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Evaluation of the efficacy of tranexamic acid on blood loss in orthognathic surgery. A prospective, randomized clinical study

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Abstract. The purpose of this prospective, randomized, double blind study was to assess the effect of tranexamic acid on blood loss, quality of surgical field and duration of surgery in adolescent orthognathic surgery patients. 50 consecutive patients, scheduled for orthognathic surgery were included. The study group ($n = 25$) received tranexamic acid 10 mg/kg as a bolus preoperatively followed by 1 mg/kg as a maintenance dose intra operatively; the control group ($n = 25$) received placebo (normal saline). All patients received moderate hypotensive anaesthesia with nitroglycerin and had surgery according to a standard protocol. Intra operative blood loss, duration of surgery, quality of surgical field, blood transfusion and complications, if any, were recorded. The mean total blood loss was 166.1 ± 65.49 ml in the study group and 256.4 ± 77.80 ml in the control group. The results showed statistically significant reduction in blood loss ($p < 0.001$) and improved quality of surgical field ($p < 0.001$) in the study group. There was no significant difference in duration of surgery and transfusion requirements between the two groups. In conclusion, preoperative and intra operative administration of the antifibrinolytic agent, tranexamic acid, is effective in controlling blood loss and improving the quality of the surgical field.

Keywords: tranexamic acid; blood loss; induced hypotension.

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Blood is a finite resource with a limited shelf life and is associated with considerable processing costs. Utilization of this resource needs critical review to reduce the risks of transmission of various blood borne diseases, infections and transfusion related complications. Conservation of blood is now recognized as a priority in all forms of surgery.

Yu et al. reported that 72.4% of orthognathic patients require double jaw surgeries and that blood loss during simple Le Fort I osteotomies is about half that of multiple segmentalized osteotomies.[1] 27–30% of patients undergoing bimaxillary osteotomy procedures require a blood transfusion.[2,3] Various preoperative and intra operative measures have been

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developed to conserve blood, including acute normovolemic hemodilution, induced hypotension, positioning the surgical field above the level of the heart, cell saving, and preoperative autologous blood donation.[4] These techniques require special knowledge, training and skill in the procedure and intensive monitoring of the patients. The cost of autologous blood donation and cell salvage is high.

The pharmacological approach to reducing bleeding and transfusion has recently emerged as an additional complementary approach to conserve blood. Kovesi and Royston[5] reviewed the clinical efficacy of various pharmacological agents and reported that the antifibrinolytic agents, aprotinin and tranexamic acid, were effective in reducing red blood cell transfusion. The lysine analogue inhibitor tranexamic acid is particularly effective in reducing perioperative blood loss in various types of surgery, such as cardiac, knee replacement, caesarian, tonsillectomy and prostatic, with no adverse effects.[6] Studies on the use of tranexamic acid during orthognathic surgery are limited.[7,8] In this prospective, randomized, double blind study, the effect of tranexamic acid on blood loss, quality of surgical field and duration of surgery was evaluated and compared to the effect of nitroglycerin induced moderate hypotension alone.

Materials and methods

This study was approved by the Ragas dental college and hospital institutional ethical committee and informed consent was obtained from all the patients. All ASA I patients aged 17–30 years scheduled for orthognathic surgery were included in the study consecutively. Subjects included had congenital or acquired skeletal deformities corrected using conventional orthognathic operations. Patients who had bone diseases, cleft lip and palate, craniofacial syndromes, patients requiring palatal expansion surgery, distraction osteogenesis, simultaneous rhinoplasty, TMJ surgery, bone graft or implant placement and endoscopically assisted surgeries were excluded from the study.

Patients were randomized by computerized random allotment to receive study drug (tranexamic acid) or placebo (0.9% normal saline). The tranexamic acid drug or placebo was titrated and preloaded in a syringe, preoperatively. They were then blinded and kept in an envelope. After randomization the specific envelope was transferred to the theatre nurse for administration according to the prescribed schedule. None of the members of the surgical team, nursing staff or the anaesthesiologist were aware of the allocation.

Table 1. Fromme's ordinal scale[6,25] for assessing quality of surgical field.

Massive bleeding, cannot carry out dissection	5
Severe bleeding; significantly compromises dissection	4
Moderate bleeding; slightly compromises dissection	3
Mild bleeding, a nuisance but does not compromise dissection	2
Minimal bleeding; not a surgical nuisance	1
No bleeding, virtually bloodless field	0

After routine history taking and clinical examination, a blood sample was taken for haemoglobin and hematocrit, coagulation screen, liver function tests, renal function test, random blood glucose, grouping and cross matching. Fitness for general anaesthesia was obtained prior to surgery and one unit of blood was reserved. Three measurements of blood pressure were taken at different time points after admission and the average of these values was used to determine the baseline preoperative blood pressure.

Pre medication comprised pentazocine 30 mg, promethazine 25 mg and glycopyrrolate 0.2 mg. They were given as intramuscular injections 30 min before surgery. Anaesthesia was induced by intravenous thiopentone sodium and succinyl choline. Nasoendotracheal intubation was done. Anaesthesia was maintained with N_2O and O_2 (60:40 ratio) and 0.5% halothane and incremental doses of the muscle relaxants vecuronium bromide, midazolam and fentanyl. Patients were given moderate hypotensive anaesthesia with intravenous nitroglycerin (3–10 μg/kg/min) titrated to maintain a mean arterial pressure (MAP) of 70–75 mmHg until the osteotomy fragments were fixed. The tranexamic acid or placebo was administered intravenously as an initial bolus dosage of 10 mg/kg before the skin incision was made over a period of 20 min, followed by 1 mg/kg intra operatively for every 1 h until the end of the surgery. Ampicillin 1 g, metronidazole 500 mg, dexamethasone 8 mg were given intravenously intra operatively.

Intra operative monitoring consisted of pulse oximetry, electrocardiography and systolic, diastolic and MAP using noninvasive blood pressure monitoring. Blood pressure was measured every 5 min during surgery. Preoperative body weight, haemoglobin concentration, hematocrit, intra operative blood loss, quality of surgical field, duration of surgery, amount of blood or blood products transfused, and complications, if any, were recorded. Haemoglobin concentration and hematocrit were measured again 48 h postoperatively.

The surgeon, who was unaware to which group the patient had been allocated, rated the surgical field every 15 min using the ordinal scale developed by Fromme et al.[9,10] (Table 1). The numerical values reported throughout the surgery were averaged and recorded.

Study variables

The primary predictor variables that would affect the outcome of the study were intra operative patient positioning, anaesthetic techniques, vasoconstrictor use and fixation of osteotomy segments. All the patients were positioned 15° head up and received hypotensive anaesthesia, defined as the anaesthetic technique in which systolic blood pressure was kept under 100 mmHg and MAP below 20–30% of the baseline value for more than 50% of surgery. In all patients, about 5 ml of 2% lignocaine with 1:80,000 adrenalin was infiltrated at the surgical site prior to making the incision. Electrocautery was used in all patients to make the incision. All surgical procedures were performed using standard osteotomy techniques by the same experienced surgical team. All patients received semi rigid internal fixation using miniplates and screws. Surgical procedures were categorized as maxillary, mandibular or bimaxillary. Maxillary procedures included: anterior maxillary osteotomy (Cupar's technique); Le Fort I osteotomy (Bell's technique); and Le Fort I osteotomy with anterior maxillary osteotomy (2 segments). Mandibular procedures included: bilateral sagittal split osteotomy (Epker modification); anterior subapical osteotomy (Hofer); and genioplasty.

The duration of anaesthesia was calculated from induction to extubation and the duration of surgery from incision to the last suture. At the end of fixation, nitroglycerin was slowly reduced, to bring the MAP to normal levels. Haemostasis was checked. Estimated blood loss was calculated by volumetric (difference between volume of fluid in the suction bottle and volume of saline used for irrigation) and gravimetric methods (difference in weight

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between blood soaked gauze and dry gauze). Blood loss up to allowable blood loss was replaced with crystalloid solutions (1:3 ratio). When blood loss was more than the allowable blood loss, it was replaced with blood, but the need to transfuse blood perioperatively was decided by the anaesthesiologist.

Estimated blood volume was calculated as 70 ml/kg for adult patients. Allowable blood loss was calculated using the following formula[11]:

$$\text{Allowable blood loss} = \frac{\text{Estimated blood volume} \times (\text{Preoperative Hb} - \text{Lowest acceptable Hb})}{\text{Average of preoperative and lowest acceptable Hb}}$$

where Hb is haemoglobin.

Data analysis

The sample size to test the difference between two means is (per group) calculated based on the following formula with power calculation of 80%.

$$\text{Sample size } n = \frac{2(Z_\alpha + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{(m_1 - m_2)^2}$$

where Z_α is Z value at α level of significance, $Z_{1-\beta}$ is power of the test, S_1^2 is variance of the sample 1, S_2^2 is variance of the sample 2, m_1 is mean of sample 1 and m_2 is mean of sample 2.

Statistical analysis was performed using Statistical Packages for Social Sciences (SPSS version 16.0) software for windows. The differences in mean values of MAP, estimated blood loss, quality of surgical field and duration of surgery between treatment and control groups were statistically analyzed using independent *t* tests. The difference between mean values of allowable blood loss and estimated blood loss was calculated using the non-parametric Mann–Whitney *U*-test in both groups. Differences were considered statistically significant when $p < 0.05$.

Results

50 consecutive patients undergoing orthognathic procedures who met the inclusion criteria were included in the study. It included 33 female patients and 17 male patients. The male to female ratio was almost 1:2. The two groups were similar with respect to gender, age, weight, preoperative and intra operative MAP and there were no significant differences between the two groups. The preoperative and intra operative data are summarized in Table 2.

The estimated blood loss was significantly less in the study group (166.1 ± 65.49 ml) than the control group (256.4 ± 77.80 ml). Surgical field rating scores were less in the study group (1.33 ± 0.33) than the control group (2.38 ± 0.53). Statistically significant reduction in blood loss and improved quality of surgical field were observed in the study group during single jaw surgery and bimaxillary surgery compared to the control group. The difference in duration of surgery was not statistically significant between the groups. In both groups, the estimated blood loss was less than the allowable blood loss. The difference between allowable blood loss and estimated blood loss was not statistically significant between the groups. None of the patients in either group required blood transfusion, nor did any patient develop thromboembolic or any other drug related complications.

Discussion

Pharmacologic therapies to decrease bleeding and allogenic blood product transfusion are important for medical and economic reasons. A number of drugs including aprotinin, tranexamic acid, epsilon amino caproic acid, desmopressin, prostacycline, dipyridamole, recombinant factor VIIa and erythropoietin have been investigated for reducing intraoperative blood loss.[5] Stewart et al.[12] have found that plasminogen activators released from the oral and nasal mucosa during craniofacial surgery cause excessive local fibrinolysis and perioperative bleeding. Pedersen[13] reported that salivary fibrinolytic activity was an important cause of bleeding from the oral mucosa. They also found that salivary fibrinolytic acitivity had not returned to preoperative normal levels 5 days after oral surgical procedures. In this study, the antifibrinolytic agent tranexamic acid was used as a haemostatic agent.

Tranexamic acid is a synthetic derivative of the amino acid, lysine, which exerts its antifibrinolytic effect through the reversible blockade of lysine binding sites on plasminogen molecules. It competitively inhibits activation of plasminogen thereby reducing conversion of plasminogen to plasmin, an enzyme that degrades fibrin clot, fibrinogen and other plasma proteins including procoagulant factors V, VIII. It is 5–10 times more potent than epsilon amino caproic acid.[6]

In the present study, tranexamic acid was administered intravenously as a 10 mg/kg initial bolus followed by 1 mg/kg/h intra operatively. Various drug regimens have been used in other studies ranging from 10 to 100 mg/kg.[14–17] Andersson et al.[18] observed that tranexamic acid at a therapeutic plasma concentration of 10 μg/ml reduced tissue plasminogen activity by 80%. Horrow et al.[19] and Fiechtner et al.[20] observed that tranexamic acid as a 10 mg/kg/h initial bolus followed by 1 mg/kg/h intra operatively resulted in adequate plasma concentration (>10 μg/ml) to prevent fibrinolysis with relatively stable drug levels throughout the procedure. Larger doses do not provide additional haemostatic benefit.

Despite the reduced intra operative blood loss and improved surgical field in the study group, there was no significant reduction in operating time compared to the control group. Precious et al.[10] and Dolman et al.[21] also showed no reduction in duration of surgery when hypotension was used. One would have assumed that if the surgical field were improved, the operation could be accomplished more quickly. Dolman et al.[21] reasoned on observing videotapes, that the dissection was performed rapidly to get the bleeding under control when it was brisk and when the field was dry, dissection was performed more slowly and duration of surgery increased.

Although statistically insignificant, the difference between allowable and estimated blood loss was slightly higher in the control group despite the increased blood loss. It is attributed to the relatively well built and higher preoperative haemoglobin value in the control group which increased the amount of allowable blood loss in this group. Controlled hypotension, haemostatic agents and other blood conservation methods are particularly important in poorly built and anaemic patients because they cannot tolerate heavy blood loss, which will affect the postoperative outcome of wound healing and infection. The study group showed decreased intra operative bleeding and a clear surgical field, which aided the surgeon in the proper trimming and precise positioning of the osteotomy segments intra operatively rather than having to struggle to achieve haemostasis.

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Table 2. Preoperative and intra operative variables in the two groups of patients.

Variable	Control group (Mean ± SD)	Study group (Mean ± SD)	*p*-value
Age (Years)	24.3 ± 3.7	23.2 ± 4.3	0.337
Sex:			
Male	9	8	0.765
Female	16	17	
Preoperative blood pressure (MAP) (mmHg)	98.4 ± 2.5	97.3 ± 3.1	0.174
Weight (Kg)	53.8 ± 10.6	49.9 ± 12.1	0.231
Total no. of cases	25	25	
Single jaw surgery	7	10	0.370
Double jaw surgery	18	15	
Estimated blood loss (ml)			
Total	256.4 ± 77.80	166.1 ± 65.49	<0.001
Single jaw surgery	200.0 ± 41.55	131.9 ± 58.81	0.019
Double jaw surgery	278.3 ± 78.224	188.9 ± 61.14	0.001
Intra operative MAP (mmHg)			
Total	73.6 ± 2.31	72.9 ± 1.58	0.259
Single jaw surgery	72.7 ± 1.38	72.6 ± 1.43	0.872
Double jaw surgery	73.9 ± 2.54	73.1 ± 1.68	0.333
Duration of surgery (min)			
Total	222.8 ± 72.18	232.8 ± 86.10	0.658
Single jaw surgery	178.6 ± 56.99	180.5 ± 83.38	0.959
Double jaw surgery	240.0 ± 71.36	267.7 ± 70.58	0.274
Surgical field assessment			
Total	2.38 ± 0.53	1.33 ± 0.33	<0.001
Single jaw surgery	2.30 ± 0.61	1.19 ± 0.21	0.002
Double jaw surgery	2.41 ± 0.51	1.43 ± 0.37	<0.001
Difference between estimated and allowable blood loss (ml)			
Total	843.0 ± 565.63	699.7 ± 380.87	0.300
Single jaw surgery	1186.1 ± 585.79	782.5 ± 324.90	0.087
Double jaw surgery	709.6 ± 513.05	644.6 ± 415.53	0.696

There has been speculation about an increased risk of thrombosis in patients receiving tranexamic acid. Intravenous tranexamic acid has also been widely used in cardiothoracic, caesarian section, and orthopaedic procedures such as hip and knee replacements, with no complications, affirming the safety margin.[6,14–17,22] In the present study, none of the patients developed thromboembolic complications. Dose reduction should be considered in patients with renal insufficiency and in high risk patients prone to develop thromboembolic complications.

Various studies have shown that aprotinin is as effective as tranexamic acid in reducing intra operative blood loss.[14,16] Wells[23] reported that anaphylaxis was a major concern with aprotinin, especially after re-exposure. Tranexamic acid is clinically as effective as high dose aprotinin in preventing perioperative bleeding and the need for allogenic transfusion. It is less antigenic and can be given repeatedly. Tranexamic acid prophylaxis costs no more than 2–3 US$ per patient compared to 50 US$ per patient for aprotinin.

In this study, the tranexamic acid group showed a 35% reduction in blood loss compared to the control group. The results correlate with the study by Choi et al.[7], but Stewart et al.[12] reported a 52% reduction in blood loss with aprotinin in orthognathic surgery. There are only limited studies on the effectiveness of antifibrinolytic agents during orthognathic surgery. Further studies with a larger population size are required to assess the effectiveness of various antifibrinolytic agents during orthognathic surgery.

Induced hypotension is thought to contribute to local ischemia, so care was taken when positioning the patient to avoid pressure sores and a flexible nasoendotracheal tube supported with minimum pressure on the nares was used to avoid skin necrosis at the nares or nasal septum. None of the patients developed ischemia related complications.

In this study no patient developed drug or anaesthesia related complications and none required blood transfusion. The advantages of this study are its prospective nature, the use of a single drug (haemostatic agent) in the study group, a well-matched control group and well-defined outcome measures. The gravimetric method was used to measure blood loss, but blood on surgical drapes, gowns and instruments was difficult to quantify accurately. Although a throat pack was placed in every case, a small amount of blood might have been swallowed. The suction bottle contained not only the irrigation fluid and blood, but also saliva and bone powder produced during the osteotomy. All these uncertainties contributed to the inaccuracy of blood loss estimation, although these would apply uniformly to all cases.

In this study, the need for transfusion was assessed by the anaesthesiologist. Available evidence does not support the use of single criterion for transfusion such as haemoglobin concentration <10 mg/dl. No single measure can replace good clinical judgement and accurate monitoring in the perioperative period. The decision to transfuse should take into consideration the level and duration of anaemia, if any, the intravascular volume, the duration of operation and the probability of massive blood loss[24] and the presence of coexisting conditions such as impaired pulmonary function, inadequate cardiac output, myocardial infarction, cerebrovascular event and any other peripheral circulatory disease.[25]

In conclusion, preoperative and intra operative administration of the antifibrinolytic agent, tranexamic acid, is effective in controlling blood loss and improving the quality of the surgical field, but had no significant effect on the incidence of blood transfusion or duration of surgery. Hypotensive anaesthesia with the haemostatic agent, tranexamic acid, is a safe, effective, and economic protocol in reducing blood loss during orthognathic surgery.

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None.

Competing interest

None declared.

Ethical approval

Obtained from Institutional ethical committee, Head of the Department of OMFS and Principal of Ragas Dental College & Hospital.

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