



Efficacy of Tranexamic Acid in reducing intra-operative bleeding during tonsillectomy

Asmatullah Achakzai¹, Muhammad Arif Achakzai¹, Hameed Ullah Achakzai¹

1. Civil Provincial
Teaching Hospital
Quetta, Pakistan

*Correspondence:
asmatullahachakzai@y
ahoo.com

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Significance:

Tonsillectomy is a very commonly performed procedure. During procedure in the department, no one was given tranexamic acid for the control of bleeding whereas, the literature strongly recommends use of such tranexamic acid for bleeding control. This study was planned to examine the effect of tranexamic acid to reduce the blood loss. If blood loss is minimized through the use of tranexamic acid, then it is used in all tonsillectomy cases.

ABSTRACT

Background: Our study aims to determine the effectiveness of tranexamic acid in decreasing the intraoperative blood loss during tonsillectomy.

Materials and Methods: Study design was randomized double-blind control trial. This study was conducted from 1 November 2017 till 30 June 2019 in the department of ENT unit-II, the civil sandeman provincial teaching hospital Quetta. Ethical approval was taken from Ethical Review Board of the civil Sandeman provincial teaching hospital Quetta. A sample of 100 patients were surveyed, 55 men and 45 woman, 10-30 year age range, 1.2:1 men to female with a mean 20 year age. Patients who met the criteria for inclusion experiencing an elective tonsillectomy were randomly assigned to two groups. Every community has equivalent patients. An injection of 10 mg/kg body weight was given intravenously into group-A 5-10 minutes prior to surgery, and normal saline of the same amount was administered intravenously into group-B. Intraoperative bleeding was measured at Operation Theatre in both groups during surgery. In intraoperative blood loss, the effectiveness of tranexamic acid / placebo was determined by measuring loss of blood computed by Gravimetric method and blood obtained in suction jar by measuring.

Results: In Group-A and Group-B patients, there was a significant difference in intra-operative loss of blood during tonsillectomy. In group A, intra-operatively, there was overall blood loss of 1404 ml and the average blood loss was 33ml. During surgery in group-B the blood loss was 3132 ml, and the average loss of blood was 62-64ml. As a result, group B was more intraoperative bleeding and consumed more time compared to group A.

Conclusion: Study group patients receiving preoperative intravenous tranexamic acid have less intraoperative loss of blood and less time consuming

than placebo patients who have not obtained tranexamic acid intravenous.

Introduction

Tonsillectomy is the surgical procedure in which the palatine tonsils are completely removed (1). Reduction of tonsils has also been done since antiquity (derived by, tonsa, Latin for "oar"). It's the most frequently done operation in otorhinolaryngology these days. Beside other indications, the most common indication is recurrent tonsillitis (chronic tonsillitis). It is usually performed above 4 years and below 42 years of age. It is done under general anesthesia. There are different methods of tonsillectomy but the most common one is the dissection and snare method. Each method has their advantages and disadvantages. The most common complication of tonsillectomy is hemorrhage because of its rich blood supply (2). Massive hemorrhage during tonsillectomy is life threatening emergency (3). Hemorrhage after tonsillectomy has a possibility of complications due to obstruction of the airway, trauma and eventually death unless identified early or intra-operatively (4). Thus, most essential part of tonsillectomy after removal is complete control of hemorrhage. Excessive intraoperative hemorrhage may need blood transfusion which further increase the risk of early and late post tonsillectomy morbidity and mortality including increased hospital stay and cost (5,6,7). Intraoperative bleeding also increases morbidity and mortality of patients due to other reasons. Thus it is necessary to avoid the morbidity and mortality due hemorrhage. So, careful homeostasis is required. Early methods for controlling bleeding are pressure and caustic agents, later on ligation by catgut, silk, noosties and packing of tonsillar fossa became popular. Negus forceps control the hemorrhage by homeostasis during tonsillectomy effectively and hemorrhage declines although types of complications remain the same (8). Tranexamic acid results in the reduction in loss of blood during traditional snare and dissection methods (9,10). Antifibrinolytic drugs are being employed which minimize blood loss by inhibiting fibrinolysis and consequently the need for blood transfusion. This further decreases the morbidity and mortality in patients. Aprotinin, Epsilon- Amino caproic acid and tranexamic acid are the anti-fibrinolytic drugs. Tranexamic acid is an alternative for synthetic lysine. It has an antifibrinolytic effect on plasminogen derivatives

through reverse blockage of the lysine binding site. This prevents plasminogen convergent into fibrin plasmin surface (11). This has been accessible since last 40 years and has only recently been developed as a prescription tool for blood loss reduction during surgery (12,13). It is now used worldwide because of its proven role in reducing and prevention of hemorrhage during tonsillectomy (14). It is effective and cheap (15). Intravenous injection of tranexamic acid was used widely (7) and successfully in different surgeries like cardiac, orthopedic, cesarean section and prostate (16). It was also used topically throughout dental and oral surgeries as mouth wash (17). Tranexamic acid has been used initially in patients undergoing adenoidectomy (18). Tranexamic acid has few side effects including headache, dizziness, and vomiting. The rationale of our study is to know the efficacy of intraoperative injection of tranexamic acid in reducing bleeding during tonsillectomy.

Tonsillectomy is a very commonly performed procedure. During the procedure in the department no one was given tranexamic acid for the control of bleeding whereas, the literature strongly recommends use of such tranexamic acid for bleeding control. This study was planned to examine the effect of tranexamic acid to reduce the blood loss. If blood loss is minimized through the use of tranexamic acid, then it can be used in all tonsillectomy cases. Current study aimed to determine the effectiveness of tranexamic acid in decreasing the intraoperative blood loss during tonsillectomy.

Materials and Methods

This double-blind random controlled trial was done from 1 November 2017 till 30 June 2019 in the department of ENT unit-II, Quetta Civil Provincial Teaching Hospital. Ethical approval was taken from Ethical Review Board of the civil Sandeman provincial teaching hospital Quetta. Based on history, clinical examinations, and investigations, 100 patients were diagnosed with recurrent tonsillitis (Chronic Tonsillitis). Consecutive patients having recurrent tonsillitis, aged 10-30 years in which 55 sufferers were men and 45 sufferers were women with such a male-to - female ratio of 1.2:1 were included. Patients underwent elective tonsillectomy by dissection and snare method under general anesthesia. Patients with acute throat infection or infection in other region of body and of any co-morbidity were excluded.

With the help of table of random numbers, all patients were randomly assigned to one of two groups, 50 patients across each group. Tranexamic acid with 10 mg/kg body weight was given intravenously 5-10 minutes prior to commencement of surgery in group-A and the patients receiving 5-10 mg of normal saline were

labeled as group-B. The operator was blinded of the intravenous injection given either tranexamic acid or normal saline according to group allocated. Patients were observed by pulse, blood pressure, respiratory rate and evidence of fresh bleeding during and on completion of surgery and thorough surgical homeostasis were ensured. Blood loss was calculated by gravimetric method and in suction jar. The calorimetric method of measuring blood content in used gauze pieces is a much more correct approach. The gravimetric estimation method was shown to fit well with the calorimetric process and is thus reasonably reliable to be used to measure intraoperative loss of blood (19). In order to measure blood as in suction jar, the amount of fluid in the suction was started pouring into a measuring cylinder and the amount of fluid present even before treatment was subtracted. The lower edge of a liquid level meniscus was considered for readings after the foam had settled. Across all weightings an HMT Company electronic measurement scale with ISI signs has been used. This has a sensitivity of 2 gm, with just low and high capacities of 10 gm and 6 kg. Until keeping on the surgical tray, gauze parts were measured to be used for operation. Post-surgery weighed again all soiled gauze parts and untouched gauze parts and the distinction was taken as the quantity of bleeding with a transformation of 1 gm=1 ml of blood (20). Its amount of blood loss evaluated in Group-A was compared to group-B level of blood loss. Therefore, the effectiveness of tranexamic acid and placebo in terms of the amount of intraoperative blood loss was determined. To test the hypothesis that intraoperative bleeding was less in group-A than in group-B, the frequencies of more or less intra-operative bleeding were calculated. Using SPSS version 20.0 data were entered and analyzed. Mean and standard age deviations were calculated for all patients. The ratio of men to women was determined. Frequencies of sometimes intraoperative bleeding were calculated during tonsillectomy and compared by applying T- test. The p- value was considered significant at 0.05 or less than 0.05.

Results:

Tests of all 100 patients who had undergone dissection and snare process tonsillectomy were done from November 2017 till June 2019. There were 55 patients male and 45 patients had men-to - woman ratio of 1.2:1 with 10-30 years of age and 20 years of average age. Many of the patients have had chronic tonsillitis. Intravenously tranexamic acid of 10 mg/kg body weight was administered to 50 group-A patients 5-10 minutes before start of surgery and normal saline of same amount was administered intravenously to the next 50

group-B patients. Intraoperative bleeding was significantly different between group-A (research group) and group-B (placebo).

In group-A there was total blood loss of 1404 ml intra-operatively and mean blood loss was 33.08 ml. In group-B patient there was total blood loss of 3132 ml during surgery and mean blood loss was 62.64 ml. This shows that the intra-operative blood loss was 44.8% less in group-A patient. Group-A patients also take less time for surgery.

Frequencies of more or reduction of intraoperative blood loss throughout tonsillectomy were compared in both groups through the application of t-test. The obtained p-value has been less than 0.05. Thus, intraoperative bleeding was less in group-A Patients who has received tranexamic acid injection intra-operatively as compare to group-B patients which has received the same amount of normal saline.

Table 1: In group-A and group-B patients with p-value shows total and mean blood loss

GROUP	TOTAL BLOOD LOSS	MEAN BLOOD LOSS	P value
Study group	1404ml	33.05ml	0.32
Controlled group	3132ml	62.64ml	2362

Study Group: 1404 ml p-value (right-tailed) = 0.32, p-value (two-tailed) = ± 0.49

Controlled Group: 3132 ml p-value (right-tailed) = 0.32, p-value (two-tailed) = ± 0.49

Discussion

Tonsillectomy remains one of the basic surgical procedures in otorhinolaryngology. The problems encountered during surgical procedure remained the same, however, the tranexamic acid has been widely used in a number of other procedures to minimize bleeding, demonstrating its effectiveness in reducing surgical bleeding. Such include prostatectomy (21) (a 52.94 per cent reduction in bleeding during surgery); caesarean section (22-23) (Showed reduction of 43.08% of bleeding during surgery), orthopedic surgery (24-25) (Showed reduction of 39.8% of bleeding during surgery) and cardiac surgery (26-27) (showed reduction of 45.32% of bleeding during surgery).

Castelli and Vogt, in their study, noted a 28 per cent (10) reduction in blood loss. Review study of older studies to tonsillectomies on the use of tranexamic acid demonstrated a significant loss of blood (28).

These all studies and numbers demonstrated the effectiveness of tranexamic acid throughout surgery in lowering intraoperative blood loss. In our study, the rate of bleeding reduction during tonsillectomy was 45.8% near George A, Kumar R's study and Kumar S showing

44.45 per cent reduction in intraoperative blood loss in patients receiving tranexamic acid intramuscular injections (29). No side effect of the tranexamic acid was mentioned in studies. In addition to surgery, tranexamic acid was also used with great success to reduce bleeding in non-operative certain situations, including epistaxis, topmost GIT bleeding, and menorrhagia, that also showed significant decrease in bleeding through the use of tranexamic acid. In spite of the enormous evidence in support of tranexamic acid success in preventing bleeding throughout tonsillectomy, studies have been conducted in which tranexamic acid has not proved to be useful, this could be due to tranexamic acid which may not have an effect on blood vessels bleeding and is more successful in managing capillary oozing(29). That's why in certain patients who underwent, in spite of giving tranexamic acid intra-operative intravenous injection does not reduce intra-operative bleeding.

Conclusion

Tonsillectomy is the basic and usual procedure of ENT surgery. Blood loss due to tonsillectomy still remains a significant cause of morbidity and mortality, despite advances in tools and techniques. Procoagulants like tranexamic acid have been used successfully in controlling intra-operative bleeding during tonsillectomy. This reduction in bleeding further decreases the need of blood transfusion and consequently the early and late morbidity and mortality of patient, without any side effect. Patients of group-A (study group) receiving intravenous tranexamic acid also take less time for surgery.

Conflict of interest: Authors do not have any conflict of interest to declare.

Disclosure: None

Human/Animal Rights: No human or animal rights are violated during this study.

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