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Original Article

Reducing blood loss during open myomectomy with intravenous versus topical tranexamic acid: A double-blinded randomized placebo-controlled trial

Nahla W. Shady [a,*], Hany F. Sallam [a], Huda Fahmy [b]

[a] Department of Obstetrics & Gynecology, Faculty of Medicine, Aswan University, Egypt
[b] Department of Anesthesia, Faculty of Medicine, Aswan University, Egypt

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ABSTRACT

Objectives: To assess the effect of Intravenous versus Topical Tranexamic acid in reducing intra-operative and post-operative blood loss in abdominal myomectomy surgeries.
Materials and methods: In a randomized double-blind placebo-controlled trial, 105 women undergoing abdominal myomectomy for symptomatic uterine leiomyomas were randomly assigned to three groups: group 1 [35 patients received 110 ml normal saline IV just before skin insion], group 2 [35 patients received 1 g tranexamic acid (2 ampoules of kapron 500 mg 5 ml Amoun company) IV just before skin in scion] and group 3 [35 patients received 2 g topical tranexamic acid (4 ampoules of kapron 500 mg 5 ml) applied on myoma bed after myomectomy]. The primary outcome was intra-operative, postoperative and all blood loss estimation.
Results: Both Group II (IV tranexamic acid) and Group III (topical tranexamic acid application) showed great reduction in intraoperative and post-operative blood loss (blood in the intraabdominal drain) compared with Group I (placebo group), (P = .0001, 0.0001, 0.0001, 0.0001), so the overall estimated blood loss in group II and III showed highly reduction compared with group I (P = .0001, .0001).
Conclusion: Intravenous and Topical Tranexamic acid application safe and reliable method to help decrease blood loss during and after open myomectomy.
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1. Introduction

Uterine leiomyomas are benign tumors of the uterus, which represent the most common neoplasms in women of reproductive age, and have a lifetime incidence of approximately 70% in the general population [1]. Approximately 20–40% of women with fibroids experience significant symptoms and consult gynecologic care [1]. The most common clinical symptoms include abnormal uterine bleeding, dysmenorrhea, pelvic pain, infertility, and recurrent pregnancy loss [1].

Currently, there are several strategies for the treatment of fibroids, but myomectomy remains the most common and the most efficient uterus-sparing treatment [2]. Nevertheless, this procedure is associated with known risks, chief of which is excessive perioperative blood loss which sometimes necessitates a hysterectomy. However, blood transfusions were still required to treat anemia in many cases. Allogenic blood transfusion would increase the risk of adverse events, such as virus infections, immunologically mediated diseases, and cardiovascular dysfunction, resulting in a financial burden and potentially life-threatening effects on patients [3,4].

The risk of bleeding depends on the number, the size and the position of fibroids removed. To reduce intraoperative hemorrhage, many interventions have been proposed to reduce bleeding and blood transfusion [5].

In a Cochrane database systematic review, highlight that: misoprostol, vasopressin, bupivacaine plus epinephrine, tranexamic acid (TA) and mechanical tourniquet more effective in controlling myomectomy-associated bleeding compared to a placebo or no treatment [5].

Recently, attention has focused on the use of TA to reduce blood loss if given prophylactically at myomectomy. This is not a uterotonic agent; TA is an anti-fibrinolytic agent better known to gynecologists for oral use as a treatment of menorrhagia, and to trauma surgeons where it has been shown to reduce blood loss [6].

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* Corresponding author.
E-mail address: nahlagyn@yahoo.com (N.W. Shady).

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Traditionally, antifibrinolytic agents have been administered intravenously in surgical settings. Safety concerns associated with intravenous administration of tranexamic acid include thrombosis, increased seizure risk, and renal impairment [8]. Considering the safety concerns with intravenous administration, there has been a growing interest in the topical use of tranexamic acid for prevention of bleeding associated with major surgical procedures. Although published reports of thromboembolic events with intravenous tranexamic acid are limited and meta-analyses do not suggest an elevated risk, the potential danger of thrombosis warrants investigation of alternative hemostatic strategies [8,9].

Topical application of TA provides a high drug concentration at the site of the wound and a low systemic concentration. Studies from cardiac and orthopedic surgery have shown an equal or superior effect of topical compared with intravenous TA on both bleeding and transfusion requirement. Topical treatment is cost-effective, and adverse effects or drug interactions have not been reported [7]. There are several published clinical trials for the use of TA in the myomectomy as well, but no consensus on its use or guidelines for management [6]. Topical application of TA to decrease postsurgical bleeding after major surgical procedures is a promising strategy [7].

An RCT investigated the efficacy of intravenous TA during abdominal myomectomy. The study was unable to demonstrate any significant impact on blood loss, duration of surgery, or need for blood transfusion [10]. Given the positive impact of TA on hemostasis in other specialties, perhaps modifications to the intravenous TA dosing and administration regimens may translate to a positive impact on hemostasis during myomectomy [7,8].

In the view of limited, good-quality evidence available to inform on the best practices for prevention of bleeding during open myomectomy our study aimed at evaluating role of IV versus Topical tranexamic acid application for prevention of hemorrhage in women with open myomectomy.

2. Materials and methods

This study was a double blinded randomized controlled study conducted at Aswan university, Egypt from September 2015 to September 2017. Study inclusion criteria were women who attended the outpatient gynecology clinic, seeking treatment for symptomatic leiomyomas and scheduled to undergo abdominal myomectomy with myoma staging from (3 to 6) according to FIGO staging [11]. Exclusion criteria were: 1-Patients undergone vaginal or laparoscopic myomectomy. 2-Patients received preoperative embolization or gonadotrophin releasing hormone analogue. 3-Cervical and broad ligament myoma. 4-Myoma FIGO staging [1,2,7,8,11].

5-Patients with cardiac, hepatic, renal or thromboembolic disease 6-patients had an allergy to tranexamic acid). The required sample size was calculated based on the power of the study of 80% and α-error of 0.05 [12].

One hundred and twenty patients were invited for the study, twelve not meeting inclusion criteria and three refused to participate therefor one hundred five patients were included in the study. All participants underwent a detailed history, general, abdominal and vaginal examinations, body mass index (BMI) was calculated and pelvic ultrasound examination was undertaken for all participants to assess the number and location of myomas and the largest myoma diameter. The participants who fulfilled the eligibility criteria were explained about the study with the beneficial and possible adverse effects of tranexamic acid. Informed consent was obtained from them after that participant was randomized to 3 groups: group 1 [35 patients received 110 ml normal saline IV just before skin incision], group 2 [35 patients received 1 g tranexamic acid (2 ampoules of kapron 500 mg 5 ml. Amoun company) IV just before skin incision] and group 3 [35 patients received 2 g topical tranexamic acid (4 ampoules of kapron 500 mg 5 ml) applied on myoma bed after myomectomy.

2.1. Randomization

Patients were randomized to three groups, each compromised of thirty-five patients according to a three-blocked randomization list which was coded (1 or 2 or 3) at 1:1:1 ratio. The three parallel groups were prepared using a Computer-generated randomization system. The allocated groups will be concealed in serially numbered sealed opaque envelopes that will only be opened after recruitment. The patient allocation will be performed prior to the induction of anesthesia by an independent person, who will not otherwise be involved in this study. The trial will be appropriately blinded; the participants, outcome assessors and the surgeon performing the procedure will be blinded to the medication type, which will be used.

2.2. Intervention

Eligible participants were allocated to one of three groups after induction of general anesthesia and immediately prior to the operation and just before skin incision. They received 1-gram tranexamic acid (10 ml) in 100 ml saline infusion or placebo (110 normal saline) by slow intravenous injection at an approximate rate of 1 ml per min. The abdomen was exposed through a midline or Pfannensteil incision, after skin incision, the subcutaneous fat and abdominal fascia were opened crosswise, and the rectus muscle was opened on the midline. The parietal peritoneum was opened longitudinally to reach the pelvic cavity. Uterus was inspected for the number, location, and shape of myomas and other pelvic organs were inspected for associated pathology. Uterine incisions on top of myoma were performed. The incision was performed using monopolar diathermy. Intracapsular enucleation of myomas was performed by gently dissecting between the myoma and the pseudo capsule. The myoma was grasped by Collins forceps and gently enucleated out. A gauze soaked with 2 g tranexamic acid (20 ml) diluted in 100 ml of sodium chloride 0.9% or placebo (120 ml of sodium chloride 0.9%) used to compress the myoma bed for 5 min. To ensure a sufficiently high concentration, the tranexamic acid was diluted only to a volume sufficient to moisten a large wound surface. 20 ml moisten at least 1500 cm^2. Myoma bed was closed by 1 or 2 layers of interrupted vicryl sutures (Vicryl 1–0 polyglactin 910; Egycryl, Taisier CO, Egypt). At the end of the surgery, 1 intraperitoneal suction drain was routinely used in all patients the drains were removed on the second postoperative day unless otherwise indicated. Number and size of myomas were recorded. Myoma size represented the mean size of each myoma. Enucleated myomas were sent to histopathology.

2.3. Blood loss estimation

Intraoperative blood loss was measured by adding the volume of the contents of the suction bottle and the difference in weight (in grams) between the dry and the soaked operation sheets and towels (1 g = 1 ml). Post-operative blood loss was measured through intraperitoneal suction drain which measured every 12 h and on removing the drain. After that, the total blood loss was calculated by the addition of intraoperative and postoperative blood loss.

2.4. Study outcome

The primary outcome was an estimation of intraoperative, postoperative and total blood loss (ml).

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