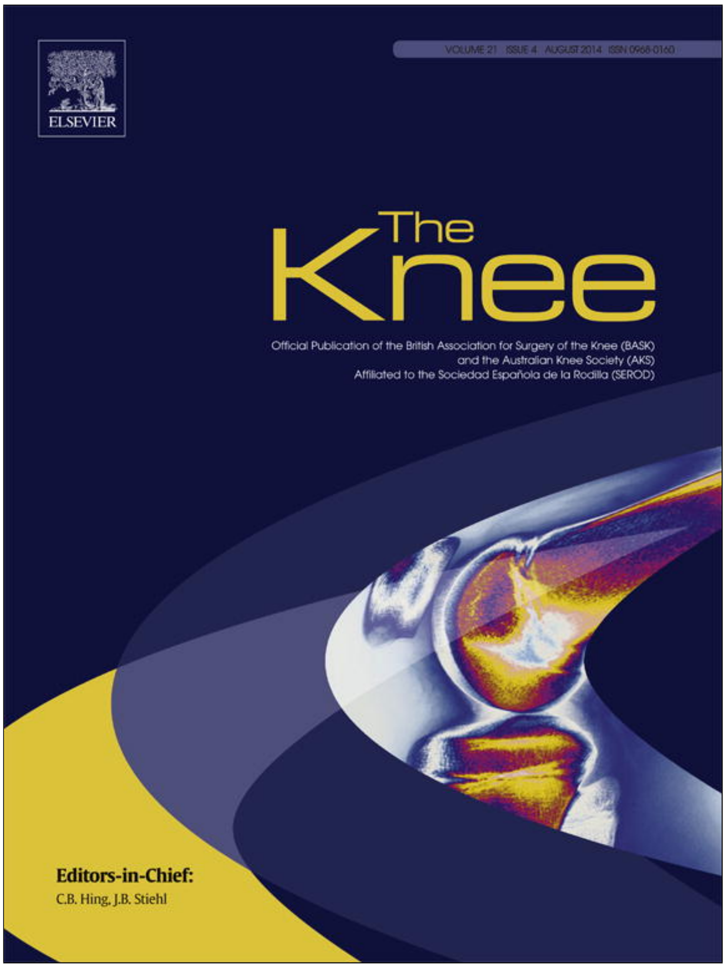
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Sealing of the intramedullar femoral canal in a TKA does not reduce postoperative blood loss: A randomized prospective study

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ABSTRACT

Background: Sealing of the femoral canal, usually with autologous bone, is a surgical procedure that is often performed during TKA surgery to decrease blood loss in the postoperative period. However, evidence as to the effectiveness of this surgical procedure is not conclusive. The objective of this study was to assess the effectiveness of this surgical action in reducing postoperative blood loss and the blood transfusion rate.
Methods: A randomized prospective study that included 201 TKAs divided into three groups (67 in each one) was carried out. The three groups were; A) bone graft sealing, B) cement sealing and C) unsealed canal. All groups were comparable with regard to pre and intra-operative data. The haemoglobin decrease at 2, 24 and 72 h was compared to the preoperative haemoglobin value. Subsequently, blood drainage at 12 and 24 h and the rate of blood transfusion were also assessed. The different complications that arose were reported.
Results: No statistical differences were obtained with regard to blood drainage at 12 h ($p = 0.102$) and 24 h ($p = 0.542$), the haemoglobin value decrease at 72 h ($p = 0.95$) and the number of blood transfusions ($p = 0.597$) in the three groups studied.
Conclusion: There was no significant difference, whether sealing the femoral canal with a bone graft, cement or when it was left unsealed, in decreasing blood loss or blood transfusion requirements in the postoperative period.
Level of evidence: Therapeutic type I.

1. Introduction

Blood loss is a significant problem after Total Knee Arthroplasty (TKA), with estimates of up to 1500 ml of total blood loss [1]. A blood transfusion may be considered necessary in some patients to avoid symptomatic anaemia and subsequent delays in postoperative rehabilitation. A series with a blood transfusion rate of up to 39% [2] in these surgeries has been reported. Studies published over recent years have shown a decrease in the rate of blood transfusion by using different methods for blood saving such as tranexamic acid, computer assisted surgery or minimally invasive surgery [3–9]. However, none of these studies have focused on a common surgical gesture such as sealing the femoral hole produced to accommodate the intramedullar femoral guide.

Over recent decades, most surgeons use an intramedullar alignment system for the placement of the femoral component of a TKA because it demonstrates greater reliability than extramedullar guides [10]. This system requires an intramedullary rod that damages cancellous bone and the intramedullary vasculature and so contributes to higher postoperative blood loss [11]. For this reason, many surgeons who routinely use this system usually seal this hole, mainly with autologous bone obtained from the bone off-cuts, with the aim of decreasing blood loss. Based on the literature, conflicting results have been observed in different studies performed with regard to this surgical action. Most of these studies were performed many years ago with high rates of transfusion that would not be acceptable now. While Ko et al. [12] concluded that sealing the femoral canal was effective in reducing haemoglobin decrease and blood transfusion in TKA but not in reducing blood drainage, Kumar et al. [13] observed a reduction in the postoperative drainage but not in the haemoglobin decrease in those patients in which the femoral canal was sealed with a bone plug.

It was initially hypothesized that autologous bone or cement sealing of the femoral canal performed during the femoral component placement is not related to blood loss in the immediate postoperative period. The aim of this study was to assess the effectiveness of sealing the femoral hole, after TKA, with cement or autologous bone in reducing the haemoglobin decrease in the immediate postoperative period. The effectiveness of this surgical gesture in reducing the blood drainage and the rate of blood transfusion was also looked at.

2. Material and methods

This study included patients diagnosed with degenerative arthritis of the knee. Patients with other diagnoses and patients with previous

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surgery on the knee, except for arthroscopy, were excluded (Fig. 1). Those patients with a varus or valgus deformity greater than 20° or a flexion deformity greater than 10° were also excluded because blood loss might be influenced by the extensive soft tissue releases performed to balance the leg alignment. Initially, 240 TKA cases were assessed for eligibility but 39 of them were excluded for one of the reasons previously described (24 with a varus or valgus mechanical axis deformity greater than 20° or flexus deformity greater than 10°, eight patients in which the diagnosis was not degenerative arthritis of the knee and seven patients had had a previous osteotomy on the knee). A total of 201 patients (56 males and 145 females) with a mean age of 72.12 (SD 8.1) years were finally inducted into the study. The clinical research ethics committee of our institution approved the study. All the patients signed informed consent to participate in the study as well as for the evaluation and publication of their results. No inter-group differences were observed in terms of demographic variables as well as for the use of antiplatelet or anticoagulation drugs previous to the surgery. These drugs were stopped following the anaesthetist protocol of our institution. Neither did preoperative haemoglobin and platelet values show differences in the three groups (Table 1).

Patients were operated on by the same surgical team made up of six surgeons in the same surgical theatre from September 2011 to February 2012. The surgical protocol performed was the same for the three groups. All patients received prophylactic antibiotics (cephazoline 2 gram intravenous or vancomycin 1 gram intravenous, in penicillin allergic patients). All patients received intradural anaesthesia and were operated on under tourniquet at a pressure of 350 mm Hg with previous exsanguination. A midline skin incision and a medial parapatellar capsulotomy were made. The patella was replaced in every case. The surgical procedure was performed following the same order: a tibial cut with an extramedullar guide, a femoral cut with an intramedullar guide, soft tissue balancing, a patellar cut and placement of the definitive cemented prosthetic components. Before this last step, randomization was performed with a computer-generated random list setting 67 patients in each group; A) the femoral hole was sealed with a 2 cm autologous bone plug obtained from the bone off-cuts, B) the femoral hole was sealed with a cement plug to 2 cm of depth (the cement was inserted in a soft state) and, C) the femoral hole was left unsealed. Patients were blinded to the type of sealing used during the process. Surgeons were blinded until the randomisation previous to setting the definitive

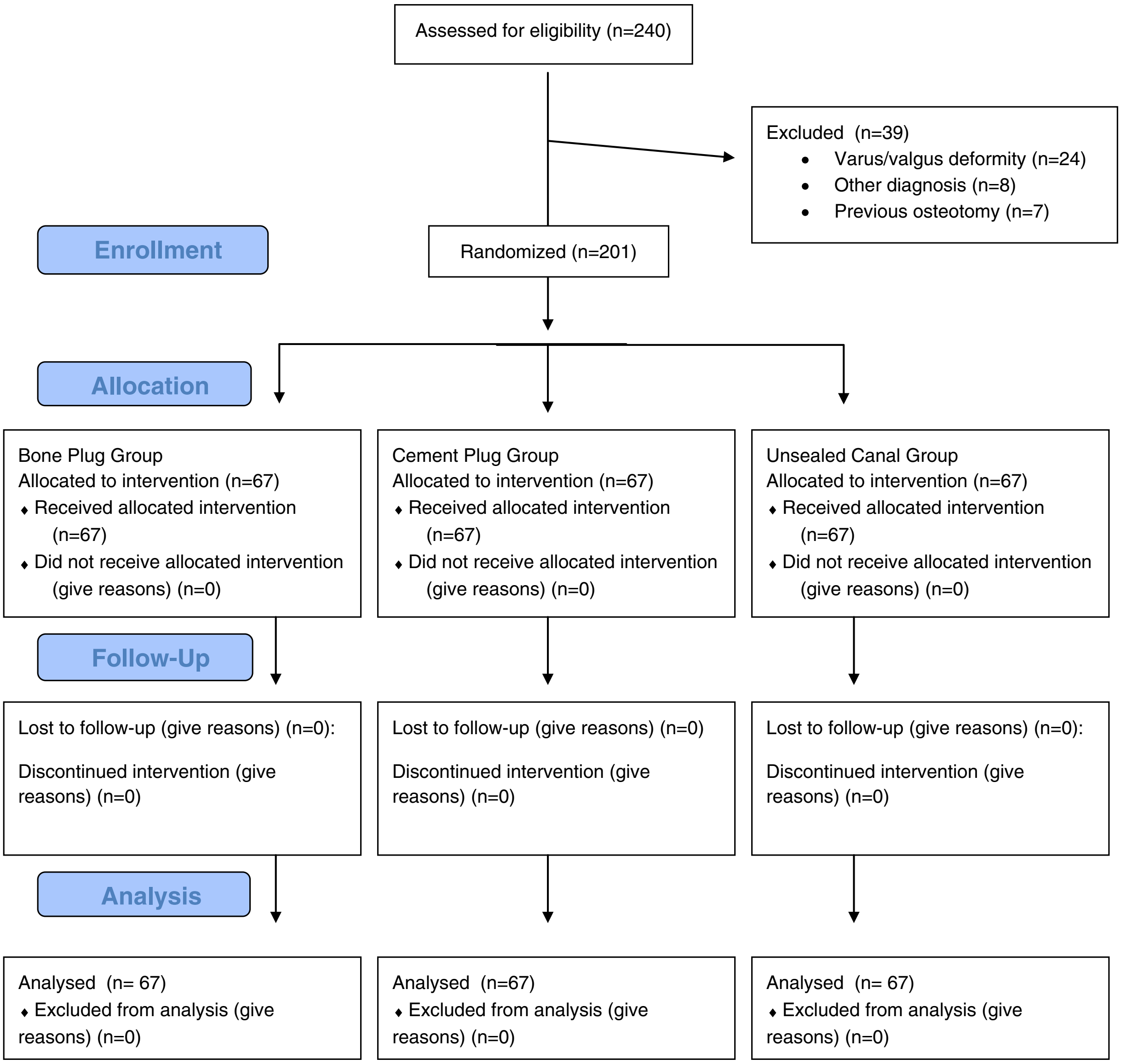

Fig. 1. Flow diagram.

Table 1
Preoperative variables distribution in groups.

	Group A	Group B	Group C	p value
Women	49 (73.1%)	49 (73.1%)	47 (70.1%)	0.941
Age (y/o ± SD)	72.42 ± 8.56	72.10 ± 7.96	71.84 ± 7.86	0.918
Weight (kg ± SD)	78.40 ± 14.41	77.61 ± 13.37	76.90 ± 12.27	0.809
Height (m ± SD)	1.57 ± 0.076	1.56 ± 0.075	1.57 ± 0.079	0.599
BMI (m^2/kg ± SD)	31.80 ± 4.84	31.65 ± 4.71	30.98 ± 4.64	0.566
Preop Hb (gr/dl ± SD)	13.68 ± 1.10	13.58 ± 1.12	13.83 ± 1.30	0.458
Acenocumarol (patients)	3 (4.5%)	2 (3%)	1 (1.5%)	0.873
Antiplatelet drugs (patients)	12 (17.9%)	11 (16.4%)	12 (17.9%)	0.508
Preoperative platelets (mill ± SD)	251.78 ± 60.45	249.97 ± 64.65	239.30 ± 59.47	0.449

Group A: autologous bone sealing; Group B: cement sealing; Group C: unplugged canal.
BMI: Body Mass Index, Hb: Haemoglobin value.

prosthetic components. Non-antibiotic-loaded cement (Simplex P. Stryker, Limerick, Ireland) and pulsatile normal saline irrigation were used in all cases. The prosthesis models used were: Triathlon® (Stryker, Kalamazoo, MI, USA), Genutech® (Surgival, Valencia, Spain) or NexGen® (Zimmer, Warsaw IN, USA). The decision to use a postero-stabilizing (PS) or cruciate-retaining (CR) model of all arthroplasties depended on the surgeon's criteria. Intra-articular drainage with continuous suction by gravity was emplaced (Bellovac-ABT, Astra-Tech AB) in all cases. The wound was closed in layers and it was covered with sterile gauze, three layers of Velband and a crepe bandage. After this, the tourniquet was released. Afterwards, the knee was placed in a fixed full extension brace for 24 h.

All patients received 24 h postoperative antibiotic prophylaxis (cephazoline 1 grams/8 hours intravenous or vancomycin 1 grams/12 hours intravenous, in penicillin allergic patients). An intravenous analgesic protocol was set up during the first 48 h that consisted of paracetamol 1 grams/6 hours intravenous and dexketoprofen 50 milligrams/12 hours intravenous. Subsequently, an oral protocol was scheduled consisting of paracetamol 1 grams/6 hours and ibuprofen 600 milligrams/6 hours. In both cases, 1 milligram/kilogram/hour of morphine subcutaneously administered and divided into four doses was scheduled as rescue analgesia. Antithrombotic prophylaxis (bemiparin 3500 IU/24 h) was initiated 8 h after the surgery and maintained for 4 weeks, as the suggested protocol by the Spanish Society of Orthopaedic Surgery. The rehabilitation protocol was initiated at 24 h after surgery with passive movements of the knee using a continuous passive motion machine (Kinetec® Spectra Knee CPM), which progressively increased the flexion for the first week to achieve the maximum possible range of motion (ROM). Weight bearing was allowed the second day after the surgery.

The main variable in the study was the haemoglobin level decrease in the postoperative period. In all patients, the first haemoglobin control was performed at 2 h of the surgery in the recovery room. The second and third haemoglobin controls were performed at 24 and 72 h after the surgery. The nursing staff registered the postoperative drainage at 12 and 24 h after the surgery in the calibrated bottle. After the last measurement, the drainage was removed from all patients. The anaesthesiologist and the nursing staff were not involved in the study and did not know the group that each patient belonged to. Neither were the patients informed of their group assignment. Blood transfusion requirements were also recorded from the patients' medical records.

The allogenic transfusion criteria in our department are the following; haemoglobin < 8 g/dl or when dyspnoea, palpitation, dizziness, or abnormal vital signs were noted even if the haemoglobin was 8–10 g/dl. So the decision to authorize a blood transfusion was based on the physician's criteria. Blood reinfusion was performed when at least 400 ml of blood had accumulated during the immediate postoperative period (6 h). The salvaged blood was reinfused within this period, and no anticoagulants were administered during salvage or reinfusion.

Follow-ups were scheduled for all patients at 1, 3 and 6 months after the surgery. Different complications arose (superficial or deep infection, joint stiffness or periprosthetic fractures) that were checked and closely followed.

3. Statistics

A power analysis showed that a difference in the haemoglobin value of 0.6 gr/dl would be detected with 80% power ($\alpha = 0.05$) in 67 patients in each group.

The quantitative variables were described with mean and standard deviation and categorical variables with frequencies and percentages. Differences between the variables of the three groups were analysed using the non-parametric Chi-Square or Fisher Exact test for categorical variables and the Kruskal–Wallis test for quantitative data. The parametric ANOVA test was used to determine differences between quantitative data. In all cases, p values < 0.05 were considered as statistically significant.

The SPSS vs. 18.0 (SPSS Inc., Chicago, Illinois, USA) statistical package was used for the statistical analysis.

4. Results

No inter-group differences were observed when intraoperative variables were assessed; the type of prosthesis, surgeon, prosthetic model and time under tourniquet (Table 2). Those patients with anti-platelet or acenocumarol treatment in the preoperative period showed no inter-group differences when the variables studied were independently assessed.

The lower haemoglobin values were obtained at the blood analysis performed at the 72 h after the surgery. All these values and those obtained at 2 and 24 h after the surgery are shown in Table 3. In this table, the differences between the preoperative values and the different postoperative haemoglobin values are also shown.

Amounts of blood loss obtained in the drainage bottle at 12 and 24 h are shown in Table 4.

Table 2
Intraoperative variable distribution in groups.

	Group A	Group B	Group C	p value
Type of prosthesis (PS/CR)	66/1	61/6	65/2	0.153
Prosthetic model (Triathlon/Genutech/LPS)	28/20/19	27/17/23	19/27/21	0.310
Surgeon (1,2,3,4,5,6)	11/16/21/4/7/8	10/15/10/17/6/9	18/14/8/8/8/11	0.809
Time under tourniquet (Min ± SD)	70.58 ± 11	69.94 ± 11.8	71.54 ± 11.9	0.417

Group A: autologous bone sealing; Group B: cement sealing; Group C: unplugged canal.

Table 3
Mean haemoglobin values in the different blood tests performed and differences between the preoperative haemoglobin value and the different postoperative values (g/dl ± SD).

	Group A	Group B	Group C	p value
Preoperative Hb	13.68 ± 1.10	13.58 ± 1.12	13.83 ± 1.30	0.458
2 h postoperative Hb	11.89 ± 1.16	11.96 ± 1.38	12.16 ± 1.21	0.431
24 h postoperative Hb	10.65 ± 1.08	10.60 ± 1.54	10.81 ± 1.12	0.601
72 h postoperative Hb	9.96 ± 1.25	9.89 ± 1.30	9.97 ± 1.27	0.950
Difference Pre-2 h	1.78 ± 0.85	1.61 ± 1.02	1.67 ± 1.01	0.612
Difference Pre-24 h	3.02 ± 0.85	2.98 ± 1.16	3.02 ± 1.09	0.961
Difference Pre-72 h	3.71 ± 1.14	3.69 ± 1.23	3.92 ± 1.22	0.470

Group A: autologous bone sealing; Group B: cement sealing; Group C: unplugged canal.
Hb: Haemoglobin value.

No patients received a blood transfusion during the surgery and 36 patients received at least one blood transfusion (including blood reinfusion) during the postoperative period (17.9%); 24 (11.9%) salvage blood reinfusion and 12 (6%) allogenic blood transfusion. In Table 5, the different blood transfusions required divided into the three groups studied are shown.

All patients had the final follow-up at 6 months. Different complications arose within this period; a femoral periprosthetic fracture (Lewis–Rorabeck type 2) [14] in a patient in group C, three superficial wound infections (Tsukayama type IIA) (one in each group), a deep joint infection (Tsukayama type IIB) [15] (group C) and two cases of TKA stiffness defined as flexion lesser than 90° 4 weeks after surgery (one in group A and another in group B). No inter-group differences were obtained with regard to these complications. The fracture occurred 10 days after the surgery due to a fall while doing rehabilitation. It was treated with a T2® retrograde nail (Stryker Instruments, Kalamazoo, Michigan, USA) with good functional and radiological outcomes at 6 months of follow-up. The superficial wound infections were identified in the first postoperative days and were treated with success with antibiotic therapy according to the culture results. The deep infection was diagnosed on the third postoperative month and was treated with a two-stage TKA replacement. TKA stiffness was treated with an intensive rehabilitation protocol.

5. Discussion

The main finding of this study was that the haemoglobin decrease following a TKA is not directly related to the sealing of the femoral canal. Our second finding is that neither blood drainage nor the rate of blood transfusion after a TKA is determined by this surgical gesture. In that sense, our hypothesis has been confirmed.

Although the TKA is performed under tourniquet by most of surgeon, the total blood loss after this procedure is quite similar to blood loss following a total hip arthroplasty (around 1500 ml) [16]. In fact, just 50% of this blood loss is obtained from the surgical field and wound drainage and the other 50% is considered as hidden loss, including haemolysis and dilution into the soft tissues [1–16]. Different methods, such as cryotherapy and drainage clamping [17,18], are used trying to diminish the amount of blood loss with no clear evidence of their effectiveness. Even the use of drains to reduce joint effusion is doubtful, although it seems to reduce haematoma formation and has no effect on wound healing [19]. In the series presented, drainage was maintained for 24 h. Ares-Rodríguez et al. performed a study defining the hourly risk of bleeding in the first 24 h following TKA and concluded that the drainage can be removed within the first 18 h with a low risk of persistent bleeding [20]. The results obtained in the series with regard to the amount of blood loss obtained from drainage in the three groups showed no statistical differences at 12 h and 24 h after the surgery. The results obtained by Ko et al. also showed similar blood drainage in both the plugged and unplugged groups at 24 and 48 h [12]. Opposite to these results, Kumar et al. obtained small differences in the reduction of blood drainage when comparing bone sealing or not sealing the femoral hole of 797 ml vs 958 ml at 24 h ($p = 0.008$) and 927 ml vs 1165 ml at 48 h ($p = 0.005$) [13], respectively. It confirms the results obtained by Raut et al. [21]. The amount of blood drained obtained in all these studies was quite superior to those obtained in our series thus making them difficult to compare. Furthermore, the possibility of sealing the femoral canal with a cement plug was not considered in the aforementioned studies.

Table 4
Mean blood loss in the drain bottles (ml ± SD).

	Group A	Group B	Group C	p value
Drainage at 12 h	147.69 ± 111.87	119.48 ± 115.50	164.70 ± 158.90	0.102
Drainage at 24 h	281.42 ± 194.09	247.01 ± 177.91	266.12 ± 208.24	0.542

Group A: autologous bone sealing; Group B: cement sealing; Group C: unplugged canal.

Table 5
Distribution of blood transfusion (number of patients).

	Group A	Group B	Group C	p value
Allogenic blood transfusion	3	3	6	0.603
Salvage blood reinfusion	7	8	9	0.962
Total	10	11	15	0.597

Group A: autologous bone sealing; Group B: cement sealing; Group C: unplugged canal.

Currently, the rate of allogenic transfusion after a TKA has been reduced from up to 30% to around 10% [2,12,22,23]. In this study, the total rate of allogenic transfusion was shown to be 6% with no differences in the three groups studied. The use of pre-donated autologous blood and salvage blood reinfusion to provide replacement of blood loss has been proven effective after a TKA [24–27]. The rate of blood transfusion (allogenic and salvage blood reinfusion) is 17.9%, with no differences with regard to the need for one of these transfusions or both in the three groups under study here. Ko et al. [12] showed an important decrease in allogenic transfusion requirements in those patients in which the femoral canal was sealed with a bone graft (64.4% vs 35.9%). In that study, the haemoglobin decrease in the sealed group was 2.3 ± 1.0 gram/decilitre and in the unsealed group was 3.5 ± 1.3 gram/decilitre ($p < 0.05$). Opposite to these results, Kumar et al. [13] showed no differences with regard to the rate of blood transfusion in both groups. Anyway, results obtained in these series are hardly comparable to the results presented in this series due to the blood saving methods developed over recent years that have significantly contributed to lowering the rate of blood transfusion after a TKA. The results obtained in this series showed a similar haemoglobin decrease, with no statistical differences, in the three groups studied at 2, 24 and 72 h after surgery. Furthermore, there were similar transfusion requirements in the three groups under study.

The most important complications observed in this series were a femoral periprosthetic fracture in a patient that had been included in the cement sealed group and a deep joint infection in the unsealed group. The fracture was treated with a retrograde intramedullar nail. This treatment was decided on instead of lateral plating due to the minimal approach needed and the type of fracture [28]. The main problem associated with this treatment was the cement plug blocking the entry point of the nail in the intercondylar region. It was necessary to gently remove the cement plug and then place the nail. This is a rare but not uncommon complication and the use of cement plug in this patient made the use of this surgical treatment more difficult. With regard to the deep infection, due to the time elapsed from the surgery, it was considered a chronic infection and it was treated with a two-stage TKA exchange.

The main limitations of this study were the inability to assess hidden blood loss and measure wound drainage. As those limitations were present in the three groups studied and those groups were comparable with regard to the preoperative and intraoperative data, we consider that those limitations do not diminish the significance of the results obtained. Another limitation was the impossibility of blinding the surgeon to the group to which each patient belonged. The fact that different prosthetic models were used for this study might also be considered a limitation although there were no statistical differences relative to the variables studied when the three groups were compared to each other.

In conclusion, in the series presented, the use of cement or an autologous bone plug to seal the intramedullar canal performed to place the femoral component of a TKA does not decrease blood loss in the postoperative period and does not affect blood transfusion requirements.

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