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ORIGINAL ARTICLE

Does fibrin sealant use in total knee replacement reduce transfusion rates? A non-randomised comparative study

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KEYWORDS
Total knee replacement;
Blood loss;
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Summary
Background: Studies assessing fibrin sealants use during total knee replacement (TKR) have produced inconsistent results. We evaluated fibrin sealant therapy in TKR procedures performed without tourniquet and without postoperative drains.
Hypothesis: Use of a fibrin sealant during TKR decreases calculated total blood loss, thereby diminishing blood transfusion requirements and costs.
Patients and methods: We studied 62 patients with primary knee osteoarthritis who underwent TKR by the same surgeon between September 2009 and December 2010. Fibrin sealant was used only in the last 31 patients, who were compared to the first 31 patients regarding calculated total blood loss, blood transfusion rate, and mean number of red-blood-cell units used per patient. Costs were compared in the two groups.
Results: In the control group, mean total blood loss calculated using the method of Gross was 1.3 ± 0.6 L, 48% of patients required blood transfusions, and the mean number of units per patient was 0.9 ± 1. In the fibrin-sealant group, 29% of patients required blood transfusions and the mean number of units was 0.6 ± 0.9. The between-group differences in favour of the fibrin-sealant group were not statistically significant. In each group, compared with patients not requiring blood transfusions, patients needing transfusions had significantly lower starting preoperative haemoglobin values and a significantly greater positive difference between the calculated total blood loss and the maximum allowable blood loss. In the test group, the cost of the 31 units of fibrin sealant was 9743 € and the cost reduction due to using 11 fewer red-blood-cell units was only 3484 €. Hospital stay was not significantly shorter in any of the two groups.
Discussion: Blood transfusion minimisation during TKR should rely chiefly on correcting pre-operative anaemia and optimizing transfusion decisions based on the difference between the

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total blood loss and the maximum allowable blood loss. Fibrin sealant did not significantly diminish transfusion requirements in our study. Randomised studies in larger patient populations are needed. The cost of fibrin sealant may exceed the expected cost savings in relation with decreased blood transfusion requirements.
Level of evidence: Level III (before-after therapeutic study).

Introduction

Blood loss minimisation during orthopaedic surgical procedures is a major concern given the limited availability of blood products and the risks associated with both blood transfusion and postoperative anaemia [1]. Strategies suggested to date include intra- and postoperative cell salvage, tranexamic acid therapy and autologous blood transfusion. However, there are numerous contraindications to tranexamic acid [2,3], and autologous blood transfusion is declining in popularity because of its cumbersome nature, particularly in elderly patients. Fibrin sealants were developed long ago and found effective in several orthopaedic procedures on the hip, knee, and spine [4—9].

Total knee replacement (TKR) is associated with significant blood loss. Thus, total blood loss (TBL) ranges from 1.2 to 1.8 L or more. Substantial bleeding occurs via the drains during the first few postoperative days [2,3,9—13], and 24 to 58% of patients require blood transfusions [8—10,14—16]. The application of fibrin sealant during TKR has been reported to decrease bloody drainage during the postoperative period [8,9], thereby diminishing the total amount of blood lost [9]. However, effects on the blood transfusion rate have varied across studies. Thus, the blood transfusion rate decrease seen with fibrin sealant was significant in a study by Levy et al. [9] but non-significant in a study by Wang et al. [8].

Here, we report a preliminary prospective non-randomised study in 62 consecutive patients undergoing TKR. Fibrin sealant was used only in the last 31 patients. To minimize postoperative blood loss, we made two changes to our usual surgical protocol at the beginning of the study: we performed step-by-step haemostasis instead of using a tourniquet, with the result that bleeding at the end of the procedure was sufficiently limited to obviate the need for drains. The study intervention consisted in spraying fibrin sealant over the entire surgical field in the last 31 patients. Our working hypothesis was that fibrin-sealant therapy would further decrease the calculated TBL, thereby diminishing blood transfusion requirements. We prospectively monitored and compared the control group and the test group in order to evaluate our working hypothesis. We also compared costs in the two groups.

Patients and methods

We included 62 patients who underwent unilateral TKR by the same surgeon (PM) at our institution between September 2009 and December 2010. The reason for TKR was advanced primary knee osteoarthritis in all patients. None of the patients had coagulation disorders.

The first 31 patients had surgery between September 2009 and February 2010, without fibrin sealant. In the last 31 patients, who had surgery between February and December 2010, a single change was made to the surgical protocol, namely the addition of a fibrin-sealant spray. Table 1 reports the main patient characteristics. No significant differences were found between the control and fibrin-sealant groups for age, sex, body mass index (BMI), or American Society of Anesthesiologists (ASA) score. The mean preoperative haemoglobin concentration was significantly higher in the fibrin-sealant group.

We used fibrin sealant derived only from human plasma (Quixil®, Ethicon, Johnson & Johnson, Depuy France, Issy-les-Moulineaux, France). This product replicates the final steps of the clotting cascade. Each 5 ml dose contains a concentrate of human clottable proteins, a solution of purified human thrombin, and calcium chloride.

The same surgical procedure was used in all 62 patients. The cementless prosthesis for primary TKR Natural Knee® II (Zimmer, Warsaw, IN, USA) was implanted via the subvastus medialis approach, without patellar resurfacing. Computer-assisted navigation was used in all patients, obviating the need for an intramedullary guidewire. No tourniquet was used, and step-by-step haemostatic electrocoagulation was performed. The Quixil® administration device was used to administer the 5 ml fibrin-sealant dose (Fig. 1). The thrombin and clottable-protein mix are packaged in two separate vials connected via two separate ports to a syringe that has a single plunger and nozzle, so that both solutions are drawn simultaneously and mixed in the syringe. We connected the syringe to a pressure regulator to achieve a uniform spray by depressing the plunger. The nozzle was held about 15 cm from the tissues, which were as dry as possible, to ensure coverage with a superficial film of fibrin sealant. Fibrin sealant was first applied to the posterior part of the joint before implantation of the prosthetic components. The remaining sealant was applied on the anterior aspect of the surgical field, after prosthesis implantation and just before wound closure. No drains were left in place. A compression bandage was used for the first 8 h.

Prophylactic low-molecular-weight heparin therapy was given for 1 month. Sitting was started on the first postoperative day and standing with weight bearing on the next day. A continuous passive motion machine was used starting on the first postoperative day, with a femoral nerve block achieved via a portable elastomeric pump loaded with ropivacaine solution. The femoral nerve block was replaced by subcutaneous opioid analgesics after 48 h and subsequently by step-1 analgesics based on the visual-analogue-scale pain score. Patients were discharged to rehabilitation centres 7 to 10 days after surgery depending on bed availability.