



Original Article

Does the suction drain diameter matter? Bleeding analysis after total knee replacement comparing different suction drain gauges[☆]

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ABSTRACT

Objectives: To evaluate bleeding and the estimated blood loss in patients who underwent total knee replacement (TKR) with different closed suction drains (3.2-mm and 4.8-mm gauge).

Methods: This was a randomized controlled trial with 22 patients who underwent TKR and were divided into two groups: Group I, with 11 patients in whom the 3.2-mm suction drain was used, and Group II, with 11 patients in whom the 4.8-mm suction drain was used. The hematocrit was measured after 24, 48 and 72 h after surgery in order to calculate the estimated blood loss. The drained volume was measured 3, 6, 12, 24, and 48 h after TKR, and thereafter both groups were compared.

Results: Regarding the hematocrit, there were no differences between groups in measured periods (24, 48, and 72 h after surgery). The total bleeding measured at the suction drains within 48 h was higher in Group II, with a statistically significant difference ($p = 0.005$); in the first 24 h, there was major bleeding in Group II (mean 893 mL), with a significant difference ($p = 0.004$). Between 24 and 48 h, there was no statistically significant difference in both groups ($p = 0.710$). The total estimated bleeding was higher in Group I, with mean of 463 mL, versus 409 mL in Group II, with no statistical significance ($p = 0.394$).

Conclusions: Bleeding was higher in the group that used the 4.8 mm gauge suction drain, with no differences in hematocrit and estimated blood loss.

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A espessura do dreno suctor importa? Análise do sangramento após artroplastia total do joelho comparando drenos suuctores de diferentes calibers

RESUMO

Palavras-chave:

Perda sanguínea cirúrgica
Artroplastia do joelho
Drenagem

Objetivos: Avaliar o sangramento através do dreno suctor (DS) e a perda sanguínea estimada em pacientes submetidos à artroplastia total do joelho (ATJ) com DS de diferentes calibers (3,2 mm e 4,8 mm).

Métodos: Ensaio clínico randomizado com 22 pacientes submetidos à ATJ, divididos em dois grupos; no grupo I, os pacientes recebiam o DS 3,2 mm e no Grupo II, o DS 4,8 mm. O hematócrito foi aferido 24, 48 e 72 horas após a cirurgia, a fim de calcular a perda sanguínea estimada. O débito do dreno foi medido 3, 6, 12, 24 e 48 horas após a ATJ e os dois grupos foram comparados.

Resultados: Em relação ao hematócrito, não se observaram diferenças estatisticamente significativas entre os grupos nos períodos aferidos (24, 48 e 72 horas pós-operatória). O sangramento total medido no DS nas 48 horas foi maior no grupo II, com diferença estatisticamente significativa ($p = 0,005$); nas primeiras 24 horas, houve maior sangramento no grupo II (média 893 mL), com diferença significativa ($p = 0,004$). Entre 24 e 48 horas, não foram observadas diferenças estatisticamente significativas em ambos os grupos ($p = 0,710$). O sangramento total estimado foi maior no Grupo I, com média de 463 mL, enquanto no Grupo II esse valor foi de 409 mL, sem significância estatística ($p = 0,394$).

Conclusões: O sangramento foi maior no grupo que usou DS 4,8 mm, sem diferenças no hematócrito e na perda sanguínea estimada.

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Introduction

The use of a wooden tube as a drain into a wound is credited to Hippocrates, at around 400 BC.¹

Total knee replacement (TKR) is a standardized surgical procedure with high success rates in the treatment of advanced degenerative osteoarthritis (OA) and rheumatoid arthritis of this joint. Substantial bleeding can occur in the subcutaneous and intra-articular space after TKR; this event can lead to blood transfusions, with their potential complications.² Drainage is commonly used with the theoretical purpose of preventing hematomas, which, in turn, may decrease joint mobility and reduce local tissue perfusion, increasing the possibility of infection. Thus, drains can also be used to lower the risk of infection and prevent healing delay in TKR.³

Primary TKR can lead to a reduction in the erythrocyte levels. Various strategies have been used in order to reduce the need for blood products, such as tourniquet placed at the thigh root, coagulation diathermy, knee position, clamped drains, infiltration with vasoconstrictor solutions, antifibrinolytics (tranexamic acid, Floseal®), and computer-assisted surgeries.⁴

The use of suction drains (SD) in arthroplasties is still controversial. It is believed that the drainage is limited only to a restricted area, failing to prevent infection if retrograde migration of bacteria occurs. Drains can also hamper rehabilitation in the immediate postoperative period. There

is no obvious advantage of using SDs, other than lower need for dressing changes during surgery; moreover, in patients undergoing TKR with SDs, the risk of transfusion is higher.⁵

With the aging population, there has been increasing demand for joint replacements, which are effective methods to improve the quality of life with recovery of movement and improvement in pain, although these surgeries cause large blood loss and lead to dramatic consequences in patients with chronic illnesses; in prosthesis revision surgeries, the losses may be higher. There are formulas to better estimate blood loss; they are applied in studies to compare blood loss between different techniques performed in surgery.⁶

To date, it is known that there is no difference regarding rate of surgical site infection and problems with surgical wound or postoperative rehabilitation, whether or not drains are used; there is a tendency to greater blood loss, hematoma formation, higher rate of use of blood products, and delay in recovery of joint function when they are used.⁷ In most publications that address TKRs with or without the use of SD, the study focus is bleeding and the rate of complications.⁵

The present study aimed to evaluate bleeding through the SD and the estimated blood loss, comparing patients who underwent TKR with SDs of different gauges (3.2 mm and 4.8 mm), as well as to observe the period in which the major bleeding occurs, which is justified by the lack of data in the literature on this particular topic.

Material and methods

This randomized clinical trial with 22 patients undergoing TKR was conducted between April and October 2015.

A protocol was created for the study. Patients who met eligibility criteria for TKR were assigned randomly into two groups (regardless of age, gender, and deformity): Group I used a 3.2-mm diameter Portovac SD, and Group II, a 4.8-mm diameter Portovac SD, installed in the joint space prior to the closure of the capsule.

The study included patients regularly registered in the institution where the study was performed, who met the classical indication for TKR advocated by Camanho et al.⁸: medial or lateral impingement with obliteration of the joint space, varus femorotibial alignment greater than 15°; valgus femorotibial alignment greater than 10°; tibiofemoral subluxation in the frontal plane greater than 10 mm; anteriorization of the tibia relative to the femur in the profile X-ray; severe impairment of two of the three joint compartments of the knee (medial tibiofemoral, lateral tibiofemoral, or patellofemoral), and failed conservative treatment for at least three months when these criteria were not met. Patients with primary degenerative osteoarthritis of the knee. For this assessment, patients with osteoarthritis of the knee ≥ stage III (Ählback modified by Keys) were considered.^{9,10}

Exclusion criteria comprised patients undergoing revision surgery, those in whom the medial joint access was not used, those who were not operated by the senior surgeon, those with rheumatoid arthritis or multiple scars, and those who refused to sign or did not understand the informed consent form. Any patient with decompensated diabetes mellitus (fasting blood glucose >140 mg/dL), uncontrolled hypertension (SBP >200 mmHg), peripheral vascular disease, previous thromboembolism, neoplasia, active infection, rheumatoid arthritis, obese with a body mass index greater than 35 kg/m², or those with a high surgical risk (American Society of Anesthesiologists [ASA] score >III) had their medical condition re-evaluated and surgery was postponed.

Patients who met inclusion criteria for this study (22) were randomized into groups accordingly to the waiting list for the procedure. Upon admission, the first patient was assigned to Group I, second, to Group II and so on; thus, odd-numbered patients were assigned to Group I and even-numbered, to Group II. The researcher had no influence on the decision process of who would be operated; only at the moment of drain insertion was he made aware of which group the patient belonged to.

The night before surgery, hemoglobin and hematocrit (Hb-pre, Ht-pre) levels were measured. These values were considered as controls; patients were weighed in kilograms and their height was measured in centimeters.

Patients underwent spinal anesthesia and received a prophylactic dose of antibiotics – cefazolin 2 g – by the anesthesiologist. A pneumatic tourniquet was applied on the root of the thigh of the limb to be operated, with a pressure of 300 mmHg for all patients. Surgical technique adopted was the standard TKR with joint access via a classic trans-quadriceps approach and patellar eversion. Authors' routine is the use

of intramedullary guides for femoral cuts and extramedullary guides for tibial cuts. The posterior cruciate ligament (PCL) was resected in all procedures. The patella was not resurfaced, and was prepared in all cases as follows: after local denervation and synovectomy, to avoid clunk syndrome, the patella was eburnated and neurotized, and a lateral fasciotomy was performed. The prosthesis used was the AKS Modular Bloqueada® (Baumer, Mogi Mirim, SP, Brazil), a non-PCL-sparing prosthesis. Portovac SDs of 3.2 mm and 4.8 mm were placed in the joint space before capsular closure. In order to standardize the drainage area, all the ends of the drains were cut so that they were 10 cm long in the joint and the lateral recess. The Portovac drain is a post-operative polyethylene closed drainage system, whose resistance is designed for a continuous and mild suction. It has a vacuum pump with a capacity of 500 mL, with an attachment cord, an intermediate section made of polyvinyl chloride (PVC), a clamp, a two- or three-way connector, and a drainage catheter with a surgical-grade stainless steel needle (3.2 mm, 4.8 mm, or 6.4 mm), used to puncture the drain passage site.¹¹ After wound closure, an inguinal-malleolar compressive occlusive Robert Jones dressing was applied. If surgery lasted over 2 h, the tourniquet was deflated and the ischemia was released; subsequently, hemostasis was assessed, inserting drains, sutures, and dressings. All surgeries were always performed by the principal investigator or under his direct assistance. Blood loss was measured through serial Hb and Ht counts at 24, 48, and 72 h (the last measurement was considered as the Hb-post and Ht-post) and through blood volume, serially measured on the SD at 3, 6, 12, 24 and 48 h after the end of the surgical procedure. In this last measurement, the SD was removed and dressing was changed. The surgeon was not involved in the measurement of SD volumes. All patients received thromboprophylaxis with enoxaparin sodium at a dose of 40 mg subcutaneous 6 h after the procedure, administered once a day for 15 days. All patients received prophylaxis for surgical site infection with cefazolin sodium at a dose of 1 g every 8 h for five days.

With the data on weight, height, and Ht-pre, Hb-pre, Ht-post, and Hb-post, blood volume of the patient was calculated according to the formula of Nadler et al.,¹² and blood loss was estimated according to the method proposed by Mercuriali and Inghilleri.¹³ In the present study, the authors chose to use the three-day postoperative hematocrit for calculation of blood loss, instead of the five-day originally described.

$$\text{Blood volume} = \text{Males: } 604 + 0.0003668 \times \text{height (cm}^3\text{)} + 32.2 \times \text{weight (kg).}$$

$$\text{Women: } 183 + 0.000356 \times \text{height (cm}^3\text{)} + 33 \times \text{weight (kg).}$$

$$\text{Estimated blood loss: } = \text{blood volume} \times (\text{Ht-pre} - \text{Ht-post}) + \text{red blood cell volume (CH).}$$

Data were presented in graphs and tables, in which the simple and relative absolute frequencies were calculated for categorical data in the group comparison. In the analysis of quantitative data, mean, standard deviation (SD), and 95% confidence intervals (95% CI) were calculated, as the normality hypothesis was accepted according to the Shapiro-Wilk test, at a significance level of 5% ($p > 0.05$). When comparing means, Student's t-test was used; categorical data were compared using Fisher's exact test. The significance level was set at 5%.¹⁴

Table 1 – Distribution by frequency of gender and age in relation to suction drain group (3.2 mm × 4.8 mm).

| Variables | Drain | | | | Total | <i>p</i> | | |
|-------------|----------------|------|----------------|------|-------|--------------------|--|--|
| | 3.2 (n=11) | | 4.8 (n=11) | | | | | |
| | f _i | % | f _i | % | | | | |
| Gender | | | | | | | | |
| Female | 0 | 81.8 | 8 | 72.7 | 17 | 0.998 ^a | | |
| Male | 2 | 18.2 | 3 | 27.3 | 5 | | | |
| Age (years) | | | | | | | | |
| <60 | 3 | 27.3 | 3 | 27.3 | 6 | 0.283 ^b | | |
| 60-70 | 5 | 45.4 | 7 | 63.6 | 12 | | | |
| ≥60 | 3 | 27.3 | 1 | 9.1 | 4 | | | |
| Mean ± SD | 65.8 ± 6.6 | | 62.8 ± 6.1 | | | | | |
| Min.-Max. | 56-78 | | 54-74 | | | | | |

f_i, simple absolute frequency; SD, standard deviation.

^a Fisher's exact test.

^b Student's t-test was used to compare the means.

The Epi-Info software version 7.1.5 for Windows, which is developed and freely distributed by the Centers for Disease Control and Prevention (www.cdc.gov/epiinfo/7), was used for statistical analysis.¹⁵

All patients read and signed an informed consent form; the study was submitted to the Research Ethics Committee (REC) of the institution, with Certificate of Presentation for Ethical Assessment (CAAE) No. 43085615.8.0000.0007, and received REC opinion No. 1019123.

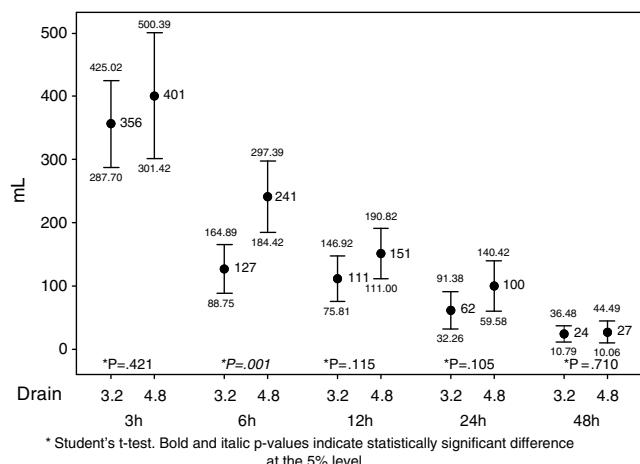
Results

Group I consisted of 11 patients, nine females and two males, aged 56-78 years, with a mean of 65.8 years and SD ± 6.6 years. Group II consisted of eight female patients and three males, with a mean age of 62.8 years (54-74, SD ± 6.1 years). Epidemiological data are summarized in Table 1.

In the observation of the SD bleeding curve at 3, 6, 12, 24, and 48 h (Fig. 1), a decrease was observed from 3 h onwards; no statistically significant differences were observed for both groups, except for the interval between 3 and 6 h, with increased bleeding in Group II (*p* = 0.001).

Regarding hematocrit, according to Fig. 2, no statistically significant differences were observed between the groups in the measured periods (24, 48, and 72 h postoperative), and the downward curve remained stable from 24 h onwards, with a constant pattern.

The total bleeding measured in the SD within 48 h (Fig. 3) was higher in Group II (mean 920 mL) than in Group I (680 mL), with statistically significant difference (*p* = 0.005); when such bleeding was stratified into 24 and 48 h, it was observed that within the first 24 h (Fig. 4), there was a higher bleeding in Group II (mean 893 mL), with statistically significant differences (*p* = 0.004). Between 24 and 48 h (Fig. 5), no statistically significant differences were observed in both groups (Group I: 24 mL × Group II: 27 mL), *p* = 0.710.



* Student's t-test. Bold and italic p-values indicate statistically significant difference at the 5% level.

Fig. 1 – Distribution, according to the mean and 95% CI, of bleeding at 3, 6, 12, 24, and 48 h, in relation to SD thickness. CI, confidence interval; SD, suction drain.

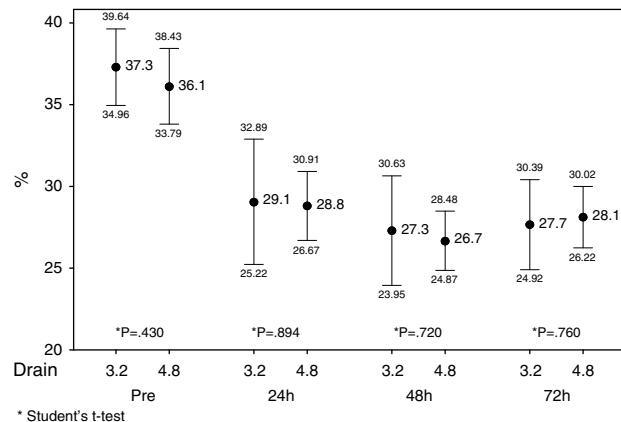


Fig. 2 – Distribution, according to the mean and 95% CI, of preoperative hematocrit at 24, 48, and 72 h postoperatively in relation to SD. CI, confidence interval; SD, suction drain.

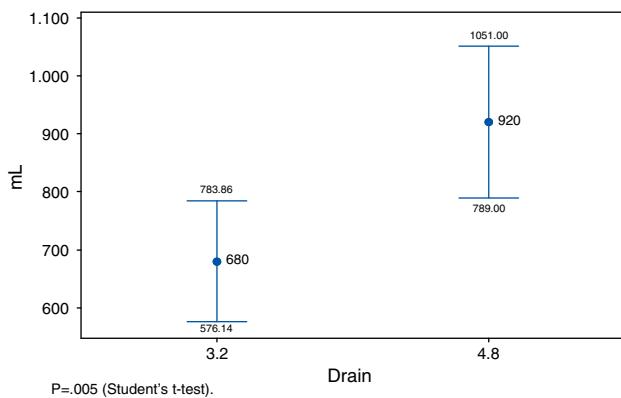


Fig. 3 – Distribution, according to the mean and 95% CI, of the total blood loss in relation to SD thickness in patients who underwent total knee replacement.
CI, confidence interval; SD, suction drain.

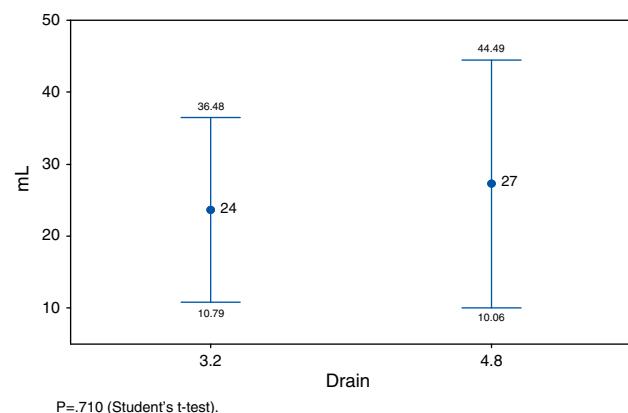


Fig. 5 – Distribution, according to the mean and 95% CI, of bleeding in between 24 and 48 h in relation to SD thickness.
CI, confidence interval; SD, suction drain.

Estimated blood loss by the formula proposed by Mercuriali and Inghilleri¹⁴ (Fig. 6) was higher in Group I, with a mean of 463 mL versus Group II, 409 mL, with no statistical significance, $p = 0.394$. The use of blood products was similar in both groups – two units of red blood cells with 300 mL each unit. In the study period, there was only one case of complication in Group II: blister formation in the wound of a patient who required two concentrated units of red blood cells.

Student's t-test was used to assess whether there was a correlation between bleeding and height, and between weight and bleeding. No correlations were observed between these variables (Tables 2 and 3), in which the values of the coefficient closest to 1 and -1 indicate a strong evidence of correlation.

Discussion

Although there is no established evidence to confirm the use of drains in TKR, it is postulated that it can reduce hematoma formation and the incidence of deep infection. Esler et al.¹⁶ suggest that these perceptions are incorrect, as

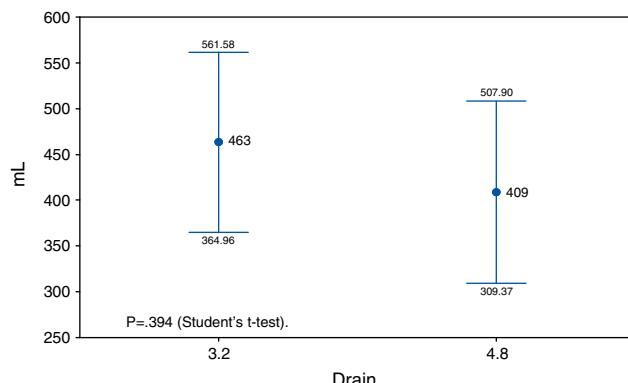


Fig. 6 – Distribution, according to the mean and 95% CI, of the estimated blood loss (Mercuriali and Inghilleri¹³) in relation to SD gauge in patients who underwent total knee replacement.

CI, confidence interval; SD, suction drain.

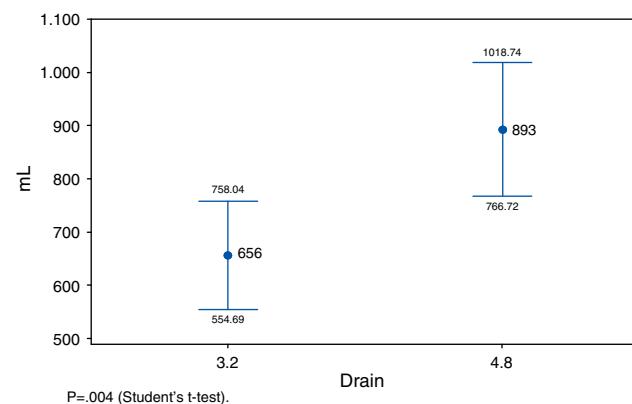


Fig. 4 – Distribution, according to the mean and 95% CI, of bleeding in the first 24 h in relation to SD thickness.
CI, confidence interval; SD, suction drain.

Table 2 – Correlation of bleeding time and height of patients who underwent total knee replacement.

| Bleeding | Height | |
|----------------|--------|----------------|
| | r | p ^a |
| 3 hours | 0.12 | 0.594 |
| 6 hours | 0.5 | 0.815 |
| 12 hours | -0.10 | 0.658 |
| 24 hours | 0.2 | 0.935 |
| Up to 24 hours | 0.7 | 0.744 |
| 48 hours | 0.1 | 0.955 |
| Blood loss | 0.7 | 0.746 |

^a r, correlation coefficient.

^a t-Test for correlation.

their study failed to demonstrate a statistically significant benefit with the use of intra-articular drain on cemented TKR. The use of SDs may even be harmful. Surgeons are used to place drains and the fear of morbidity of deep infection is

Table 3 – Correlation of bleeding time and weight (in kg) of patients who underwent total knee replacement.

| Bleeding | Weight | |
|----------------|--------|----------------|
| | r | p ^a |
| 3 hours | 0.3 | 0.886 |
| 6 hours | 0.39 | 0.72 |
| 12 hours | -0.1 | 0.977 |
| 24 hours | -0.12 | 0.568 |
| Up to 24 hours | 0.16 | 0.486 |
| 48 hours | 0.23 | 0.295 |
| Blood loss | 0.18 | 0.430 |

r, correlation coefficient.
a t-Test for correlation.

understandable; therefore, there is resistance to changing this practice.

Parker et al.¹⁷ found that the only definite advantage of using drains, demonstrated in a meta-analysis, was to reduce the bleeding through the wound, as shown by the smaller number of dressings in the group in which drains were used. Furthermore, the use of drains reduced local lesions at the surgical site.

The number of blood transfusions in this study was similar in both groups (two concentrated units of red blood cells in each). In studies until 2004, the authors reported that closed suction drainage increased transfusion requirements after elective hip and knee arthroplasties, and greater benefits were not observed.¹⁷

Only SDs were used in the joint cavity. The data in the study by Seo et al.² suggest that subcutaneous drainage is similar to that used for closed suction intra-articular drainage, with equivalent blood loss and without adverse effects on functional results; therefore, the use of SD in the subcutaneous is a reasonable option against intra-articular.

Higher bleeding was observed in both groups within the first 6 h, with a higher value in the group of patients with the 4.8-mm drain, but without a statistically significant difference ($p=0.421$). Goes et al.¹⁸ compared the laboratory results of opening the drain at six and 12 h after TKR, and did not observe statistically significant differences in laboratory values. However, the volume of drained blood was higher when the drain was opened after 6 h. Those authors only used 4.8-mm drains. Roy et al.¹⁹ conducted a study with immediate drain opening 1 h after the end of surgery; they observed blood loss and increased need for blood products in the group where the drain was opened immediately. These authors did not mention the thickness of the drain; they stated that two access routes were placed in the joint space and were removed after 48 h.

It was observed that the bleeding after 24 h becomes insignificant; in 1991, Willemen et al.²⁰ concluded that the clinical evaluations of surgical wound healing were similar for all groups (drain removed after 24 and 48 h) and clearly showed no advantage in continuing use of the drain after 24 h; if drainage is maintained for a longer period, there is an increased risk of bacterial contamination. 85% of the total

volume was drained during the first 24 h; in the following 24 h, an average of only 50 mL of blood was drained, but the authors did not mention the gauge of the drains. Drinkwater and Neil²¹ recommend that drains in hip or knee replacements should also be removed after 24 h.

Beer et al.,³ in their classical publication from 1991, went further, demonstrating that there is no difference regarding the incidence of edema or persistent draining through the wound. The return to active quadriceps function and knee range of motion in patients who underwent TKR was also not affected by the use of SDs. They concluded that the routine use of drains in uncomplicated surgery is unnecessary. Similarly, Zhang et al.,²² in a meta-analysis published in 2014, concluded that, for primary surgery without major complications, it is preferable to not use SDs; the surgeon should assess the benefits and drawbacks. In the present study, there was only one complication (blisters) in the 4.8-mm SD group.

Andrade et al.,²³ in a Brazilian publication that compared the use or non-use of 3.2-mm SDs, came to the conclusion that, beyond six months post-operative, there is no benefit in the use of closed SD in TKR. However, range of motion at the end of the first month was better in the group that used SD.

In the present study, bleeding was higher within the first 6 h after surgery for both groups, as the drains remained open. Yildiz et al.²⁴ took into account the clamping of the drain for 6 h after TKR and observed that, in the group in which the tourniquet was released after the sutures and bandages were applied and the drain was closed for 6 h, there was less blood loss. Souza Leão et al.²⁵ did not take into account clamping of the SD in TKR, and compared blood loss with early or late release of the tourniquet; they found no statistically significant differences in bleeding, but there was no mention of the diameter of the drains. Hemoglobin and hematocrit levels also were similar for both groups.

In a recent meta-analysis, Li et al.²⁶ concluded that, through the current evidence, the use or non-use of SDs has similar utility and clinical significance in primary TKR. However, due to some limitations (few patients involved in each study and only three randomized controlled trials), their findings should be interpreted with caution. Therefore, future studies of high methodological quality and long-term follow-up are necessary to update the meta-analysis, in order to better assess the importance and effectiveness of the use of drains.

It is well established that the total number of hip replacements, and especially TKRs, will increase over the next 25 years.²⁷ These operations are known to have a high volume of blood loss; however, it is difficult to compare the amount of these losses given the fact that many different formulas are used to calculate losses. A precise method for calculating estimated blood loss in joint replacements is essential for a better assessment of the perioperative losses estimates. With this in mind, in 1996 Mercuriali and Inghilleri¹³ developed an algorithm to calculate probable losses and the need for blood transfusions. This formula is based on preoperative hematocrit (Ht-pre) and hematocrit on the fifth postoperative

day (Ht-post). The hematocrit should be written in decimal units. This formula requires the patient's blood volume to be calculated by the formula postulated by Nadler et al.¹³ (in milliliters of blood) and also requires the volume of blood (red blood cells) transfused. The estimate obtained by the Mercuriali formula is given in milliliters of red blood cells.

The limiting factors of the present study include the small follow-up time (only during admission), in which no differences were observed in joint function and the rate of infection; other complications were not the object of this study, which probably would show further advantages of one method over the other and could abound for further research. Pain was also not quantified. A sample with a larger number of patients would provide more robustness to the statistical analysis. As patients were on the first three days of intravenous hydration and blood count also depends on the hydration status, perhaps numbers were higher than the noted, proving the low use of blood products; however, a theoretical framework that takes into account the hydration of patients was not retrieved. A group without SD – control – would be ideal to compare the blood count and the estimated blood loss, and hence justify the use or non-use of SD.

Conclusions

The present data allows for the conclusion that patients undergoing TKR have higher bleeding when they have a 4.8-mm SD inserted. Estimated blood loss is similar, regardless of the thickness of the drains used. Bleeding is higher in the first 24 h after surgery, especially in the first 6 h; during the last 24 h, bleeding is negligible, and therefore the use of the drain is unnecessary. Reduction in hematocrit was similar for both groups and was more pronounced on the first day, remaining stable thereafter. Bleeding through SD in TKR is a reality that cannot be underestimated; the surgeon should be aware of possible complications of this event and promptly resolve it. Rational use of the drain and choice of its gauge are at the surgeon's discretion, bearing in mind that thicker drains can cause increased bleeding.

Conflicts of interest

The authors declare no conflicts of interest.

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