

DOES INTRAVENOUS TRANEXAMIC ACID REDUCE BLOOD LOSS DURING SURGICALLY ASSISTED RAPID PALATAL EXPANSION?

Cerrahi Destekli Hızlı Üst Çene Genişletmesi Sırasında Damar İçi Traneksamik Asit Kullanımı Kan Kaybını Azaltır mı?

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ABSTRACT

Purpose: The purpose of this study was to evaluate the efficacy of tranexamic acid (TXA) in reducing blood loss during surgically assisted rapid palatal expansion (SARPE) procedure.

Subjects and Methods: A total of 34 patients (12 male, 22 female) who had been treated surgically under general anesthesia with SARPE including pterygoid disjunction for transverse maxillary deficiency (TMD) were included in this study. The study group (n=17) received intravenous (IV) TXA 10 mg/kg as a preoperative bolus; the control group (n=17) received normal saline solution. Preoperative and postoperative haemoglobin and haematocrit values, intraoperative blood loss, and any blood product transfusion were recorded.

Results: Blood loss during SARPE was statistically significantly less in the study group than the control group (p=0.0001).

Conclusion: Preoperative IV administration of TXA can effectively control blood loss during when SARPE with pterygoid disjunction is performed.

Keywords: Hemorrhage; maxillary expansion; SARPE; tranexamic acid; blood loss

ÖZ

Amaç: Bu çalışmada damar içi traneksamik asit (TXA) kullanımının cerrahi destekli hızlı üst çene genişletmesi sırasında (SARPE) sırasında meydana gelen kan kaybı üzerine etkisinin değerlendirilmesi amaçlanmıştır.

Hastalar ve Yöntem: Bu çalışmaya üst çenede transvers yetersizliği (ÜTY) bulunan ve genel anestezi altında pterigoid ayırma yapılarak SARPE ile tedavi edilen toplamda 34 hasta (12 erkek, 22 kadın) dahil edilmiştir. Çalışma grubuna (n=17) damar içi 10 mg/kg TXA girişim öncesinde; kontrol grubuna ise (n=17) yine damar içine serum fizyolojik verilmiştir. Girişim öncesinde ve sonrasında hemoglobin ve hematokrit değerleri, girişim sırasındaki kan kaybı ve kan ürünleri transfüzyonu kaydedilmiştir.

Bulgular: SARPE girişimi sırasında çalışma grubunda ölçülen kan kaybı değerlerinin kontrol grubuna göre daha düşük olduğu ve bu farkın istatistiksel olarak çok ileri düzeyde anlamlı olduğu belirlenmiştir (p=0.0001).

Sonuç: Girişim öncesinde damar içi yolla TXA uygulaması ile pterigoid ayırma yapılan SARPE işlemi sırasında meydana gelen kan kaybı etkili bir şekilde kontrol altına alınabilir.

Anahtar kelimeler: Hemoraji; üst çene genişletmesi; SARPE; traneksamik asit, kan kaybı

Introduction

Transverse maxillary deficiency (TMD) is one of the most common skeletal dysplasias observed in clinical practice (1). It can be treated with several techniques such as slow orthodontic expansion, rapid palatal expansion, and SARPE (2). The recommended technique for adult patients with TMD is SARPE because of the limited osteogenic activity of the palatal suture (3). SARPE is a well-established procedure to treat TMD with low morbidity, but some complications have also been described in the literature. Although this technique is considered to be relatively safe when compared to other orthognathic surgical methods, blood loss can occur and transfusion may be required (4-10). In particular, disjunction of the pterygomaxillary process combined with conventional SARPE osteotomy may increase the haemorrhagic complication rate depending on the damage to the pterygoid venous plexus (11). Tranexamic acid (TXA) is a reversible antifibrinolytic agent that completely blocks the conversion of plasminogen to plasmin. TXA inhibits the proteolytic action of plasmin on the fibrin clot and prevents thrombolysis, rather than the formation of a new clot. TXA has been reported to reduce bleeding in total knee arthroplasty, spinal surgery, and cardiac surgery (11). However, studies regarding the use of intravenous (IV) TXA during orthognathic surgery procedures performed on the well-vascularized head and face region are limited.

Therefore, the aim of this study is to evaluate the efficacy of IV TXA in reducing blood loss during SARPE in combination with pterygomaxillary disjunction. The null hypothesis tested in this research is that the IV TXA does not have any effect on the examined variables related to blood loss during SARPE with pterygomaxillary disjunction procedure.

Subjects and Methods

Study Design

The study protocol was in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Istanbul University, Faculty of Medicine (Ref. No: 27415); written informed consent was obtained from all patients. This study involved 34 patients who had undergone SARPE at Istanbul University, Faculty of Dentistry, Department of Oral and Maxillofacial Surgery from January 2014 through September 2015. The study criterion was the presence

of TMD and use of SARPE with pterygomaxillary disjunction. The inclusion criteria were: skeletally mature patients diagnosed with TMD of >5 mm, good oral hygiene, and healthy periodontal structures. The exclusion criterion were previous surgery at donor and/or recipient sites, maxillary sinus disease, systemic disease that would contraindicate oral surgery, chronic periodontitis, use of anticoagulant drugs and smoking.

Study variables

The primary outcome variable was the amount of intraoperative bleeding. All patients were admitted to the hospital for preoperative assessment and anesthetic consultation 1 or 2 days before surgery. The medical history of each patient was recorded, and a blood sample was taken to evaluate complete blood count, international normalised ratio (INR), prothrombin time (PT), activated partial thromboplastin time (aPTT), and cross-matching. Body weight, age, gender, allergy, previous surgery, alcohol use, smoking, systemic disease, hospitalization period, duration of surgery, intraoperative blood loss, haemoglobin concentration, haematocrit, INR, PT, aPTT, and any complications were recorded. Postoperative haemoglobin concentration, haematocrit, aPTT, INR, and PT were measured on the day of surgery.

Surgical Technique

The same surgical team treated all of the patients, and surgery was performed under general anesthesia by the same surgeon. The same type of fixed hyrax palatal expansion device was used for all of the patients, and the devices were applied 1 or 2 days before SARPE. All patients underwent general anesthesia with nasotracheal intubation. After the induction of general anesthesia, infiltration of local anesthetic (articaine-HCl, Ultracaine, Sanofi, Istanbul, Turkey) was performed to provide haemostasis around the operative site. Before osteotomy and separation of the palatal suture, the expansion device was activated by preloading to facilitate separation (Figure 1). A full-thickness incision at the deepest site of the maxillary buccal vestibular sulcus, extending from the first molar to the contralateral first molar, was performed. A mucoperiosteal flap was elevated, exposing the maxilla from the anterior maxillary process to the zygomatic buttresses. The anterior attachment of medial nasal cartilage and anterior

nasal spine was separated, and the nasal mucosa lining the inferomedial site of the nasal airway was elevated. After elevation of the flaps, a Le Fort I osteotomy and maxillary anterior vertical osteotomy were performed by using a Lindemann bur (2 mm in diameter, 23 mm in length) (Figure 2). Bilateral pterygomaxillary separation was performed by using a curved chisel osteotome, and lateral nasal osteotomies were performed by using guided chisel osteotomes. Finally, transpalatal osteotomy was performed by using a straight chisel osteotome and the preloaded palatal suture was separated (Figure 3). After the separation process, the expansion device was deactivated and the flap was closed.

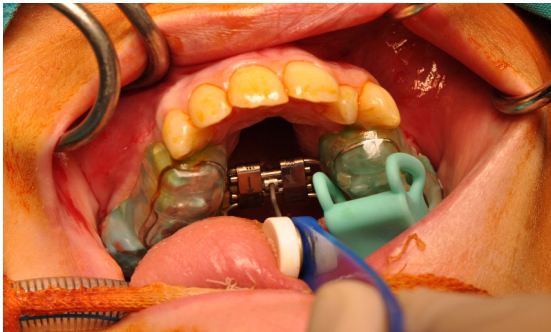


Figure 1. Preloading of the expansion device to facilitate palatal separation

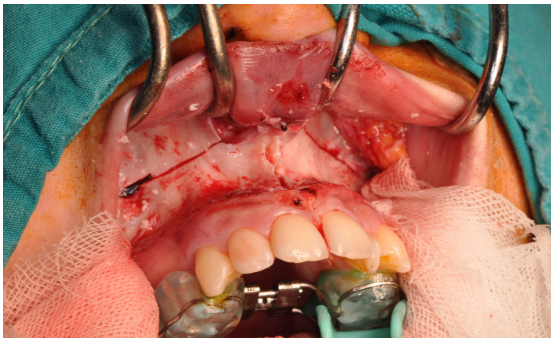


Figure 2. Vertical and horizontal osteotomies.

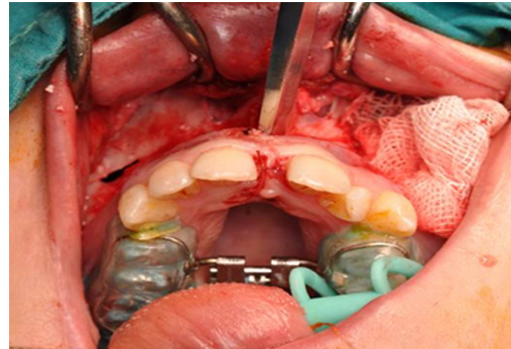


Figure 3. Separation of palatal suture with chisel osteotome.

Statistical analysis

Statistical analysis was performed using NCSS (Number Cruncher Statistical System) 2007 Statistical Software (NCSS, LLC, Kaysville, UT, USA) for the comparison of intraoperative blood loss in study and control groups. An independent t-test was used for the evaluation of descriptive statistical methods (mean, standard deviation) in addition to paired comparisons. Qualitative data were evaluated by using the chi-square test. p-values less than 0.05 were considered as statistically significant ($p < 0.05$).

Results

No significant difference was observed among control and study groups for the age and gender variables. Differences in average weights between control and study groups were not significant either. On the other hand, the mean amount of intraoperative blood loss in the group which had received IV TXA was found to be significantly less than that of the controls ($p = 0.0001$) (Table 1).

Table 1. Statistical differences between control and study group (TXA: Tranexamic acid, SD: standard deviation).

	Control Group	TXA Group	p
Age (mean±SD)	22.18±5.66	22±4.54	0.921
Gender	Male	9 (52.94%)	0.301
	Female	14 (64.71%)	
Weight (mean±SD kg)	62.76±13.45	67.06±14.54	0.378
Blood Loss (mean±SD cc)	219.71±72.96	52.65±17.51	0.0001

Discussion

TXA is a synthetic analogue of the amino acid lysine that inhibits fibrinolysis by blocking the conversion of plasminogen to plasmin (11). TXA has been shown to reduce blood loss and the need for blood transfusion in a variety of operations such as total knee arthroplasty (12, 13), spine surgery (14), cardiac surgery (15), caesarean section, and tonsillectomy (16). Although the effectiveness of TXA for the reduction of blood loss during operations has been well-documented, there is an ongoing debate about the timing, dosage, and method of use. The terminal half-life of TXA is 1.9 hours and it is mostly eliminated in the urine (17). The duration of the operation may be the most important factor in determining the timing of TXA administration. Although a single preoperative dose of TXA for operations shorter than 1.9 hours can be adequate, continuous infusions may be required for longer operations (18). Senghore *et al.* (19) reported that a single IV preoperative dose of TXA was effective in preventing postoperative bleeding in healthy patients undergoing third molar surgery. SARPE is a relatively short procedure when compared to other orthognathic surgery interventions. In this research, only a single preoperative dose of TXA was used in the study group. Additional doses may be required if the operation is longer than 1.9 hours.

Some clinical trials of IV and topical administration of TXA in maxillofacial surgery have been reported. Karimi *et al.* (20) showed that the preoperative IV administration of TXA significantly reduced intraoperative bleeding in bimaxillary surgery. In addition, Sankar *et al.* (21) observed that IV administration of TXA was effective in controlling blood loss and in improving the visibility of the surgical area, but had no significant effect on the incidence of blood transfusion or duration of surgery in orthognathic operations. In addition to IV administration of TXA, its topical use as an irrigation fluid or mouthwash has been suggested as a useful method for the management of postoperative bleeding after oral surgery in patients who are receiving anti-coagulant therapy (22-27). Carter *et al.* (24) showed that the effectiveness of 4.8% TXA mouthwash was the same as autologous fibrin glue in warfarin-treated patients undergoing dental extraction. In addition, Sindet-Pedersen *et al.* (26) found that 4.8% TXA mouthwash was effective in bleeding prevention after oral surgery in anticoagulant-treated patients.

Hypotensive anesthesia is a basic technique for intraoperative bleeding management, and some studies used TXA in combination with hypotensive anesthesia during orthognathic operations (28). Although hypotensive anesthesia alone is a useful method for reducing intraoperative bleeding, it is very difficult to distinguish the effectiveness of TXA when used in combination with hypotensive anesthesia. Therefore, TXA administration was used without hypotensive anesthesia in this study. Authors used IV TXA (10 mg/kg) in the study group, based on a report about therapeutic plasma concentrations (29). Some studies reported the use of different dosages of TXA ranging from 10 to 100 mg/kg (18). However, it is also known that larger doses of TXA have no additional effect on haemostasis.

The maxillofacial region is a vulnerable area for haemorrhagic complications due to its well-vascularized anatomic structures, and these complications may occur during orthognathic procedures (30). Although SARPE is considered to be a relatively safe procedure, it may cause haemorrhagic complications which are usually related to the pterygomaxillary disjunction process (31). No consensus has been reached regarding the requirement for pterygomaxillary disjunction during SARPE (31). Although some researchers suggest that pterygoid disjunction is not required, authors believe that it is essential for the long-term stability of maxillary expansion, as separating the palatal suture without pterygoid disjunction can be difficult in some cases. During SARPE with pterygomaxillary disjunction, damages to the venous plexus may lead to haemorrhagic complications due to short distance between the plexus and the osteotomy lines. Therefore, authors routinely use TXA for the management of intraoperative bleeding during SARPE with pterygomaxillary disjunction. Findings of the present study regarding the effects of TXA on blood loss during SARPE procedures are consistent with those of the previous studies (20, 32, 33). In addition, no adverse reactions or complications were observed.

Conclusion

The present study demonstrated that preoperative IV administration of TXA significantly reduced intraoperative bleeding in SARPE with pterygomaxillary disjunction.

Source of funding

None declared.

Conflict of interest

None declared.

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