

ORIGINAL RESEARCH

Efficacy And Safety of Tranexamic Acid in Reducing Blood Loss and Transfusion Requirements During Percutaneous Nephrolithotomy

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Abstract: **Introduction:** This study examines TXA as a fibrinolysis inhibitor and blood clot stabilizer to evaluate its effectiveness in improving patient outcomes, reducing blood transfusion rate, and the potential to shorten the surgery duration and hospital stay. **Materials and Methods:** In this prospective case-control study, 200 patients with kidney stones candidates for Percutaneous nephrolithotomy (PCNL) surgery referred to Tehran's Shohada Tajrish Hospital were selected. In this regard, 100 of them, who received tranexamic acid during the surgery, were allocated to the case group, and the other 100 who did not receive it were assigned to the control group. Statistical tests were used to compare the data between the two groups. **Results:** The results revealed that 200 patients with kidney stones, with a mean age of 43.38, including 126 males and 46 females, were included in the study. The frequency distribution of demographic data and clinical findings between the two case and control groups was similar ($p>0.05$). Tranexamic acid administration in the case group compared with the control group reduced the need for blood transfusion by 81 % and reduced the mean surgery period by 21.34 minutes. Additionally, the hemoglobin drop in the case group was significantly lower than that in the control group ($P<0.05$). The mean change of creatinine did not show a significant difference between the two groups ($P>0.05$). **Conclusion:** The results indicate that the prescription of tranexamic acid during PCNL surgery effectively prevents bleeding and hemoglobin drop and reduces the need for blood transfusions and surgery periods without causing specific renal complications.

Keywords: Percutaneous nephrolithotomy, Tranexamic acid, Bleeding, Blood transfusion

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1. Introduction

Kidney stones or nephrolithiasis are one of the types of urinary stones that may be in the kidney, ureter, bladder, or urinary tract, but are commonly formed in the kidney and are known as kidney stones. It is more common at the ages of 20 to 50 years, and it is more common in men (1). Its prevalence is reported to be 1-5% in different regions. It is estimated at 2-3% in developed countries and 0.5-1% in developing countries (2). In this regard, 75% of them are calcium, including oxalate, calcium phosphate, or a combination of oxalate and phosphate. Several factors, such as inappropriate nutrition, drug use, environmental factors, genetic fac-

tors, and many other issues, affect it (3). About 50% of patients experience urinary tract recurrence within 5 years after treatment. Thus, urinary stones are recurrent and harmful to the efficient and active workforce, so treatment should be used for the cases that are less aggressive, low-cost, and can be easily repeated if necessary (4,5). If medical treatments do not work, endourology surgeries are one of the most common treatments for nephrolithiasis, which has widely replaced surgery. In this technique, the stone is broken by the impact waves and transmitted through water using an endoscopic view (6). Percutaneous nephrolithotomy (PCNL) is an approved lithotripsy method for most nephrolithiasis due to fewer complications and a quick return to daily activities. This technique is a selective treatment for large stones (larger than 2 cm), resistant to Extracorporeal shockwave lithotripsy (ESWL), stones in the lower calyx of the kidney (7).

Despite its multirole benefits, such as high success, low com-

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plications, and rapid recovery, PCNL still has high disadvantages compared to other urology methods (8). Bleeding during nephrolithotomy can be worrying for patients and surgeons (9). Bleeding management during surgery is vital to maintain the patient's immunity and ensure optimal surgical outcomes (10). Several techniques and pharmaceutical factors are used to minimize bleeding during surgery. Studies have indicated that drugs such as dexmedetomidine and clonidine can significantly reduce bleeding during surgery compared to placebo (11). In addition, tranexamic acid (TXA) is effective in reducing blood loss during surgeries like prostatectomy and highlights the importance of selecting drug interventions appropriate to the patient's needs (12). Effective management strategies not only increase the surgeon's satisfaction with surgery but also help patients recover better (13).

Tranexamic acid is an artificial derivative of lysine, which is primarily known as an antifibrinolytic agent that prevents it from converting to plasmin by connecting to plasminogen, thus stabilizing blood clots and excessive bleeding (14). Tranexamic acid (TXA) applications have expanded significantly in recent studies. However, TXA may increase the risk of deep vein thrombosis (DVT) and other thrombotic events; therefore, it is contraindicated in patients with a history of cerebrovascular accident (CVA) or DVT. (15). Several studies have indicated the effect of TXA on the consequences of bleeding in various fields of surgery (16). Tranexamic acid has demonstrated significant efficacy in reducing bleeding during kidney stone surgeries, particularly with procedures such as percutaneous nephrolithotomy (PCNL) (17). Patients who received TXA experienced shorter operations and shorter hospital stays (17). Moreover, results from several studies indicate that TXA not only reduces blood loss but also decreases the need for blood transfusions, thereby enhancing patient immunity and promoting faster recovery (18). This study investigates the effectiveness of TXA in reducing the level of bleeding caused by PCNL procedures in patients with kidney stones referred to Shohada Tajrish Hospital in 2023 to evaluate the efficiency of this drug in controlling bleeding during surgery in a specialized clinical environment.

2. Materials and Methods

The present case-control study was conducted on patients with kidney stones under PCNL surgery referred to Shohada Tajrish Hospital in 2013. Given the frequency of samples in article (27), Mokhtari et al. (19), and Batagello et al. (20), and considering $p = 0.7$ and with a 95% confidence interval, the sample was calculated to be 100 in each group. A continuous sampling method based on inclusion and exclusion criteria was used. The inclusion criteria included having in-

formed consent to participate in the study, a definitive diagnosis of kidney stones, and candidates for PCNL surgery, and non-use of drugs interfering with tranexamic acid. The exclusion criteria also included unwillingness to continue cooperation and participate in the study, deteriorating the patient, the need for vital measures and interventions for the patient, and the death of the patient for any reason before the surgery), history of taking oral contraceptive pills, and history of thrombosis or thromboembolism or hyper coagulopathy.

All patients underwent PCNL surgery performed by a single consistent surgical team. A 500 mg dose of tranexamic acid was administered intravenously in the operating room just before surgery.

After obtaining the approval of the Ethics Committee (IR.SBMU.MSPREC.1402.050) and receiving a letter from the Research Deputy of the School of Medicine, Shahid Beheshti University of Medical Sciences, and submitting it to the respected officials of Shohada Tajrish Hospital, the method of conducting the study was explained, and sampling permission was obtained. We accessed the information of patients who were candidates for PCNL using the clinical files of patients in the clinical department of the hospital, the Hospital Information System (HIS), laboratory findings, and imaging. The required demographic data, including age, gender, underlying disease, and drugs, were collected by interviewing patients.

Clinical data, including stone place, stone size, kidney side, hydronephrosis severity, and preoperative creatinine and hemoglobin levels, were collected and recorded using clinical file data, radiology findings, and laboratory tests. Patients were assigned to one of the case or control groups based on receiving or did not receive tranexamic acid.

The surgery duration was calculated from the beginning to the end of the surgery. Hemoglobin and blood creatinine levels were also recorded 12 hours after surgery. The rate of hemoglobin drop was calculated as the difference between hemoglobin before surgery and hemoglobin 12 hours after surgery. The collected data were compared between the case and control groups. Statistical tests, including univariate regression and multivariate regression models, were used to identify the relationships between the use and non-use of TXA and bleeding conditions during and after surgery. The study data were analyzed using SPSS software.

3. Results

The total number of patients participating in the study was 200 people, with a mean age of 43.38 years. The youngest patient was 12 years old, and the oldest was 77 years old. The majority of them were male, did not have an underlying disease, and did not use specific drugs. The stones were mostly

in the left kidney and the pelvis site, with a mean size of 23.28 mm and mild hydronephrosis. The mean surgery period was 101.10 minutes from the beginning to the end. The mean postoperative hemoglobin decreased compared to preoperative hemoglobin, and a few patients needed blood transfusions.

As shown in Table 1, the frequency of demographic characteristics such as age, gender, history of the underlying disease, and used drugs did not show a significant statistical difference between the case and control groups.

As shown in Table 2, the frequency of clinical findings such as stone place, stone size, kidney side, hydronephrosis severity, preoperative hemoglobin, and preoperative and postoperative creatinine levels did not show a significant statistical difference between the case and control groups, and the two groups were matched regarding frequency distribution of the clinical data ($P>0.05$). However, the distribution of findings such as the need for blood transfusions, the mean postoperative hemoglobin, and the surgery duration was significantly different between the two groups ($P<0.05$).

As shown in Table 3, the statistical tests of logistic and linear univariate regression tests showed the relationship between the administration of tranexamic acid and both variables requiring blood transfusion and surgery duration was significant when the intervening variables were not adjusted. After including the demographic variables such as age, gender, history of the underlying disease, and drug use, and clinical variables such as stone place, stone size, kidney side, hydronephrosis severity, and preoperative hemoglobin, which is likely to affect the need for blood transfusions and surgery duration, the multiple regression statistical test showed that tranexamic acid administration could independently and after adjusting other variables affect the two variables of need for blood transfusions and surgery duration. Accordingly, it reduced the need for blood transfusion in patients receiving tranexamic acid compared to patients who did not receive this drug, with an odds ratio of 0.19 ($OR = 0.19$) or 81%. The results also indicated that administering tranexamic acid reduced the duration of surgery by an average of 21.34 minutes compared to patients who did not receive the drug ($B = -21.34$).

As shown in Table 4, the mean change in blood creatinine before and after surgery does not show a significant difference between the two groups of control and case. However, the change in the mean hemoglobin levels of the two groups was statistically significant, while the mean drop in hemoglobin in the case group patients was significantly less than that of the control group patients (not receiving tranexamic acid).

4. Discussion

The results revealed that tranexamic acid administration in the case group significantly reduced hemoglobin loss and the need for blood transfusion. The results that indicated TXA significantly reduces hemoglobin drop and the need for blood transfusions compared to the control group are consistent with the high number of previous studies to support TXA use in various fields of surgery. Past studies, such as the systematic examination of pelvic fracture surgeries, showed that TXA administration significantly reduces blood transfusion rates at a risk ratio of 0.72, indicating a lower likelihood of needing blood products among people treated with TXA. In addition, studies have revealed that TXA effectively reduces estimated blood loss in various surgical environments, including orthopedic and oncological surgeries, confirming the results of the present study (21).

Feng et al. examined the effectiveness of tranexamic acid in reducing blood loss and blood transfusions during percutaneous nephrolithotomy. The patients who received tranexamic acid experienced less bleeding and needed fewer blood transfusions (22). In another meta-analysis study, Wang and co-workers investigated the effect of tranexamic acid on the need for blood transfusions in PCNL patients. It was shown that tranexamic acid significantly reduced blood transfusions and hemoglobin drops after PCNL (23). The results of another random clinical trial study revealed that the overall risk of blood transfusions in patients who received tranexamic acid was significantly reduced (20). Samudera and colleagues also investigated the effect of tranexamic acid on bleeding during PCNL surgery. The study indicates promising roles of tranexamic acid in the control of bleeding in these patients (24). Another meta-analysis study on 11 clinical trials with 1842 patients showed a reduction in blood administration rates, a reduction in bleeding rates, and a reduction in hemoglobin drops among those who received tranexamic acid compared to the control group (25).

Another clinical trial reported that the administration of tranexamic acid reduces bleeding rates than placebo, although it raises concerns about cardiovascular immunity, such as thromboembolic events (26). However, none of the patients who received TXA experienced DVT or thromboembolic events.

Tranexamic acid, an antifibrinolytic agent, has been shown to reduce bleeding in various surgical settings. However, its safety and efficacy when used prophylactically before PCNL remain areas of clinical interest. This study demonstrated that TXA is effective in reducing bleeding during PCNL. Additionally, none of the patients in our study experienced vascular or cardiac complications such as DVT, CVA, or cardiovascular events. Therefore, the use of TXA was shown to be safe.



The studies showed that TXA is effective in minimizing blood loss and blood transfusions in various fields of surgery while maintaining the patient's desirable immunity. Generally, the evidence supports the routine use of tranexamic acid as a beneficial intervention in surgical methods to increase patient outcomes related to bleeding. Studies showed the importance of TXA in postoperative management to reduce blood loss and blood transfusion needs, indicating its potential as a standard factor in surgical protocols aimed at improving patient outcomes. This study also indicated that tranexamic acid administration significantly reduced the surgical duration because of improved visibility due to less bleeding. These results are consistent with those of previous studies. This could be due to TXA's efficiency in minimizing blood loss and improving surgical outcomes. Bansal et al. conducted a clinical trial on Indian patients who underwent nephrolithotomy. In line with the results of the present study, they showed that tranexamic acid administration reduced the surgery duration significantly compared to the control group (27).

Mokhtari et al. conducted a clinical trial on Iranian PCNL patients. They showed that tranexamic acid significantly reduced the surgery duration and the length of hospital stay (19). In a meta-analysis study by MacDonald on 964 patients who underwent PCNL in 11 studies, MacDonald et al. showed that tranexamic acid significantly reduces the surgery duration (28). Another meta-analysis study by Lee et al. on patients who underwent PCNL surgery also proved the effect of tranexamic acid on reducing the surgery duration, which is consistent with the results of the present study (25). Similarly, the studies on TXA fracture surgery showed that TXA can indirectly affect the surgical period by increasing procedure efficiency by significantly reducing the bleeding during surgery (29).

Studies in neurosurgery and abdominal aortic aneurysm surgeries have consistently shown the role of TXA in reducing bleeding during surgery, which is vital for maintaining vision and accelerating surgery (30). However, a study on patients with pelvic fractures and acetabulum, inconsistent with the results of our study, did not show a significant difference during surgery, but it showed a reduction in postoperative hospital stay among people who received TXA. Although immediate surgery may not be affected, overall recovery can be achieved (31). This study also revealed that tranexamic acid administration did not affect blood creatinine level. These results that showed tranexamic acid administration does not significantly affect blood creatinine levels enrich the discourse on kidney immune TXA, especially in surgical settings. Previous studies have provided different results on the effect of TXA on kidney function. For example, consistent with our study results, a systematic survey of TXA in spine surgery revealed that TXA effectively reduces blood

loss, does not significantly increase the risk of thromboembolic events, and does not negatively affect the renal parameters, including creatinine levels (32). Similarly, a study of cardiac surgery patients did not report any significant changes in kidney function after TXA administration, which strengthened the concept of a safe profile. Inconsistent with the results of our study, some studies have raised concerns about the potential impacts of nephrotoxic on high-risk populations, indicating that it must be used with more caution.

4.1. Limitation

A limitation of our study is the inability to perform matching between groups, as it was designed as a case-control study. We recommend conducting future research as a matched, prospective clinical trial to better control for potential confounding factors.

5. Conclusion

TXA administration during PCNL surgery reduced blood loss, decreased the need for blood transfusions, and shortened surgical duration without causing specific complications such as deep vein thrombosis (DVT) or renal impairment.

6. Appendix

6.1. Acknowledgment

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6.2. Conflict of Interest Statement

The authors declare that there is no conflict of interest regarding the publication of this article.

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6.4. Authors contributions

All authors made substantial contributions to the conception, design, data acquisition, analysis, and interpretation of the study. They participated in drafting and critically revising the manuscript and approved the final version for publication.

6.5. Availability of data

It is available.

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Table 1: Distribution of the demographic characteristics of the patients studied based on receiving tranexamic acid (case group) or non-receiving tranexamic acid (control group)

Variable	Sub-variable	tranexamic acid administration status				P value
		Control group (n=100)		Case group (n=100)		
		f	%	f	%	
Gender	Male	59	59	67	67	*0.241
	Female	41	41	33	33	
Underlying disease	No disease	83	83	71	71	**0.372
	Hypertension	10	10	14	14	
	Diabetes	5	1	12	12	
	Heart disease	1	1	1	1	
	Hypothyroidism	1	0	1	1	
	Kidney disease	0	0	1	1	
Used drug	Not	94	94	97	97	*0.306
	Yes	6	6	3	3	
Variable		Mean	SD	Mean	SD	P_Value
Age (year)		43.17	10.41	43.60	12.80	***0.795

*Chi-square, ** Fisher Exact Test , ***Independent T-test

Table 2: Distribution of clinical findings and laboratory data of patients studied based on receiving tranexamic acid (case group) or non-receiving it (control group)

Variable	Sub-variable	tranexamic acid administration status				P value
		Control group (n=100)		Case group (n=100)		
		f	%	f	%	
kidney side	left	49	49	56	56	*0.322
	right	51	51	44	44	
stone place	Pole	24	24	14	14	*0.318
	Calyx	24	24	28	28	
	pelvis	44	44	51	51	
	ureter	8	8	7	7	
Hydronephrosis severity	mild	69	69	66	66	*0.641
	moderate	23	23	22	22	
	Severe	8	8	12	12	
Need for blood transfusion	No	88	88	96	96	*0.037
	Yes	12	12	4	4	
Variable		Mean	SD	Mean	SD	P_Value
Stone size (mm)		23.16	10.07	23.40	7.67	**0.820
Surgery duration (minutes)		110.70	32.38	91.50	22.185	**0.001>
Preoperative creatinine (mg/dl)		1.13	0.37	1.12	0.34	**0.856
Preoperative hemoglobin (g/dl)		13.42	1.54	13.57	1.56	**0.496
Postoperative creatinine (mg/dl)		1.20	0.34	1.23	0.31	**0.505
Postoperative hemoglobin (g/dl)		12.27	1.40	13.12	1.60	**0.001>

*Chi-square, ** Fisher Exact Test , ***Independent T-test



Table 3: Investigating the relationship between the use and non-use of tranexamic acid and the need for blood transfusion and the surgery duration using univariate and multivariate statistical tests

Test type	Variable	OR	P-Value	95% CI		
				Lower	Upper	
need for blood transfusion	Univariate logistic	Non-administration of tranexamic acid administration of tranexamic acid	Reference (RF=1)			
	0.30		0.047	0.09	0.98	
	multivariate logistic	Non-administration of tranexamic acid administration of tranexamic acid	Reference (RF=1)			
	0.19		0.026	0.04	0.82	
Test type		Variable	B	P-Value	95% CI	
					Lower	Upper
the surgery duration	Univariate linear	Non-administration of tranexamic acid administration of tranexamic acid	Reference (RF=1)			
	-19.20		0.001>	26.94-	11.45-	
	multivariate linear	Non-administration of tranexamic acid administration of tranexamic acid	Reference (RF=1)			
	21.34-		0.001>	29.47-	13.21-	

OR; Odds Ratio, CI; Confidence Interval

Table 4: Investigating the relationship between the use and non-use of tranexamic acid and the need for blood transfusion and the surgery duration using univariate and multivariate statistical tests

Variable	Control group		Case group		Mean dif- ference	P_Value
	95% CI		Mean	SD		
	Lower	Upper	Mean	SD		
hemoglobin (g/dl)	-1.15	1.15	-0.45	0.55	-0.70	>0.001
	-0.95					
Creatinine (mg/dl)	0.07	0.21	0.11	0.24	-0.04	0.212
	-0.10	0.02				

SD; Standard Deviation