Comparison of intraoperative bleeding and surgical fields with and without tranexamic acid in Functional endoscopic sinus surgery

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Received: 03rd July, 2017 **Accepted:** 12th October, 2017

Abstract

Functional endoscopic sinus surgery (FESS) requires good intraoperative surgical field visualization for better identification of structures. Among the many modalities for improving visibility, antifibrinolytic agent like Tranexamic acid has shown good results in many other surgeries. In this study, we have evaluated the effect of a single bolus dose of 15mg/kg intravenous Tranexamic acid when used as an adjunct.

Materials and Methods: We have studied group T (n=30), who received Inj. Tranexamic acid against group C (n=30) i.e. control group. They were compared for surgical field using Boezaart scale, surgical duration and blood loss. Statistical analysis was done by unpaired t test and chi square test as was appropriate.

Results: T group showed significantly lower values of Boezaart scale score i.e. better visualisation for surgical field ($p<0.001$). Blood loss was also less in T group (103±23.97 ml) as against group C (150±62.33 ml). The duration of surgery was 53.83 ±8.57 minutes in group T and 62.3±11.8 minutes in group C. Both the differences were statistically significant.

Conclusion: We found that Tranexamic acid has a beneficial role in functional endoscopic sinus surgeries by improving the quality of surgical field when used as an adjunct.

Keywords: Tranexamic acid, surgical field, functional endoscopic sinus surgery.

Introduction

Functional endoscopic sinus surgery (FESS) is now increasingly performed for chronic sinusitis not responding to medical treatment and for nasal polyposis. Poor intraoperative surgical field reduces visibility, makes identification of structures difficult and prolongs operative time. At times it may lead to incomplete surgery. Antifibrinolytic agent like Tranexamic acid in various doses and infusions has shown good results for improving surgical field and reducing bleeding in FESS as well as other surgeries like total knee replacement, scoliosis repair etc. In this study we have evaluated the effect of a single bolus dose of 15mg/kg intravenous Tranexamic acid as an adjuvant for improvement of surgical field during FESS.

Materials and Methods

After approval from institutional ethical committee, 60 ASA grades I and II patients aged 18-60 years, posted for functional endoscopic sinus surgery for nasal polyposis were enrolled for the study. A written, valid and informed consent was obtained from all patients. They were randomly assigned to either Tranexamic acid group (T) n=30, or control group (C) n=30. Patients having cardiorespiratory illness, hypertention, asthma, obesity (BMI>30), known coagulopathies, those on anticoagulants, antiplatelets or NSAIDs, those having history of deep vein thrombosis, stroke, ischemic heart disease, peripheral vascular disease, those having active hematuria, those with history of convulsive disorders, patients on oral contraceptives and patients with psychiatric illness were excluded from study.

After thorough preoperative assessment, randomization was done by a random number table. Upon arrival in operation theatre, standard monitors like electrocardiogram (ECG), non invasive blood pressure (NIBP) and pulse oximetry were attached and baseline values of pulse rate and mean arterial pressure were noted. Intravenous line was secured and Ringers lactate solution was started. Premedication was given with Inj. Midazolam 0.03mg/kg and Inj Fentanyl 2mcg/kg iv, Inj. Glycopyrrolate 4mcg/kg and Inj. Ondansetron 4mg intravenously. Patients in group T received inj. Tranexamic acid 15 mg/kg as a slow intravenous bolus and patients with group C received 10ml normal saline by an observer blinded to the contents of the syringes. General anaesthesia was induced with Inj Propofol, in induction dose (till the loss of eyelash reflex) and Inj. Vecuronium 0.1mg/kg was given to facilitate intubation with appropriate sized Portex cuffed entotracheal tube. An end tidal CO2 (ETCO2) monitor was attached to the endotracheal tube and mechanical ventilation was initiated. Throat packing was done with appropriate sized moistened roller gauze. Head up position by 15^0 was given to both the groups. Anesthesia was maintained with O2:N2O (50:50) and Isoflurane titrated to keep the systolic blood pressure between 90-100 mm of Hg and a mean arterial

pressure more than 60 mm of Hg. The surgeon then infiltrated the field with 5-6 ml of 2% Lignocaine with Adrenaline (1:200000).Blood pressure and heart rate were recorded every 15 minutes during the surgery and then immediately after recovery. End tidal co2 was monitored every 15 minutes intraoperatively. The surgeries were performed by same surgical team using the same techniques and instruments. The surgeons who were blinded to the use of Tranexamic acid, assessed the quality of the surgical field at 15, 30, 45 and 60 mins after starting the surgical procedure with a predefined scale adapted from that of Boezaart *et al.* [1] as follows:

0 = No bleeding
1 = Minimal bleeding: Not a surgical nuisance and no suction required
2 = Mild bleeding: Occasional suction required, but does not affect dissection
3 = Moderate bleeding: Slightly compromises surgical field, frequent suction required
4 = Severe bleeding: Significantly compromises surgical field, frequent suction required, bleeding threat field just after removal of suction
5 = Massive bleeding: Prevent dissection.

Blood loss was estimated by weighing sponges and measuring operative suction volume. Upon completion of surgical procedure, nose was packed by surgeons. Anesthetic agents were discontinued and neuromuscular blockade was reversed with Inj. Neostigmine 0.04 mg/kg and Inj. Glycopyrollate 0.01 mg/kg body weight. After meeting the required criteria, oral suctioning and throat pack removal, patients were extubated. Post-operative care was carried out according to usual institutional protocols. Post operatively, patients were monitored for any side effects like nausea, vomiting, hypotention, pruritus, convulsions and hemorrhagic or thrombotic complications for 24 hours. They were observed for any signs or symptoms suggesting any thrombotic complication till their discharge.

Statistical analysis

We have used α=0.05 with a power (1-β) of 0.9 with regards to the study conducted by Eldaba AA et al[2] using the surgical area bleeding score as the main response variable. We have studied 30 patients per group. Continuous data was analysed by unpaired t-test and categorical data by chi square test. A p- value of >0.05% was considered significant.

Results

Demographic parameters of age, sex and weight were comparable in both groups (Table 1). Intraoperative mean arterial blood pressure and ETCO2 were also comparable in both groups (Table 2). Surgical field score is shown in Table 3 as the number of patients from each group having a particular score. The recordings made at 15, 30 and 45 minutes of surgery are shown. There is a clinically as well as statistically significant better score in group T as compared to group C. None of the patients in either group had a score of 5, i.e. massive bleeding preventing any dissection. The intraoperative blood loss and surgical duration are shown in table 4. Both the parameters were significantly less in group T. No post-operative complication like nausea, vomiting, pruritus, convulsions or any thrombotic event was noted.

Table 1: Demographic parameters

Variable	Group T	Group c	P-value
Age (years)	39.03(±8.54)	40.23(±9.7)	0.6019
Weight (kg)	62.1(±6.99)	63.23(±8.54)	0.5771
Sex(males/females)	13/17	15/15	0.6048

Table 2: Intraoperative Mean Arterial Pressure and end tidal CO2

Time	Parameter	Group T	Group C	p-value
Baseline	MAP*(mm Hg)	72.86(±5.07)	74.16(±6.33)	0.3836
After induction	MAP	81.9(±5.62)	82.83(±7.49)	0.588
15mins	MAP	67.16(±3.66)	68.26(±3.49)	0.238
30 mins	MAP	68.46(±3.70)	69.46(±3.3)	0.2738
45 mins	MAP	66.86(±2.83)	68.36(±3.65)	0.0805
After induction	ETCO2#	40.06(±3.61)	39.56(±3.5)	0.5881
15 mins	ETCO2	33.96(±2.3)	33(±2.39)	0.1184
30 mins	ETCO2	31.5(±2.38)	32.03(±2.02)	0.3563
45 mins	ETCO2	31.73(±2.65)	32.66(±2.32)	0.1535

*MAP = mean arterial pressure, # + end tidal CO2.

Table 3: Surgical field score

Score*	15 min		30 min		45 mins	
	Group T	Group C	Group T	Group C	Group T	Group C
1	8	1	6	0	8	2
2	16	9	17	6	18	10
3	6	13	4	16	4	9
4	0	7	3	8	0	9
5	-	-	-	-	-	-
P value	<0.001		<0.001		<0.001	

* = surgical field scale adapted from Boezaart et al.
Data expressed as number of patients in each category.

Table 4: Intraoperative blood loss and duration of surgery

Parameter	Group T	Group C	p-value
Estimated blood Loss(ml)	103.33(±23.97)	150.33(±62.33)	<0.001
Duration of surgery (minutes)	53.83(±8.57)	62.33(±11.8)	0.002

Discussion

Nasal polyposis, chronic rhinosinusitis etc. are the important indications where FESS is increasingly being performed. However different pathologies have different propensities to bleed. We have included cases of nasal polyposis in our study.

Many methods are evaluated to create bloodless field during FESS like reverse Trendelenburg position[3], topical vasoconstrictors,[4] steroids and manipulation of ventilator settings.[3,5] Others like use of hypotensive agents such as beta blockers, magnesium sulphate, clonidine and sodium nitroprusside are also studied.[1,6-10] All our patients were prepared with preoperative steroids and topical vasoconstrictor (Local infiltration with 5-6 ml 2 % lignocaine with adrenaline) was given by surgeons. Intraoperatively we had given a 15^0 head up position to all patients. The two other important factors that affect the quality of surgical field are mean arterial pressure and end tidal CO2. Both these factors were comparable in the two groups. Thus keeping both groups comparable for the above mentioned confounding factors, we have studied the additional benefit of intravenous bolus Tranexamic acid.

Tranexamic acid is a synthetic derivative of amino acid lysine. It inhibits the interaction of plasmiogen and heavy chain of plasmin with lysine residues on the surface of fibrin. Tranexamic acid induced suppression of fibrinolysis leads to reduction in blood levels of D-dimer.[2] The drug has no effects on other coagulation parameters.[11,12.] The drug acts on the initial steps of fibrinolysis. Once the cascade phenomenon is set in, the efficacy of Tranexamic acid markedly decreases. So it is better if given before the incision for maximal effect.[13-15] In our study we have given the drug during premedication, i.e. at least 10-15 minutes before surgical incision was taken.

Blood loss both intraoperative and post operative during FESS is generally not a major consideration the blood loss averaging to less than 400 ml.[16,17] Rather it is the surgical field visualization that is of importance to surgeons. Duration of FESS surgeries is generally less than two hours, so we have given only a single bolus dose. The instruments and microdebriders used by surgeons and the surgical team were similar in both groups.

Authors have used various scales for grading surgical field like Wormald grading scale,[12] Boezaart scale,[1] 10 point visual analogue scale,[18] etc. We have used Boezaart scale as it is easy to use and allows for minimum subjective variation.

Some other studies with some differences in format, have pointed out beneficial effects of Tranexamic acid when given during FESS.[19,16,2] A single bolus dose of 25 mg/kg and 10 mg/kg were used by Eldaba et al[2] nd Khafagy et al[19] respectively. The dose of 15 mg/kg that we have used is in the previously found effective range. In our study, 6 patients in group T had a Boezaart scale score of 3 or more i.e. had moderate to severe bleeding compromising surgical field and requiring suctioning as against 20 patients from group C at 15 minutes. Similarly at 30 minutes, 7 patients from group T and 24 patients from group C had a score of 3 or more. At 45 minutes, the number was 4 and 18 in group T and C group respectively. However no patient in any group had massive bleeding preventing dissection leading to abandoning of procedure. These findings are coherent with that of Eldaba et al,[2] though the doses used by them were higher. Langille et al[17] in their study using bolus as well as infusion of TA, found no improvement in surgical field. Both these studies have included patients having mixed disease types i.e. nasal polyposis as well as chronic sinusitis. Again it is not specified how much

prior to incision was the drug administered. These factors may account for the effect seen in our study at the given dose.

This effect was also reflected in shorter surgical duration in the group receiving Tranexamic acid. There was also a reduced blood loss in Tranexamic acid group (103.33±23.97 ml) as against group C (150.33±62.33 ml). However clinically, blood loss in neither group was significant enough to require blood replacement.

We have followed the patients till discharge and no signs and symptoms suggesting thrombotic complication was noted in them.

Conclusion

We found that when used as an adjunct, Tranexamic acid remarkably improved the surgical field visualization during Functional endoscopic sinus surgery.

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