## **ORIGINAL ARTICLE**

# Compare Mean Blood Loss in Patients Undergoing Tonsillectomy with and without Tranexamic Acid

MUHAMMAD ASIF ASHRAF<sup>1</sup>, ISHFAQ AHMED<sup>2</sup>, SANAULLAH BHATTI<sup>3</sup>, DEEPAK RAI<sup>4</sup>, SARA SAMAD QURESHI<sup>5</sup>, RANA FARRUKH TASLEEM<sup>6</sup>

<sup>1</sup>Senior Registrar, Department of ENT, Bakhtawar Amin Trust and teaching Hospital, Multan

<sup>2</sup>Assistant Professor, Department of ENT, Bilawal Medical HospitalKotri, LUMHS

<sup>3</sup>Assistant professor, Department of ENT, Bakhtawar Amin Trust and teaching Hospital, Multan

<sup>4</sup>Senior registerar, Department of ENT, United medical and dental college Karachi

<sup>5</sup>Senior Registrar, Department of ENT, Bakhtawar Amin Trust and teaching Hospital, Multan

<sup>6</sup>Consultant ENT specialist, MBBS, FCPS, Health Department Multan Punjab Corresponding author: Ishfaq Ahmed, Email: Ishfaqarain37@Yahoo.Com

ABSTRACT

**Introduction:** Tonsillectomy is one of the most common surgeries in ENT department and bleeding is one of the most serious complications related to tonsillectomy. Tranexamic acid is a plasminogen inhibitor which has been successfully used to control bleeding in a variety of surgeries.

**Objective:** The objective of this study is to compare mean blood loss in patients undergoing tonsillectomy with and without Tranexamic acid.

Study Design: Randomized controlled trail

Setting: This study was carried out at the Department of ENT Jinnah Hospital Lahore

Sample Technique: Non-probability, consecutive sampling

Study Duration: The study was done in 6 months after the approval of synopsis [March 8, 2017 till September 8, 2017]

**Materials and Methods:** Sixty Patients were randomly divided into 2 equal groups using lottery method in group-A and group-B. Patients in Group-A received tranexamic acid after induction intravenously as 15 mg/kg (single bolus dose) over 10 min. Patients in group B were served as control group and they did not receive tranexamic acid before tonsillectomy. All surgeries were carried out by a single consultant having more than 5 years of experience after post-graduation. Blood loss was measured by researcher himself as per operational definition.

**Results:** The mean age of cases in Tranexamic group was  $19.70 \pm 12.12$  years while in control group was  $21.53 \pm 15.44$  years. In Tranexamic acid group there were 18(60%) male and 12(40%) female cases while in control group there were 21(70%) male and 9(30%) female cases. The mean blood loss in Tranexamic acid group were  $30.27 \pm 8.85$  ml and in control group was  $67.67 \pm 14.91$  ml. The mean blood loss was significantly less in Tranexamic acid group as compared to control group, p-value < 0.05. **Conclusion:** The mean blood loss in cases with Tranexamic acid were significantly lower as compared to control group. So in future every patient selected for tonsillectomy must be given TXA to reduce the blood transfusion and related complications of the patients.

Keywords: ENT, Tonsillectomy, Bleeding, blood transfusion, Tranexamic acid

#### INTRODUCTION

With a prevalence of 20%-40% of all surgical procedures in otolaryngology [1-2], tonsillectomy is one of the most common surgical procedures performed. Significant morbidity and probable complications are part of the tonsillectomy post-operative course. Researchers and surgeons have been working to improve tonsillectomy techniques throughout the years in an effort to lessen the risk of complications after the procedure. Having your tonsils removed should be a quick, painless, and mostly trouble-free procedure [3]. Hemorrhage is possible during or after a tonsillectomy. Hemorrhage that occurs more than 24 hours following surgery is classified as secondary haemorrhage (more than 24 h after surgery, typically one week postoperative). Blood loss during surgery is managed intraoperatively [1].

Although tranexamic acid (TXA) has been around for more than 40 years, its value as a pharmaceutical tool for minimising blood loss during surgery and after severe trauma has just lately been recognised [4]. Although TXA has a clinical indication for preventing and reducing bleeding following tonsillectomy [4-5], it is not commonly used for this purpose. Epistaxis and posttonsillectomy bleeding account for a sizable fraction of ENT surgeons' morbidity and emergency workload [6].

Blood loss in a recent study across all ages was reported to be 36.6423.76 ml in the study group and 66.3229.59 ml in the control group (notice that they did not report standard deviation along with the mean; we did so using the data they supplied in their paper) [7].

The purpose of this research was to determine if Tranexamic acid had any effect on postoperative bleeding in patients who had had tonsillectomy. Unfortunately, we were only able to locate a single international study that looked at the effectiveness of TXA in reducing blood loss in patients who had undergone tonsillectomy, and they preferred the function of TXA. 7 Tonsillectomy is a common procedure, and significant bleeding is a potential risk, thus this study will help us understand the significance of TXA in our local population undergoing tonsillectomy. The plasminogen inhibitor tranexamic acid has been used effectively to manage blood loss throughout a wide variety of medical procedures. Once we determine whether or not TXA reduces blood loss during tonsillectomy, it will be routinely administered to all patients who qualify for the procedure in an effort to cut down on the number of patients who require a blood transfusion and the difficulties that come with it.

#### MATERIALS AND METHODS

This randomized controlled trial was conducted at Department of ENT Jinnah Hospital Lahore during from the period March 8, 2017 to September 8, 2017. Total 60 patients of either gender with ASA physical status I–II undergoing tonsillectomy due to acute tonsillitis were included. Patient's ages were ranging between 4-45 years. All patients having Hb < 11 at the time of surgery, patients with known history of liver or kidney dysfunction (was assessed on available clinical record) [AST / ALT > 4, IU, urea > 20 mg/dl, creatinine > 1-3 mg/dl], patients with inherited coagulopathy or preoperative use of anticoagulant therapy within 5 days before surgery, allergy to Tranexamic acid, and patients with history of neurologic or psychiatric disease were excluded.

A prior informed consent was obtained from patients and attendants before obtaining information such as their names, ages, prevision C-sections, parities, gestational ages, and contact information. Patients were assigned to one of two groups using a lottery system: group A or group B. Both groups had the same number of members. After the induction, patients in Group-A were given tranexamic acid intravenously at a dose of 15 mg/kg as a single bolus that was administered over a period of 10 minutes. Patients in group B acted as the study's control group; however, they were not given tranexamic acid prior to having their tonsils removed. A single consultant with more than five years of experience after completing their post-graduate training performed all of the surgical procedures. As required by the operational criteria, the researcher personally took the blood loss measurements.

All of the information that was collected and presented in proforma was entered into SPSS version 20 and analysed. For quantitative data such as age, Hb levels, and blood loss, the mean and standard deviation were employed. Calculations were made based on frequency and percentage for qualitative data such as gender. The independent sample t-test was utilised to make comparisons between the two study groups' blood loss. In order to address the effect modifiers, the data were stratified according to age, gender, and duration of sickness. A post-stratification independent sample t-test addressed effect modifiers respectively were both applied. A p-value of less than 0.05 was taken to indicate statistical significance.

#### RESULTS

The mean age of cases in Tranexamic group was 19.70  $\pm$  12.12 years while in control group was 21.53  $\pm$  15.44 years. Table – 1

	able in Beeenpare etalleace et age (Jeale) in bear groupe								
			No.	Mean	S.D	Minimum	Maximum		
	Age (years)	Tranexamic acid	30	19.70	12.12	4.00	41.00		
		Control	30	21.53	15.44	4.00	45.00		
		Total	60	20.62	13.79	4.00	45.00		

Table 1: Descriptive Statistics of age (years) in both groups

In Tranexamic acid group there were 18(60%) male and 12(40%) female cases while in control group there were 21(70%) male and 9(30%) female cases. Table -2

Table 2: Gender distribution in both groups

		Study groups	Total		
		Tranexamic acid	Control	IUlai	
Condor	Male	18(60.0%)	21(70.0%)	39(65.0%)	
Gender	Female	12(40.0%)	9(30.0%)	21(35.0%)	
Total		30(100.0%)	30(100.0%)	60(100.0%)	

The mean Hb in Tranexamic and control group was  $13.08 \pm 1.28$  and  $13.30 \pm 1.16$  mg/ dl respectively. Table -3

Table -3: Descrip	tive Statistics	of Hb in	both groups
-------------------	-----------------	----------	-------------

		No.	Mean	S.D	Minimum	Maximum
	Tranexamic acid	30	13.08	1.28	11.30	15.60
Hb	Control	30	13.30	1.16	11.20	15.60
	Total	60	13.19	1.22	11.20	15.60

The mean blood loss in Tranexamic acid group were 30.27  $\pm$ 8.85 ml and in control group was 67.67  $\pm$  14.91 ml. The mean blood loss was significantly less in Tranexamic acid group as compared to control group, p-value < 0.05. Table -4

Table -4: Descriptive Statistics of blood loss (ml) in both groups

		No.	Mean	S.D	Minimum	Maximum
Blood	Tranexamic acid	30	30.27	8.85	16.00	44.00
loss	Control	30	67.67	14.91	40.00	90.00
	Total	60	48.97	22.44	16.00	90.00

p-value < 0.001

In age group of 4-14 years, the mean blood loss in Tranexamic acid group was  $33.38 \pm 6.58$  ml and in control group was  $65.21 \pm 15.01$ ml. In 15 - 45 years of age group the mean blood loss in Tranexamic acid group was  $27.88 \pm 9.78$  and in control group was  $69.81 \pm 14.96$ . The mean blood loss was significantly lower in Tranexamic acid group as compared to control group in both age groups, p-value < 0.05. Table -5

Table-5: Descriptive Statistics of blood loss (ml) in both groups with respect to age groups

Age groups (years)	Study groups	No.	Mean	S.D	p-value	
4 1 4	Tranexamic acid	13	33.38	6.58	-0.001	
4-14	Control	14	65.21	15.01	<0.001	
45 45	Tranexamic acid	17	27.88	9.78	-0.001	
15-45	Control	16	69.81	14.96	<0.001	

In male cases, the mean blood loss in Tranexamic acid group was  $30.39 \pm 7.95$  ml and in Control group was  $68.76 \pm 14.94$  ml. In female cases the mean blood loss in Tranexamic acid group was  $30.08 \pm 10.44$  ml and in control group was  $65.11 \pm 15.40$  ml. The mean blood loss was significantly lower in Tranexamic acid group as compared to control group in both male and female cases, p-value < 0.05. Table -6

Table-6: Descriptive Statistics of blood loss (ml) in both groups with respect to gender

Gender	Study groups	No.	Mean	S.D	p-value
Mala	Tranexamic acid	18	30.39	7.95	<0.001
Male	Control	21	68.76	14.94	
Female	Tranexamic acid	12	30.08	10.44	-0.001
	Control	9	65.11	15.40	<0.001

In cases with duration of disease < 7 days, the mean blood loss in Tranexamic acid group was  $33.50 \pm 7.26$  ml and in control group was  $71.80 \pm 13.19$  ml. In cases with duration of disease ≥ 7 days the mean blood loss in Tranexamic acid group was  $28.65 \pm 9.30$  ml and in control group was  $65.60 \pm 15.59$  ml. The mean blood loss was significantly lower in Tranexamic acid group as compared to control group regardless of duration of disease, p-value < 0.05. Table -7

Table -7: Descriptive Statistics of blood loss (ml) in both groups with respect to duration of disease

Duration	Study groups	No.	Mean	S.D	p-value
	Tranexamic acid	10	33.50	7.26	0.004
< 7 days	Control	Control 10 71.8		13.19	<0.001
> 7da	Tranexamic acid	20	28.65	9.30	0.004
2 /days	Control	20	65.60	15.59	<0.001

### DISCUSSION

Tonsillitis is an illness that causes inflammation of the tonsils, which are two oval pads of tissue in the back of the throat, one on each side. Infection with a virus or bacteria is a common trigger [8]. Whether or not streptococcal infection is present, 40% of patients will feel better in three days, and 85% will feel well within a week [9]. It is believed that the tonsils aid the immune system by blocking germs from entering the body through the mouth. Inflamed tonsils seem puffy and red, with a coating of yellow or white. There is some evidence that tonsil infections are infectious and can be passed from person to person by saliva or mucous membranes. Common symptoms of tonsillitis include a painful throat, high body temperature, enlarged lymph nodes in the neck, and difficulty swallowing [10].

Common signs and symptoms include a sore throat, red and swollen tonsils, pain when swallowing, high temperature (fever), coughing, headache, fatigue, chills, a general feeling of being unwell (malaise), white pus -filled spots on the tonsils, swollen lymph nodes (glands) in the neck, pain in the ears or neck, weight loss, difficulty ingesting and swallowing meal or liquid intake, and difficulty losing weight. Acute tonsillitis is characterised by a bright red tonsil with white patches or pus streaks on its surface [11]. The removal of the tonsils is a common and efficient surgical treatment that has been around for a very long time. Hemorrhage control is the most crucial aspect of tonsillectomy. Hemorrhage is still the most common and potentially fatal consequence following tonsillectomy. Hemorrhage is a concern after tonsillectomy as well because it can cause airway blockage, shock, and mortality if it is not detected quickly or treated incorrectly [12].

Inhibiting the interaction of plasminogen and the heavy chain of plasmin with lysine residues on the surface of fibrin is how the synthetic lysine derivative tranexamic acid achieves its antifibrinolytic effect. As a result of taking tranexamic acid, D-dimer levels in the blood drop, indicating that fibrinolysis is being inhibited. However, the medication does not change how your blood clots. Several surgical procedures (including caesarean sections and prostatectomy) benefit from the use of tranexamic acid to lessen blood loss [13].

To determine if intraoperative administration of tranexamic acid is effective in preventing blood loss during tonsillectomy, a recent study examined the drug's effects when given before surgery. Fifty individuals who had a tonsillectomy were randomly assigned to one of two groups. Individuals in Group I (the research cohort): tranexamic acid 10 mg/kg intravenously. No injections of tranexamic acid were administered to participants in Group II (the control group). The degree of intraoperative bleeding in each case was measured. There was a statistically significant decrease in bleeding among the study group compared to the control group (p 0.05). None of the expected negative reactions to the medication materialised. In conclusion, a single intravenous dosage of tranexamic acid at 10 mg/kg preoperatively is beneficial in controlling bleeding after tonsillectomy [14].

In current study the mean blood loss in Tranexamic acid group were 30.27 ±8.85 ml and in control group was 67.67 ± 14.91 ml. Similar findings are reported by another study i.e. mean blood loss in the study group was 36.64±23.76 ml, while the mean blood loss in the control group was 66.32 ±29.59 ml (note, they did not report S.D along with mean, we calculated from observations they provided in their article) [7]. Similarly, Soliman et al. conducted another study to assess the effect of tranexamic acid on bleeding in pediatric patients undergoing elective tonsillectomy. This study included 225 patients classified into three groups: (n = 75): Group A: The tranexamic acid was given after induction intravenously as 15 mg/kg over 10 min. Group B: The tranexamic acid was given after induction intravenously as 15 mg/kg over 10 min and continued infusion as 5 mg/kg/h during surgery. Group C (control group): The patients did not receive tranexamic acid. The bleeding was assessed by the extent of blood loss using the Boezaart blood grading scale, measuring blood in the suction jar, and by visual estimation of 4 · 4 gauze pads. The Results indicated that comparison of Boezaart blood grading scale and amount of blood loss was insignificant between the three groups (p > 0.05). Thus, this study showed no effect of tranexamic acid in decreasing the tonsillectomyrelated bleeding and there is no complication related to tranexamic acid [15]. These findings are not in favorable to our statistics.

Also, in 2014, a look back at clinical records from January 2007 to January 2013 showed that 476 children between the ages of 3 and 16 were affected. So, giving a single dose of tranexamic acid intraoperatively to a child after a tonsillectomy might lower the chance of a primary bleed, making it easier for the child to go home the same day as surgery. The results of this observational study show that a large, prospective, multicenter, randomised

controlled trial 100 could be helpful and is needed. In the same way, George at el did a randomised control trial in 2011 to see if preoperative intravenous tranexamic acid worked to stop bleeding after a tonsillectomy. One group got 10 mg kg1 of intravenous tranexamic acid before their tonsillectomy. Patients in the other group were given a fake medicine. In each case, the amount of bleeding was looked at. Less bleeding happened in the study group in a way that was statistically very clear. The drug had no negative effects. This result is the same as what other studies have found for tonsillectomy, other surgeries, and other conditions that cause bleeding. So, this study also found that tranexamic acid given intravenously before surgery at a dose of 10 mg kg1 is effective at stopping bleeding after a tonsillectomy [16].

#### CONCLUSION

The mean blood loos in cases with Tranexamic acid were significantly lower as compared to control group. So in future every patient selected for tonsillectomy must be given TXA to reduce the blood transfusion and related complications of the patients.

#### REFERENCES

- Soliman R, Alshehri A. Assessment of the effect of tranexamic acid on perioperative bleeding in pediatric patients undergoing tonsillectomy. Egyp J Anes 2015;31(4):297-301.
- Faramarzi A, Heydari ST. Prevalence of post-tonsillectomy bleeding as day-case surgery with combination method; cold dissection tonsillectomy and bipolar diathermy hemostasis. Iranian journal of pediatrics 2010;20(2):187-92.
- Ali M, Rafique A, Dastgir M, Rashid M, Maqbool S, Bashir S. Comparison of bipolar electrocautry and cold steel dissection methods for tonsillectomy. Pak Armed Forces Med J 2014;64(1):34-8.
- Perel P, Al-Shahi Salman R, Kawahara T, Morris Z, Prieto-Merino D, Roberts I, et al. CRASH-2 (Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage) intracranial bleeding study: the effect of tranexamic acid in traumatic brain injury--a nested randomised, placebo-controlled trial. Health Technol Assess 2012;16(13):1-54.
- Robb PJ, Thorning G. Perioperative tranexamic acid in day-case paediatric tonsillectomy. Ann Royal Coll Surg Eng 2014;96(2):127-9.
- Robb P. Tranexamic acid–a useful drug in ENT surgery? J Laryngol Otol 2014;128(07):574-9.
- George A, Kumar R, Kumar S, Shetty S. A Randomized Control Trial to Verify the Efficacy of Pre-Operative Intra Venous Tranexamic Acid in the Control of Tonsillectomy Bleeding. Ind J Otolaryngol Head Neck Surg 2011;63(1):20-6.
- 8 Simon HB. Bacterial infections of the upper respiratory tract. Ann Intern Med 2006.
- Teng C, Shajahan Y, Khoo E, Nurjahan I, Leong K, Yap T. The management of upper respiratory tract infections. Med J Malaysia 2001;56(2):260-6.
- Eisenberg M. Rheumatic heart disease in the developing world: prevalence, prevention, and control. Eur Heart J 1993;14(1):122-8.
- Spellerberg B, Brandt C. Streptococcus. Manual of Clinical Microbiology, Eleventh Edition: Am Soc Microbiol; 2015. p. 383-402.
- 12. Macnamara M. Acute and chronic pharyngeal infection. Otolaryngol Head Neck Surg 2008:891-2,024.
- Mayur G, Purvi P, Ashoo G, Pankaj D. Efficacy of tranexamic acid in decreasing blood loss during and after cesarean section: a randomized case controlled prospective study. J Obstet Gynecol India 2007;57(3):227-30.
- Santosh U, Prashanth K, Abhilash S. A Comparative Study to verify the Efficacy of Preoperative Intravenous Tranexamic Acid in Control of Tonsillectomy Bleeding. Int J Otorhinolaryngol Clin 2016;8(1):22-5.
- Soliman R, Alshehri A. Assessment of the effect of tranexamic acid on perioperative bleeding in pediatric patients undergoing tonsillectomy. Egypt J Anaesth 2015;31(4):297-301.
- 16 George A, Kumar R, Kumar S, Shetty S. A randomized control trial to verify the efficacy of pre-operative intra venous tranexamic acid in the control of tonsillectomy bleeding. Indian J Otolaryngol Head Neck Surg 2011;63(1):20-6.