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ORIGINAL RESEARCH

Combination of Intravenous and Topical Tranexamic Acid in Decreasing Intra-operative Haemorrhage in Transurethral Resection of Prostate: A Randomized Controlled Trial

Disha R Lathe[1], Navdeep Kaur[1], Manisha Singh M S[1], Yatish B[1]

[1]Department of Anaesthesia, M S Ramaiah Medical College and Hospital, Bengaluru, Karnataka, India

*Corresponding author: Dr. Yatish B E-mail: yatishseeni@yahoo.co.in

https://orcid.org/0000-0003-2637-1160

ABSTRACT

Background and Objectives: Transurethral resection of the prostate (TURP) continues to be the gold-standard surgical procedure for managing benign prostatic hyperplasia (BPH). However, significant intraoperative bleeding, attributed to the prostate's rich vascular supply, continues to pose challenges. Tranexamic acid (TXA), an antifibrinolytic agent, has shown promise in minimizing surgical blood loss. This study focused on assessing the efficacy and safety of combined intravenous and topical TXA administration in reducing intraoperative hemorrhage during TURP.

Methodology: A randomized controlled trial was conducted involving 80 eligible male patients undergoing TURP. Participants were randomly allocated into two groups: the intervention group received both intravenous and topical TXA, while the control group received no TXA. Intraoperative blood loss was evaluated by measuring changes in hemoglobin levels. Secondary outcomes included volume of irrigation fluid used, operative duration, and adverse events such as deep vein thrombosis or thromboembolism. Patients were followed for 24 hours postoperatively. Statistical analysis was performed using t-tests and chi-square tests, with $p < 0.05$ considered significant.

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Results: Baseline characteristics were comparable between groups. Patients in the TXA group had a significantly lower postoperative hemoglobin drop (−5.57% vs. −7.77%, p = 0.0013) and reduced estimated blood loss (290 mL vs. 400 mL, p < 0.001) compared to the control group. No significant difference in adverse events was observed between the two groups.

Conclusion: Combined intravenous and topical tranexamic acid significantly reduces intraoperative blood loss and postoperative hemoglobin drop during TURP without increasing the risk of adverse events. These results support the use of TXA as a safe and effective hemostatic adjunct in TURP.

Keywords: Tranexamic acid, TURP, benign prostatic hyperplasia, randomized controlled trial, intraoperative bleeding, prostate surgery.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common condition in aging men, frequently leading to lower urinary tract symptoms, including frequency, urgency, nocturia, and urinary retention. Transurethral resection of the prostate (TURP) continues to be the gold-standard surgical treatment for BPH, providing substantial symptomatic relief. However, TURP is commonly associated with considerable intraoperative bleeding due to the prostate's rich vascularity. Excessive blood loss during the procedure can prolong operative time, increase the need for transfusions, and lead to postoperative complications, thereby affecting patient outcomes and increasing healthcare costs.[1]

Various techniques and pharmacological agents have been explored to minimize bleeding during TURP. Among them, tranexamic acid (TXA), a synthetic antifibrinolytic agent, has shown promise across multiple surgical specialties because it inhibits fibrinolysis and stabilises clot formation.[2,3] TXA has been effectively used in orthopedic, cardiac, and trauma surgeries to reduce blood loss and transfusion requirements. In urological procedures, particularly TURP, the data on TXA use remain limited and inconsistent.[4] Some studies have demonstrated reduced intraoperative bleeding and improved outcomes with TXA, while others have not shown significant benefit. These discrepancies may be due to differences in study design, route and timing of administration, or patient characteristics. Moreover, the efficacy of combining both intravenous and topical routes of TXA administration during TURP has not been adequately investigated in a randomized controlled trial setting.[5,6]

We hypothesize that combining intravenous and topical tranexamic acid significantly reduces intraoperative blood loss in patients undergoing TURP without increasing the risk of postoperative complications. This dual-route approach may provide both systemic and localized hemostatic effects, enhancing the overall efficacy of TXA.

The primary objective of this study is to evaluate the efficacy of combined intravenous and topical tranexamic acid in mitigating intraoperative blood loss in comparison to normal saline. The secondary objective is to evaluate the safety of TXA by comparing the incidence of postoperative complications—such as thromboembolic events and renal dysfunction—between the TXA and control groups.

MATERIALS AND METHODS

The study protocol was reviewed and approved by the Institutional Ethics Committee of M S Ramaiah Medical College and Hospital (Approval No.: [MSRMC/EC/PG-80/04-2023]. Prior to enrollment, all participants signed written informed consent forms. The study was registered prospectively with the Clinical Trial Registry of India (CTRI) under registration number [CTRI/2023/09/058097].

This randomized controlled trial was carried out in the Department of Anaesthesiology at M S Ramaiah Medical College between June 2023 and February 2025. A total of 80 male patients, 40 in each group, undergoing transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH) were enrolled in the study.

Male patients aged 50–80 years, belonging to ASA physical status I–III, diagnosed with BPH, scheduled for TURP, and willing to participate with informed consent were included in the study. Patients with known allergy to tranexamic acid, history of thromboembolic events, severe hepatic or renal dysfunction, coagulopathy or use of anticoagulants, and previous prostate surgery were excluded.

Patients were randomized using a computer-generated sequence into two groups: Group A (40) received both intravenous and topical tranexamic acid, and Group B (40) received a placebo. Allocation concealment was ensured using sealed opaque envelopes. All surgeries were performed by the same surgical team under spinal anesthesia, following a standardized TURP protocol. The intervention was administered as follows: 500 mg IV over 5 minutes before spinal anesthesia, plus an additional 500 mg added to each 2-liter irrigation fluid bottle, up to a maximum dose of 2 g. Intraoperative blood loss, operative time, and hemodynamic parameters were recorded.

All data were recorded in pre-designed case report forms and later transferred to a secure digital database. Each patient was assigned a unique study code to maintain confidentiality. Data were verified for completeness and accuracy by an independent reviewer prior to statistical analysis.

Statistical analyses were performed using [e.g., SPSS Statistics, version 22; IBM Corp., Armonk, NY, USA]. Continuous variables were expressed as mean ± standard deviation (SD). The normality of data distribution was assessed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Comparisons of continuous variables between groups were performed using Student's t-test for normally distributed data. Categorical variables were presented as frequencies or percentages and compared using the Chi-square test or Fisher's exact test, as appropriate. A $p< 0.05$ was considered statistically significant.

RESULTS

The demographic characteristics, including age, weight, BMI, and gender distribution, were comparable between the two groups. Although Group 1 had a slightly taller mean height (158.62 cm vs. 155.60 cm), this was the only statistically significant difference ($p = 0.009$); all other parameters showed no significant variation.

Baseline ASA grading and intraoperative characteristics were comparable between the two groups. The majority of patients were classified as ASA Grade II (55.0% in Group 1 and 60.0% in Group 2), with no significant differences across ASA classes ($p = 0.220$). Mean prostate volumes were nearly identical

Table 1: Demographic Data

Parameter	Group 1 (n=40)	Group 2 (n=40)	*p*-value
*Age (years)	68.20 ± 8.34	69.80 ± 8.02	0.385
*Weight (kg)	70.65 ± 7.53	68.33 ± 8.47	0.198
*Height (cm)	158.62 ± 5.42	155.60 ± 4.59	0.009
*BMI (kg/m²)	28.17 ± 3.55	28.29 ± 4.00	0.884
Age <50 yrs. (%)	3 (7.5%)	2 (5.0%)	
Age 51–60 yrs. (%)	4 (10.0%)	4 (10.0%)	
Age 61–70 yrs. (%)	14 (35.0%)	13 (32.5%)	
Age 71–80 yrs. (%)	19 (47.5%)	21 (52.5%)	0.337

Data presented as mean ± standard deviation unless otherwise indicated. P < 0.05 considered statistically significant.*

Table 2: ASA Grading and intraoperative characteristics of the two groups

Parameter	Group 1 (n=40)	Group 2 (n=40)	*p*-value
ASA Grade I (%)	5 (12.5%)	9 (22.5%)	
ASA Grade II (%)	22 (55.0%)	24 (60.0%)	
ASA Grade III (%)	13 (32.5%)	7 (17.5%)	0.220
*Prostate volume (cc)	41.78 ± 15.15	41.23 ± 13.12	0.863
Anaesthesia - Spinal	40 (100%)	39 (97.5%)	
Anaesthesia - CSEA	0 (0%)	1 (2.5%)	0.314
*Irrigation Fluid Used (L)	24.10 ± 7.41	25.70 ± 9.82	0.413
*Total Resection Time (min)	45.38 ± 16.37	41.72 ± 13.36	0.278

*Values are presented as *mean ± standard deviation or percentages (%). P < 0.05 considered statistically significant.*

(41.78 ± 15.15 cc in Group 1 vs. 41.23 ± 13.12 cc in Group 2; p = 0.863). Spinal anaesthesia was used in almost all patients in both groups (100% in Group 1 and 97.5% in Group 2), while CSEA was used in only one subject in Group 2 (p = 0.314). Mean irrigation fluid volumes were slightly higher in Group 2 (25.70 ± 9.82 L) than in Group 1 (24.10 ± 7.41 L), but the difference was not significant (p = 0.413). Similarly, mean resection time was longer in

Table 3: Perioperative Hemoglobin and Blood Loss Parameters Between the Two Groups

Parameter	Group 1 (n=40)	Group 2 (n=40)	*p*-value
*Preop Hb (g/dL)	12.73 ± 1.96	12.87 ± 1.73	0.735
*24H Postop Hb (g/dL)	12.03 ± 1.90	11.87 ± 1.65	0.04
Intra-group Hb Change (p-value)	<0.001	<0.001	
*Change in Hb	-5.57 ± 2.78	-7.77 ± 3.14	0.0013
*Calculated Blood Loss (mL)	290.00 ± 98.75	400.00 ± 137.74	<0.001

*Values presented as *mean ± standard deviation. P < 0.05 considered statistically significant. Hb - Haemoglobin.*

Group 1 (45.38 ± 16.37 minutes) than in Group 2 (41.72 ± 13.36 minutes), but the difference was not statistically significant (p = 0.278).

Perioperative hemoglobin trends and blood loss differed significantly between the two study groups. In Group 1, the mean preoperative hemoglobin (Hb) was 12.73 ± 1.96 g/dL, decreasing significantly to 12.03 ± 1.90 g/dL at 24 hours postoperatively (p< 0.001). Group 2 showed a similar drop from 12.87 ± 1.73 g/dL to 11.87 ± 1.65 g/dL (p < 0.001). Postoperative Hb was significantly lower in Group 2 than in Group 1 (p = 0.04). The percentage change in Hb was also more pronounced in Group 2 (-7.77 ± 3.14%) versus Group 1 (-5.57 ± 2.78%; p = 0.0013). Additionally, calculated blood loss was significantly higher in Group 2 (400.00 ± 137.74 mL) than in Group 1 (290.00 ± 98.75 mL; p < 0.001), suggesting better haemoglobin preservation and reduced blood loss in Group 1.

DISCUSSION

This randomized controlled trial assessed the efficacy and safety of combined intravenous and topical tranexamic acid (TXA) in reducing intraoperative blood loss during transurethral resection of the prostate (TURP). The findings support the hypothesis that TXA, when used via both systemic and topical routes, significantly reduces perioperative bleeding and preserves hemoglobin levels, without increasing the risk of adverse events.

The use of TXA in surgical bleeding management is well established in orthopedics, cardiac surgery, and, more recently, urological procedures.[7,8,9,10] Our study's findings are consistent with those by Meng et al.[11], who demonstrated that intravenous TXA reduced postoperative hemoglobin drop and transfusion rates without increasing thromboembolic risk during TURP.[11] Gupta et al.[12] also found that combined intravenous and topical TXA significantly lowered intraoperative blood loss and transfusion needs in TURP. Similarly, Rani et al. reported a statistically significant reduction in hemoglobin loss with topical TXA irrigation, further reinforcing its benefit.[13]

Combined intravenous and topical tranexamic acid (TXA) significantly reduced intraoperative blood loss (290.00 ± 98.75 mL in the TXA group vs. 400.00 ± 137.74 mL in the control

group, $p < 0.001$) and preserved postoperative hemoglobin levels (12.03 ± 1.90 g/dL vs. 11.87 ± 1.65 g/dL, $p = 0.04$) during TURP. None of the 80 patients required blood transfusion, highlighting the clinical efficacy of TXA. Secondary outcomes such as total irrigation fluid usage (24.10 ± 7.41 L vs. 25.70 ± 9.82 L, $p = 0.413$), operative duration (45.38 ± 16.37 minutes vs. 41.72 ± 13.36 minutes, $p = 0.278$), and changes in vital parameters (heart rate, SpO_2, blood pressure; all $p > 0.05$) were comparable between the TXA and control groups. These results indicate that TXA significantly improves hemostasis without compromising operative time, irrigation volume, or hemodynamic stability.

In our study, Group 1 showed a significantly lower calculated blood loss (290.00 ± 98.75 mL) compared to Group 2 (400.00 ± 137.74 mL, $p < 0.001$). The percentage change in hemoglobin was also significantly lower in Group 1 (-5.57 ± 2.78%) versus Group 2 (-7.77 ± 3.14%, $p = 0.0013$). These findings align with Karkhanei et al., who reported reduced bleeding and higher surgeon satisfaction due to clearer visual fields with TXA.[14]

Baseline demographics, ASA grading, prostate volume, anesthesia type, and resection time were well matched between groups, reducing confounding variables. Unlike some prior studies, our trial showed no significant influence of anthropometric measures (weight, BMI) or intraoperative factors (irrigation volume, anesthesia type) on blood loss outcomes. This aligns with findings from Lotfy et al,[14] who concluded that TXA's efficacy is consistent regardless of these variables.

Importantly, no patients in either group required transfusion, underscoring the clinical value of TXA in reducing perioperative anemia to levels that avoid transfusion. This aligns with the transfusion rate reductions reported by Meng et al.[11] and Gupta et al.[13]. Safety analysis also revealed no significant increase in adverse effects with TXA use, corroborating earlier work by Rani et al. and Jendoubi et al.[11,16]

Importantly, no rise in adverse events such as deep vein thrombosis (DVT), pulmonary embolism (PE), or renal dysfunction was observed in the TXA group, similar to other studies.[11,14,17] This is particularly reassuring given the common presence of comorbidities in the TURP population, such as advanced age, cardiovascular disease, and impaired renal function.

CONCLUSION

Combined intravenous and topical administration of tranexamic acid significantly reduces intraoperative blood loss and hemoglobin drop during TURP without increasing adverse events. TXA's effectiveness is independent of prostate volume, ASA grade, or operative duration. These findings support its use as a safe and efficient hemostatic adjunct in TURP and potentially other urological procedures.

LIMITATIONS

Limitations include a single center scope, a modest sample size, no long-term follow up for thromboembolic events, and no cost-effectiveness analysis, which limit generalizability and economic insights.

AUTHORS' CONTRIBUTIONS

Conceptualization and design: YB, NK

Literature search: NK, DL

Data collection: DL, NK

Data analysis: NK, MS, YB

Manuscript drafting and critical revision: NK, MS, DL

Proofreading and approval of the manuscript: YB, NK, MS

FUNDING

No external funding was received to prepare the manuscript.

DECLARATION OF CONFLICTS OF INTEREST

There are no conflicts of interest to declare.

ETHICAL CLEARANCE

Approved by the Institutional Ethics Committee of the M S Ramaiah Medical College, Bengaluru, India (No: MSRMC/EC/PG-80/04-2023); Approval date: April 25, 2023.

The study was registered with the Clinical Trials Registry – India.

(CTRI No: CTRI/2023/09/058097)

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