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Original contribution

The effect of intravenous tranexamic acid on blood loss and surgical field quality during endoscopic sinus surgery: a placebo-controlled clinical trial☆,☆☆

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Abstract

Study Objectives: To evaluate the effects of intravenous (IV) tranexamic acid on blood loss and surgical field quality during functional endoscopic sinus surgery (FESS).

Design: Randomized, double-blinded, controlled trial.

Setting: Operating room and postoperative recovery area of a university-affiliated hospital.

Patients: 84 consecutive, adult, ASA physical status 1 and 2 patients undergoing FESS.

Interventions: Patients were randomized to receive either IV tranexamic acid 10 mg/kg (TA group) or sterile water 0.1 mL/kg (placebo group) as a bolus dose immediately after induction of anesthesia.

Measurements: Amount of blood loss and bleeding and satisfaction scores were obtained from the surgeon.

Main Results: Blood loss in the TA group was 184 ± 64 mL and in the placebo group, 312 ± 75 mL on average ($P < 0.01$). The median (range) bleeding score in the TA group was significantly lower than the placebo group [2 (1-3) vs 2.5 (2-4); $P < 0.0001$]. The surgeon was more satisfied with the surgical field in the TA group than the placebo group [median score: 4 (3-5) vs 3 (1-5), $P < 0.001$].

Conclusion: Intravenous tranexamic acid effectively reduces bleeding and improves the surgical field during FESS.

1. Introduction

Bleeding during functional endoscopy sinus surgery (FESS) remains a challenge for both surgeons and anesthesiologists [1]. Although major blood loss during FESS is rare, maintaining an optimal surgical field is crucial for the surgeon; even a small amount of blood may disturb the endoscopic view, increasing the likelihood of complications, lengthening the operative procedure, and possibly resulting in incomplete surgery [2].

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Several techniques have been suggested to improve the surgical field in sinus surgery. Bipolar diathermy, packing, topical vasoconstrictors, and induced hypotension are among the most commonly used techniques [2-4]. Of these, diathermy may result in local tissue damage and subsequent bleeding [2]. Topical vasoconstrictors may result in hemodynamic instability, especially in patients with a history of hypertension or ischemic heart disease. Induced hypotension exposes patients to more anesthetic drugs and consequently their side effects. Furthermore, none of these drugs consistently provides a desirable bloodless field for the surgeon.

Earlier studies have confirmed the favorable effects of antifibrinolytics, including tranexamic acid, on bleeding tendency in patients undergoing cardiac, major orthopedic, transplantation, and prostate surgeries [5,6]. Of particular interest is the increasing use of tranexamic acid by oral surgeons in the form of mouthwash for dental extractions [7,8] and in the management of epistaxis with hereditary hemorrhagic telangiectasia [9,10]. Only two studies have reported the efficacy of topical [11] and oral [12] forms of tranexamic acid in achieving hemostasis and improving the surgical field in nasal surgeries, including FESS. In this study, the efficacy of intravenous (IV) tranexamic acid in reducing bleeding associated with nasal surgery (ie, FESS) was examined.

2. Materials and methods

2.1. Patients

This prospective study was approved by the Tehran University Ethics Committee and written, informed consent was obtained from all patients. Between June 2008 and February 2009, a total of 84 ASA physical status 1 and 2 patients, aged 19 to 64 years, and undergoing FESS for chronic sinusitis, were enrolled in the study. Patients receiving anticoagulants or having a bleeding diathesis were excluded. Patients were randomly allocated to receive either 10 mg/kg of IV tranexamic acid (Rasht Pharmaceutical Co., Rasht, Iran; TA group) or sterile water 0.1 mL/kg (placebo group) as a bolus dose immediately after induction of anesthesia.

2.2. Anesthesia and surgery protocols

All patients were premedicated with oral oxazepam 10 mg two hours before surgery, then IV fentanyl 4 μg/kg and lidocaine 1.5 mg/kg three to 5 minutes before intubation. After the application of 100% oxygen at 5 L/min for 5 minutes, anesthesia was induced with propofol 2.0 mg/kg and atracurium (0.5 mg/kg). After tracheal intubation, anesthesia was maintained with propofol 100 μg/kg/min, remifentanil 0.1 μg/kg/min, and atracurium. Controlled mechanical ventilation with an initial tidal volume of 10 mL/kg and respiratory rate of 10 breaths/min was adjusted to maintain normocapnia. At the end of anesthesia, muscle relaxation was reversed with neostigmine 0.04 mg/kg and atropine 0.02 mg/kg. Before induction of anesthesia, all patients received isotonic crystalloid 3.0 mL/kg for volume expansion. During surgery, maintenance fluids were standardized for patients based on their weight, and blood loss was replaced with Ringer's lactate in a 3:1 ratio. None of the patients required transfusion of blood products.

The same anesthesia and surgical teams performed all procedures using the same technique. Based on the study protocol, none of the patients received preoperative or intraoperative local vasoconstrictors. Cutting forceps and grabbing instruments were used, but a microdebrider was not used for any procedure included in the study.

2.3. Assessment of blood loss, surgical field quality, and other covariates

Intraoperative blood loss was estimated by the attending anesthesiologist at the end of surgery by accounting for loss of blood and irrigation fluid in the 25 mL-graded suction canister, and nasopharyngeal packing (measured weight of packing on the electronic scale). Moreover, at the end of a surgery, the surgical field was graded in terms of bleeding by the surgeon using the scale used by Boezaart et al in 1995 (Table 1) [13]. The surgeon's satisfaction with surgical field quality was also graded in a 5-item Likert scale, where 1 = poor and 5 = excellent. Hemodynamic parameters, including systolic and diastolic arterial blood pressure (BP), and heart rate (HR) were recorded at 15-minute intervals. Prothrombin time, partial thromboplastin time, and complete blood count were measured before surgery and 6 hours postoperatively.

The occurrence of possible side effects of treatment such as nausea and vomiting was evaluated in the post-anesthesia care unit (PACU). Patients stayed in the hospital

Table 1 Boezaart et al grading scale for scoring of surgical field bleeding [13]

Grade	Assessment
0	**No bleeding** (cadaveric conditions).
1	**Slight bleeding:** no suctioning required.
2	**Slight bleeding:** occasional suctioning required.
3	**Slight bleeding:** frequent suctioning required. Bleeding threatens surgical field a few seconds after suction is removed.
4	**Moderate bleeding:** frequent suctioning required and bleeding threatens surgical field directly after suction is removed.
5	**Severe bleeding:** constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible.