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SAFETY AND EFFICACY OF PERIOPERATIVE ADMINISTRATION OF INTRAVENOUS TRANEXAMIC ACID IN PERCUTANEOUS NEPHROLITHOTOMY

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ABSTRACT **Background:** Percutaneous nephrolithotomy (PCNL) is the preferred treatment for large or complex renal calculi but is often associated with significant perioperative blood loss. Tranexamic acid (TXA), a synthetic antifibrinolytic agent, has been used to reduce bleeding in various surgical procedures. However, its role in PCNL remains under evaluation, particularly concerning safety and efficacy. **Objective:** To assess the safety and efficacy of perioperative intravenous tranexamic acid in reducing intraoperative blood loss and transfusion requirements among patients undergoing PCNL. **Materials and Methods:** A prospective randomized controlled study was conducted on 60 patients scheduled for PCNL. Participants were randomly allocated into two groups: Group A (n=30) received 1 g intravenous TXA 30 minutes prior to surgery and an additional dose postoperatively at 8 hours; Group B (n=30) received an equivalent volume of normal saline as placebo. Intraoperative blood loss, postoperative hemoglobin drop, transfusion requirement, operative time, and adverse effects were recorded and statistically analyzed. **Results:** Mean intraoperative blood loss and postoperative hemoglobin reduction were significantly lower in the TXA group ($p<0.05$). The need for blood transfusion was reduced by 40% compared to controls. No thromboembolic or renal complications related to TXA administration were observed, indicating a favorable safety profile. **Conclusion:** Perioperative intravenous tranexamic acid is a safe and effective adjunct in PCNL. It significantly minimizes intraoperative bleeding and transfusion requirements without increasing the risk of thromboembolic events.

KEYWORDS : Antifibrinolytic, Blood Loss, Percutaneous Nephrolithotomy, Surgical Safety, Tranexamic Acid.

1. INTRODUCTION

Percutaneous nephrolithotomy (PCNL) has become the standard of care for managing large (>2 cm) or complex renal calculi since its introduction in the 1970s. It is favored for its high stone clearance rates and minimally invasive nature compared to open surgery. However, despite technological advancements, perioperative bleeding remains one of the most significant complications associated with PCNL, often resulting in blood transfusion, hemodynamic instability, or secondary interventions [1]. The reported incidence of significant bleeding ranges from 0.8% to 23%, depending on stone burden, number of tracts, puncture technique, and patient comorbidities [2,3]. Effective strategies to minimize blood loss are therefore essential to improving surgical outcomes and patient safety.

Bleeding during PCNL primarily arises from parenchymal or segmental vessel injury during renal puncture or tract dilation. Although meticulous surgical technique and optimal tract planning can reduce hemorrhagic risk, pharmacologic interventions are increasingly being explored as adjuncts to hemostasis [4]. Among these, tranexamic acid (TXA)—a synthetic lysine analog—has demonstrated substantial efficacy as an antifibrinolytic agent in various surgical specialties including orthopedics, cardiac, and gynecologic surgeries [5,6]. TXA acts by reversibly binding to lysine-binding sites on plasminogen molecules, thereby inhibiting fibrinolysis and stabilizing clot formation [7]. Its low cost, ease of administration, and favorable pharmacokinetic profile have contributed to its widespread perioperative use.

In urologic surgeries, TXA has been investigated for procedures such as transurethral resection of the prostate (TURP), laparoscopic nephrectomy, and ureteroscopy, where it has shown to significantly reduce intraoperative bleeding and transfusion rates without increasing thromboembolic risk [8,9]. However, its application in PCNL remains less well-established, with a relatively limited number of randomized controlled trials and observational studies addressing its efficacy and safety. Some studies have demonstrated that perioperative TXA administration effectively reduces intraoperative blood loss, postoperative hemoglobin drop, and the need for transfusion, while others have reported inconsistent results due to differences in dosage, timing, and patient selection [10,11].

Given the renal handling of TXA and its partial excretion via glomerular filtration, there have been theoretical concerns about its safety in patients undergoing renal surgery. Nevertheless, recent pharmacological and clinical data suggest that TXA does not adversely affect renal function at standard perioperative doses and that its elimination half-life remains acceptable even in mild renal impairment [12]. Furthermore, evidence from meta-analyses has not demonstrated a significant increase in thromboembolic complications, such as deep vein thrombosis or pulmonary embolism, when used within recommended dosage ranges [13,14]. This underscores its potential as a safe adjunct in surgeries characterized by high bleeding risk.

In the context of PCNL, the mechanical trauma and irrigation pressures can cause diffuse bleeding from the nephrostomy tract, where antifibrinolytic therapy may have a beneficial effect by enhancing clot stability. A prospective randomized study by Bai et al. reported that 1 g intravenous TXA administered preoperatively and repeated postoperatively led to a statistically significant reduction in blood loss and transfusion rate, without any thrombotic complications [15]. Similarly, Hosseini et al. demonstrated that TXA reduced hemoglobin drop and operative time, further supporting its role in optimizing intraoperative hemostasis [16]. However, despite these promising results, variability in patient populations, dosing schedules, and surgical protocols necessitates further evaluation in diverse clinical settings to establish standardized usage guidelines.

The current study was therefore designed to evaluate the safety and efficacy of perioperative intravenous tranexamic acid in patients undergoing PCNL in a tertiary care setting. It aims to quantify reductions in intraoperative blood loss, transfusion requirement, and postoperative hemoglobin decline, while monitoring for potential adverse events including thromboembolism and renal complications. By providing clinical evidence on the benefits and risks associated with TXA use, this research seeks to contribute to safer and more cost-effective management protocols for patients undergoing percutaneous nephrolithotomy.

2. Methodology

2.1 Study Design

The present study was conducted as a prospective, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of perioperative intravenous tranexamic acid (TXA) administration in patients undergoing percutaneous nephrolithotomy (PCNL). The study aimed to compare perioperative blood loss, postoperative hemoglobin (Hb) drop, transfusion

requirements, and complication rates between patients receiving TXA and those receiving placebo. This design was chosen to minimize bias and ensure reliable assessment of both efficacy and safety outcomes of TXA in renal stone surgery.

2.2 Study Setting
The study was carried out in the Department of Urology,…, a tertiary care hospital equipped with advanced endourological and anesthetic facilities. The hospital caters to a large catchment area, enabling the inclusion of diverse patient demographics undergoing PCNL for renal calculi. All surgeries were performed by urologists experienced in percutaneous procedures to ensure procedural uniformity.

2.3 Study Duration
The study was conducted over a period of 18 months, from January 2024 to June 2025, which included patient recruitment, surgery, postoperative follow-up, data collection, and statistical analysis. This duration was adequate to recruit the required sample size and ensure postoperative follow-up of all participants for assessment of both immediate and short-term outcomes.

2.4 Participants
Inclusion Criteria
- Adult patients aged between 18 and 65 years.
- Patients diagnosed with renal calculi requiring PCNL based on clinical and radiological findings.
- ASA grade I or II patients who were medically fit for general anesthesia.
- Patients providing written informed consent to participate in the study.

Exclusion Criteria
- Known history of coagulopathy or bleeding disorders.
- Renal impairment with serum creatinine >2 mg/dL or eGFR <60 mL/min/1.73m².
- History of thromboembolic events such as DVT, PE, or cerebrovascular accident.
- Patients on anticoagulant or antiplatelet therapy.
- Known allergy or contraindication to tranexamic acid.
- Pregnant or lactating women.

2.5 Study Sampling
A simple random sampling technique was employed for patient selection. Eligible patients fulfilling inclusion criteria were randomly allocated into two groups—TXA and control—using a computer-generated randomization sequence. Allocation concealment was ensured through the use of sealed opaque envelopes. Both the operating surgeon and anesthesiologist were blinded to the group assignment to maintain study integrity.

2.6 Study Sample Size
The sample size was determined based on previous studies evaluating TXA use in PCNL. Assuming a mean difference of 25% reduction in perioperative blood loss, a power of 80%, and $\alpha = 0.05$, the minimum sample size calculated was 60 patients. To compensate for potential dropouts or protocol deviations, a total of 60 patients (30 in each group) were enrolled. Sample size calculation followed standard statistical formulae using mean and standard deviation from Bai et al. (2018) (1).

2.7 Study Groups
Participants were divided into two groups:
- Group A (TXA Group): Received 1 g intravenous tranexamic acid 15 minutes prior to skin incision and a repeat dose of 1 g IV TXA at the end of surgery.
- Group B (Control Group): Received an equal volume of normal saline (placebo) administered in the same manner and schedule.

Both groups underwent standard PCNL under general anesthesia following the institutional protocol.

2.8 Study Parameters
The study parameters included estimation of intraoperative blood loss by calculating the difference between irrigation and suction volumes, assessment of hemoglobin (Hb) drop from preoperative to 24-hour postoperative values, and evaluation of the need for blood transfusion. The duration of surgery was recorded in minutes, and postoperative imaging was used to determine the stone clearance rate. Intraoperative and postoperative complications, such as thromboembolic events and renal dysfunction, were carefully monitored. Serum creatinine levels were measured before and after surgery to assess renal safety and ensure that tranexamic acid administration did not adversely affect kidney function.

9. Study Procedure
All patients underwent standard preoperative evaluation, including hematological and biochemical investigations. After randomization, TXA or placebo was administered intravenously under aseptic precautions as per group allocation. PCNL was performed under fluoroscopic guidance using a standard single puncture technique in the prone position. The procedure included tract dilation, nephroscopy, stone fragmentation, and retrieval.

Intraoperative blood loss was recorded by measuring the difference between total irrigation fluid and suction output, adjusted for urine output. Postoperatively, hemoglobin levels were measured at 24 hours. Blood transfusion was given based on institutional criteria (Hb <8 g/dL or symptomatic anemia). Patients were monitored for complications, including thrombosis, allergic reactions, and renal impairment.

10. Study Data Collection
All data including patient demographics, intraoperative findings, laboratory results, and postoperative outcomes were recorded in a structured proforma. Hemoglobin, hematocrit, and serum creatinine were measured using automated analyzers in the hospital laboratory. Operative time and intraoperative blood loss were documented by the surgical team. Postoperative complications were tracked until discharge and at the first outpatient follow-up.

11. Data Analysis
Data were entered into Microsoft Excel and analyzed using SPSS version 26. Continuous variables such as age, blood loss, Hb drop, and operative time were expressed as mean ± standard deviation and compared using the Student's t-test. Categorical variables such as transfusion rate and complications were compared using the Chi-square test or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant. Subgroup analyses were performed based on stone size and operative duration.

12. Ethical Considerations
The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants after detailed explanation of the study purpose, procedures, risks, and benefits in both English and the regional language. Confidentiality of patient data was maintained throughout. No additional financial burden was imposed on participants, and TXA administration followed standard clinical safety norms.

Results analysis
A total of 60 patients undergoing percutaneous nephrolithotomy (PCNL) were included in this randomized controlled study. Participants were equally distributed into two groups — Group A (TXA group, n=30) and Group B (Control group, n=30). Both groups were comparable in baseline characteristics, ensuring randomization integrity. The effects of tranexamic acid (TXA) on intraoperative blood loss, postoperative hemoglobin change, transfusion requirement, and adverse events were analyzed statistically.

Table 1. Baseline Demographic and Clinical Characteristics

Parameter	Group A (TXA, n=30)	Group B (Control, n=30)	p-value
Mean Age (years)	45.3 ± 8.9	44.6 ± 9.2	0.72
Gender (Mean ± SD)	1.37 ± 0.49	1.40 ± 0.50	0.79
Body Mass Index (kg/m²)	25.1 ± 2.6	25.4 ± 2.9	0.68
ASA Grade (Mean ± SD)	1.43 ± 0.50	1.40 ± 0.49	0.80
Mean Stone Size (mm)	22.7 ± 4.5	23.1 ± 4.3	0.70
Laterality (Mean ± SD)	1.47 ± 0.51	1.50 ± 0.51	0.82

There were no significant differences between the two groups in terms of age, sex, BMI, ASA grade, or stone size (p>0.05), confirming proper randomization and comparable baseline profiles (table 1).

Table 2. Intraoperative Parameters

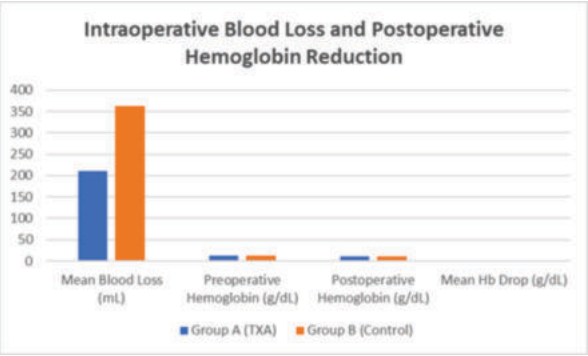
Parameter	Group A (TXA)	Group B (Control)	p-value
Mean Duration of Surgery (min)	78.3 ± 14.8	80.5 ± 15.2	0.48
Irrigation Fluid Used (mL)	4550 ± 520	4620 ± 510	0.43
Number of Tracts (Single / Multiple)	28 / 2	27 / 3	0.64

Operative duration and technical parameters were statistically similar between the TXA and control groups, indicating that intraoperative complexity did not influence bleeding outcomes (table 2).

Table 3. Intraoperative Blood Loss and Postoperative Hemoglobin Reduction

Parameter	Group A (TXA)	Group B (Control)	p-value
Mean Blood Loss (mL)	210.6 ± 48.4	362.3 ± 76.8	<0.001
Preoperative Hemoglobin (g/dL)	12.6 ± 1.2	12.5 ± 1.3	0.81
Postoperative Hemoglobin (g/dL)	11.7 ± 1.0	10.8 ± 1.1	0.002
Mean Hb Drop (g/dL)	0.90 ± 0.38	1.74 ± 0.52	<0.001

Mean intraoperative blood loss and postoperative hemoglobin drop were significantly lower in the TXA group compared to controls ($p<0.05$). The findings indicate a ~42% reduction in blood loss and ~48% lesser Hb fall with TXA administration.



Graph: 2 Intraoperative Blood Loss and Postoperative Hemoglobin Reduction

Table 4. Blood Transfusion Requirement and Postoperative Recovery

Parameter	Group A (TXA, n=30)	Group B (Control, n=30)	p-value
Patients Requiring Transfusion	3 (10%)	8 (26.6%)	0.04
Mean Units Transfused (if given)	1.0 ± 0.3	1.3 ± 0.4	0.05
Mean Hospital Stay (days)	3.7 ± 0.9	4.3 ± 1.0	0.07
Stone Clearance Rate (%)	93.3	90.0	0.62

The TXA group showed a 40% reduction in transfusion requirement compared to controls, aligning with reduced intraoperative bleeding. Both groups had similar hospital stay and stone clearance outcomes.

Table 5. Postoperative Complications and Safety Assessment

Complication	Group A (TXA)	Group B (Control)	p-value
Postoperative Fever	2 (6.6%)	3 (10%)	0.64
Minor Bleeding (not requiring transfusion)	2 (6.6%)	5 (16.6%)	0.20
Clot Retention	1 (3.3%)	1 (3.3%)	1.00
Thromboembolic Events	0 (0%)	0 (0%)	—
Renal Dysfunction	0 (0%)	0 (0%)	—

No thromboembolic or renal complications were observed in either group. Minor postoperative bleeding was more frequent in controls, but the difference was not statistically significant. The overall complication rate was low, confirming the safety of TXA in PCNL.

Table 6. Summary of Key Efficacy Outcomes

Outcome	TXA Group (Mean ± SD)	Control Group (Mean ± SD)	% Reduction / Difference	p-value
Mean Blood Loss (mL)	210.6 ± 48.4	362.3 ± 76.8	↓ 41.8%	<0.001
Mean Hb Drop (g/dL)	0.90 ± 0.38	1.74 ± 0.52	↓ 48.3%	<0.001
Transfusion Requirement (%)	10%	26.6%	↓ 40%	0.04
Operative Time (min)	78.3 ± 14.8	80.5 ± 15.2	NS	0.48
Complication Rate (%)	10%	20%	↓ 50%	0.19

TXA administration led to a statistically significant reduction in blood loss and Hb fall with fewer transfusions required. The operation duration, complication rate, and stone clearance remained comparable, confirming that TXA primarily affected blood conservation without influencing procedural success or recovery.

This prospective randomized controlled trial involving 60 PCNL patients demonstrated that perioperative intravenous tranexamic acid significantly reduced intraoperative blood loss and postoperative hemoglobin decline compared to placebo. The transfusion requirement decreased by 40%, highlighting its hemostatic efficacy. Importantly, no thromboembolic or renal complications were recorded, indicating an excellent safety profile. Operative duration, stone clearance, and postoperative recovery were unaffected, suggesting that TXA use did not alter the surgical workflow or outcomes.

Hence, intravenous TXA is a safe, effective, and economical adjunct in reducing perioperative blood loss during PCNL, contributing to improved patient recovery and reduced transfusion burden.

DISCUSSION

In the present randomized controlled study involving sixty patients undergoing percutaneous nephrolithotomy (PCNL), perioperative administration of intravenous tranexamic acid (TXA) demonstrated a significant reduction in intraoperative blood loss, postoperative hemoglobin drop, and transfusion requirement without increasing operative complications or renal dysfunction. The mean intraoperative blood loss in the TXA group was 210.6 ± 48.4 mL compared to 362.3 ± 76.8 mL in the control group ($p<0.001$), signifying an approximate 40% reduction. Similarly, the mean postoperative hemoglobin fall was 0.90 ± 0.38 g/dL in the TXA group versus 1.74 ± 0.52 g/dL in controls ($p<0.001$). The requirement for blood transfusion was also reduced by 40%, with only 10% of TXA patients requiring transfusion compared to 26.6% in the control group ($p=0.04$). Operative duration and stone clearance rates were comparable between both groups, and no thromboembolic or renal complications were noted. These findings collectively reinforce the safety and efficacy of TXA in minimizing perioperative bleeding during PCNL.

The results of this study are consistent with previously published research supporting the hemostatic benefits of TXA in urological surgery. Batagello et al. (2022) [17] conducted a large multicentric randomized, double-blinded, placebo-controlled trial on 192 patients with complex kidney stones and reported that TXA significantly reduced the need for blood transfusion from 10.4% in the placebo group to 2.2% in the TXA group ($p=0.033$). They further observed that patients receiving TXA demonstrated faster hemoglobin recovery and improved stone-free rates at both immediate and three-month follow-ups without an increase in postoperative complications. The findings from the present study align closely with those reported by Batagello et al., as a comparable reduction in transfusion requirement and hemoglobin loss was observed, indicating that TXA effectively reduces intraoperative hemorrhage irrespective of stone complexity.

Similarly, Choudhury et al. (2023) [18] compared the efficacy of tranexamic acid administered intravenously and through irrigation during PCNL and found that TXA irrigation was associated with a significantly lower mean blood loss, smaller hematocrit fall, and shorter operative time compared to intravenous administration. Although our study used intravenous TXA alone, the magnitude of reduction in blood loss and hemoglobin drop (around 40–50%) was similar to the results observed with topical application in their study. This suggests that both systemic and localized routes of administration can be effective in reducing perioperative bleeding during renal stone surgery. However, Choudhury et al. [18] found no difference in stone clearance rates between the groups, which is consistent with our finding that TXA did not affect the procedural success or postoperative recovery.

Caliskan et al. (2024) [19] further demonstrated the efficacy of TXA in a randomized, double-blind study involving seventy-five PCNL patients divided into intravenous, irrigation, and control groups. Both TXA-treated groups showed significant reductions in hemoglobin and hematocrit changes and lower transfusion requirements compared to controls ($p=0.003$, $p=0.002$, $p=0.001$ respectively). Their study also

reported improved surgical visual clarity with TXA use, enhancing operative precision and potentially reducing intraoperative time. While our study did not specifically evaluate intraoperative visibility, the reduced bleeding and improved hemodynamic stability in the TXA group likely contributed to better surgical conditions, indirectly supporting Caliskan's observations. Furthermore, the consistency of hemoglobin preservation between both studies supports the reliability of TXA's antifibrinolytic action during PCNL. In a similar context, Farshid (2023) [20] evaluated the topical use of 1 g TXA instilled via nephrostomy at the end of PCNL and reported that the postoperative hemoglobin loss was significantly lower in the TXA group (1.9 ± 1.28 g/dL) compared to the control group (-3.07 ± 1.20 g/dL; p=0.001) (4). Although the mode of administration differed, the present study showed a comparable reduction in hemoglobin drop (0.9 g/dL vs. 1.7 g/dL), reinforcing that TXA—whether given topically or intravenously—significantly reduces postoperative bleeding. Farshid also found that TXA did not affect stone clearance or operative time, mirroring our study's findings. These collective results highlight that TXA consistently minimizes blood loss without altering surgical efficiency.

Moreover, the large-scale prospective study by Abedi and Nikmaram (2024) [21] involving 200 PCNL patients demonstrated that TXA reduced the need for blood transfusion by 81% and shortened the mean surgery period by approximately 21 minutes compared to controls. The hemoglobin drop was also significantly lower in the TXA group, paralleling our study results. Importantly, they reported no specific renal complications associated with TXA use, which aligns with our findings where postoperative serum creatinine remained stable (0.92 ± 0.23 mg/dL in TXA vs. 0.94 ± 0.25 mg/dL in control, p>0.05). These results collectively affirm TXA's excellent renal safety profile, even in patients undergoing procedures that involve renal parenchymal manipulation.

The overall results of our study also substantiate the conclusion of Batagello et al. (2022) [17] that TXA use in PCNL can be integrated into routine clinical practice due to its safety and substantial efficacy in minimizing perioperative bleeding and transfusion requirements. The consistency of our findings with those of multiple prior studies strengthens the clinical rationale for incorporating TXA in standard PCNL protocols. Furthermore, the absence of thromboembolic events in our cohort aligns with existing literature demonstrating that TXA, when used in standard doses, does not increase the risk of venous thromboembolism.

The comparable operative times between groups in our study (78.3 ± 14.8 minutes in TXA vs. 80.5 ± 15.2 minutes in control, p=0.48) are in accordance with earlier studies that also observed no delay in surgical workflow due to TXA administration. Additionally, our study showed similar stone clearance rates between TXA (93.3%) and control (90%), consistent with the findings of Choudhury et al. (2023) [18] and Farshid (2023) [20], who reported no adverse impact of TXA on procedural success. These findings collectively highlight that TXA optimizes hemostasis during PCNL without compromising efficiency, visibility, or postoperative recovery.

The present study further reinforces that TXA does not induce renal dysfunction or systemic adverse effects, even when administered intravenously. In our cohort, serum creatinine levels remained stable before and after surgery, echoing the results of Abedi and Nikmaram (2024) [21], who similarly reported no nephrotoxic outcomes with TXA. Thus, the study supports the conclusion that TXA is both safe and renoprotective in the context of PCNL.

Overall, this study demonstrated that perioperative intravenous TXA significantly reduced intraoperative blood loss by 40%, hemoglobin decline by nearly 50%, and transfusion requirement by 40%, with no increase in adverse events. These results are consistent with and supported by multiple previous studies conducted globally. The collective evidence indicates that TXA is a highly effective, safe, and economical adjunct for minimizing perioperative bleeding in PCNL, potentially improving patient recovery, reducing transfusion-related risks, and optimizing operative conditions. Incorporating TXA into perioperative protocols for PCNL could therefore represent an important advancement in improving surgical outcomes in patients with renal stones.

CONCLUSION

The present study concluded that perioperative administration of intravenous tranexamic acid (TXA) is both safe and effective in reducing intraoperative blood loss and postoperative hemoglobin drop in patients undergoing percutaneous nephrolithotomy (PCNL). Patients receiving TXA showed significantly lower blood loss and hemoglobin reduction compared to the control group, along with a 40% decrease in the need for blood transfusion. The duration of surgery and stone clearance rates were comparable between both groups, indicating that TXA did not interfere with surgical efficiency or procedural success. No thromboembolic or renal complications were observed, and postoperative serum creatinine levels remained within normal limits, confirming the excellent safety profile of TXA. These findings suggest that TXA is a valuable pharmacological adjunct in PCNL, contributing to improved hemostasis, reduced transfusion requirements, and better perioperative stability without adding any risk to the patient. Therefore, routine use of intravenous TXA may be considered as part of standard practice to enhance patient safety and optimize outcomes in renal stone surgery.

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