A Comparative Study to verify the Efficacy of Preoperative Intravenous Tranexamic Acid in Control of Tonsillectomy Bleeding

UP Santosh, KB Prashanth, Abhilash

ABSTRACT

Objectives: This study was conducted to assess the efficacy of the drug tranexamic acid administered preoperatively in controlling the bleeding during tonsillectomy intraoperatively.

Materials and methods: A total of 50 patients who underwent tonsillectomy were randomized into two groups. Group I (study group): Intravenous tranexamic acid was given with dose of 10 mg/kg. Group II (control group): Tranexamic acid injection was not given. Intraoperative amount of bleeding was assessed in each case.

Results: The study group had significant reduction in bleeding and the p-value was <0.05, which was statistically significant, when compared to control group. There were no side effects of the drug observed.

Conclusion: Single intravenous dose of tranexamic acid at a dose of 10 mg/kg preoperatively is effective in control of tonsillectomy bleeding.

Keywords: Bleeding, Tonsillectomy, Tranexamic acid.

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INTRODUCTION

Tonsillectomy is an effective surgical procedure when there is an appropriate indication and it is an age-old surgery which is still practiced today. Control of hemorrhage is the most important part of tonsillectomy surgery. Even today the deadliest complication of tonsillectomy in some patients is hemorrhage and is a life-threatening complication. Post tonsillectomy too, hemorrhage becomes a risk due to airway obstruction, shock, and ultimately death, if not diagnosed early or inappropriately treated.1

Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts its antifibrinolytic effect through the reversible blockade of lysine binding sites on plasminogen molecules and thereby inhibiting the interaction of plasminogen and the heavy chain of plasmin with lysine residues on the surface of fibrin. Suppression of fibrinolysis by tranexamic acid is manifested by reduction in blood levels of D-dimer. However, the drug has no effect on blood coagulation parameters.2,3 Tranexamic acid is used successfully in various surgical procedures to reduce the amount of bleeding (e.g. cesarean section,4,5 prostatectomy6). In this study, we assessed the efficacy of tranexamic acid in reducing tonsillectomy bleeding intraoperatively.

MATERIALS AND METHODS

A total of 50 patients who underwent tonsillectomy at Chigateri district hospital and Bapuji teaching hospital attached to JJM Medical College, Davangere from July 2014 to July 2015 were included in this study, after taking informed consent and required clearance from the ethical committee.

Inclusion Criteria

All patients of chronic tonsillitis satisfying “PARADISE CRITERIA” for tonsillectomy were included in our study.

Exclusion Criteria

- Patients undergoing adenotonsillectomy
- Known allergy to the tranexamic acid drug
- Participation in any other clinical trial
- Preoperative use of anticoagulant therapy within 5 days of surgery
- Fibrinolytic disorders requiring intraoperative anti-fibrinolytic treatment
- Hematological diseases (thromboembolic events, coagulopathy, and hemolytic disease).

Out of 50 patients in our study, 25 patients (study group) were given preoperative intravenous tranexamic acid of doses 10 mg/kg/BW, 3 to 4 hours before surgery. Another 25 patients who were kept as a control group were not given intravenous tranexamic acid preoperatively.

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To maintain uniformity of the study, tonsillectomy was performed under general anesthesia with dissection and snare method, and the same surgeon operated on all 50 patients.

Blood loss was calculated by gravimetric method and by measuring the blood collected in the suction jar. Though the colorimetric method is the more correct method of measuring blood content in the used gauze pieces, it has been proven that the gravimetric method of estimation correlates well with the colorimetric method and hence is accurate enough to be used to evaluate intra-operative blood loss. For measuring blood in the suction jar, the fluid in the suction jar was poured into a measuring cylinder. The lower edge of the fluid meniscus after the foam had settled was considered for the readings. The suction jar is emptied completely before the procedure in all the cases. An electronic weighing scale of HMT Company with ISI mark was used for all the weighings. It had a sensitivity of 0.1 to 500 gm respectively. Gauze pieces and the swabs to be used for the surgery were weighed before keeping on the surgery tray under strict aseptic precautions. Postsurgery all soiled gauze pieces and swabs were weighed again and the difference was taken as the amount of bleeding with the conversion of 1 m = 1 mL of blood. All observations were collected, documented, tabulated, and analyzed. Tests of statistical significance were applied and the results were arrived at.

**OBSERVATION AND RESULTS**

A total of 50 patients of chronic tonsillitis undergoing tonsillectomy in Chigatiyer District Hospital and Bapuji Teaching Hospital attached to JMJ Medical College, Davangere, during the period of July 2014 to July 2015 were included in the study. Patients were selected on random basis. All the patients underwent conventional dissection and snare method of tonsillectomy.

In our study, most of the patients undergoing tonsillectomy are seen in the age group of 10 to 15 years. The mean age group is 13.5 to 14.5 years. There is no significant difference noted with regards to sex distribution, who are undergoing tonsillectomy.

### Table 1:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>n</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Statistical analysis</th>
<th>Unpaired t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood loss</td>
<td>Study group</td>
<td>25</td>
<td>66.12</td>
<td>40.95</td>
<td>2.65, p&lt;0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>25</td>
<td>106.84</td>
<td>64.72</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean blood loss in the study group is 66.12 mL and in the control group is 106.84 mL. On applying unpaired t-test, we got a value of 2.65, suggesting a p-value of <0.05. Thus, the reduction in bleeding due to studied drug is statistically highly significant. There were no complications observed in both the study and control groups. There were no adverse effects of tranexamic acid in any of the cases in the study.

### DISCUSSION

Tonsillectomy is an age-old procedure and is one of the basic surgery done by the otolaryngologists very frequently. Even though it is a simple procedure, the complications associated with it are quiet high. The main complication observed during tonsillectomy is hemorrhage, which is one of the major cause of morbidity and mortality. It is against this backdrop that made us to conduct this study.

During tonsillectomy bleeding occurs, resulting in hemodilution and initiation of both coagulation system and fibrinolytic system by releasing tissue plasminogen activator. Plasminogen is a single-chain serine protease characterized by an active site and five kringle domains, four of which bind to lysine residues in interacting molecules. Physiological activators of plasminogen are the two serine proteases: Tissue plasminogen activator and urinary plasminogen activator. Tranexamic acid acts by reversibly blocking the lysine binding sites of plasminogen, thus preventing its activation to plasmin and therefore stopping the lysis of polymerized fibrin resulting in control of bleeding during tonsillectomy surgery.

Various surgeries are done with a usage of intravenous tranexamic acid to know the efficacy of the drug as well as reduction in bleeding during intraoperative period. But the studies undertaken in assessing the efficacy and
the reduction of tonsillectomy bleeding are very minimal, which made us to conduct this study.

The study done in prostatectomy showed a reduction of 52.94% with tranexamic acid. In orthopedic and cardiac surgeries, like total knee arthroplasty and coronary bypass, also tranexamic acid caused a reduction of 45.32 and 39.81% respectively. In endoscopic sinus surgery in children, done by Eldaba, it has been shown that single intravenous bolus dose of tranexamic acid improves quality of surgical field and reduces duration of surgery and intraoperative bleeding. In all these studies, no side effect of tranexamic acid is reported.

Besides surgeries, tranexamic acid is used to control bleeding in certain nonoperative conditions with a lot of success, such as controlling upper gastrointestinal bleeding and menorrhagia. Many studies have been undertaken in assessing the efficiency of the drug in nonoperative conditions also.

In this study, the efficacy of administering preoperative intravenous tranexamic acid in reducing tonsillectomy bleeding during intraoperative was examined. There was a significant decrease in the volume of bleeding observed in the study group when compared to the control group.

The dose of tranexamic acid used in the present study was within the dose range previously found effective. It has been proposed that therapeutic plasma concentration of tranexamic acid is 5 to 10 mg/L and is maintained for approximately 3 hours. Considering the relative short duration of tonsillectomy procedure, we assumed that a single intravenous bolus dose of tranexamic acid 10 mg/kg/BW would fulfil the goal.

Tranexamic acid by its antifibrinolytic property inhibits the breakdown of clot formed around the oozing capillaries and small blood vessels and thus prevents intraoperative and postoperative hemorrhages. Usually, the formed clots naturally resolves on its own without hampering the vascular retraction and the tranexamic acid might act on the smooth muscle cells of the capillaries and small blood vessels causing contraction and retraction and helps in arresting of bleeding. In our study, none of the cases had any complications of large clot formation or dispersal of clot.

Tranexamic acid is a plasminogen inhibitor which has been successfully used to control bleeding intraoperatively. A similar study is done by Castelli and Vogts that 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 groups when compared to control groups during intraoperative period. Later bleedings occurred only in 27.5% (control: 67.5%) and stopped after 2 hours (mean of control: 5.6 hours), though complication rate was high both in study and control groups in their study.

Even though tranexamic acid is used to reduce the intraoperative bleeding, there have been two studies which showed tranexamic acid has not proven to be useful for two surgeries, i.e., total hip replacement by Lemay et al and third molar extraction by Senghore and Harris. This could be because tranexamic acid may not be having effect on major vessel bleeding and is more effective in controlling capillary and small blood vessels oozing. Here too no side effects of the particular drug exist.

CONCLUSION

We conclude that tranexamic acid if administered preoperatively in tonsillectomies is highly effective in reducing/controlling the intraoperative bleeding. However, further studies are required with a large sample size.

REFERENCES


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