Prostatic Diseases and Male Voiding Dysfunction

Intraprostatic Injection of Tranexamic Acid Decrease Blood Loss During Monopolar Transurethral Resection of the Prostate: A Randomized Controlled Clinical Trial

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OBJECTIVE To assess the role of intraprostatic injection of tranexamic acid (TXA) in reducing blood loss during transurethral resection of the prostate (TURP).

METHODS We conducted a randomized, controlled, double-blind trial involving 60 patients with benign prostatic hyperplasia aged 50-85 years, undergoing monopolar TURP. Patients' prostatic weights ranged from 50 to 80 g. They were divided equally into two groups: group I received an intraprostatic injection of 1 g of TXA (Cyklokapron) dissolved in 50 mL of 0.9 % saline at multiple sites, while group II (control) received a 60 mL saline injection. Comprehensive clinical assessments and standard laboratory tests, including screenings for TXA hypersensitivity, were performed for all patients.

RESULTS Group I exhibited significantly lower intraoperative blood loss and hemoglobin concentration in irrigation fluid immediately postsurgery and at the 6-hour postoperative mark compared to group II ($P < .05$). Coagulation parameters—activated partial thromboplastin time, prothrombin time, fibrinogen level, and thrombin clotting time—showed no significant differences between the groups preoperatively or at 6 and 24 hours postoperatively. No thromboembolic events or other complications were reported in either group.

CONCLUSION The intraprostatic injection of TXA during monopolar TURP is safe, with minimal adverse effects, and effectively reduces blood loss.

REGISTRATION The study was registered on ClinicalTrials.gov No (ID: NCT05913466). UROLOGY xx: xxx–xxx, xxxx. © 2024 Elsevier Inc. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

Benign prostatic hyperplasia (BPH) is characterized by an increase in stromal and epithelial cells in the periurethral region of the prostate, a process known as hyperplasia, not hypertrophy.[1] The exact cause of BPH remains elusive; however, one hypothesis suggests that a "reactivation" of embryonic processes may contribute to its development. BPH predominantly affects older men, making it a prevalent condition.[2] In recent years, a variety of noninvasive and minimally invasive modalities have gained popularity for managing voiding symptoms associated with BPH.[3]

Transurethral resection of the prostate (TURP) is one of the most established and commonly performed surgical interventions for BPH, often hailed as the "gold standard." Significant complications include difficulty in urination (5.8%), a need for surgical correction (5.6%), urinary tract infections (3.6%), bleeding requiring blood transfusions (2.9%), and TUR syndrome (1.4%). Given the prostate's abundant vascular supply, bleeding represents a significant complication of TURP.[4]

Perioperative blood loss during TURP is influenced by several factors, including the size of the prostate, the weight of the resected tissue, the duration of surgery, preoperative urine culture, treatment with finasteride, the use of acetylsalicylic acid, the type of anesthesia, blood pressure, and patient age.[5] The growth of the adenoma also correlates with increased formation of

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Funding Support: *None to declare.*

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Submitted: March 20, 2024, accepted (with revisions): May 14, 2024

irregular blood vessels and angiogenesis, elevating the risk of significant intraoperative bleeding during resection.[6,7]

Urine and urothelium exhibit a high concentration of plasminogen activators, facilitating clot dissolution and thereby increasing postoperative blood loss. Administering antifibrinolytic agents could mitigate this postoperative hemorrhage following TURP.[8]

Tranexamic acid (TXA), a lysine derivative, acts as an antifibrinolytic by reversibly binding to human plasminogen. Recent evidence-based research supports TXA's effectiveness in reducing blood loss during cardiac, liver, and orthopedic surgeries. TXA's ability to penetrate extravascular spaces and accumulate in tissues allows it to stabilize blood clots and inhibit tissue fibrinolysis.[9,10]

Bleeding during TURP poses a significant risk. Various strategies have been explored to lessen postoperative hemorrhage. Among these, the topical or intravenous application of TXA has shown promise due to its tolerability and efficacy. We hypothesized that intraprostatic injection of TXA could safely control bleeding when administered locally.[11,12]

Hence, this study aims to determine the efficacy of intraprostatic injections of TXA in reducing blood loss during monopolar TURP.

METHODS

In this randomized, double-blind trial, we enrolled 60 patients with BPH aged between 50 and 85 years, presenting with prostate weights of 50-80 g. These patients underwent TURP from May 2022 to July 2023.

Informed written consent was obtained from all participants after a detailed discussion about the nature of the procedure and associated risks. Each patient was thoroughly informed about the study's objectives and assigned a confidential code number to ensure anonymity. The research was approved by the institutional ethics committee (Approval no: RC 5-5-2022) and registered at ClinicalTrials.gov (ID: NCT05913466).

The exclusion criteria were stringent, disqualifying patients with preoperative heart and cerebrovascular diseases, a history of or high risk for thrombosis, renal insufficiency, ongoing anticoagulation therapy, an extended preoperative resting period, a diagnosis of prostate cancer, or any form of blood coagulation dysfunction. Participants who had previously received 5-alpha reductase inhibitors, warfarin, or aspirin before the surgery were also excluded from the study.

Sample Size Calculation

The sample size was determined using G*Power 3.1.9.2, a software developed by the University of Kiel in Germany. A pilot study involving ten individuals showed a mean (± standard deviation [SD]) hemoglobin (Hb) concentration of 13.01 ± 0.80 g/dL in group I, which received TXA, compared to 12.3 ± 0.58 g/dL in group II (the control group), which received a placebo. The sample size was calculated based on an effect size of 0.99, a 95% confidence interval, a 90% study power, and a 1:1 group ratio, with an additional six cases per group to account for potential dropouts. Consequently, 30 patients were recruited for each group.

Randomization and Blindness

Patients were randomly assigned to one of two groups using a computer-generated sequence, maintaining a 1:1 ratio. Group I (n = 30) received an intraprostatic injection of 1 g of TXA (Cyklokapron) dissolved in 50 mL of 0.9% saline, while group II (the control group, n = 30) received an injection of 60 mL of saline alone. A single physician was responsible for the uniform preparation of the injections, and a particular nurse measured blood loss volumes both during and after surgery. Importantly, both individuals were blinded to the group assignments of the patients.

Preoperative Assessment

Comprehensive medical and surgical histories were recorded for each participant, including demographic data (age, BMI, prostate size, International Prostate Symptom Score [IPSS]), and a history of comorbidities (hypertension, diabetes, smoking, hyperlipidemia, and symptoms such as chest pain and dyspnea), as well as previous medications. Patients underwent a clinical examination, accompanied by routine laboratory investigations, which included a complete blood count, coagulation studies (prothrombin time [PT], thrombin time [TT], activated partial thromboplastin time [APTT], and fibrinogen levels), renal function tests, and liver function tests.

A digital rectal examination, transrectal ultrasound, and prostate-specific antigen tests (total, free, and ratio) were conducted for all participants to confirm the diagnosis of BPH.

To assess hypersensitivity to TXA, an intradermal injection consisting of 0.5 mL of the drug, diluted at a 1:1 ratio with normal saline, was administered to each patient. A positive reaction was defined as the development of a wheal larger than 1 cm in diameter at the injection site within 20 minutes.[13]

Operative Procedure

All procedures were conducted by the same expert surgeon, who was blinded to the patients' group assignments and the specific injections administered. Prophylactic antibiotics were administered during the induction of anesthesia. After spinal anesthesia was administered, patients were placed in the lithotomy position. TXA was then administered directly into the prostate under cystoscopic guidance. Specifically, 1 g of TXA (Cyklokapron) was dissolved in 50 mL of 0.9% saline solution, with a total volume of 60 mL being strategically injected into various regions of the prostate. This was done using an endoscopic 23-gauge, 35 cm, 8 mm urethral needle. The

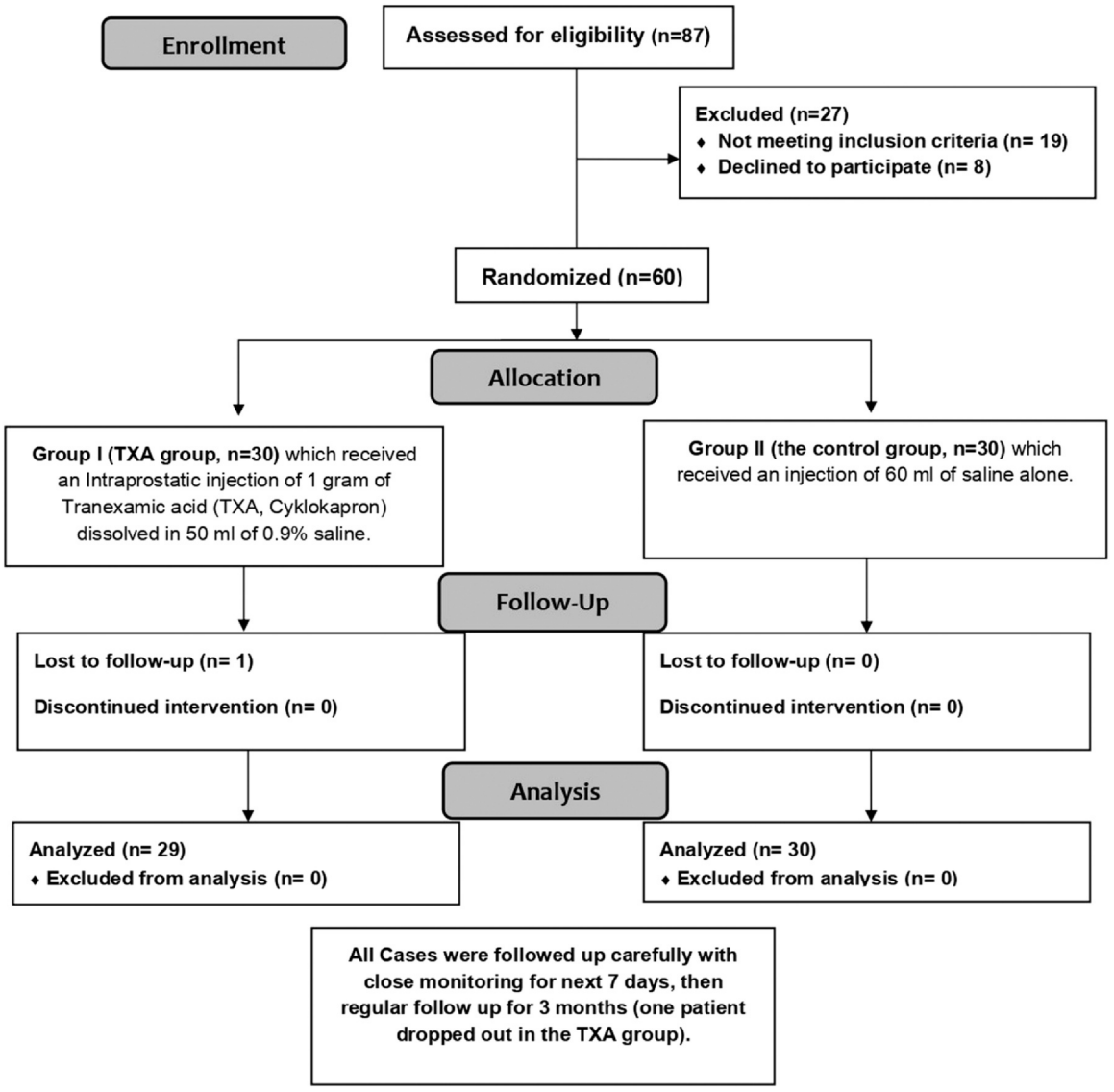

Figure 1. CONSORT flowchart of the enrolled patients.

injections targeted areas directly beneath those more vulnerable to bleeding, with key sites including the two lateral lobes at the 5-o′clock and 7-o′clock positions, the median lobe, and the apical tissue. After the injection, these sites were cauterized using monopolar electrocautery. The TURP was then performed using a 26-French continuous flow resectoscope.

Assessment of Blood Loss (Irrigation Fluid Hb Concentration)

Bladder irrigation was maintained for 24 hours postoperatively, with fluid collections made at three intervals: immediately postsurgery (V1), 6 hours postoperation (V2), and 24 hours postoperation (V3). The total volume collected was measured, and 5000 U of heparin was added to each irrigation fluid container to prevent coagulation. After thorough mixing, 5-mL samples were extracted and analyzed using cyanide methemoglobin spectrophotometry at 540 nm to determine the Hb concentration. Blood loss was estimated using specific formulas: (1) Hb concentration in irrigation fluid (g/L) = absorbance of fluid × 367.7; (2) Bleeding volume (mL) = (Hb concentration in irrigation fluid (g/L) × rinse volume (mL)) / preoperative Hb concentration (g/L).[14]

Postoperative Monitoring

Aside from assessing blood loss, preoperative measurements were taken to evaluate coagulation functions, including PT, TT, APTT, and fibrinogen levels at 6 and 24 hours postoperation. We also diligently monitored patients for signs of changes in consciousness, respiratory status, lower limb edema, chest tightness, and urine output post-TURP to identify any adverse effects associated with TXA, such as pulmonary embolism, myocardial infarction, renal failure, and seizures.

Table 1. Baseline characteristics of the studied groups.

		Group I (n = 30)	Group II (n = 30)	*P* Value
Age (y)		67.3 ± 9.71	68.7 ± 10.4	.583
BMI (kg/m^2)		25.9 ± 1.58	26.1 ± 1.47	.614
Comorbidities	HTN	16 (53.3%)	12 (40%)	.438
	DM	12 (40%)	10 (33.3%)	.789
	Smoking	19 (63.3%)	17 (56.7%)	.792
	Hyperlipidaemia	10 (33.3%)	7 (23.3%)	.567
Complaint	Hematuria	12 (40%)	10 (33.3%)	.474
	Retention	5 (16.7%)	9 (30%)	
Prostate size (g)		64.5 ± 10.44	68.1 ± 11.47	.217

BMI, body mass index; DM, diabetes mellitus; HTN, hypertension.
Data presented as mean ± SD or frequency (%).

Postoperative Outcomes

Evaluations included the duration of hospital stay following the operation, the quality of endoscopic visibility (rated on a scale of 1 to 3, where 1 indicates good, 2 denotes fair, and 3 signifies poor),[15] and blood loss, both during and after surgery. Blood loss was determined from bladder irrigation fluid collected at three intervals: immediately following the surgery (V1), 6 hours postoperation (V2), and 24 hours postoperation (V3).[6]

Follow-up Evaluations

Follow-up evaluations were conducted over the subsequent 3 months for all patients to identify any delayed complications, such as infections or secondary hemorrhage.

Statistical Analysis

Statistical analysis was conducted using IBM SPSS version 28, based in Chicago, IL. We reported quantitative data as average values along with their standard deviations (SDs). These metrics were compared between the two groups using the unpaired Student's *t* test. For qualitative data, we presented these as percentages (%) and counts, and employed Fisher's exact test or the chi-square test, depending on suitability. A two-tailed *P*-value below .05 was deemed indicative of statistically significant differences.

RESULTS

In this study, an eligibility assessment was conducted on 87 patients. Nineteen did not meet the specified requirements, and eight declined to participate. The remaining 60 patients were evenly divided into two groups of 30. An analysis and follow-up were subsequently conducted on the assigned patients (Fig. 1).

The baseline characteristics, including age, BMI, comorbidities (hypertension, diabetes mellitus, smoking, and hyperlipidemia), complaints (hematuria and retention), prostate size, and surgical urological parameters, were insignificantly different between the groups (Table 1).

Preoperative Hb and hematocrit (HCT) levels were insignificantly different between the groups, but significantly higher in group I compared to group II at 6 and 24 hours postoperatively ($P < .05$). The coagulation profile, including fibrinogen level (FB), TT, PT, and APTT, showed no significant differences between the groups either preoperatively or at 6 and 24 hours postoperatively. Platelet count, serum creatinine, and serum urea levels were also insignificantly different between the groups both preoperatively and at 6 hours postoperatively.

Blood loss and irrigation fluid Hb concentration were significantly lower in group I compared to group II immediately and at 6 hours postoperatively ($P < .05$), but showed no significant differences at 24 hours postoperatively between the groups (Table 2).

Regarding the postoperative outcomes, the quality of endoscopic visibility was significantly better in group I compared to group II ($P = .033$). Additionally, the operative time was significantly shorter in group I than in group II. The bleeding and clot retention incidence was also significantly lower in group I compared to group II ($P = .019$). Hospital stay, occurrences of perforation, and late complications were insignificantly different between the studied groups (Table 3).

DISCUSSION

Post-TURP blood loss is associated with increased urinary fibrinolytic activity, which leads to enhanced clot lysis. This increase is primarily due to the release of urokinase from the prostate. Moreover, both urine and the urothelium are rich in plasminogen activators, which activate the fibrinolytic system.[8,16] Consequently, the administration of antifibrinolytic agents, such as TXA, has been shown to effectively reduce blood loss during TURP.[17] The local application of TXA has also been proven to decrease blood loss across various surgical disciplines, including cardiac, dental, oral, endoscopic sinus surgery, and knee arthroplasty, without significant risks of thromboembolic complications or systemic absorption.[18,19]

Thromboelastography is a sophisticated technology designed to assess the fibrinolytic system and comprehensively evaluate propensities for clot formation

Table 2. Laboratory investigations of the studied groups.

		Group I (n = 30)	Group II (n = 30)	*P* Value
Hb (g/dL)	Preoperative	13.3 ± 0.73	13.4 ± 0.74	.986
	6 h postoperative	12.6 ± 1.1	11.2 ± 0.75	**< .001***
	24 h postoperative	12.5 ± 0.68	10.96 ± 0.6	**< .001***
HCT (%)	Preoperative	45.6 ± 3.41	45.2 ± 2.96	.687
	6 h postoperative	37.5 ± 1.74	34.7 ± 1.91	**< .001***
	24 h postoperative	35.6 ± 1.94	33.7 ± 2.12	**.001***
PT (s)	Preoperative	12.2 ± 0.72	12.1 ± 0.82	.464
	6 h postoperative	12.16 ± 0.79	12.30 ± 0.81	.511
	24 h postoperative	12.35 ± 0.80	12.26 ± 0.79	.663
APTT (s)	Preoperative	33.83 ± 1.02	33.73 ± 1.20	.729
	6 h postoperative	33.67 ± 1.09	3.17 ± 1.05	.112
	24 h postoperative	33.60 ± 1.16	33.23 ± 1.10	.215
FB (g/L)	Preoperative	3.52 ± 0.33	3.54 ± 0.27	.801
	6 h postoperative	3.55 ± 0.27	3.56 ± 0.34	.967
	24 h postoperative	3.53 ± 0.32	3.50 ± 0.30	.711
TT (s)	Preoperative	16.10 ± 0.88	16.33 ± 0.76	.277
	6 h postoperative	16.17 ± 0.87	16.00 ± 0.79	.441
	24 h postoperative	15.87 ± 0.78	16.13 ± 0.82	.201
Platelet ($\times 10^9$/L)	Preoperative	293.9 ± 84.76	296 ± 82.62	.922
	6 h postoperative	246.83 ± 81.87	240.9 ± 80.76	.779
Serum creatinine (mg/dL)	Preoperative	1.10 ± 0.24	1.08 ± 0.26	.681
	6 h postoperative	1.04 ± 0.3	1.06 ± 0.15	.709
Serum urea (mg/dL)	Preoperative	50.7 ± 9.4	48.1 ± 8.06	.255
	6 h postoperative	49.13 ± 10.84	47.07 ± 4.06	.335
Blood loss	Immediately	137.73 ± 34.28	158.9 ± 14.63	**.007***
	6 h postoperative	54.1 ± 16.06	69.1 ± 22.92	**.005***
	24 h postoperative	53.03 ± 19.2	63.8 ± 26.13	.073
Irrigation fluid Hb concentration (g/dL)	Immediately after	0.2 ± 0.06	0.3 ± 0.09	**< .001***
	6 h postoperative	0.1 ± 0.02	0.6 ± 0.23	**< .001***
	24 h postoperative	0.15 ± 0.08	0.16 ± 0.03	.712

APTT, activated partial thromboplastin time; FB, fibrinogen level; Hb, hemoglobin; HCT, hematocrit; PT, prothrombin time; TT, thrombin clotting time.

Data presented as mean ± SD.

* Statistically significant as *P* value < .005.

throughout the preoperative and postoperative stages. Despite its potential, thromboelastography is infrequently applied in clinical settings.[20]

The intravenous administration of TXA carries potential risks, such as pulmonary embolism and thrombosis.[21] To mitigate these systemic side effects, the localized application of TXA during surgical procedures warrants further evaluation. A comprehensive Cochrane review encompassing 29 trials with 2612 participants undergoing cardiac surgery, total knee and hip arthroplasty, spine surgery, and dental surgery demonstrated that localized application of TXA resulted in a 29% reduction in blood loss.[22]

To date, only a handful of studies have investigated the use of TXA, whether administered intravenously or locally, in urological surgery, such as percutaneous nephrolithotomy (PCNL). Kumar and colleagues[23] utilized intravenous TXA in PCNL and found a significant reduction in the Hb drop—1.39 g/dL in the TXA group compared to 2.31 g/dL in the control group ($P < .001$).

Table 3. Complications and postoperative outcome of the studied groups.

		Group I (n = 30)	Group II (n = 30)	*P* Value
Quality of endoscopic	Poor	3 (10%)	5 (16.7%)	**.033***
	Fair	9 (30%)	17 (56.7%)	
	Good	18 (60%)	8 (26.7%)	
Operative time (min)		98.80 ± 15.69	108.40 ± 14.80	**.018***
Hospital stay (d)		2.37 ± 0.49	2.6 ± 0.5	.073
Early complications	Perforation	0 (0%)	1 (3.3%)	1.0
	Bleeding and clot retention	2 (6.67%)	9 (30%)	**.019***
Late complications	Thromboembolic events	0 (0%)	0 (0%)	—
	Infection	1 (33.3%)	0 (0%)	1.00
	Secondary hemorrhage	0 (0%)	1 (33.3%)	1.00

Data presented as mean ± SD or frequency (%).

* Statistically significant as *P* value < .05.

Bansal and Arora[24] incorporated 0.1% TXA into the irrigation solution used during PCNL and reported a notable decrease in blood loss during the perioperative period compared to a placebo group (154.5 mL vs 212.6 mL, $P < .001$). Additionally, the mean reductions in Hb and HCT levels observed within the TXA group were significantly less than those in the placebo group (1.71 vs 2.67 g/dL, $P < .001$, and 4.23 vs 7.78, $P < .001$, respectively). Furthermore, the mean operative time was considerably shorter in the TXA group compared to the placebo group (68.45 vs 87.62 minutes, $P < .001$).

Likewise, Samir and colleagues[8] found that a high-dose regimen of TXA efficiently managed blood loss in patients with enlarged prostates undergoing bipolar TURP. While there are limited studies assessing the local application of TXA in urology, Tawfick et al[25] found that incorporating TXA into irrigation fluid significantly reduced blood loss, with the TXA group experiencing an average blood loss of 340 mL compared to 515 mL in the control group. The postoperative declines in HCT and Hb levels also demonstrated statistical significance. Conversely, Moharamzadeh and colleagues[26] noted no significant impact of topical TXA application on blood loss in a study involving 50 patients with painless hematuria.

To date, no study has explored the intraprostatic injection of TXA during TURP. We hypothesized that TXA, when locally injected, would be safe for use, even in patients on systemic anticoagulation. This method allows for more targeted delivery, ensuring the medication is concentrated and confined to a specific area. Despite historical concerns regarding the use of antifibrinolytic agents in treating hematuria—due to fears of clot-induced kidney obstruction—a study from 2011 dispelled these concerns.[4]

Our findings revealed no significant differences in baseline characteristics, comorbidities, complaints, or prostate size. Hb and HCT levels were notably higher in group I than in group II at 6 and 24 hours postoperatively. The coagulation profile—including PT, APTT, fibrinogen level (FB), TT, platelet count, serum creatinine, and serum urea levels—showed no significant differences between the groups either preoperatively or at 6 and 24 hours postoperatively.

Blood loss and irrigation fluid Hb concentration were significantly lower in group I compared to group II immediately and at 6 hours postoperatively, with no significant differences observed at 24 hours postoperatively between the groups. Regarding early complications, there were no incidents of thromboembolic events, including lower limb and pulmonary embolisms, or other notable complications in either group. Perforation occurred in one patient (3.3%) in group II but was not observed in any patient in group I. Bleeding and clot retention occurred in two patients (6.67%) in group I and nine patients (30%) in group II, with the incidence of bleeding and clot retention significantly lower in group I ($P = .019$). The frequency of perforation incidents did not significantly vary between the two groups. Additionally, the quality of endoscopic visibility was significantly better in group I compared to group II ($P = .033$). Hospital stay durations were comparable between the two groups.

Regarding late complications, one patient from group I returned to the emergency room after 2 weeks with signs of infection, while one patient from group II was admitted with secondary hemorrhage 17 days post-discharge. Both cases were managed medically without the need for further intervention.

Previous case reports suggest that intraprostatic injection of TXA offers numerous benefits. This method strategically modulates the coagulation balance at a local level, rather than affecting the entire systemic circulation. By reducing local trauma, such as that caused by cautery, this technique prevents the reinitiation of the wound-healing process, which could be compromised in patients on full anticoagulation therapy. The technique is noted for its simplicity and effectiveness, offering rapid relief after weeks of unsuccessful treatments in patients requiring anticoagulation. Follow-up data suggest the enduring nature of the outcomes, implying that initial local management could potentially be maintained over an extended period.[27]

In the realm of surgical management of BPH, TXA has been explored in various capacities to mitigate perioperative blood loss. Although the direct intraprostatic injection of TXA, as discussed in our study, represents a novel approach, there is a well-documented background of TXA usage in urological surgeries that warrants a comprehensive discussion.[28] Previous studies have demonstrated the efficacy of TXA in reducing blood loss in PCNL and TURP procedures when administered intravenously or topically through irrigation fluids.[29,30]

A particularly relevant study by Vanderbruggen et al[30] underscores the safety and effectiveness of systemic TXA in TURP, providing a pivotal comparison to our localized administration approach. This study, along with others,[31,32] supports the hypothesis that TXA, when used judiciously, can significantly reduce the Hb drop and thus the need for postoperative blood transfusions.

However, the use of TXA is not devoid of controversy and potential risks, particularly concerning thromboembolic events. Our approach aims to minimize systemic exposure by localizing the application to the prostate, thereby potentially reducing these risks. The localized application of TXA in urological surgeries is not extensively documented, making our study a significant contribution to the field. This approach may open avenues for safer surgical practices, particularly in patients at higher risk of bleeding and thromboembolic complications.

Thus, our preliminary findings suggest a promising avenue for reducing blood loss during TURP with potentially fewer systemic effects compared to traditional systemic administration. Future studies should aim to further delineate the safety profile of this technique, ideally through larger, multicentric trials to validate our

findings and possibly extend them into standard practice, tailoring interventions to individual patient risk profiles.

Complications like TUR-syndrome and significant bleeding are well-known risks of monopolar transurethral resection of the prostate (M-TURP), impacting both patient safety and surgical outcomes. Data from 10,654 M-TURPs shows a 2.9% incidence of transfusion-requiring bleeding and a 0.8% occurrence of TUR-syndrome, influenced by factors such as surgical duration and technique.[33]

The European Association of Urology (EAU) Guidelines limit the resection size to 80 mL and recommend completing the surgery within 90 minutes to minimize risks.[34,35]

Our findings suggest that using intraprostatic TXA can advance the management of bleeding in M-TURP, potentially shortening surgery time and reducing the risks of TUR-syndrome. This method boosts surgical efficiency and mitigates medicolegal risks, addressing a major concern in urological practice related to surgical complications.[12,36]

By potentially decreasing TUR-syndrome and other complications, our approach could improve patient outcomes and protect against legal and professional risks for surgeons. Intraprostatic TXA could redefine standard care, enhancing safety and efficiency in M-TURP, especially when bipolar resectoscopes are unavailable.

However, our study has some limitations, including a small sample size and the necessity for external validation through multicenter studies. Therefore, future multicentre studies with larger sample sizes are required to validate our findings.

CONCLUSION

The administration of intraprostatic TXA during monopolar TURP has been demonstrated to be a safe technique associated with minimal adverse effects. Importantly, it effectively reduces blood loss during the procedure.

Ethical Approval

The study was approved by the Research Ethics Committee, with Approval no: RC 5-5-2022.

Informed Consent

All participants in the study provided their informed consent.

Animal Studies

N/A.

Declaration of Competing Interest

The authors have no conflict of interest to declare.

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