Research Article

Role of Tranexamic Acid in Intraoperative Blood Loss and Postoperative Edema and Ecchymosis in Primary Elective Rhinoplasty: A Randomized Controlled Trial

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Abstract

Background: Rhinoplasty often involves significant bleeding and postoperative complications. Tranexamic acid (TXA) may reduce these issues. This study evaluates the effect of preoperative TXA on blood loss, surgery duration, and postoperative complications in rhinoplasty patients.

Objective: To compare blood loss during surgery, edema, and ecchymosis after surgery in patients administered with TXA or normal saline undergoing primary elective rhinoplasty.

Methodology: Sixty-eight patients requiring rhinoplasty were included in this randomized control trial (RCT). Thirty-four patients received TXA 20 ml preoperatively (Group-A) while thirty-four received 0.9% normal saline (Group-B). Outcomes between both groups were assessed in terms of surgery duration, intraoperative bleeding, edema, and ecchymosis between both groups.

Results: All the patients completed the study. The mean age in group A was 33.59±9.25 years while 31.21±9.22 years in group B. The duration of surgery in group A turned out to be 103.38±10.37 mins while in group B it was 120±11.31 mins with notably reduced duration of surgery in group A (P = 0.0001). Group A showed notably lower intraoperative blood loss (148.88±30.75) ml as compared to the placebo group which received normal saline (180.44±24.75 ml, P = 0.0001). The incidence of postoperative edema and ecchymosis compared to the placebo group was significantly lower.

Conclusion: Preoperative tranexamic acid lowers postoperative side effects such as edema and ecchymosis and greatly reduces blood loss and shortens surgery duration in patients undergoing rhinoplasty.

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Introduction

Rhinoplasty is one of the foremost aesthetic surgical operations. Conducting a thorough preoperative clinical assessment, which encompasses an examination of Naso-facial proportions and a systematic investigation of the nasal structure, is of paramount importance as the primary stage in achieving a satisfactory outcome in rhinoplasty procedures.[1] Tranexamic Acid (TXA) is a pharmacological agent with antifibrinolytic properties. Its primary mode of action involves the disruption of the coagulation cascade by inhibiting the synthesis of plasmin, hence promoting the stabilization of platelet plaques. This outcome is accomplished through the utilization of a synthetic derivative of the amino acid lysine, which effectively binds and competitively obstructs plasminogen molecules. Consequently, this process successfully impedes the destruction of pre-existing plaques.[2,3]

Numerous therapies have been identified as effective in mitigating eyelid edema and ecchymosis after rhino-

plasty.[4] Tranexamic acid functions as an antifibrinolytic drug by inhibiting the binding of lysine to plasminogen, hence diminishing the localized breakdown of fibrin by plasmin.[5] Several systematic reviews and meta-analyses have been published, providing robust evidence that the use of tranexamic acid is linked to decreased bleeding in various surgical procedures.[6-9] Although tranexamic acid has been used intravenously and orally in surgical procedures, there is a limited body of research specifically investigating the oral administration of this drug in rhinoplasty surgery.[10,11] A study reported the mean intraoperative bleeding in the tranexamic acid group 213+65 mL, and in the normal saline group 254 + 55 mL, ecchymosis was observed in 25% in the normal saline group, and 3.8% in the tranexamic acid group, edema was observed in 29.2% in the normal saline group and 3.8% in tranexamic acid group patients' undergone rhinoplasty.[12]

Mitigating the potential for complications is a paramount necessity in every surgical intervention. Patients who are receiving elective rhinoplasty surgery necessitate a sense of assurance regarding the anticipated results of their procedure, along with a minimized likelihood of experiencing any complications. The current study was conducted to assess the efficacy of tranexamic acid in minimizing difficulties associated with elective rhinoplasty, hence alleviating the associated anxiety and panic experienced by patients. The findings of this study could potentially provide a therapeutic approach that enhances the favorable effects of the process, hence increasing the number of patients who choose this way to improve their health outcomes.

Methodology

A multicentric randomized controlled trial was conducted. Both hospital's ethical board gave its approval before the study could be carried out. The study duration was six months from March, 2023 to September, 2023. The calculation of sample size is performed by using the WHO sample size calculator, keeping the mean intraoperative blood loss in the tranexamic acid group undergone rhinoplasty (213+65 mL) and keeping the mean intraoperative bleeding in the normal saline group undergone rhinoplasty (254 + 55 mL), power 80% and confidence level 95%.[12] A total of 68 patients aged 18 to 50 years undergoing primary elective rhinoplasty for cosmetic or reconstructive purposes were included. Patients were required to provide written informed consent outlining the goal of the study and reassuring them that there were no dangers associated with participating. All included patients met the specific surgical requirements for rhinoplasty. Patients with coagulopathies, hypertensive patients, and diabetes were excluded. Any patient with contradiction to use of TXA were also excluded.

Age, gender, and address were among the demographic details that were noted. The blocked randomization technique was used to evenly split patients undergoing elective rhinoplasty into two groups.

Group A received 20 mL (10 mg/kg) of tranexamic acid intravenously preoperatively, and Group B received normal saline 0.9%. All patients received 750 mg of cefuroxime and 8 mg of Dexamethasone intravenously at induction of anesthesia. Hypotensive anaesthesia was administered and local anaesthesia with the vasoconstricting agent (2% Xylocaine with adrenaline 1:10000) was injected. Standard surgical maneuvers were used to correct the specific requirement of each individual patients.

The procedure was conducted with double blinding to assess intraoperative blood loss, postoperative edema, and ecchymosis. The entire process was supervised by a consultant with at least five years of post-fellowship experience. All patient data were recorded in a pre-made proforma. All the patients were advised Serratiopeptidase as routine post-operative medicine. The duration of surgery was recorded in minute. The amount of bleeding that occurred during the surgery was calculated and recorded in milliliters (mL) using suction canisters and sponges. The amount of blood removed during surgery is determined by subtracting the quantity of irrigation fluid utilized during the surgery from the total amount of fluid collected in the suction canister at the conclusion of the surgery. The volume of blood absorbed by each 4×4 inch gauze during a procedure is computed by multiplying the number of gauze completely saturated with blood by 10 milliliters (an approximate average of blood absorbed per gauze). These two measurements were then combined to calculate the overall intraoperative blood loss. The quantity of blood collected during the operation in the group that received tranexamic acid was compared with that of the control group.[13]

Periorbital ecchymosis and edema were recorded at 48 hours postoperatively. The criterion for assessing periorbital ecchymosis scoring: 0 points indicate no extension; 1 point indicates extension towards the center; 2 points indicate extension up to the pupil; 3 points

indicate extension beyond the pupil; 4 points indicate extension up to the outer corner of the eye.14 for post operative edema around the eyelids scoring: 0 point indicates no presence, 1 indicates a modest amount, 2 indicates coverage up to the iris, 3 indicates reaching the pupil, and 4 indicates a significant amount of swelling with the eyelid closed.[15]

SPSS ver 23 was used for data analysis. The Chi-Square test along with the T-test was applied for the comparison of outcomes. P value was kept at < 0.05 as significant.

Results

The mean age in group A was 33.59±9.25 years while it was 31.21±9.22 years in group B. In group A male patients were 22 (64.7%) while female patients were 12(35.5%). In group B male patients were 20 (58.8%) while females were 14 (41.5%).

The outcomes in our study were assessed in terms of intraoperative blood loss, duration of surgery, edema, and ecchymosis. The duration of surgery in group A turned out to be 103.38±10.37 mins while in group B it was 120±11.31 mins with notably reduced duration of surgery in group A (P = 0.0001). Group A showed notably lower intraoperative blood loss 148.88±30.75 ml as compared to the placebo group which received normal saline 180.44±24.75 ml (P = 0.0001) as shown in Table 1.

Table 1: *Intraoperative bleeding (ml)*

Groups	N	Mean	Std. Deviation	P value
Group A (TXA)	34	148.88	30.758	0.0001
Group B (Normal saline)	34	180.44	24.752	

Regarding the side effects such as ecchymosis and edema, it was observed that the TXA group showed a lower incidence of both side effects as shown in Table 2 and Table 3.

Table 2: *Postoperative Edema*

		Postoperative eyelid edema				Total	P value
		0	1	2	3		
Groups	Group A (TXA)	2	9	14	9	34	0.06
		5.9%	26.5%	41.2%	26.5%	100.0%	
	Group B (Normal saline)	0	2	10	22	34	
		0.0%	5.9%	29.4%	64.7%	100.0%	
Total		2	11	24	31	68	
		2.9%	16.2%	35.3%	45.6%	100.0%	

Table 3: *Postoperative ecchymosis*

		Ecchymosis				Total	P value
		0	1	2	3		
Groups	Group A (TXA)	1	7	18	8	34	0.02
		2.9%	20.6%	52.9%	23.5%	100.0%	
	Group B (Normal saline)	0	2	13	19	34	
		0.0%	5.9%	38.2%	55.9%	100.0%	
Total		1	9	31	27	68	
		1.5%	13.2%	45.6%	39.7%	100.0%	

Discussion

Due to the highly vascular area encountered in rhinoplasty, considerable blood loss may result from the procedure. Reducing the consequent need for blood transfusion is the main objective of most interventions, as blood transfusion can lead to various complications such as blood-borne infections and diseases.[16]

Research indicates that the use of Tranexamic Acid during surgery can significantly lower blood loss during and after the procedure. This finding has been observed in several surgical procedures.[17]

According to many recent meta-analyses, Tranexamic Acid has been shown to effectively reduce intraoperative blood loss.[18-23] Furthermore, TXA reduces bleeding in healthy people following third molar extraction surgery. Oral administration of TXA has a 50% lower gastrointestinal absorption than intravenous administration, and it may be linked to a lower risk of thromboembolic consequences.[24,25]

In our study, we observed a significant decrease in the intraoperative blood loss in the TXA group 148±30.75 ml as compared to the placebo group which received saline solution 180.44±24.75 ml. The results of this study demonstrate that, when compared to a placebo, the administration of 20 ml TXA can dramatically minimize intraoperative blood loss. Our study's outcomes were comparable to those of patients who received 1 g of oral TXA starting two hours before surgery and continuing for five days, undergoing functional endoscopic sinus surgery combined with septoplasty and conchotomy.

This review demonstrated in their analysis of various studies that TXA significantly reduces intraoperative blood loss and post-operative swelling.[26]

Another outcome parameter that we studied was the mean surgery time, the TXA group showed significantly lower mean surgery duration than the placebo group 103.38±10.37 vs 120±11.31 mins (P=0.001). A study found similar results in terms of lower duration of surgery in the TXA group as compared to the placebo

group.[27]

Postoperative ecchymosis and edema are considered to be the most common side effects of rhinoplasty, we observed that the frequencies of both side effects were notably lower in the TXA group as compared to the placebo group. Studies have shown that postoperative edema and ecchymosis were notably reduced in the TXA group.[12,27]

Conflict of interest: none

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Conclusion

We find that preoperative tranexamic acid helps minimize surgical side effects including edema and ecchymosis and dramatically minimizes blood loss in patients undergoing rhinoplasty.

Author's Contribution

The following authors have made significant contributions to the manuscript as under:

Muhammad Raza Tahir: conception and design or analysis and interpretation of the data, actual write-up of manuscript

Farrukh Aslam Khalid: conception and design or analysis and interpretation of the data, actual write up of the manuscript, final approval of the version to be published

Muhammad Amin: interpretation of the data, drafting of the article or critical revision for important intellectual content, critical appraisal of findings with literature search

Maruf Zahid: interpretation of the data, drafting of the article or critical revision for important intellectual content, critical appraisal of findings with literature search

Rida Naeem: interpretation of the data, drafting of the article or critical revision for important intellectual content, critical appraisal of findings with literature search

Hafsa Khalid: drafting of the article or critical revision for important intellectual content, critical appraisal of findings with literature search

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