to be a very logical and effective way of reducing the size of postoperative wound hematomas [5].

On other hand, some may argue that drains may provide an entry access point for bacteria through the drain itself or through its tract, persistent wound discharge with even fistula formation, and intra-articular fibrosis with subsequent poor functional outcome [7,8].

The debate over prophylactic wound drainage transcends orthopedic surgery. Lawson Tait's say 'when in doubt, drain' was countered by Halsted (1898) who argued that 'no drainage at all is better than the ignorant employment of it' [9].

While many surgeons may continue the 'routine' practice of prophylactic wound drainage, there is increasing clinical evidence that the use of drains confer no advantages over their nonuse in clean orthopedic wounds [10].

The literature carries conflicting reports on the use of drains. A meta-analysis by Parker *et al.* [11] suggested that they may do harm more than good and that their only proven benefit is a reduced need for the change of dressing.

Moreover, many authors reported significantly increased need for postoperative transfusions in patients treated with drains [12–14].

Murphy *et al.* [15] in a prospective, randomized trial involving 40 patients concluded that there is a

statistically significant difference between both groups regarding the total blood loss.

Ovadia *et al*. [16] found that the use of drains gave an increased need for transfusion. Combining these results gives a trend toward increased transfusion requirements if wounds are drained, but the difference was not statistically significant.

Nicolajsen *et al.* reported without data no difference in the requirement for transfusion between groups.

Widman *et al.* [17] stated that 'the total blood loss, of course, was higher in the drained group, since this included the drained blood. The group with drains needed more blood transfusions'.

Della Valle *et al.* [18] found that patients receiving CSD had more marked reductions in hematocrit (10.4 vs. 7.4) (P = 0.03), and a longer hospital stay (5.1 vs. 4.7 days) than those without a drain (P = 0.01).

Walmsley *et al.* [19] found that there was no significant difference between the groups in terms of the mean preoperative and postoperative hemoglobin levels or the length of hospital stay. However, in the drained group the percentage of patients requiring transfusion was significantly higher (33 vs. 26.4%; P = 0.042).

In this randomized controlled trial result show:

As regarding hemoglobin levels

In our series, we found that there was nonsignificant difference in the levels preoperatively and 24 h postoperatively, while in 48 h postoperative there was a significant difference of more reduction in group A (using drain), mean Hb reduction 48 h postoperatively in group A 3.01 ± 0.57 and in group B 2.57 ± 0.04, while the time of drain removal was 24 h postoperatively, it seemed that more blood loss occurred in group A than in group B at 48 h postoperatively (1 day after drain removal reflecting the drain effect), which may indirectly indicate that using CSD caused more blood loss (of about 0.44 mg/dl of Hb) in group A than in group B. This is in accordance with Biggi *et al*. [20], Della Valle *et al.* [18], and many authors (Table 6).

As regarding volume of blood transfusion

There was a significant difference, with more patients needed transfusion in the group of patients treated with CSDs (37/50; 74% in group A, 26/50; 52% in group B), and also the mean volume of transfusion was more in the same group (565 ± 15 ml in group A, 260 ± 0.00 ml in group B) This is in agreement with Ovadia *et al*. [16], Widman *et al*. [17], and most of other studies (Table 7).

As regarding early surgical site infection

In our randomized controlled trial, there was nonsignificant difference between the two study groups regarding early wound infection (two patients in group A and only one patient in group B) but considered numerically statistically nonsignificant. This is in accordance with Kim *et al*. [21], Ovadia *et al*. [16], Niskanen *et al.* [22], and Widman *et al.* [17] whereas Walmsley *et al*. [19] classified SSIs into superficial and deep infection gave the same results.

As regarding wound discharge, need for dressing reinforcement, and ecchymosis

There was significant difference between two groups with more incidence of discharge in nondrained patients (33/50 in group A, 36/50 in group B) with subsequent need for dressings changing (40/50 in group A, 46/50 in group B). Also more number of

Table 5 Hospital stay and early surgical site infection in study groups

Items	Group A (n=50)	Group B (n=50)	P
Hospital stay (days) (mean±SD)	4.37±1.21	4.22±1.37	0.753 (NS)
Early surgical site infection [n (%)]	2 (4.0)	1 (2.0)	0.470 (NS)

NS, non significance.

Table 6 Postoperative hemoglobin level and blood loss

References	Number of patients	Mean postoperative Hb level		Reduction in Hb level		Blood loss		Impact of using drain
		Drain	No drain	Drain	No drain	Drain	No drain	
Murphy *et al*.[15] and Scott (1993)	40					1.455 ml	1.134 ml	More loss with drain
Kim *et al*. [21]	48 (96 hips)					112.18 g	226.2 g	More loss with no drain
Widman *et al*. [17]	22					734 ml	624 ml	More loss with drain
Ovadia *et al*. [16]	30	9.9	10.2					More loss with drain
Walmsley *et al*. [19]	552 (577 hips)	10.3	10.5					More loss with drain
Ikpeme *et al*. [10]		9.9	9.4					More loss with no drain
Biggi *et al*. [20]	37			3.75	2.98			More loss with drain
Our study	100	9.69	10.27	3.01	2.57			More loss with drain

patients showed wound ecchymosis in the nondrained group (23/50 in group A, 30/50 in group B). This is in agreement with Kim *et al*. [21] and Niskanen *et al*. [22], but in disagreement with Dora *et al.* [23] (Table 8).

As regarding hospital stay

There was nonsignificant difference between two groups with mean number of days (4.37 in group A) and (4.22 in group B). This is in agreement with Biggi *et al*. [20], Ovadia *et al*. [16], Parker *et al.* [11], and Walmsley *et al.* [19].

But Kleinert *et al.* [24] showed significant longer hospital stay in the group of patients treated with drain either with or without reinfusion.

After reviewing literatures concerned with the same topic we compared our results with the results of other studies. The following tables show comparison between the results of different items in our study and the other studies.

Conclusion

If we have to give a recommendation that is based on solid clinical evidence about the use of drain in primary THA, we conclude that patients must be evaluated carefully preoperatively. If the patients' clinical manifestation show anemia (Hb level at a lower margin of normal range), we recommend that drain should not be used to decrease the risk for blood loss and subsequent requirement for transfusion, and if the general condition of the patient is just normal with high preoperative Hb level (high normal of 15 g/dl or more), the closed-suction drainage to be used for the favor of better wound condition (wound tension and discharge, need for dressing reinforcement, wound ecchymosis).

Limitations

Being a prospective, randomized, controlled study, comparing the impact of using the suction drainage system to no drainage in a specific region, using the same protocol and following the guidelines with all patients added strengths to the study. However:

(1) Postoperative laboratory assessment of blood loss (Hb level) was of short duration in the first 24 h and 48 h detecting early reduction in Hb and hematocrit only which may need further assessment on third and seventh days postoperatively to detect late reduction
(2) The number of cases enrolled in this study was relatively small, especially regarding wound infection outcome. In order to get a statistically significant difference and obtain reliable results sample size should be more
(3) Many variables influence the Hb level and drain output. By conducting the same operative technique, we tried to minimize differences of intraoperative blood loss. But, several factors that still could affect clinical outcome included different fluid therapy.

Table 7 Need for blood transfusion

References	Number of patients needed transfusion/%		Impact of using drain
	Drain	No drain	
Ovadia *et al.* [16]	9/18 (50)	2/12 (16.66)	Increase significantly
Widman *et al.* [17]	9/10 (90)	6/12 (50)	Increase
Della Valle *et al.* [18]	21/53 (39.62)	18/51 (35.28)	Increase
Johansson *et al.* [25]	36/54 (66.66)	28/51 (54.90)	Increase significantly
Walmsley *et al.* [19]	93/282 (32.97)	78/295 (26.44)	Increase
Kumar *et al.* (2007)	13/19 (68.42)	10/15 (66.66)	Increase
Strahovnik *et al.* [26]	22/46 (47.82)	30/42 (71.42)	Decreased significantly
Cheung *et al.* [27]	19/52 (36.53)	6/48 (12.50)	Increase significantly
Ikpeme *et al.* [10]	7/31 (22.58)	0/31 (0)	Increase significantly
Kleinert *et al.* [24]	4/40 (10)	4/40 (10)	Equal
Our study	37/50 (74)	26/50 (52)	Increase significantly

Table 8 Number of needed dressings

References	Number of patients	% of patients needed dressing/number dressing per patients		Significance
		Drain	No drain	
Kim *et al.* [21]	48 (96 hips)	6.3%	22.9%	More in undrained (S)
Niskanen *et al.* [22]	58	9/31 (29%)	21/27 (77.8%)	More in undrained (S)
Dora *et al.* [23]	100	2.9 (number of dressing per patient)	1.6 (number of dressing per patient)	More in drained (S)
Our study	100	40/50 (80%)	46/50 (92%)	More in undrained (S)
		1.7 (number. of dressing per patient)	2.02 (number of dressing per patient)	

S, significant.

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Conflicts of interest
There are no conflicts of interest.

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