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Original Article

Prospective randomized study after the use of drains in total knee arthroplasty with implant

Rogério Franco de Araujo Goes,^{1,*} Anselmo Fernandes da Silva,² Fábio Soares Lyra,²
Fabricio Bolpato Loures,³ Idemar Monteiro Da Palma,⁴
Hugo Alexandre de Araujo de Barros Cobra,⁵ Pedro José Labronici⁶

¹Clinical Head and Physician in charge of the Knee Group of Prof. Dr. Donato D'Ângelo Orthopedics and Traumatology Service, Hospital Santa Teresa, Petrópolis, RJ, Brazil.

²Resident Physician of Prof. Dr. Donato D'Ângelo Orthopedics and Traumatology Service, Hospital Santa Teresa, Petrópolis, RJ, Brazil.

³Physician of Prof. Dr. Donato D'Ângelo Orthopedics and Traumatology Service, Hospital Santa Teresa Petrópolis, RJ, Brazil.

⁴Assistant Physician of the Knee Group, Instituto Nacional de Traumatologia e Ortopedia (INTO), Rio de Janeiro, RJ, Brazil.

⁵Head of the Knee Surgery, INTO/RJ, Rio de Janeiro, Brazil.

⁶PhD in Medicine from the Universidade Federal de São Paulo, Escola Paulista de Medicina; Clinical Head of Prof. Dr. Donato D'Ângelo Orthopedics and Traumatology Service, Hospital Santa Teresa, Petrópolis, RJ, Brazil

Research conducted at Prof. Dr. Donato D'Ângelo Orthopedics and Traumatology Service of the Hospital Santa Teresa, Petrópolis, RJ, Brazil, and in the Faculdade de Medicina de Petrópolis, Petrópolis, RJ, Brazil

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Objective: to compare the laboratorial results of opening suction drainage 6 hours and 12 hours after total knee arthroplasty surgery. **Methods:** prospective and randomized study in 88 patients undergoing with total knee arthroplasty in two groups: in one group the opening suction drainage was performed 6 hours (n = 45) after the surgery and in the other 12 hours (n = 43) after the surgery. **Results:** the outcome was a significant fall in the three laboratorial variables (hemoglobin, red blood cells and hematocrit) between the pre and post-operative in the total sample and in the six and 12 hour opening suction drainage groups. In the group with opening suction drainage after 12 hours, the drainage volume was significantly lower than in the group with opening suction drainage after 6 hours (p = 0.0003). However, no significant difference was observed in the absolute delta of the laboratorial variables between the two groups. **Conclusion:** the opening suction drainage in six and 12 hours did not show significant difference from the laboratorial values although the volume of the blood drained was higher in the opening suction drainage in six hours.

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*Corresponding author: R. Visconde de Uruguai 484, Petrópolis, RJ, Brazil.
E-mail: rsgoes3@uol.com.br.

Introduction

Total knee arthroplasty is widely used in the treatment of osteoarthritis and moderate or severe rheumatoid arthritis. However, the use of suction drains in the joint is still controversial. In theory, drainage prevents hematoma formation at the surgical site, decreases tension over the incision (which consequently decreases pain), reduces the retardation of wound healing and reduces the risk of infection.^{1,2} However, the drainage system inevitably increases bleeding because the tamponade effect does not occur at the surgical site. In addition, it can cause a retrograde infection.³ However, several studies have shown that postoperative drainage in total knee arthroplasty is not necessary, although it is still widely used by orthopedic surgeons.³⁻⁷

Despite the blood loss that occurs after total knee arthroplasty during the first postoperative hours (37% in the first two hours and 55% in the following hours), drainage clamping may be used to create a temporary tamponade effect and to control bleeding.^{8,9}

This study aimed to compare the laboratory results of the open suction drainage at six and 12 hours after total knee arthroplasty.

Materials and Methods

Between May 2010 and July 2011, total knee arthroplasty was performed on 102 patients at the Hospital Santa Teresa, Petrópolis, RJ, Brazil. The criterion for this prospective and randomized study was the treatment of patients with primary knee arthrosis using the same type of cemented implant (Nexgen®). In all cases, patellar arthroplasty was included. Patients were advised to suspend the use of any medication that could interfere with coagulation at least 15 days prior to surgery. Fourteen patients were excluded; eight patients were excluded due to the loss of the drains after surgery and six patients due to their use of implants. Of the 88 patients treated with total knee arthroplasty, there were no bilateral cases or any bleeding disturbances observed after surgery. The patients were randomly divided into two groups after surgery using an envelope: the first group had open suction drainage at six hours (n = 45) after surgery and a second group had opened suction drainage at 12 hours (n = 43) after surgery. Osteoarthritis was diagnosed according to Alhback10 into five types, and the cases were treated on the basis of type II.

A surgeon with more expertise supervised all of the patients who underwent surgery, and the same surgical technique and pneumatic tourniquet were performed. Rachianesthesia was used on all of the patients. In cases with varus deformity (n = 59), the medial parapatellar approach was used, and in cases with valgus (n = 29) Kerbish, a lateral approach was used.¹¹ The tourniquet was released after wound closure. In addition, a vacuum aspiration drain of 4.8 mm in diameter was used. The drain and compression dressing were maintained for 24 hours. The patients were then subjected to a protocol for thromboembolism prevention, which began six hours after the

end of the surgery using heparin of a low molecular weight over 10 days.

Immediately after surgery, the patients were immobilized with a compression bandage for two days. On the third day, after removal of the bandage, the patients were advised to start walking.

The general profile of the 88 patients who participated in this study, which includes the mean, standard deviation (SD), median and the minimum and maximum values of the numerical variables, are shown in Table 1.

In addition, the frequency (n) and percentage (%) of the basal categorical variables are shown in Table 2.

Statistical evaluation

A descriptive analysis is presented in the tables containing the observed data, which were expressed as the frequency (n) and percentage (%) of the categorical data (qualitative). In addition, the mean, standard deviation (SD), median and minimum and maximum values for the numerical data are also provided.

The statistical analysis was performed using the following methods:

- a comparison of the basal numerical variables between the groups with a tourniquet opening (6 hours vs. 12 hours) was performed using Student's t-test for independent samples or the Mann-Whitney test. For the categorical variables, the 2 test or Fisher's Exact test was used;

- the variation in the pre- and post-treatment laboratory variables was calculated using Student's t-test for paired samples;

- the differences in the drain volume and in the deltas of the laboratory variables between the two groups with the tourniquet opening were analyzed using the Mann-Whitney test.

Non-parametric tests were performed because some of the variables did not present a normal distribution (Gaussian distribution) due to dispersion of the data and the rejection of the normality hypothesis according to the Kolmogorov-Smirnov test. The criterion for the determination of significance was set at 5%. Statistical analyses were performed using the SAS 6.11 software package (SAS Institute, Inc., Cary, North Carolina, USA).

Results

Our study consisted of two patient groups: the first and second groups had an open suction drain at six (n = 45) and at 12 hours (n = 43) after surgery, respectively.

In addition, we performed statistical analyses to confirm whether there was a significant difference in the basal variables between the groups regarding the numerical variables. The mean \pm standard deviation (SD), median of the basal numerical variables according to the group (six vs. 12 hours) and corresponding descriptive level of Student's t-test for independent variables (age and laboratory variables) or the Mann-Whitney's test (valgus and varus angle) are shown

in Table 3. Importantly, there was no difference in the basal numerical variables between the two groups.

Furthermore, the presence of an association with the categorical variables was also determined. The frequency (n) and percentage (%) of the basal categorical variables according to the group (six vs. 12 hours) and corresponding descriptive

Table 1 - General description of the basal numerical variables.

Basal variable	Mean	SD	Median	Min	Max
Age (years)	68.6	7.7	68	50	83
Valgus Angle (degrees)	14.3	5.2	15	2	23
Varum Angle (degrees)	7.4	3.9	7	3	20
Preoperative Hematocrit	41.3	3.9	41	30	54
Preoperative Hemoglobin	13.7	1.5	13.6	10.2	17
Preoperative Red Blood Cells	4.71	0.55	4.6	3.75	6.8
Drain Volume (mL)	195.5	105.1	200	10	500

SD: Standard Deviation; Source: Hospital Santa Teresa

Table 2 - General description of the basal category variables.

Variable	Category	n	%
Time of drain opening	12 h	43	48.9
	6 h	45	51.1
Gender	male	33	37.5
	female	55	62.5
	gonarthrosis	74	84.1
Etiology	osteonecrosis	11	12.5
	Arthritis	3	3.4
Skin Color	white	60	68.2
	mulatto/black	28	31.8
	II	5	5.7
Ahlback Classification	III	35	39.8
	IV	26	29.5
	V	22	25.0
Angle Deviation	valgus	29	33.0
	varum	59	67.0

level (p-value) of the χ^2 test or Fisher's Exact test are shown in Table 4.

Moreover, we also performed statistical analyses to confirm whether there was a significant variation between the pre- and postoperative period in the laboratory variables. The mean \pm standard deviation and corresponding descriptive level (p-value) of Student's paired t-test are provided in Table 5.

A significant decrease in the three laboratory variables between the pre- and postoperative period was observed in the total sample and in the two groups treated with drain opening at six and 12 hours.

An additional objective of this study was to confirm whether there was a significant difference in the drain volume and in the levels of laboratory variables between the two groups (opening time at six hours vs. 12 hours). The mean \pm standard deviation (SD) and mean of the drain volume, absolute deltas of the laboratory variables and corresponding descriptive level of the Mann-Whitney test are shown in Table 6.

The absolute delta was calculated using the following formula:

Absolute Delta = variable after treatment - variable before treatment.

Importantly, the group with the drain opening time at 12 hours after surgery presented a significantly lower drain volume compared to the group treated at six hours ($p = 0.0003$) after surgery. However, no significant difference was observed in the absolute delta of the laboratory variables between the groups.

Discussion

Total knee arthroplasty is a widely used procedure that produces good results.¹² Although it is controversial, drainage is a procedure that is normally used after arthroscopy; thus, it should be re-evaluated by surgeons.^{13,14} However, a point of discussion is whether the drainage system offers benefits regarding wounds, and if so, when do these benefits occur? In theory, drainage evacuates the developing hematoma at the surgical site and aids in wound healing.² Waugh et al.¹⁵ support the use of drainage after several orthopedic procedures because it prevents hematoma formation and reduces the incidence of complications in the wound. However, other studies have shown that the placement of the drain after total knee arthroplasty does not affect the incidence of complications, mean time of hospitalization and functional recovery. Moreover, drainage after total knee arthroplasty reduces the tamponade effect and increases blood loss in the wound.^{2,3,5,16-20} In addition, Kim et al.² observed that, unlike drained wounds (10.1%), wounds that were not drained demonstrated a high incidence (60.9%) of bleeding, which would soak the dressings and cause ecchymosis and erythema around the wound.

The time for drainage release varies among different studies. In one study, Aksoy et al.¹⁴ closed the wound, covered it with elastic bandages, and the drain was closed for two hours. They did not observe a significant difference in the amount of drained blood, in the levels of hemoglobin and hematocrit, or in the need for a transfusion during the postoperative period. In another study, Sedna et al.²¹ closed the drain for one hour after total knee arthroplasty and reported a reduction in bleeding in the postoperative period. Furthermore, Roy et al.²² used the technique of clamping the drain for one hour after surgery and showed that the amount of blood loss was 732 mL (620-845 mL) in the group with the closed drain and 1,050 mL (728-1,172 mL) in the control group. Although blood loss was significantly reduced and a decrease in the mean hemoglobin rate was observed in these patients, a transfusion was not required among the groups. Kiely et al.²³ used the technique of clamping the drain for two hours and did not find a difference regarding blood loss, a reduction in hemoglobin levels or the need for a transfusion. However, Stucinskis et al.²⁴

Table 3 - Basal numerical variables according to the drain opening time.

Basal Variable	Time of 12 h		Time of 6 h		p-value ^a
	Mean ± SD	Median	Mean ± SD	Median	
Age (years)	68.2 ± 7.5	68	69.0 ± 8.0	69	0.62
Valgus Angle (degrees)	13.9 ± 6.1	15	15.1 ± 3.2	15	0.81
Varum Angle (degrees)	8.5 ± 4.9	8	6.7 ± 2.8	7	0.26
Pre Hematocrit	41.2 ± 4.2	41.0	41.4 ± 3.8	41.0	0.83
Pre Hemoglobin	13.8 ± 1.4	13.9	13.5 ± 1.5	13.5	0.22
Pre Red Blood Cells	4.67 ± 0.51	4.6	4.75 ± 0.59	4.8	0.49

SD: Standard Deviation; Student's paired t -test.

Table 4 - Basal category variables according to the drain opening time.

Variable	Category		Time of 12 h		p-value ^a	
	N	%	n	%		
Gender	male	16	37.2	17	37.8	0.95
	female	27	62.8	28	62.2	
Etiology	gonarthrosis	35	81.4	39	86.7	0.50
	osteonecrosis	7	16.3	4	8.9	
	arthritis	1	2.3	2	4.4	
Skin Color	white	29	67.4	31	68.9	0.88
	mulatto/black	14	32.6	14	31.1	
Ahlback Classification	II	3	7.0	2	4.4	0.60
	III	18	41.9	17	37.8	
	IV	14	32.6	12	26.7	
Angle Deviation	valgus	19	44.2	10	22.2	0.028
	varum	24	55.8	35	77.8	

^aχ² test or Fisher's Exact test.

SD: Standard Deviation; Student's paired t -test or Mann-Whitney test.

Source: Hospital Santa Teresa.

Table 5 - Laboratory variables between the pre- and postoperative care in the total sample and according to the drain opening time group.

Variable	Sample	pré-op Mean ± SD	pós-op Mean ± SD	p valor ^a
Total	Hematocrit	41.3 ± 3.9	32.5 ± 4.2	0.0001
	Hemoglobin	13.7 ± 1.5	10.8 ± 1.3	0.0001
	Red Blood Cells	4.71 ± 0.55	3.73 ± 0.53	0.0001
of 12 hours	Hematocrit	41.2 ± 4.2	32.35 ± 3.80	0.0001
	Hemoglobin	13.8 ± 1.4	10.9 ± 1.4	0.0001
	Red Blood Cells	4.67 ± 0.51	3.70 ± 0.55	0.0001
of 6 hours	Hematocrit	41.4 ± 3.8	32.7 ± 4.6	0.0001
	Hemoglobin	13.5 ± 1.5	10.7 ± 1.3	0.0001
	Red Blood Cells	4.75 ± 0.59	3.76 ± 0.52	0.0001
	Hemoglobina	13.5 ± 1.5	10.7 ± 1.3	0,0001
	Hemácia	4.75 ± 0.59	3.76 ± 0.52	0,0001

SD: Standard Deviation; Student's paired t -test.

Source: Hospital Santa Teresa.

Table 6 - Drain volume and deltas of the laboratory variables according to the drain opening time (12 h and 6 h).

Basal Variable	Time of 12 h		Time of 6 h		p-value ^a
	Mean ± SD	Median	Mean ± SD	Median	
Drain volume (mL)	158.6 ± 98.5	150	230.7 ± 99.9	250	0,0003
Delta of hematocrit	-8,9 ± 4,5	-8,9	-8,7 ± 4,5	-11	0,62
Delta of hemoglobin	-3,0 ± 1,7	-3,4	-2,7 ± 1,5	-2,7	0,39
Delta of red blood cells	-1,0 ± 0,6	-1,0	-1,0 ± 0,6	-1,1	0,90

SD: standard deviation. ^aMann-Whitney.

and Shen et al.²⁵ maintained the drain clamp for four hours during the postoperative period and found a significant reduction in blood loss. Taken together, the amount of blood transfusion in both studies was reduced, but Stucinskas did not report a difference in the postoperative levels of hemoglobin and hematocrit. Furthermore, Raleigh et al.²⁶ used a method of intermittent clamping for five minutes every two hours during the first six hours after surgery. The drain was then clamped again in the 12th hour and in the 24th hour for five minutes. The results showed that although the amount of bleeding was reduced, there was no difference in the transfusion rates in the postoperative period. In addition, Prasad et al.²⁷ compared two intermittent methods for drain clamping. Using two patient groups, they maintained drain clamping in the first group for one hour and then every two hours for 10 minutes in the second group for the first 24 hours. Blood loss in the second group was significantly lower compared to the first group; however, no significant differences in the blood transfusion rates and in the levels of hemoglobin were observed. Tai et al.²⁶ demonstrated that drain clamping for less than four hours did not reduce drainage and did not change the blood transfusion rates. In our study, there was no difference between the levels of hemoglobin, hematocrit and the amount of red blood cells between patients with a drain opening at six and 12 hours, as demonstrated by the absolute delta determined during pre- and postoperative care. However, there was a similar significant decrease in the laboratory variables after treatment in both groups.

Most studies have focused on the amount of blood loss by draining in the postoperative period but have not examined the amount of blood lost after a tourniquet release in the compression dressing or in the blood soaked in the tissues.^{22,27,28} Our study demonstrated that there was a reduction in the levels of hemoglobin, hematocrit and red blood cells in both groups. In the group with the drain opening after six hours, the amount of drained blood was 230.7 mL. In the group with the drain opening after 12 hours, the amount of drained blood was 158.6 mL. In addition, a difference was observed between the two groups that were treated at six and 12 hours, and a similarity between the laboratory levels was most likely due to the blood loss in the tissues and dressings, which could not be measured.

The positive aspect of this study was the presence of a difference in bleeding regarding the aspiration drain between the groups treated at six and 12 hours, although this difference

has not yet been confirmed at the laboratory level due to the blood dissipation in the tissues and dressings in the group treated at 12 hours. A negative aspect of this study was the lack of comparison with clinical results.

Conclusions

Patients undergoing total knee arthroplasty with drain opening at six and 12 hours after surgery did not show a significant difference in laboratory values. However, the volume of blood drained was higher after drain opening at six hours.

Conflicts of Interest

The authors declare no conflicts of interest.

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