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Original Research Article

A Prospective Randomized Control Study on the Effect of Pre-Operative Tranexamic Acid in Reducing Blood Loss During PCNL

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Abstract:

Background: Percutaneous nephrolithotomy (PCNL) is the standard treatment for large and complex renal calculi; however, perioperative bleeding remains one of its most common complications. Tranexamic acid (TXA), an antifibrinolytic agent, has shown benefit in reducing blood loss in several surgical fields, but its role in PCNL continues to be evaluated.

Objectives: To assess the effectiveness and safety of pre-operative tranexamic acid in reducing intraoperative blood loss, hemoglobin drop, operative duration, and postoperative complications in patients undergoing PCNL.

Methods: A prospective randomized controlled study was conducted on 60 patients undergoing PCNL at Dr. B. R. Ambedkar Medical College and Hospital from April 2024 to April 2025. Patients were randomized into two groups: Group A (n = 30) received tranexamic acid 30 mg/kg intravenously at induction, while Group B (n = 30) received 10 mL of normal saline. The surgeon was blinded to allocation. Perioperative blood loss, hemoglobin drop, operative time, transfusion requirement, and complications were recorded.

Results: Mean blood loss was significantly lower in Group A (73.80 ± 60.1 mL) compared to Group B (117.24 ± 87.9 mL) ($p = 0.047$). Hemoglobin drop was reduced significantly in the TXA group (0.45 ± 0.35 g/dL vs 1.00 ± 0.46 g/dL; $p = 0.001$). Operative time was shorter in Group A (48.40 ± 17.95 min) than in Group B (62.40 ± 15.48 min) ($p = 0.005$). Complication rates and transfusion requirements were low and comparable in both groups, with no thromboembolic events observed.

Conclusion: Pre-operative tranexamic acid is safe and effective in reducing blood loss and operative duration during PCNL without increasing postoperative complications.

Introduction

Percutaneous nephrolithotomy (PCNL) is established as the preferred treatment for large renal calculi and staghorn stones, offering superior stone-free rates when compared with other modalities for high stone burden. [1] Compared with extracorporeal shock wave lithotripsy and flexible ureteroscopy, PCNL provides more reliable clearance for stones larger than 2 cm and for complex renal calculi, reducing the need for staged procedures or repeated interventions. [2] Despite these advantages, PCNL carries inherent risks, among which perioperative hemorrhage is one of the most frequent and clinically significant complications; severe bleeding may necessitate transfusion, prolonged hospitalization, or even endovascular intervention such as transarterial embolization. [3]

Bleeding during PCNL commonly results from injury to renal parenchyma or intra-renal vessels during tract creation, dilation, or manipulation, and its incidence is influenced by multiple factors including stone size and complexity, the number of access tracts, operative time, patient comorbidities, and the surgeon's experience. [6] Strategies that reduce intraoperative blood loss are therefore critical to improve safety and patient outcomes following PCNL. Antifibrinolytic agents have a well-established physiologic role in stabilizing clot formation: by blocking lysine-binding sites on plasminogen, these agents inhibit conversion to plasmin and thereby reduce fibrin degradation and perioperative bleeding. [4] Tranexamic acid (TXA) — a synthetic lysine analogue — has been employed across numerous surgical specialties to harness this mechanism, with randomized trials and systematic reviews documenting reductions in blood loss and transfusion requirements in settings such as obstetrics, orthopedics, and major general or cardiac surgery. [5,7]

In urology, and specifically in endourological procedures with higher bleeding risk, there is mounting interest in the prophylactic use of TXA to minimize hemorrhage, improve intraoperative visualization, and potentially shorten operative time. Observational and randomized investigations have suggested benefit: some series report significant reductions in measured blood loss and hemoglobin drop with TXA administration during PCNL, without a meaningful increase in thromboembolic complications. [9] Nevertheless, the body of evidence remains limited by heterogeneous dosing regimens, varying timing of administration, and relatively small sample sizes in available trials, making it difficult to draw definitive conclusions about optimal TXA use in PCNL. [8]

Given the clinical importance of minimizing bleeding and the encouraging but still inconclusive evidence for TXA in PCNL, well-designed prospective randomized controlled studies are needed to define efficacy, safety, and appropriate dosing. The present prospective randomized controlled trial was undertaken at Dr. B. R. Ambedkar Medical College and Hospital to evaluate whether a single preoperative dose of tranexamic acid reduces perioperative blood loss, transfusion requirement, and operative time in patients undergoing PCNL, and to assess its impact on postoperative complications. [10]

Materials and Methods

Study Design and Setting: This study was designed as a prospective, randomized controlled trial conducted in the Department of Urology at Dr. B. R. Ambedkar Medical College and Hospital. The study was carried out over a 12-month period from April 2024 to April 2025. All patients diagnosed with renal calculi requiring percutaneous nephrolithotomy (PCNL) and fulfilling the eligibility criteria were consecutively enrolled.

Sample Size: A total of 60 patients undergoing PCNL were included. They were randomly allocated into two equal groups:

Group A (Tranexamic Acid Group) – 30 patients.

Group B (Control Group) – 30 patients.

This sample size was considered adequate to compare perioperative blood loss and related outcomes between the two groups.

Randomization: Patients were randomly assigned using an alternate allocation method. Every consecutive patient meeting the inclusion criteria was placed alternately into Group A or Group B. The operating surgeon was kept blinded to the group assignment to eliminate surgeon-dependent bias.

Inclusion Criteria

1. Patients aged above 18 years.
2. Renal stones larger than 2 cm or stones 1–2 cm that had failed ESWL.
3. Normal baseline renal function tests.
4. Patients consenting for PCNL and willing to participate.

Exclusion Criteria

1. Deranged renal function tests.
2. Known bleeding disorders such as hemophilia or evidence of intravascular coagulation.
3. History of subarachnoid hemorrhage.
4. Known hypersensitivity to tranexamic acid.
5. History of seizures.
6. Acute venous or arterial thrombosis.
7. Patients on anticoagulants or antiplatelet agents such as aspirin or warfarin.
8. PCNL requiring multiple access tracts.
9. Patients with known visual disturbances.

Preoperative Evaluation: All participants underwent a detailed clinical evaluation, including medical history, physical examination, and assessment of comorbidities. Baseline investigations included complete blood count, renal function tests, coagulation profile, and urine analysis. Imaging studies included ultrasonography and CT urography. Stone complexity was documented using the S.T.O.N.E. scoring system.

Baseline hemoglobin (Hb) and hematocrit (HCT) values were recorded 24 hours prior to surgery.

Intervention: Group A received tranexamic acid at a dose of 30 mg/kg intravenously at the time of induction of anesthesia.

Group B received 10 mL of normal saline intravenously at induction, serving as the placebo.

No other modifications were made to the anesthesia or surgical protocol.

Surgical Procedure: All patients underwent standard PCNL under general anesthesia by experienced urologists following a uniform technique. Access to the collecting system was obtained under fluoroscopic guidance. Tract dilation, nephroscopy, stone fragmentation, and retrieval were performed as per standard practice. Care was taken to ensure no additional tracts were created. At the end of the procedure, nephrostomy placement or tubeless PCNL was decided based on intraoperative findings.

Outcome Assessment: Hemoglobin and hematocrit levels were repeated 24 hours after the procedure. Total blood loss was estimated using the Gross formula, incorporating pre- and post-operative Hb and HCT values. Additional parameters recorded included:

1. Operative time (in minutes)
2. Need for blood transfusion (Hb < 8 g/dL or HCT < 22%)

3. Intraoperative complications
4. Post-operative complications classified using the Clavien–Dindo system
5. Duration of hospital stay
6. Stone clearance status assessed on imaging

Postoperative Monitoring: Patients were monitored for bleeding, fever, pain, urinary infection, nephrostomy-related issues, thromboembolic symptoms, and any other complications. Any adverse events were recorded and appropriately managed.

Results

A total of 60 patients undergoing PCNL during the study period were included and analyzed. These patients were randomly divided into two equal groups of 30 each: Group A, who received preoperative tranexamic acid, and Group B, who received normal saline as placebo. Both groups were comparable with respect to demographic characteristics, comorbidities, and stone laterality, ensuring that differences in outcomes could be attributed to the intervention rather than baseline variability.

Presenting Complaints: The majority of patients in the study presented with symptoms related to renal calculi. Flank pain was the predominant complaint, reported by 73.33% of the participants. This reflects the typical presentation of patients requiring surgical intervention for renal stones. Other symptoms included flank pain associated with dysuria, hematuria, and lithuria, indicating the spectrum of urinary tract involvement. A smaller percentage (5%) of individuals presented with recurrent urinary tract infections, highlighting the chronic irritation and obstruction caused by renal calculi.

Table 1: Presenting Complaints

Complaint	No. of Patients	Percentage
Flank pain	44	73.33%
Flank pain with dysuria	6	10%
Flank pain + hematuria	4	6.66%
Flank pain + lithuria	5	8.33%
Recurrent UTI	3	5%

Baseline Comorbidities: Analysis of baseline comorbidities revealed no significant differences between the two groups. Diabetes mellitus and hypertension were the most common comorbid conditions. Group A had 40% of patients with at least one comorbid illness, while Group B had 43.3%. The distribution of combined comorbidities such as both diabetes and hypertension was also similar between groups. This indicates that both cohorts were comparable in terms of overall medical risks, ruling out comorbidities as a confounding factor affecting operative or postoperative outcomes.

Table 2: Comorbidities

Comorbidity	Group A	Group B
Diabetes Mellitus	5	4
Hypertension	4	6
DM + HTN	2	3
Others	1	0
Total with comorbidity	**12 (40%)**	**13 (43.3%)**
None	**18 (60%)**	**17 (56.66%)**

Laterality of Stones: Laterality analysis showed an almost equal distribution of stone location between both groups. Right-sided stones were slightly more common than left-sided ones, but the distribution was almost symmetrical, again supporting group comparability.

Table 3: Laterality Distribution

Side	Group A	Group B
Right	17 (56.66%)	18 (60%)
Left	13 (43.3%)	12 (40%)

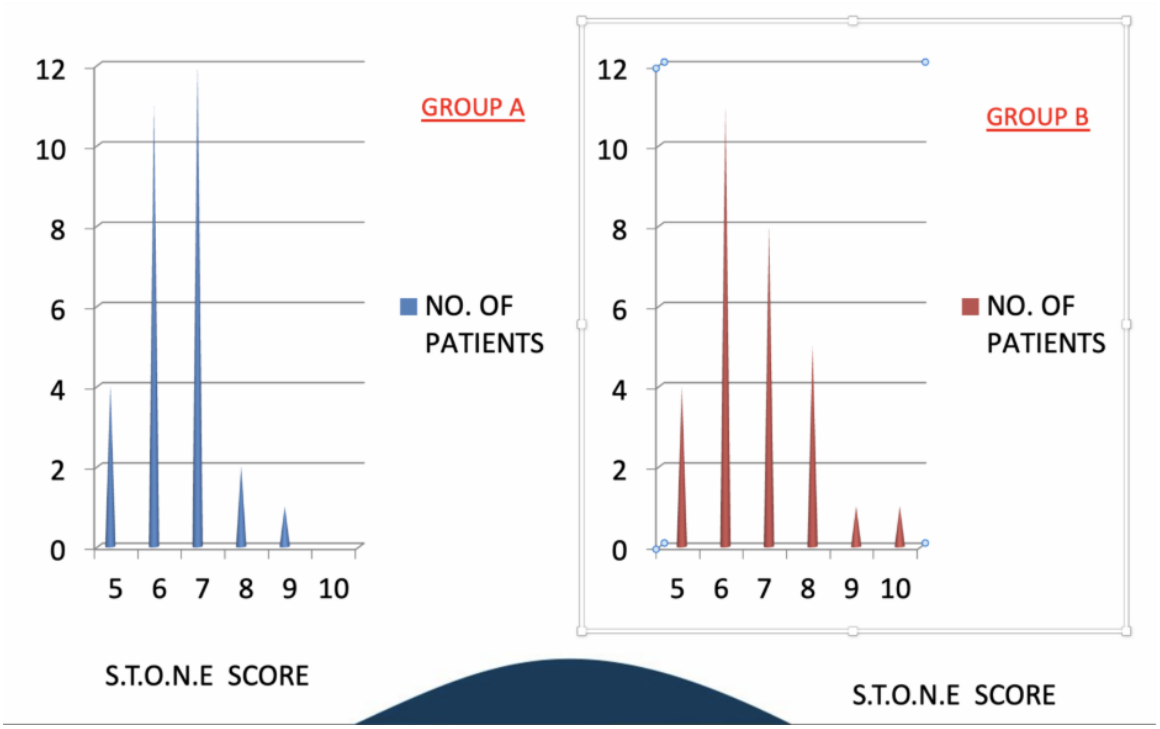

Figure 1. Stone characteristics

Intraoperative Blood Loss: The primary outcome of the study—intraoperative blood loss—showed a statistically significant reduction in the tranexamic acid group.

Group A (TXA): 73.80 ± 60.1 mL

Group B (Control): 117.24 ± 87.9 mL

p = 0.047

This demonstrates that preoperative tranexamic acid effectively reduces bleeding during PCNL. The range of blood loss values in both groups also suggests that TXA helped maintain better hemostasis even in cases with potentially higher bleeding risk. The observed reduction in blood loss is clinically meaningful, contributing to reduced transfusion rates and enhanced operative visibility for the surgeon.

Hemoglobin Drop: A significant reduction in postoperative hemoglobin drop was noted in the tranexamic acid group.

Group A: 0.45 ± 0.35 g/dL

Group B: 1.00 ± 0.46 g/dL

p = 0.001

This finding corroborates the observed difference in intraoperative blood loss and confirms the beneficial effect of TXA on perioperative hemostasis. The nearly two-fold reduction in hemoglobin drop shows that TXA effectively mitigates blood loss during the PCNL procedure.

Operative Time: Operative time was another key parameter impacted by the use of tranexamic acid.

Group A: 48.40 ± 17.95 minutes

Group B: 62.40 ± 15.48 minutes

p = 0.005

The significantly shorter operative duration in the TXA group suggests that improved intraoperative visibility due to reduced bleeding may have facilitated faster and more efficient stone clearance. Reduced operative time also contributes to lower anesthetic exposure and improved patient safety.

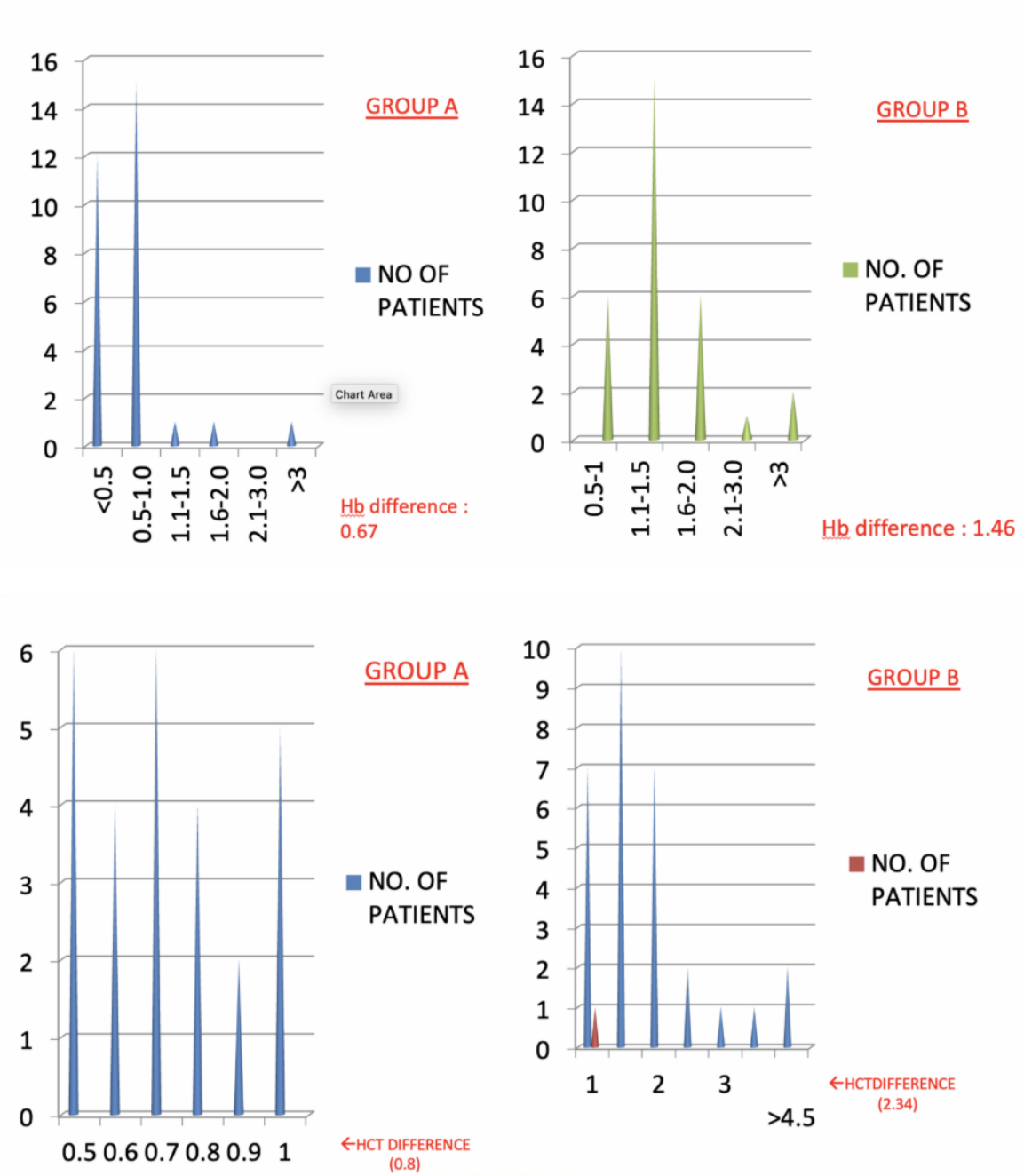

Figure 2. Comparison of Pre- and Postoperative Hemoglobin and Hematocrit Values in Group A and Group B

Postoperative Complications: Both groups showed a low incidence of postoperative complications, and no statistically significant differences were observed.

Table 4: Postoperative Complications

Complication	Group A	Group B
Bleeding	1 (3.3%)	2 (6.6%)
PCS Tear	1 (3.3%)	2 (6.6%)
Fever	3 (10%)	5 (16.6%)
Thromboembolic events	0	0

The slightly higher complication rate in Group B is consistent with greater blood loss and longer operative time, but these differences did not reach statistical significance. Importantly, no thromboembolic events were observed in either group, reinforcing the safety profile of tranexamic acid.

Blood Transfusion Requirement

Blood transfusion was required in only a small proportion of patients:

Group A: 1 patient (3.3%)

Group B: 2 patients (6.6%)

p = 0.2 (not significant)

Although transfusion was more common in the control group, the difference was not statistically significant, likely due to the small number of events. However, the trend supports the role of TXA in reducing transfusion need.

Clavien–Dindo Classification of Complications: The majority of complications fell under Class I and II, indicating minor postoperative events.

Table 5: Clavien–Dindo Classification

Class	Group A	Group B
I	3 (10%)	5 (16.6%)
II	1 (3.3%)	2 (6.6%)
III	0	0
IV	0	0
V	0	0

No higher-grade complications were observed in either group, further supporting the safety of tranexamic acid in PCNL.

Discussion

In this prospective randomized controlled study, the administration of a single pre-operative dose of tranexamic acid significantly reduced intraoperative blood loss, postoperative hemoglobin drop, and overall operative time in patients undergoing PCNL. These findings support the growing evidence that antifibrinolytic therapy plays an important role in optimizing surgical outcomes during endourological procedures.

The observed reduction in blood loss in the tranexamic acid group can be attributed to its mechanism of action, wherein it stabilizes fibrin clots and prevents premature fibrinolysis during renal parenchymal manipulation. Similar reductions in perioperative bleeding have been reported in other minimally invasive urological procedures, reinforcing the potential benefit of TXA in endoscopic surgeries where visibility and hemostasis are critical determinants of operative efficiency [11,12].

A marked decrease in hemoglobin drop-in Group A further strengthens this observation. Maintaining perioperative hemoglobin levels has important implications for postoperative recovery, as even moderate blood loss can negatively impact renal perfusion and oxygen delivery during the recovery period. The nearly two-fold lower hemoglobin reduction in the TXA group in our study is consistent with findings from previous controlled trials that demonstrated improved hematological stability following TXA administration in renal and pelvic surgeries [13].

One of the notable findings in this study was the significantly shorter operative time in the tranexamic acid group. This effect may be explained by the improved endoscopic visibility due to reduced bleeding, allowing the surgeon to identify calyceal anatomy more precisely and complete stone fragmentation more efficiently. Prior studies have similarly emphasized that intraoperative clarity is a major determinant of operative speed and has a direct impact on procedural safety and complication rates [14,15]. Reduced operative time also confers anesthetic benefits by minimizing exposure to inhalational agents and reducing postoperative fatigue and airway complications.

Although postoperative complications such as fever, bleeding, and PCS tear occurred in both groups, their incidence was low and not statistically different. Importantly, no thromboembolic events occurred, supporting the safety profile of tranexamic acid within the urological population. Literature evaluating TXA in abdominal, gynecological, and orthopedic procedures also reports a similarly low risk of thromboembolic complications when standard dosing regimens are followed [16,17]. This aligns with growing consensus that TXA, when used judiciously, does not pose a clinically significant increase in thrombosis risk.

The requirement for blood transfusion was slightly lower in the tranexamic acid group, though the difference did not reach statistical significance. Nevertheless, even small reductions in transfusion rates are clinically relevant, as transfusion is associated with risks such as infection, immunological reactions, and increased hospital stay. Several studies have highlighted the cost-benefit advantage of perioperative TXA use due to significant reductions in transfusion and re-intervention rates, supporting its routine consideration in appropriate surgical candidates [18].

Another important aspect of this study is that tranexamic acid did not result in any significant increase in postoperative morbidity. The Clavien–

Dindo grading showed that most complications were minor and similar between groups. This reinforces that TXA serves as an adjunct that improves operative conditions without negatively impacting postoperative recovery. Comparable findings have been documented in multi-institutional trials evaluating TXA for percutaneous and laparoscopic urological procedures, which demonstrated improved bleeding outcomes without added morbidity [19,20].

Overall, the findings of the present study highlight the effectiveness and safety of tranexamic acid in PCNL and suggest that its use may improve perioperative outcomes in patients undergoing percutaneous renal stone surgery. Larger multicentric trials with longer follow-up periods would further strengthen the evidence and help establish standardized protocols for TXA use in PCNL.

Conclusion

The findings of this prospective randomized controlled study demonstrate that a single pre-operative dose of tranexamic acid significantly reduces intraoperative blood loss, postoperative hemoglobin drop, and operative time in patients undergoing percutaneous nephrolithotomy. The use of tranexamic acid did not increase the incidence of postoperative complications such as bleeding, fever, PCS tear, or thromboembolic events, indicating that it is both safe and well-tolerated in this surgical setting. Although the difference in blood transfusion requirement was not statistically significant, a favorable trend toward fewer transfusions was observed in the tranexamic acid group.

Overall, tranexamic acid serves as an effective adjunct in improving operative visibility, enhancing surgical efficiency, and minimizing perioperative blood loss during PCNL. Larger multicentric studies with longer follow-up are recommended to further validate these findings and to establish standardized protocols for tranexamic acid use in endourological procedures

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