COMPARISON OF FLOSEAL® AND ELECTROCAUTERY IN HEMOSTASIS AFTER TOTAL KNEE ARTHROPLASTY

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ABSTRACT

Objective: To evaluate whether hemostasis with eletrocauterization in comparison with Floseal® leads to different bleeding rates during total knee arthroplasty. Methods: A comparative study was performed between two groups: group with ten consecutive total knee arthroplasties with Floseal® used as hemostatic method and control group with ten consecutive total knee arthroplasties with eletrocauterization as hemostatic method. Bleeding parameters such as debit of the drain, liquid infusion and blood transfusion rate were recorded. Results: Floseal® group received less blood transfusion, less liquid infusion and lower drainage in absolute numbers compared to the control group. However, no parameter was statistically significant. Conclusion: Hemostasis with Floseal® is as effective as hemostasis with eletrocauterization, what makes it a viable alternative to patients with contraindication to electric scalpel use. ***Level of Evidence II, Prospective Comparative Study.***

Keywords: Arthroplasty. Knee. Hemorrhage.

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INTRODUCTION

Total arthroplasty is a procedure with excellent results in the treatment of degenerative diseases of the knee. However, it is not a procedure without complications.[1] Complications depend on factors related to the patient, the environment and the surgical technique.[2]

A possible complication of total knee arthroplasty is excessive blood loss, which can cause both systemic complications and problems related to concentrated transfusions of red blood cells.[3-5] A number of alternatives have been studied to minimize bleeding during and after surgery and its complications, including: infusion of tranexamic acid intravenously, local use of adrenaline, use of navigation system for bone cutting and even draw blood from the patient to perform auto-transfusion after the surgery.[6-9] Another alternative to minimize bleeding is the use of the hemostatic agent Floseal®, composed of thrombin and bovine gelatin.[10] This compound has already made significant benefits to control bleeding in several medical applications,[11-14] including orthopedic surgery,[5-17] but has not proven to be particularly efficient in total knee arthroplasty.[18] The primary objective of this work is to assess whether hemostasis with electrocautery compared to Floseal® during primary total knee arthroplasty leads to different rates of perioperative bleeding.

MATERIALS AND METHODS

We conducted a comparative study between two groups: one study group with ten consecutive cases of primary prosthesis using Floseal® as hemostatic method, and the control group with 10 consecutive cases of primary prosthesis using electrocautery as hemostatic method. The study included the first 20 patients with primary arthrosis undergoing primary total knee arthroplasty. Patients with bleeding disorders or using medications that affect blood clotting were excluded from the study. Anesthetic care, operative and postoperative periods were equal and standardized for both groups.

Anesthetic care

All study patients underwent spinal anesthesia with isobaric marcaine 0.5%. The anesthesia team used for volume replacement lactated ringer saline at doses of 10 to 15 ml per kg body weight per hour, and colloidal solution of 6% hydroxyethyl starch in a maximum dose of 1,500 ml during the first 24 hours.

The criteria adopted for blood transfusion by the clinical and anesthetic team were: heart rate higher than 120 associated with mean arterial pressure lower than 80 mm Hg or blood pressure less than 100 mm Hg (systolic) and 60 mmHg (diastolic), pulse oximetry lower than 90% and tachypnea (respiratory rate higher

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than 20). The presence of any of these signs or the need to use vaso-active drug to maintain blood pressure were considered "trigger condition" for blood transfusion.

Surgical standardization

Before beginning the procedure, all patients were evaluated according to the objective criteria of the Knee Society Scoring (KSS).[19]
All surgeries were performed with the use of an inflated pneumatic tourniquet after venous emptying by elevation of the member for three minutes, without using elastic bandage for limb exsanguination. The pressure used in pneumatic tourniquet was 300 mmHg. Data were collected on the time of limb ischemia and surgical time, in minutes, of all the patients. The surgical time, defined as the time between the start of the skin incision and the last point of incision in the skin was measured in minutes.
The surgical approach used was the medial parapatellar way. The implants used were primary arthroplasties with replacement of the posterior cruciate ligament fixed with cement.
In the control group, after placement of the implants, the surgical route was tamponed with surgical dressings and bandages for five minutes, after deflating the tourniquet. After tamponed, hemostasis was performed with monopolar electrocautery. In the study group, Floseal® was applied before release of the tourniquet, the regions of potential bleeding, especially in the superior, medial, and lateral recesses. The surgical approach was then tamponed the same way as in the control group. After the tamponed period (five minutes), the product was again applied to the bleeding sites with a bandage at those points for two minutes. The process was repeated as many times as necessary to achieve bleeding control. In this group adjunctive hemostasis with electrocautery was not used, Floseal® being the exclusive hemostatic agent.

Post-operative care

All patients received the same analgesia, consisting of common analgesic, anti-inflammatory and opioids, with dose adjustment according to kidney function and contraindications. The antithrombotic prophylaxis was performed in all patients, starting 12 hours after surgery and the daily maintenance dose of enoxaparin 40 mg subcutaneously was used until the tenth postoperative day.
We followed the same rehabilitation protocol in both groups. Volume replacement on postoperative period followed the predefined guidelines described in anesthetic care.

Quantification of bleeding

Quantification of bleeding was done through three steps: measuring the volume administered during hospitalization (colloid solutions used in surgery and number of units of packed red blood cells transfused in each patient during hospitalization), the measurement of hemoglobin (Hb) levels 24h prior to surgery and on the third postoperative day and quantification of DPV debt.

RESULTS

Twenty patients were consecutively operated and divided into two groups. Group A, which used the pro-coagulant Floseal®, was formed by seven females and three males. The mean age was 67.8 years old (range 54-81 years). Group B, which homeostasis was made with electrocautery comprised six females and four males. The mean age was 66.6 years old (range 59-77 years).
The average range of motion (ROM) preoperatively ($p = 0.191$) did not differ between groups, and both groups showed one patient with flexion contracture of 5 degrees. The calculation of KSS preoperative ($p = 0.429$) tourniquet time ($p = 0.41$) and surgical time ($p = 0.177$) also showed no statistical difference. (Table 1)
Considering the postoperative data for testing the efficacy of anti-coagulation with Floseal®, the measurements of Hb drop (g/dL) ($p = 0.2$), total debit drain (ml) ($p = 0.195$), colloid infusion (ml) ($p = 0.363$) and infusion of crystalloid (ml) ($p = 0.383$) showed no statistical differences. Four patients in the control group received a concentrate of red blood cells and only one patient in group A required one blood transfusion bag ($p = 0.303$). (Table 2)
For statistical analysis we used Fischer's test and Student's *t* test. Any variable studied was statistically significant ($p < .05$).

Table 1. Comparison of preoperative data between the group that used Floseal® and the group using electrocautery.

	Group A	Group B	p
Range of motion (degrees)	86.5 +/- 12.5	94.5 +/- 13.8	0.191
KSS	49 +/- 710.1	46.6 +/- 6.7	0.429
Tourniquet time (min)	91.6 +/- 14.63	106.4 +/- 15.44	0.41
Surgical time (min)	130.5 +/- 16.4	140 +/- 13.74	0.177

Table 2. Comparison of peri-and post-operative periods between the Floseal® and electrocautery groups.

	Group A	Group B	p
Hb level drop (g/dL)	3.34 +/- 0.92	3.94+/- 1.1	0.2
DPV debit (ml)	260.5 +/-165	183 +/- 77.3	0.195
Colloid infusion (L)	0.45+/- 0.37	0.3 +/- 0.34	0.363
Crystalloid infusion (L)	1.95+/- 0.36	2.16+/- 0.64	0.383
Blood transfusion (number of concentrate bags)	1	4	0.303

DISCUSSION

In order to control and prevent bleeding after a total knee arthroplasty, some alternatives have been studied. Some have proven efficacy and few side effects, but others have not yet an established role in knee surgery. The use of Floseal® in surgeries with the potential risk of bleeding has well-established benefits. Urologic and neurological surgeries and procedures in the ear, nose and throat had significant less bleeding with the use of this product.[11-14] In the context of orthopedic surgery, and especially in knee surgeries , its effectiveness is still controversial , with few and limited studies on the subject. Kim *et al.*[18] showed no significant differences using or not the product in unilateral knee arthroplasties. However, Comadoll *et al.*[20] showed that the use of Floseal® can significantly reduce the postoperative hemoglobin level drop, although it has not cause differences in the rates of blood transfusions. We analyzed preoperative data of groups of patients and there was no significant difference between the characteristics of the samples. Thus, despite not having been performed prior randomization of cases, we consider that the groups were homogeneous. The standardization of the surgical technique and lack of difference in surgical and tourniquet time,

also reduce the interference of these factors in the final outcome. Our study showed in absolute numbers a smaller amount of bleeding if taking into account the drainage output and the Hb level drop postoperatively, besides a lower amount of fluid infusion in the postoperative period using Floseal®. There were also fewer transfusions in the group that used the product, the variable that is the most significant, in our opinion, to prove its effectiveness. However, none of these variables showed any statistical difference. One possible cause of the lack of statistical difference is the small number of patients in both groups. One possible advantage of using Floseal® is to avoid the potential risk of wound complications with the use of electrocautery, mainly in the coagulation mode, although this problem is usual in abdominal surgeries.[21,22] Electrocautery, however has major advantage due to its low cost and wide availability.

Thus, the primary significance of the study lies in the fact that Floseal® present itself as an equally effective alternative to traditional electrocautery. In patients with contraindications to electrocautery or that require additional procedures to allow their use, such as patients at high risk of arrhythmias or pacemaker users, Floeal® can be used safely.[23-25] In our study , no patient had allergic or adverse reactions to the use of Floseal®, although there are reports in the literature regarding allergy to the product.[26,27] Based on our results, we recommend using Floseal® in selected patients who are restricted to the use of electrocautery, rather than indiscriminately.

CONCLUSION

Hemostasis using the Floseal® was similar to hemostasis using electrocautery, making it a viable alternative for patients who have contraindications to the use of the electric scalpel.

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