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Case Report

A CASE CONTROL STUDY TO COMPARE THE EFFICACY OF PRE-OPERATIVE INTRAVENOUS TRANEXAMIC ACID IN THE CONTROL OF INTRAOPERATIVE TONSILLECTOMY BLEEDING.

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ABSTRACT

INTRODUCTION

Tonsillectomy is one of the most performed surgeries all over the world. Modern methodologies, use of bipolar scissor dissection, bipolar radio frequency ablation, harmonic scalpel, micro-debrider endoscopic tonsillectomy, laser tonsillectomy, and the like, have revolutionized the tonsillectomy procedure. To compare the efficacy of preoperative intravenous Tranexamic acid in the control of intraoperative tonsillectomy bleeding.

MATERIALS AND METHODS:

This prospective clinical study was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery, Adichunchanagiri Institute of Medical Sciences, B. G. Nagara, Mandya District. The study period was from November 2016 to May 2018. A sample size of a minimum of 107 patients who satisfied the inclusion criteria was included in the study. Dissection tonsillectomy was done in all cases. In the study group, pre-operative intravenous Tranexamic acid will be given in the dosage of 10mg/kg/body weight.

RESULTS:

The most common age group in the study and control group was 11-20 years. In the study group, 30 females (56.6%) and 23 males (43.4%), and in the control group, 33 females (61.1%) and 21 males (38.9%). The grading was done according to Brodsky's grading scale; in the study group, maximum cases (39.6%) had grade 3 tonsillar hypertrophy, and in the control group, maximum cases (31.5%) had grade 2 and grade 3, respectively. Mean intraoperative blood loss was 135.96 ml in the study group and 159.81 ml in the control group. P value was calculated to be <0.001, thus statistically proving significance.

CONCLUSION:

In this study, we have proved the efficacy of pre-operative intravenous use of Tranexamic acid in the control of intra-operative tonsillectomy bleeding with no recorded side effects. No side effects of tranexamic acid were noted during the study. So, it is a safe drug to be used.

KEYWORDS: *Tonsillectomy, Tranexamic acid, post-tonsillectomy hemorrhage; Tonsillar hemorrhage; blood loss; antifibrinolytic drug.*
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INTRODUCTION

Celsus, the first person who reported excision of tonsils, described the technique as "the tonsils are loosened by scraping around them and then torn out". Achievement of haemostasis is done using a mouthwash made of vinegar and a medicated paint on the tonsillar fossa. Later, Altius of Amida (Tigris) explained another technique for tonsillectomy in the sixth century (first half), where a hook snared the tonsil and a knife amputated it. He forewarned of haemorrhage, which turned out to be fatal if excision was too deep.

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Tranexamic acid (trans-4-aminomethyl-cyclohexane carboxylic acid) is a relatively safe antifibrinolytic drug with weak non-competitive inhibition of plasmin at high concentrations. Native human plasminogen contains one lysine binding site with high affinity for tranexamic acid (kd = 1.1µmol-1) and four or five with low affinity (kd = 750 µmol 1-1). The binding of plasminogen and of the heavy chain of plasmin to fibrin monomer is also mediated through the lysine binding sites of plasminogen to specific lysine residues of fibrin;; this interaction is virtually completely blocked by the synthetic antifibrinolytic amino acids. Hence, this study is undertaken to compare the efficacy of pre-operative intravenous use of Tranexamic acid in the control of intraoperative tonsillectomy bleeding.

METHODOLOGY:

This case–control observational study was conducted, and data were collected from the Department of Otorhinolaryngology at Adichunchanagiri Institute of Medical Sciences, Mandya district, during the period from November 2016 to May 2018. All cases admitted and operated for Tonsillectomy during the study period were included in the study. A total of 107 cases were analysed and included in the study.

Inclusion criteria:

1) Patients of age groups (above 4 years and below 50 years) and all sexes.
2) Patients undergoing tonsillectomy for Chronic tonsillitis and Tonsillectomy for any other indications. Exclusion criteria :

1) Patients undergoing adenotonsillectomy,
2) Known allergy to Tranexamic acid,
3) Participation in any other clinical trial,
4) Disturbances of colour vision,
5) Preoperative use of anticoagulant therapy within 5 days of surgery,
6) Fibrinolytic disorders requiring intra-operative anti-fibrinolytic treatment,
7) Haematological diseases (thromboembolic events, haemoglobinopathy, coagulopathy, thrombocytopenia, and haemolytic disease).

Tonsillectomy was performed by the dissection and snare method on both sides. All cases included in the study were randomized in equal proportions into a control group and a study group. In the study group, pre-operative intravenous tranexamic acid was given in the dosage of 10 mg kg-1 body weight, and in the control group, 5cc of plain saline was injected intravenously before surgery. Blinding was achieved as the patient did not know which group he/she were operated on. Statistical analysis was done using mean, standard deviation, frequency, percentage, Chi-square, Unpaired t-test, and graphs. Data entry was done in MS Excel, and analysis was done using IBM SPSS version 22.

ETHICAL CONSIDERATION:

ADICHUNCHANAGIRI INSTITUTE OF MEDICAL SCIENCES, No. AIMS/IEC/1545/2016-2017

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FIG 1. Tonsillectomy is being performed in our operating theatre

FIG 2: INSTRUMENTS

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RESULTS:

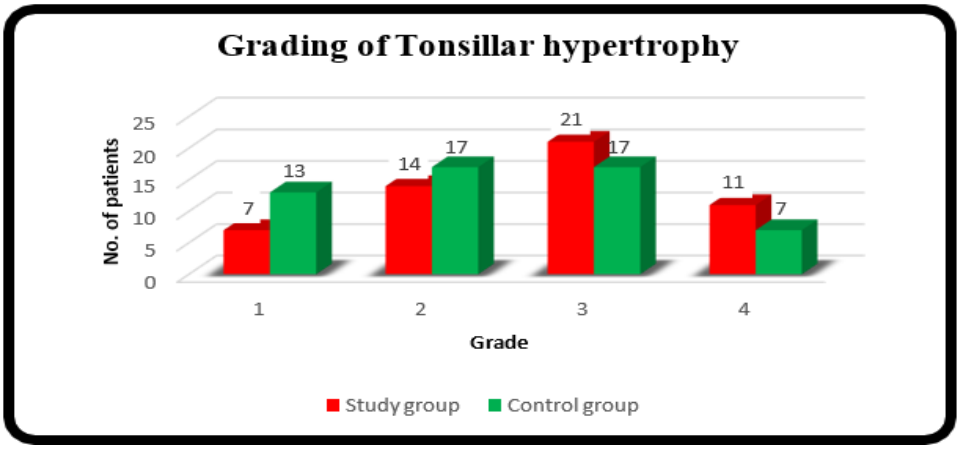
Results have been tabulated below

Grading of tonsillar hypertrophy:

Table 1. Grading of Tonsillar hypertrophy

Grade	No. of patients		Percentage	
	Study	Control	Study	Control
1	7	13	13.3	24
2	14	17	26.4	31.5
3	21	17	39.6	31.5
4	11	7	20.7	13
Total	53	54	100	100

On applying Brodsky's grading scale for tonsillar hypertrophy, in the study group maximum grading was grade 3 in 21 patients, constituting 39.6% of cases, grade 2 followed in around 14 patients, constituting 26.4% of cases. Grade 4 was seen in 11 patients, which constituted 20.7 % of cases. Grade 1 was seen in 7 patients, which constituted 13.3% of the total cases in the study group. In the control group maximum grade was grade 2, and grade 3 had 17 patients, constituting 31.5% of the total cases. Grade 1 followed in around 13 patients, which constituted 24% of cases. Grade 4 was seen in 7 patients, which constituted 13% of the total cases in the control group. In both groups, Grade 0 was not encountered during the duration of the study.



Graph 1. Grading of Tonsillar hypertrophy

Amount of Intraoperative blood loss:

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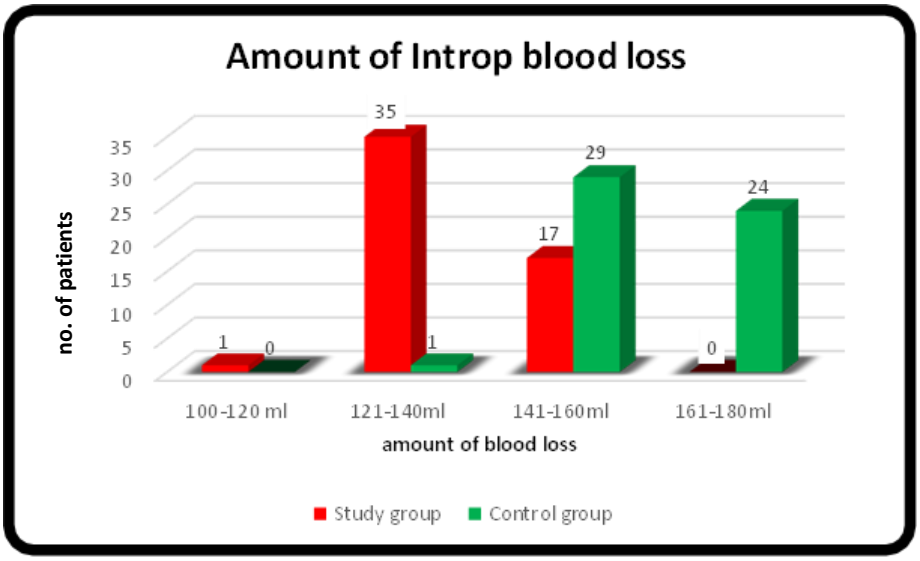
Table 2. Amount of Intraoperative blood loss

Amount of intraoperative blood loss	Study group		Control group	
	No. of patients	**Percent**	**No. of patients**	**Percent**
100-120 ml	1	2	0	0
121-140ml	35	66	1	1.8
141-160ml	17	32	29	53.7
161-180ml	0	0	24	44.5
Total	53	100	54	100



Graph 2. Amount of Intraoperative blood loss

Mean Blood loss:

Blood loss was found to be higher in the control group. On applying the Unpaired t-test (t=-14.855, df=104.242, P value <0.001), the mean amount of intraoperative blood loss between the study group and control group was found to be significant.

TABLE 3: Mean blood loss

Mean amount of Intraoperative blood loss	Study Group	Control Group
	135.96 ml (**SD:8.57**)	159.81ml (**SD:8.02**)

Discussion

Tonsillectomy is an age-old procedure and is one of the basic surgeries done by the otorhinolaryngologists very frequently. The first tonsillectomy was performed in 1000. C., and the surgery gained popularity in the 1900s. Presently, various instruments are available for performing

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this surgery with ease, but the dissection and snare method is still widely followed. The main complication observed during tonsillectomy is haemorrhage, which is the major cause of morbidity and mortality.

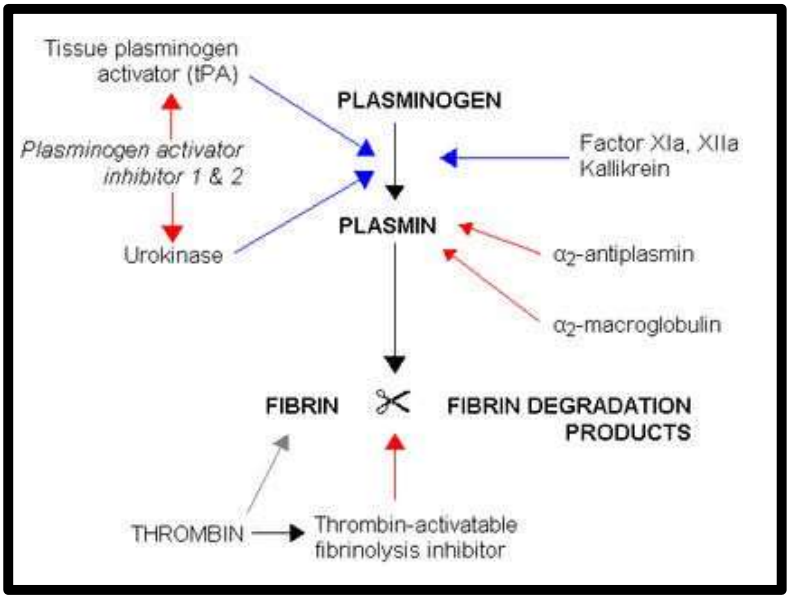

FIG 3. FIBRINOLYSIS (SIMPLIFIED) Blue arrows denote stimulation, and the red arrows' inhibition.

Tranexamic acid (trans-4-aminomethyl-cyclohexane carboxylic acid) is a relatively safe anti-fibrinolytic drug with weak non-competitive inhibition of plasmin at high concentrations. Native human plasminogen contains one lysine binding site with high affinity for tranexamic acid (k =1.1µmol 1^{-1}) and four or five with low affinity (k = 750µmol 1^{-1}). The binding of plasminogen and of the heavy chain of plasmin to fibrin monomer is also mediated through the lysine binding sites of plasminogen to specific lysine residues of fibrin;; this interaction is virtually completely blocked by the synthetic antifibrinolytic amino acids. It is primarily the high-affinity lysine binding site of plasminogen that is involved in its binding to fibrin;; saturation of this binding site with tranexamic acid displaces plasminogen from the fibrin surface. The study aimed to compare the efficacy of preoperative intravenous Tranexamic acid in the control of intraoperative tonsillectomy bleeding.

Age Distribution:

In our study, out of 107 cases, the ages of the patients varied from 5 to 38 years. In the study group, among 53 patients, the majority of the cases, with a frequency of 17 cases, were in the age groups <10, 11-20, and 21-30 years. In the control group, among 54 patients, the majority of the cases were in the 11-20 years age group, with a frequency of 19 cases. This was in accordance with the study done by Ajay George et al, where maximum cases (out of 100 cases, 24 in the study group and 23 in the control group) were encountered between the 11-20 years age group. In a study done by UP Santhosh et al, the majority of cases were in the 10-15-year age group. A study conducted by F Sarkas also had the majority of cases in the same age group, i.e., 11-20 years old. It implies the preponderance of the younger age group towards the disease.

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Table 4. Age Distribution comparison

Authors of the study series	Age group (in years) with the majority of cases	
Ajay George et al	***Study group***	***Control group***
F Sarkas et al	11-20 years	11-20 years
UP Santhosh et al	11-20 years	11-20 years
	10-15 years	10-15 years

Gender Distribution:

In our study, we had 107 case subjects, out of which in the study group (53 cases) 30 were females and 23 males in the study group (54 cases), 33 females and 21 males. The male-to-female ratio was 0.77 and 0.64 in the study group and control group, respectively. This agrees with the sex distribution in the study done by Ajay George et al and F Sarkas et al, where the females in the study group were 27 and in the control group were 21, and the males in the study group were 23 and in the control group were 29.

Table 5. Gender Distribution

Authors of the study series	No. of females		No. of females	
	Study	**Control**	**Study**	**Control**
Ajay George et al.	27	21	23	29
F Sarkas et al	27	21	23	29

Amount of Intraoperative blood loss:

In our study, the mean amount of intraoperative blood loss in the study group was 135.96 ml, and in the control group was 159.81 ml. Thus, the reduction in the intraoperative blood loss in the study group was less compared to the control group. This was in accordance with the study done by Ajay George et al, the mean blood loss in the study group was 36.64ml, and in the control group was 66.32ml. In a study done by UP Santhosh et al, the mean blood loss in the study group was 66.12ml and in the control group was 106.84 ml. A study done by F Sarkas et al, the mean blood loss in the study group was 36.64ml, and in the control group was 66.32ml. This reflected the fact that pre-operative use of Pro coagulants like Tranexamic acid shows a reduction in the intraoperative blood loss and has the advantage of achieving haemostasis faster and decreasing the time taken for the tonsillectomy procedure.

Table 6: Amount of Intraoperative blood loss

Authors of the study series	Mean intraoperative blood loss (ml)	
	Study group	**Control group**
Ajay George et al.	36.64	66.32
UP Santhosh et al.	66.12	106.84
F Sarkas et al.	36.64	66.32

A similar study was done by Castelli G and Vogts E, which included a total of 80 patients randomized equally into the study and control groups, and noticed that a statistically significant reduction of blood loss (28%) was observed in the study group when compared to the control group (44.75%) during the intraoperative period. Though the complication rate was high in both the study and control groups in their study, there was a reduction of blood loss in

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the study group. A study done by PJ Robb and G Thorning, had followed 476 children between the ages of 3 and 16 years who underwent Coblation tonsillectomy after receiving intravenous tranexamic acid at a dose of 10-15 mg/kg, showing a reduction in primary perioperative and postoperative haemorrhage and facilitating day case discharge after tonsillectomy surgery.

Comparison with similar studies done for other surgeries:

Similar studies done for a variety of surgeries have shown the efficacy of tranexamic acid in the reduction of operative bleeding. In these studies, there were no side effects of tranexamic acid reported. **Schott U., Jacobsson A. et al.** A study done in prostatectomy showed a reduction of blood loss (52.94%) after using Tranexamic acid. **Mayur G., Purvi P. et al.** A study done in caesarean section, using Tranexamic acid, showed a reduction of blood loss (43.09%). **Hiippala S., Strid L. et al.** A study done in total knee arthroplasty showed a reduction of blood loss (45.32%). **Aflatoon MA. et al.** A study done in coronary bypass showed a reduction of blood loss (33.00%).

Table 7. Comparison with similar studies done for other surgeries

Study parameters	Schott U., Jacobsson A. et al Prostatectomy	Mayur G., Purvi P. et al. Cesarean section	Hiippala S., Strid L. et al. Total knee arthroplasty	Aflatoon MA. et al. Coronary bypass
Sample size	40	100	28	66
Study/control	20/20	50/50	15/13	33/33
Reduction in Bleeding	52.94%	43.09%	45.32%	33.00%

Comparison with similar studies done for certain haemorrhagic conditions:

Tranexamic acid is not only used for operative procedures but also has been used to reduce bleeding in certain non-operative conditions. In these studies, there was also no side effect of Tranexamic acid reported. **Biggs JC., Hugh TB. et al.** A study done in non-operative conditions, like Upper Gastrointestinal bleeding, showed a reduction of blood loss using Tranexamic acid and was proven using criteria like transfusion requirements, transfusion rates, and surgical intervention rate, as it is not possible to collect blood in upper gastrointestinal bleeding accurately. **Sheila T., Callender et al.** A study done in a condition like menorrhagia showed a 34.05% reduction in blood loss after using Tranexamic acid.

Table 8. Comparison with similar studies done for certain haemorrhagic conditions

Study parameters	Biggs JC., Hugh TB. et al.	Sheila T., Callender et al.
Condition	Upper Gastrointestinal bleeding	Menorrhagia
Sample size	200	32
Study/Control	103/97	16/16
Reduction in bleeding	Bleeding reduction was	34.05%

Studies showing doubtful efficacy of tranexamic acid:

Despite the overwhelming evidence in favour of the efficacy of tranexamic acid in the reduction of tonsillectomy bleeding, there have been studies where tranexamic acid has not proven to be useful. In some studies, tranexamic acid has not reduced operative bleeding. However, even in these studies, Tranexamic acid has reduced post-operative bleeding, hence reducing morbidity. This could be because tranexamic acid may not affect major vessel bleeding and is more effective in controlling capillary oozing. In these studies, there was also no side effect of Tranexamic acid reported. **Erik L., Joanne G., et al.** A study done in a Total

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hip replacement surgery showed a 10.96% reduction in intraoperative blood loss and 56.15% in postoperative blood loss. **Senghore N., Harris M.** A study done in a dental procedure (third molar extraction) showed a 15.93% reduction in intraoperative blood loss and 54.17% in postoperative blood loss.

Table 9: Studies showing doubtful efficacy of tranexamic acid:

Study parameters	**Erik L., Joanne G. et al.**		**Senghore N., Harris M.**	
Surgery	Total Hip replacement		Third molar extraction	
Sample size	39		52	
Study/Control	20/19		26/26	
Reduction in bleeding	**Intra OP**	**Post op**	**Intra OP**	**Post OP**
	10.96%	56.15%	15.93%	54.17%

CONCLUSION

Tonsillectomy is the most common procedure performed in the Otorhinolaryngology department. The procedure has been in practice for more than a century now. Haemorrhage has been the most consistent complication associated with the procedure. Various means to achieve haemostasis are presently in practice, with each method having its own advantages and disadvantages. Tranexamic acid is a plasminogen inhibitor that has been successfully used to control bleeding in a variety of surgeries. In this study, we have proved the efficacy of Pre-operative intravenous use of Tranexamic acid in the control of intra-operative tonsillectomy bleeding with no recorded side effects.

The present study was conducted on 107 subjects who presented to the ENT outpatient department of Adichunchanagiri Institute of Medical Sciences, B.G. Nagara, with chronic tonsillitis from November 2016 to May 2018. The most common age group in the study and control group was 11-20 years. In the study group, 30 females (56.6%) and 23 males (43.4%), and in the control group, 33 females (61.1%) and 21 males (38.9%). The grading was done according to Brodsky's grading scale; in the study group, maximum cases (39.6%) had grade 3 tonsillar hypertrophy, and in the control group, maximum cases (31.5%) had grade 2 and grade 3, respectively. The intraoperative blood loss in the study group was found to be less than 160ml in all cases, while in the control group, around 44.5% cases had more than 160ml blood loss. Mean intraoperative blood loss was 135.96 mL in the study group and 159.81 mL in the control group. P value was calculated to be <0.001, thus statistically proving significance.

Source of funding:

The study had no funding.

Conflict of interest:

The authors declare no conflict of interest.

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