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Original article

Bleeding reduction after topical application of tranexamic acid together with Betadine solution in total knee arthroplasty. A randomised controlled study



L.H. Carvalho Jr.^{a,b}, E. Frois Temponi^{a,*}, L.F. Machado Soares^a, M.B.J. Gonçalves^a,
 L. Paiva Costa^a, M.L.A. Tavares de Souza^a

^a Hospital Madre Teresa, Belo Horizonte, MG, Brazil

^b Departamento do Aparelho Locomotor, Faculdade de Medicina, Universidade Federal de Minas Gerais, Belo Horizonte, MG, Brazil

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ABSTRACT

Introduction: Topical application of tranexamic acid to the knee joint before closure in total knee arthroplasty reduces postoperative bleeding without increase in complication. However, it is unknown the effectiveness of topic TXA performed with other topical medications, like povidone-iodine solution.

Materials and methods: One hundred and twenty-five patients were randomized to receive 100 mL of povidone-iodine solution (control: group A) or 1.5 (group B) and 3.0 g (group C) of topical TXA in povidone-iodine solution applied into the knee before closure in total knee arthroplasty.

Results: The patients in the TXA groups had higher mean postoperative hemoglobin levels ($P=0.01$ and $P=0.03$ in groups B and C, respectively) and a reduced postoperative blood loss in the TXA groups ($P=0.07$ and $P=0.09$ in groups B and C, respectively). No significant complications were observed.

Discussion: In this study, topical application of tranexamic acid after total knee arthroplasty together with povidone-iodine solution results in higher postoperative hemoglobin levels and lower blood loss compared with those in the control group without other complications.

Level of evidence: I–I: high-powered prospective randomized trial.

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1. Introduction

Several authors have published reports describing a reduction in blood loss and transfusion rates following total knee arthroplasty (TKA) after using an anti-fibrinolytic agent: tranexamic acid (TXA) [1]. This concern came to the fact that postoperative blood loss associated with TKA ranges from 1450 to 1790 mL, causing anaemia and other complications [2–5]. Blood transfusion is necessary in 10–38% of these patients [6–8]. The major cause of postoperative blood loss following TKA is attributable to both surgical trauma and local fibrinolysis, primarily after tourniquet release at the end of the procedure [9].

Topical TXA application is a medication with minimal systemic absorption and results in an important and effective decrease in bleeding [9–12]. However, it is unknown the effectiveness of

topic TXA performed simultaneously with other topical medications, like povidone-iodine solution. Povidone-iodine solution is safe, inexpensive, simple to use, and readily available within most operating rooms; in addition, it has broad-spectrum bactericidal activity that includes methicillin-resistant *Staphylococcus aureus* [13–17]. Brown et al. reported that Betadine® (povidone-iodine solution) lavage may represent a reasonable way (0.97% to 0.15% $P=0.04$) of reducing acute postoperative deep infection in TKA [15].

The main objective of this study was to assess the efficacy of topical TXA application used together with povidone-iodine solution after TKA, secondarily analysing the effects of this agent on haematimetric indices and postoperative blood loss. Our hypothesis was that in conjunction with povidone-iodine solution, TXA had an antibibrinolytic effect.

2. Material and methods

A total of 125 patients undergoing TKA in Hospital Madre Teresa between 2012 and 2013 by a single surgeon (L.H.C. Jr.) were enrolled in this prospective, randomised, placebo-controlled

* Corresponding author. Hospital Madre Teresa, Av Raja Gabaglia 1002, 30441-070 Belo Horizonte, MG, Brazil. Tel.: +55 3 198 185 808.

E-mail addresses: luciohcj@gmail.com (L.H. Carvalho Jr.), dufrois@hotmail.com (E. Frois Temponi).

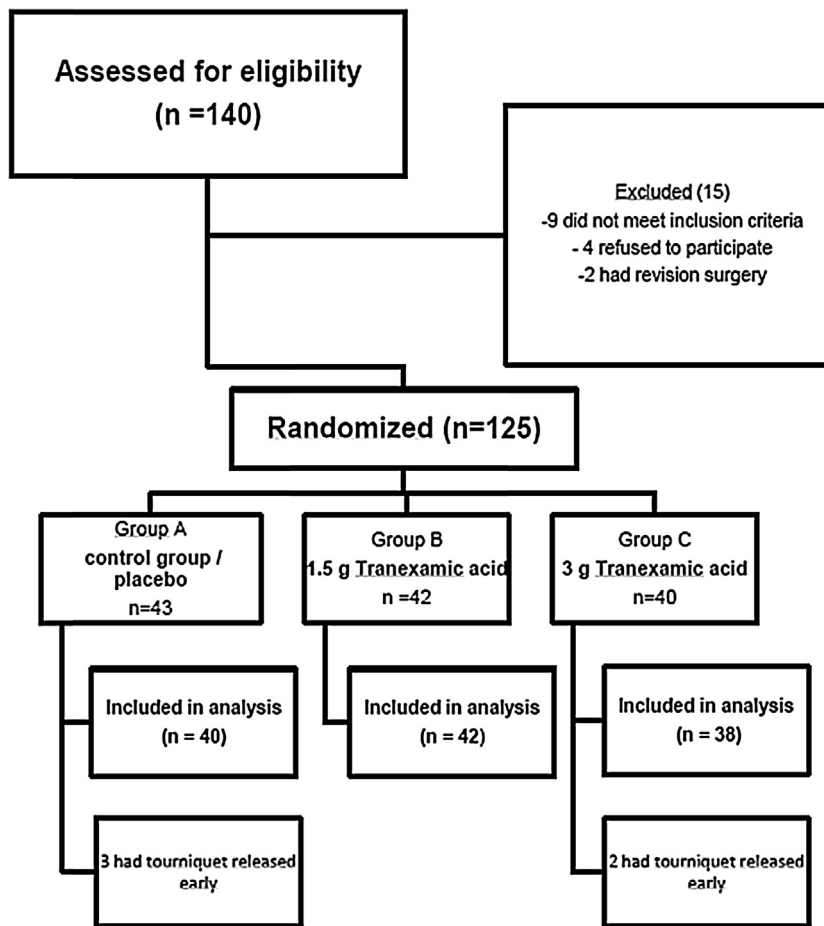


Fig. 1. Flow diagram indicating the number of patients assessed and included at each stage of the trial.

study (Fig. 1). The Ethical Committee of the Hospital Madre Teresa approved the details of this study, and written informed consent was obtained from each participant before starting this study (CAAE–Brazilian Ministry Health 05286512.0.0000.5127). No financial incentives were offered to encourage subjects to participate.

All adult patients who were scheduled for a primary TKA at Hospital Madre Teresa were eligible for inclusion. Exclusion criteria included the following: allergy to TXA or povidone-iodine solution, preoperative anaemia, refusal of blood products, preoperative use of anticoagulants (acetylsalicylic acid, enoxaparin, or any other, oral or intravenous, agent), fibrinolytic disorders, coagulopathy, arterial or venous thromboembolic disease and pregnancy. Moreover, the following patients were excluded from the study: patients with major comorbidities, such as ischaemic heart disease, patients with a history of myocardial infarction and those with severe pulmonary disease.

The doses chosen for the current investigation were based on previous studies of topical TXA in patients undergoing TKA, showing efficacy with doses of 1.5 g and 3 g for reducing the bleeding [9,10,12]. A diluted povidone-iodine solution (Betadine® solution – 0.35%) was used together and in the same time at the end of procedure for all groups, as shown by Brown et al. [15]. Patients in this study were randomised into three groups using a computerized program and were administered TXA as follows:

- group A patients (control) received Betadine® solution (0.35%) (200 ml – 0.35%);

- group B patients received 1.5 g (100 mg/mL) TXA (Transamin®, NIKKHO, Rio de Janeiro, Brazil) in Betadine solution (200 ml – 0.35%);
- group C patients received 3 g TXA (Transamin®, NIKKHO, Rio de Janeiro, Brazil) in Betadine solution (200 ml – 0.35%).

No control group was used with isolated TXA solution due to existence of data in the literature to substantiate the reduction in bleeding with this solution alone in the same doses used [9,11,12,18–21].

All patients received a spinal anaesthesia [12–15 mg isobaric bupivacaine (0.5%)] with a femoral and sciatic nerve block [125 mg ropivacaine (0.5%) associated to 75 µg of clonidine] guided by ultrasonography for postoperative analgesia. All the procedures were performed using pneumatic tourniquet around the upper part of the thigh with a pressure of 350 mmHg. A midline skin and medial parapatellar capsular incision was made to expose the knee joint. An identical type and appropriately sized, posterior stabilized knee prosthesis was used in every patient (NexGen – Zimmer®, Warsaw, Indiana, United States). After all components were implanted, the joint was thoroughly irrigated and the study medication (TXA) with Betadine solution (200 ml – 0.35%) was applied to the open joint surfaces and was left in contact with the tissues for five minutes, as described by Wong et al. [9]. The surgeon subsequently suctioned away excess of solution by placing the suction tip without touching the joint or the surrounding tissue surfaces. The wound was closed and a 3.2 mm-diameter drains without suction was utilized. The tourniquet was released only after wound closure. To prevent venous thromboembolism, patients received enoxaparin

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