



OUTCOME OF TREATMENT IN PATIENTS RECEIVING INTRAVENOUS TRANEXAMIC ACID DURING PERCUTANEOUS NEPHROLITHOTOMY AT TERTIARY CARE HOSPITAL

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ABSTRACT

Background: PCNL serves as the standard treatment for large renal stones though it typically leads to considerable blood loss from the procedure. Patients treated with the antifibrinolytic medication tranexamic acid experience decreased bleeding during surgical procedures and after surgery because this drug blocks the fibrinolytic process. Additional research studies need to explore the value of TXA for PCNL because its therapeutic potential has proved effective in other surgical specialties.

Objective: This study aims to determine how intravenous administration of tranexamic acid impacts surgical bleeding amounts and transfusion rates together with post-operative hospital length of stay for patients who undergo PCNL.



Methods: The study was executed as a randomized controlled trial in the Department of Urology at Liaquat National Hospital, Karachi for six months. The research enrolled 118 patients who received PCNL and distributed them randomly between two separate groups. The participants in Group A received 1g of intravenous tranexamic acid through an intravenous route exactly twenty minutes before the procedure began while Group B members got normal saline as their placebo treatment. Both pre-operative and post-operative assessments measured patients' hemoglobin and hematocrit levels while recording the need for transfusions and determining the period of hospital stay. SPSS v16 handled the data analysis while $p \leq 0.05$ indicated statistical significance.

Results: The TXA-treated patients showed a minimal reduction of mean hemoglobin levels which amounted to 1.0 ± 0.4 g/dL while mean hemoglobin levels in the placebo group descended to 1.9 ± 0.6 g/dL ($p < 0.001$). The patients in Group A experienced a lower mean hematocrit loss percentage ($2.8 \pm 1.1\%$) than those in Group B ($4.9 \pm 1.4\%$) and this difference reached statistical significance ($p < 0.001$). A total of 10.2% of patients receiving TXA needed transfusion therapy whereas 28.8% of placebo group patients needed transfusion therapy ($p = 0.01$). Patients who received TXA spent 2.7 ± 0.8 days in the hospital while patients who received placebo required 3.4 ± 1.0 days ($p = 0.002$). Patients experienced no negative side effects or signs of thromboembolic complications during the study period.

Conclusion: Clinical administration of IV tranexamic acid reduces perioperative bleeding transfusion rates and hospitalization duration in patients undergoing arbuscular nephrolithotomy procedures while maintaining good safety outcomes. The use of intravenous tranexamic acid serves as a successful surgical tool that helps improve urological medical results.

KEYWORDS: Tranexamic acid, percutaneous nephrolithotomy, blood loss, hemoglobin, hematocrit, transfusion, hospital stay, antifibrinolytic.

INTRODUCTION

Medical practitioners consider percutaneous nephrolithotomy (PCNL) as the optimal treatment for large renal stones exceeding 2cm especially when they have complex or staghorn characteristics. PCNL rises as the optimal treatment method because it provides successful stone-free results and



minimal invasiveness surpassing ESWL and fURS for managing large renal calculi ^{1,2}. The main complication of PCNL is hemorrhage which represents the most frequently observed serious problem ^{3,4}. The incidence of significant bleeding following PCNL-reported cases show wide variations between 1% and 23% based on the combination of stone size and patient situation and clinical experience level ⁵. Hemorrhage leads to higher transfusion needs together with longer hospital stays and potential need for repeat treatments and rarely requires emergency embolization intervention ⁶. During PCNL the main bleeding site originates from segmental renal arteries that get injured through tract creation or stone fragmenting processes ⁷. Bleeding control during and after PCNL demands normal therapy combined with possible blood transfusions together with the use of embolization as an emergency option. Research into antifibrinolytic agents including tranexamic acid (TXA) has occurred because medical practitioners identified the requirement to actively stop bleeding ⁸. TXA functions as a synthetic lysine analogue by blocking plasminogen activation to plasmin which reduces fibrinolysis activity and strengthens clot formation in the body ⁹. Research indicates TXA shows effective outcomes in different surgical fields including orthopedics and cardiac surgery as well as trauma because it decreases transfusion needs and blood loss ^{10,11}. Doctors now conduct more studies aimed at investigating the use of TXA specifically for urological procedures that include PCNL. The renal urothelial tissue possesses elevated levels of urokinase and plasminogen activators which create natural bleeding susceptibility ¹². The anti-fibrinolytic effect of TXA helps control bleeding risks that occur during PCNL procedures ¹³. The use of TXA in PCNL has been validated through clinical trial evidence as well as analysis of existing studies. Multiple studies show that giving TXA during surgery decreases blood loss during operations in addition to minimizing postoperative decreases of hemoglobin levels and need for blood transfusions and operation duration while preventing an increase in thromboembolic conditions ¹⁴⁻¹⁶. A 2020 analysis which studied more than 1,000 patients found that PCNL patients who received TXA experienced a 0.5–1 g/dL blood hemoglobin decrement combined with about 40% decreased transfusion rates ¹⁷.

The full integration of TXA administration during PCNL remains limited since medical professionals are hesitating about the risks of thrombosis and the inconsistent standardization of



dosing protocols¹⁸. Clinical research demonstrates the security of using TXA if administered properly while existing yet inactive thromboembolic conditions remain excluded¹⁹. There are no reported significant thromboembolic event increases among patients receiving the recommended standard dose TXA in controlled study settings²⁰. The therapeutic outcome of TXA becomes observable thirty minutes after intravenous infusion while its kidney-based elimination process follows. The application of these medications should be handled carefully when treating patients who have kidney dysfunction²¹. Medical personnel administer the standard dosage of TXA by either giving 1 g of medication or by increasing the weight-based dose to 10–20 mg/kg starting 20–30 minutes before surgical procedures²². Surgical protocols that include TXA administration could provide benefits to resource-limited clinical settings by reducing the demanding requirements of blood transfusions along with their adverse risks which cover transfusion reactions and increased hospital expenses and immune system changes²³. The implementation of tranexamic acid becomes especially important in tertiary care facilities of Pakistan and other low-to-middle-income countries because both blood supply and cost efficiency remain substantial issues²⁴. The objective of this research is to measure the effects of intravenous TXA treatment on PCNL procedural results by examining postoperative hematologic indicators and transfusion requirements and hospital stay duration. This study aims to discover a safe and productive way for surgical blood reduction in order to enhance patient results and strengthen evidence-based urological practice²⁵.

METHODOLOGY

The researchers designed this randomized controlled trial in the Urology Department of Liaquat National Hospital in Karachi during six months after CPSP (College of Physicians and Surgeons Pakistan) approved the study synopsis. The research observed perioperative effects between intravenous tranexamic acid (TXA) treatment in patients undergoing percutaneous nephrolithotomy (PCNL) when compared to placebo administration. The goal consisted of investigating vital perioperative indicators such as postoperative changes in hemoglobin and hematocrit measurements and blood transfusion requirements together with hospitalization duration. The research used non-probability consecutive sampling to gather participants. PCNL



patients aged 30 to 70 years with either gender and presenting stones greater than 2cm qualified for the study. Furthermore the study included patients who had complicated anatomical conditions and multiple renal calculi. The research excluded participants to protect their safety and eliminate elements that could affect the results. The study excluded patients whose serum creatinine exceeded 1.5 mg/dL as well as those with congenital renal defects and bleeding conditions or sepsis or anticoagulation therapy patients or those with acute coronary syndrome and stroke and asthma and chronic obstructive pulmonary disease (COPD) and chronic renal failure or chronic liver disease. Ethical approval from the institutional review board at Liaquat National Hospital became available prior to the enrollment process. Each participant provided written consent after learning about every detail of the study together with its risk factors and advantages. All participants received assurance that their contributions would not affect their usual care plan while their information remained completely confidential. All sensitive personal data received encoded ID placeholders before secure storage in an electronic database locked by a password that only the primary researcher could access. The research divided eligible consenting patients between two study groups named Group A (intervention) and Group B (control). Sealed opaque envelopes accomplished random distribution of patients through adequate allocation concealment. A dose of 1 gram (10 ml) intravenous tranexamic acid as recommended by Goodman & Gilman's "The Pharmacological Basis of Therapeutics" was given to patients in Group A 20 minutes before their surgery at a dosage between 2.5–100 mg/kg. The patients within Group B received 10 ml of normal saline intravenously as a placebo treatment prior to surgery execution at the 20-minute mark.

All procedures took place under general anesthesia through the hands of consultant urologists whose experience spanned at least ten years for standardization and minimized operational differences. Patient positioning in the prone posture represents our institution's usual approach to perform PCNL procedures. The procedure for renal calyceal system access used either the triangulation (parallax) technique or the bull's-eye (eye of the needle) method according to the surgeon's choice. After establishing access to the renal calyceal system the surgeon used Alken's metallic telescoping dilators to achieve dilation from 9 French to 27 French. The 30 French Amplatz sheath served as a device for nephroscopic access after being placed over dilators. Stone



fragmentation needed a pneumatic lithotripter while the stone fragments required grasping forceps for removal. Stone clearance assessment occurred both during surgery through fluoroscopic evaluation then postoperatively through a plain abdominal X-ray KUB completed the day after surgery. The decision to place a nephrostomy tube relied on the operating findings which included both the length of the procedure and quantification of residual irrigation fluid. Nephrostomy tubes received removal scheduled for the initial or second day after the operation. Medical staff measured patients' hemoglobin alongside hematocrit before surgery and 24 hours post the operation. The evaluation method determined the extent of blood loss that took place during the postoperative period through the measurement of value differences. Healthcare providers considered a postoperative fall in hemoglobin approaching or beyond 2 g/dL combined with blood hemoglobin levels diving below 9 g/dL to warrant blood transfusion. The hospital admission period was measured through days between the end of PCNL surgery and patient release from medical care. Medical staff continuously observed patients throughout the entire postoperative period for indications of fever together with infection and urinary leakage as well as excessive bleeding. All medical incidents received care based on hospital management protocols. The research-made specific proforma collected patient information about demographics combined with stone data while recording intraoperative observations with postoperative results.

The research data entered SPSS version 16 for analysis. A statistical analysis of numerical variables examined data through the combination of mean values along with standard deviation (after conducting the Shapiro-Wilk test to determine normal distribution). When data distribution was non-normal researchers chose to display findings through medians supported by interquartile ranges (IQR). The researchers documented qualitative data points such as gender distribution along with blood transfusion needs and stone removal outcomes as frequencies with corresponding percentages. For variable comparison between groups we used independent t-test or Mann-Whitney U test for continuous values and Chi-square test or Fisher's exact test for categorical values. The analysis with age-based and gender-based categories took place before comparison testing based on residence status. Endpoints in post-stratification were evaluated using these same



statistical methods. The researchers treated a p-value that was equal to or less than 0.05 as statistically significant.

RESULTS

One hundred eighteen patients undergoing percutaneous nephrolithotomy (PCNL) participated in the study that distributed them into two equal groups. Tranexamic acid served as intravenous medication to Group A (n=59) but Group B (n=59) received normal saline as placebo. The two studied groups displayed similar demographics relating to mean age as well as gender percentages and pre-surgical blood tests measuring hemoglobin and hematocrit. Patients in Group A attained a mean age of 48.6 ± 10.1 years and patients in Group B had a mean age of 49.3 ± 9.6 years without a significance difference ($p=0.64$). Male patients made up 61% of Group A participants and 58% of Group B participants according to our analysis. The distribution by sex showed no difference that reached statistical significance ($p=0.73$). The preoperative hemoglobin measured 13.1 ± 1.4 g/dL in Group A and 13.0 ± 1.3 g/dL in Group B without any significant difference between the groups ($p=0.78$). Additionally, both groups possessed similar preoperative hematocrit levels of $39.3 \pm 3.9\%$ and $39.0 \pm 4.1\%$ ($p=0.66$). Both groups demonstrated different postoperative parameters for hemoglobin and hematocrit respectively. The participants in Group A maintained higher post-surgical hemoglobin levels (12.1 ± 1.2 g/dL) compared to Group B (11.1 ± 1.5 g/dL) with $p<0.001$ significance for TXA group benefits. The mean postoperative hematocrit measurement for Group A participants was $36.5 \pm 3.5\%$ while Group B participants had $34.1 \pm 3.8\%$ ($p<0.001$). Patients receiving TXA experienced an average change in hemoglobin level of 1.0 ± 0.4 g/dL while those in the placebo received 1.9 ± 0.6 g/dL resulting in a statistically meaningful difference ($p<0.001$). Group A patients experienced a hematocrit decline of $2.8 \pm 1.1\%$ while Group B patients showed a reduction of $4.9 \pm 1.4\%$ ($p<0.001$). The study results showed that 10.2% of patients (6 individuals) needed blood transfusion in Group A while 28.8% (17 patients) required transfusion in Group B. The significant statistical outcome ($p=0.01$) points to TXA administration before surgery decreasing the frequency of blood transfusions substantially. Patients received discharge from hospital at a shorter timeframe in Group A with an average period of 2.7 ± 0.8 days while Group B patients required 3.4 ± 1.0 days for hospital stay ($p=0.002$).



Research findings demonstrated that stone clearance achieved 91.5% in Group A patients yet remained at 88.1% in Group B although this difference proved insignificant ($p=0.54$) Table 1. Both study groups demonstrated similar results without any recording of major complications or thromboembolic events Figure 1. Physicians treated postoperative fever and urinary leakage equally in both groups and handled them through conservative methods

Parameter	Group A (TXA)	Group B (Placebo)	p-value
Mean Age (years)	48.6 \pm 10.1	49.3 \pm 9.6	0.64
Male Patients (%)	61%	58%	0.73
Pre-op Hemoglobin (g/dL)	13.1 \pm 1.4	13.0 \pm 1.3	0.78
Post-op Hemoglobin (g/dL)	12.1 \pm 1.2	11.1 \pm 1.5	<0.001
Hemoglobin Drop (g/dL)	1.0 \pm 0.4	1.9 \pm 0.6	<0.001
Pre-op Hematocrit (%)	39.3 \pm 3.9	39.0 \pm 4.1	0.66
Post-op Hematocrit (%)	36.5 \pm 3.5	34.1 \pm 3.8	<0.001
Hematocrit Drop (%)	2.8 \pm 1.1	4.9 \pm 1.4	<0.001
Blood Transfusion Required (%)	10.2%	28.8%	0.01
Hospital Stay (days)	2.7 \pm 0.8	3.4 \pm 1.0	0.002
Stone Clearance Rate (%)	91.5%	88.1%	0.54

Table 1. Comparison of Outcomes Between TXA and Placebo Groups

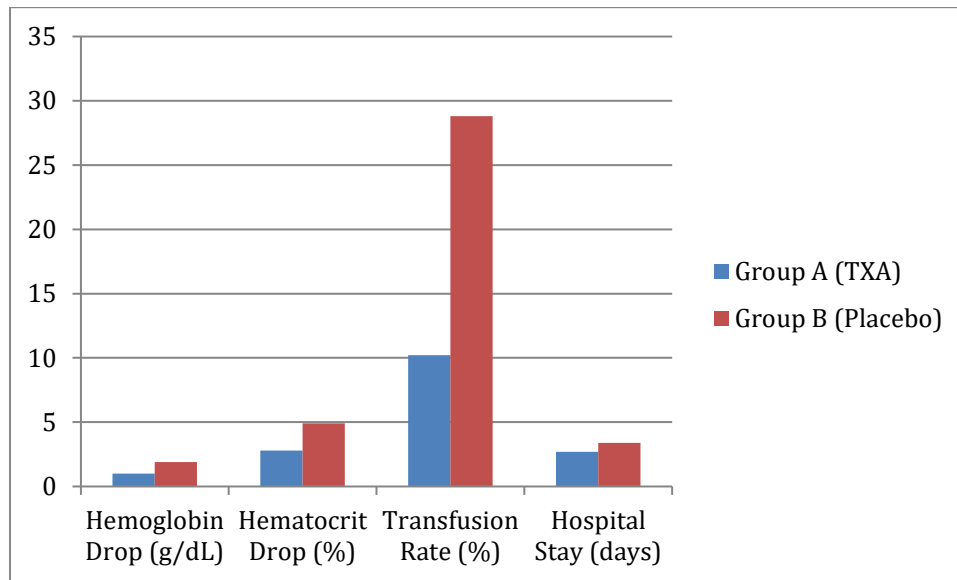


Figure 1. Comparison Of Key Postoperative Outcomes

DISCUSSION

Researchers conducted a randomized controlled trial to determine how intravenous tranexamic acid (TXA) affects blood loss and transfusion needs for patients who have percutaneous nephrolithotomy (PCNL). Research data shows that patients receiving tranexamic acid therapy experienced less hemoglobin and hematocrit level reduction and reduced need for blood transfusion with shorter hospitalization duration while avoiding additional complications. The collection of evidence demonstrates the advantage of antifibrinolytic medications as a way to enhance results from urological surgical procedures. The treatment of complex stones together with long operation times produces bleeding complications that frequently occur during PCNL procedures. Intravenous tranexamic acid (TXA) therapy resulted in lower average hemoglobin decrease of 1.0 ± 0.4 g/dL than placebo treatment resulting in 1.9 ± 0.6 g/dL drop which illustrates TXA's effectiveness in achieving control of bleeding. The intervention group had a significantly lower decline in hematocrit compared to controls ($2.8 \pm 1.1\%$ vs. $4.9 \pm 1.4\%$) along with both differences establishing statistical significance at $p < 0.001$. Research results by multiple previous studies confirm that TXA administration during PCNL generates decreased bleeding amounts



during surgery and following treatment . This study demonstrated an important outcome when 10.2% of TXA group patients needed blood transfusion compared to 28.8% of placebo group patients ($p=0.01$). Blood product transfusion entails various dangers such as immunological responses as well as infectious pathogen spread that increase the cost of medical care. The clinical effectiveness of TXA in decreasing the need to transfuse blood proves important especially when blood products are not available in resource-constrained situations. The study results support findings by Rashid et al. and Lee et al. who reported substantial transfusion reduction after TXA administration during PCNL procedures . Hospital stay provides information about surgical recovery along with healthcare resource utilization. Patients who received TXA spent fewer days in hospital at mean 2.7 ± 0.8 days compared to placebo patients who remained hospitalised for 3.4 ± 1.0 days according to statistical analysis ($p=0.002$). The reduced duration of hospital stay creates pleased patients who face fewer treatment-related complications and minimized costs while healthcare facilities achieve better bed availability. The study results indicate better intraoperative hemostasis leads to quicker postoperative recovery as well as earlier discharge since hospital stay duration showed significant differences with placebo.

The safety characteristics of TXA administration remained favorable because both thromboembolic events and adverse drug reactions were absent during the study. The pro-thrombotic characteristics of TXA remain a concern for medical staff who perform genitourinary tract procedures because this area naturally contains high levels of fibrinolysis properties. The clinical use of TXA in urological surgeries and other surgical procedures did not lead to significant increases in thromboembolic events when suitable patient selection criteria were followed according to published meta-analytic research . Stone clearance statistics between the placebo group at 88.1% and the TXA group at 91.5% revealed no statistical variations between the two groups. Upon achievement of better surgical clarity from blood loss reduction it enables more accurate stone fragmentation and removal techniques. The impact of TXA on stone clearance results can only be fully understood through studies that enroll more participants. This research study demonstrated strong points from its randomized design and adequate participant numbers and standardized surgical handling procedures in treatment groups. TXA has several drawbacks



during its utilization. The research findings may be difficult to generalize across different medical settings since it was conducted at a single institution. The study did not involve long-term assessment for delayed complications including thromboembolism.

CONCLUSION

The research results indicate it is appropriate to administer tranexamic acid intravenously as standard procedure for PCNL patients particularly when surgery is expected to be risky or complex. The administration of TXA leads to extensive blood loss reduction together with minimized transfusion necessity without compromising patient safety standards. Future research must include multi-center trials with extended follow-up periods to develop standardized drug protocols and prove both safety and effectiveness of intravenous tranexamic acid treatment.

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