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Reducing blood loss in simultaneous bilateral total knee arthroplasty: Combined intravenous–intra-articular tranexamic acid administration. A prospective randomized controlled trial

Fatih Karaaslan [*,a], Sinan Karaoğlu [b], Musa Uğur Mermerkaya [a], Ali Baktir [c]

[a] Bozok University Faculty of Medicine, Department of Orthopaedics and Traumatology, TR-66200 Yozgat, Turkey
[b] Memorial Kayseri Hospital, Department of Orthopaedics and Traumatology, TR-38010 Kayseri, Turkey
[c] Modern Dünya Hospital, Department of Orthopaedics and Traumatology, TR-38010 Kayseri, Turkey

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ABSTRACT

Background: We asked whether tranexamic acid (TXA) administration could reduce blood loss and blood transfusion requirements after simultaneous bilateral total knee arthroplasty (TKA). This study examined the role of a novel method of TXA administration in TKA.
Methods: TXA was administered as a bolus dose of 15 mg/kg 10 min before the inflation of the tourniquet on the first side. This was followed by intra-articular administration of 3 grams at 10 min before the deflation of the tourniquet. IV infusion of 10 mg/kg/h was continued for 3 h following completion on the second side. We measured volume of drained blood 48 h postoperatively, decrease in hemoglobin levels 12 h postoperatively, amount of blood transfused (BT), and number of patients requiring allogenic BT.
Results: Median postoperative volume of drained blood was lower in the group receiving TXA (500.00mL) than in control subjects (900.00mL) ($p < 0.05$) [95% CI (−525.00) to (−300.00)]. The median hemoglobin decrease 12 h postoperatively was lower in patients receiving TXA (2.10 g/dL) than in control subjects (3.10 g/dL) ($p < 0.05$) [95% CI (−1.60) to (−0.60)]. The amount of BT and number of patients requiring BT were lower in patients receiving TXA than in control subjects. Nevertheless, the number of allogeneic units of packed red blood cells transfused in the postoperative period was not significantly higher in the control group than in the TXA group ($p = 0.109$) [95% CI (0.101) to (0.117)].
Conclusions: This prospective randomized study showed that during simultaneous bilateral TKA, TXA reduced blood loss with negligible side effects.

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1. Introduction

TKA is an excellent surgical procedure for patients with painful arthritic knees. However, TKA is associated with several potential unresolved problems, including blood loss, postoperative pain, and leg swelling. The current surgical technique in total knee arthroplasty (TKA) usually includes the use of a tourniquet, prevents intraoperative bleeding but not substantial postoperative blood loss. Resolution of these problems would increase patient satisfaction [1] and raise the overall quality of TKA. One of the main problems with TKA is the need for blood transfusion (BT) in some patients. Although the incidence is low, serious complications involving allogeneic BTs have been reported (e.g., viral infections and graft-versus-host disease) [2]. Replacing blood loss by BTs is considered undesirable because of the associated risks of immunological reactions and disease transmission. Transfusion is the most common form of transplantation and the introduction of allogeneic cells and soluble antigens frequently induces an alloimmune response. Blood transfusion is also immunomodulatory, having the potential for both activating and immunosuppressive properties. This recipient response can drive a number of immunological sequelae including delayed haemolytic transfusion reactions, platelet refractoriness. Immunosuppressive effects have been observed in some patient populations and animal models and have been shown to contribute potentially to both negative and positive clinical outcomes including increased susceptibility to infection [3,4].

Control of bleeding with antifibrinolytic agents may be a preferable alternative. Tranexamic acid (TXA), a synthetic analogue of the amino acid lysine, acts by competitively blocking the lysine binding site of plasminogen, which in turn leads to inhibition of fibrinolysis [5]. TXA has been found to reduce blood loss in both total hip and knee arthroplasty over a range of dose regimens [6] without an increase in complications such as deep venous thrombosis [7]. Level I evidence provided by meta-analyses has shown that intravenous TXA appears to be effective and safe in reducing allogeneic BT and blood loss in TKA without increasing

* Corresponding author at: Bozok Universitesi Tip Fakultesi, Ortopedi ve Travmatoloji Bolumu, Yozgat, Turkey. Tel.: +90 354 212 70 60; fax: +90 354 214 06 12.
E-mail address: Fkaraaslan@Gmail.Com (F. Karaaslan).

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the risk of thromboembolic complications [6,8]. To our knowledge, no study has evaluated the efficacy of combined intravenous and intra-articular administration of TXA in the control of bleeding following TKA. Thus, the purpose of this study was to evaluate the efficacy of combined intravenous and intra-articular administration of TXA in regard to postoperative blood loss and need for blood transfusion following simultaneous bilateral TKA.

2. Patients and methods

Institutional review board approval and informed consent from all patients were obtained. The study protocol was approved by the local Ethics Committee (No. 25/7; 28 November 2012). Patients, who underwent simultaneous bilateral cemented total knee replacement at our institution were included in this prospective randomized controlled study.

The exclusion criteria were as follows: bleeding or clotting disorders, preoperative anticoagulation therapy, abnormal coagulation profile, renal disorders or insufficiency, sickle cell disease, and allergy to local anesthetics/TXA.

In total, we prospectively enrolled 81 consecutive patients (162 knees), were accepted to participate in the study, chosen from 87 patients with a diagnosis of osteoarthritis scheduled to have primary, simultaneous bilateral TKA. The patients were randomly allocated into one of the two groups by computer-generated randomization. This was a double-randomized trial. Written informed consent was obtained from all patients. A detailed clinical history of each patient and his or her associated medical comorbidities were noted.

The patients who were randomized into the TXA group received both intravenous TXA and intra-articular TXA. The control group did not receive TXA. The anesthetist, surgeon, and observer were blinded to the study group (randomized double-blinded).

TXA (Transamine, 250 mg/2.5 ml; Pharmacia, Actavis, Turkey) and a saline infusion were prepared in two separate but identical saline bottles for infusion by the hospital pharmacy and were given a random code number. TXA was administered as a bolus dose of 15 mg/kg 10 min before the inflation of the tourniquet on the first side.

All TKA were performed through a standard medial parapatellar approach under tourniquet control. All wounds were closed over a negative suction drain. After clamping of the drain the knee was injected with 100 mL of the TXA solution (three grams TXA/100 mL saline) as was found effective in prior studies [9,10]. The drain was clamped for two hours and then released.

One study [11] demonstrated a minimum TXA dose of 10 mg/kg to obtain the desired antihaemorrhagic effect. Therefore, we continued with a lower dose to minimize the side effects. Because the mean duration of the effect of TXA is approximately three hours, a second dose may be administered after this period to extend the effect over the first six hours, when most bleeding occurs [5]. Intravenous infusion of 10 mg/kg/h was continued for the next three hours after completion of the second side. Equal volumes of placebo were administered at the same rate and by the same route. The dosage protocol suggested by Henry et al. [12] was modified by the authors of this study. The choice of anesthetic drug was dependent upon individual patient factors. A pneumatic tourniquet was used in all cases and was not released until skin closure. Either general anesthesia or the combination of a spinal/epidural block with a peripheral nerve block was used. The surgical procedure was standardized in all patients and was conducted by the same surgeon. All knees were exposed by a medial parapatellar approach and underwent placement of a cruciate-substituting total knee prosthesis; the Consensus Knee System (CA, USA) was used in all cases.

All patients received postoperative analgesics and a standard fluid resuscitation protocol (35 cm^3/kg/24 h IV Lactated Ringer's solution). No patient was given nonsteroidal anti-inflammatory drugs in the postoperative period. A haemoglobin (Hb) level of <10 g/dl was considered to be the indication for BT. The suction drain in the surgical site was removed 24 h postoperatively. The amount of drained blood was measured every six hours. Hb levels were measured on postoperative days one and two, and the difference between the preoperative level and lowest postoperative level was taken as the drop in the Hb level. The number of units of packed red blood cells received in each group was documented. Postoperatively, all patients received a total of four doses of prophylactic antibiotic (cefazolin sodium, 1000 mg) over 24 h, and prophylaxis for deep vein thrombosis was initiated with low-molecular-weight heparin (enoxaparin sodium, 40 mg) at eight hours postoperatively. All patients were subjected to a similar physical rehabilitation protocol in which continuous passive machine motion was initiated within 12 h of surgery and was continued on postoperative day one. Patients were mobilized with support using a walker on postoperative day one.

Thromboembolic and other complications were noted during the hospital stay. All patients underwent bilateral venous Doppler ultrasonography between days seven and 14 as routine screening for thrombosis. Patients were examined in the postoperative period for the presence of calf swelling, and those with clinical suspicion of deep vein thrombosis underwent a Doppler venous scan. The assessment was performed by a single observer who was not involved in the surgery.

The size of the study was calculated as follows. According to a previous study [13], the rate of transfusion requirement was 41.7% without TXA and 11.1% with TXA. To obtain a power of 0.80 and an alpha value of 0.05, 32 cases were required in each group. Accounting for potential exclusions, 40 cases were included in each group.

3. Statistical analysis

The statistical analysis involved the use of frequency tables for categorical variables. For continuous variables, descriptive statistics (n, mean, median, standard deviation [SD], minimum, and maximum) were tabulated. The preoperative Hb level (g/dl), postoperative Hb level, change in Hb level (preoperative Hb − lowest postoperative Hb level) and drain out values were analyzed descriptively.

On analysis, using a Shapiro-Wilk test, all the variables (except Hb change values, drain output values and BT units) were found to have a normal distribution of data. Therefore, parametric tests of significance (Student's t test) were used for statistical analysis. Analysis of data pertaining to Hb change, drain output values and BT units were done using nonparametric tests (Mann–Whitney U test). The proportion of patients who received BT was analyzed using the Fisher Freeman Halton test. Power analysis was also done and a p value less than 0.05 was taken as statistically significant with 95% confidence interval.

All statistical calculation was performed using NCSS (Number Cruncher Statistical System) 2007&PASS (Power Analysis and Sample Size) 2008 Statistical Software (NCSS LLC, Kaysville, Utah, USA).

4. Results

Eighty-one patients were enrolled (41 in the TXA group, 40 in control group) and completed the study. The patients' average age, sex, operative time, and hospitalization periods were comparable in both groups (Table 1).

In the TXA group, the mean ± SD preoperative Hb level was 13.43 ± 1.60 g/dl, and the minimum Hb level was 8.70 ± 1.55 g/dl. In the control group, the mean ± SD preoperative Hb level was 13.62 ± 1.10 g/dl, and the minimum Hb level was 13.60 ± 1.08 g/dl. The median hemoglobin decrease 12 h postoperatively was lower in patients receiving tranexamic acid (2.10 g/dL) than in control subjects (3.10 g/dL) ($p < 0.05$) [*95% CI (−1.60) to (−0.60)*]. The median total postoperative drainage (both right and left knees) in the TXA and control groups was 500.00 ml and 900.00 ml, respectively. The volume of blood loss in the TXA group was significantly lower than that in the control group ($p < 0.05$) [*95% CI (−525.00) to (−300.00)*]. The preoperative Hb level, postoperative Hb level, change in Hb level, and drain output are tabulated in Table 2.

A summary of BT in the two groups is shown in Table 3. In the TXA group, seven patients (10 units) underwent BT; three patients (7.31%) received one unit and four patients (9.75%) received two units. In the control group, 13 patients (24 units) underwent BT; six patients (15.0%) received one unit, three (7.5%) received two units, and four (10.0%) received three units. The patients in the control group received an average of 0.60 units of

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