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Original research article

EFFECT OF PRE-OPERATIVE TRANEXAMIC ACID ADMINISTRATION ON POST-OPERATIVE HEMOGLOBIN LEVEL IN PERITROCHANTERIC FRACTURES

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Abstract: *Peritrochanteric fractures, a common orthopaedic challenge, often necessitate surgical intervention to restore mobility and prevent complications in the elderly population. Despite advancements in surgical techniques, optimizing perioperative care remains critical to improving outcomes. Tranexamic acid (TXA), an antifibrinolytic agent, has effectively reduced blood loss and transfusion requirements in various surgical procedures.* ***Objective****: To assess the influence of pre-operative TXA administration on postoperative haemoglobin levels, intraoperative blood loss, transfusion rates, and adverse events in peri trochanteric fractures.* ***Methodology:*** *Employing a Prospective Double-Blind study design at Jinnah Medical College Hospital Karachi from January 2020 to January 2021. Ninety participants were enrolled: 45 in the experimental group and 45 in the control group. The AO/OTA Classification categorised fracture severity. The statistical analysis compared the baseline characteristics, postoperative outcomes, and adverse events across groups using t-tests for continuous variables and chi-square tests for categorical data. The main result, the haemoglobin levels after surgery, was examined using analysis of covariance (ANCOVA) to account for any factors that may affect the outcome. The study was performed using the statistical software SPSS (version 23.0).* ***Results****: Baseline characteristics, including age, gender distribution, BMI, and fracture severity, were comparable between groups. Post-operative haemoglobin levels were similar (Experimental: 11.5 ± 1.2 g/dL; Control: 11.9 ± 1.4 g/dL), but the experimental group exhibited significantly lower intraoperative blood loss (350 ± 50 mL vs 380 ± 60 mL, p=0.032). Transfusion rates were comparable (Experimental: 8.9%; Control: 11.1%), and adverse event incidences, including infections (Experimental: 6.7%, Control: 8.9%), thromboembolic events (Experimental: 2.2%, Control: 4.4%), and cardiovascular complications (Experimental: 4.4%, Control: 2.2%), were comparable, emphasising TXA's safety profile.* ***Conclusion:*** *Pre-operative TXA administration in peritrochanteric fractures may effectively reduce intraoperative blood loss without adverse effects on post-operative haemoglobin levels or increased adverse event rates. These findings contribute valuable insights into the potential benefits of TXA in optimising surgical outcomes in this specific orthopaedic context.*

Keywords: tranexamic acid, peri trochanteric fractures, hemostasis, orthopaedic surgery, adverse events

Introduction

Peritrochanteric fractures, a common orthopaedic challenge, often necessitate surgical intervention to restore mobility and prevent complications in older people (1). Despite advancements in surgical techniques, optimising perioperative care remains critical to improving outcomes. TXA, an antifibrinolytic agent, has effectively reduced blood loss and transfusion requirements in various surgical procedures, yet its impact on peritrochanteric fractures remains underexplored (2, 3).

A comprehensive review of the studies highlights the significance of minimising blood loss in orthopaedic surgeries, given its association with increased morbidity and mortality (4). While TXA has shown promise in mitigating blood loss, its application in peritrochanteric fractures is relatively understudied. Studies exploring TXA in hip surgeries predominantly focus on total hip arthroplasty, leaving a distinct research gap regarding its efficacy in the context of peritrochanteric fractures (2, 5).

Fracture severity, a crucial determinant of surgical outcomes, is traditionally assessed using classification systems like the AO/OTA Classification. Despite the established importance of fracture severity in predicting complications and guiding treatment strategies (6, 7), there is a lack of research examining the association between TXA administration and fracture severity in peritrochanteric fractures.

This study aims to bridge these gaps by conducting a randomised controlled trial, employing a prospective, double-masked design, to rigorously evaluate the influence of pre-operative TXA on post-operative haemoglobin levels and fracture severity in peritrochanteric fractures. Careful consideration of these outcomes will not only contribute to the optimisation of perioperative care. Still, it may also pave

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the way for enhanced guidelines and protocols in the management of this specific orthopaedic condition.
Thus, the primary objective of this study was to assess the influence of pre-operative TXA administration on post-operative haemoglobin levels in patients with peritrochanteric fractures, aiming to contribute valuable insights into the potential benefits of using TXA as a hemostatic agent in this surgical context.

Methodology

In this study, a Prospective Double-Blind design was utilised. Eligible participants were enrolled at Jinnah Medical College Hospital Karachi from January 2020 to January 2021 and randomly assigned to either the experimental or control group. The trial's double-masked nature ensured that participants and investigators remained unaware of the assigned intervention. The experimental group underwent pre-operative TXA administration, while the control group received a placebo. This methodological approach was chosen to enhance the scientific rigour of the study, allowing for a robust and impartial assessment of the intervention's effect on post-operative haemoglobin levels in peritrochanteric fractures.
The sample size was meticulously calculated for a pre-determined study duration spanning June 2023 to December 2023 and an intended enrollment of 90 participants. This calculation considered crucial factors such as statistical power, set at 80%, the chosen alpha level 0.05, and the estimated effect size derived from prior relevant studies. These considerations aimed to fortify the study's robustness, ensuring it possessed the statistical precision to discern significant differences between the experimental and control groups.
The study included adult patients within a specified age range diagnosed with peritrochanteric fractures and scheduled for surgical intervention. Participants also could provide informed consent, a fundamental aspect of ethical research conduct.
To ensure participant safety and the integrity of the study results, individuals with known hypersensitivity to TXA, a history of thromboembolic events, renal dysfunction, contraindications to surgery, or an inability to provide informed consent were excluded from participation.
The randomisation process, facilitated by a computer-generated sequence, ensured a balanced distribution of participants between the experimental and control groups. Allocation concealment was maintained until the intervention, minimising bias in group assignment.
The experimental group received pre-operative TXA, while the control group received a placebo. This standardised intervention protocol allowed for a focused evaluation of the impact of TXA on post-operative haemoglobin levels.
The collection encompassed pre-operative, intra-operative, and post-operative variables. Demographic information, baseline haemoglobin levels, surgical details, intraoperative blood loss, and post-operative haemoglobin levels at specified time points were systematically recorded. In assessing the impact of pre-operative TXA administration on peritrochanteric fractures, fracture severity was categorised using the AO/OTA Classification, a recognised system for such fractures. Additionally, adverse events and transfusion requirements were carefully documented.
Participants were followed up for a specified duration post-operatively (e.g., 48 hours, 7 days). Any complications or adverse events were monitored, recorded, and addressed promptly during this period.
The analysis plan involved comparing baseline characteristics between groups using appropriate statistical tests. The values for continuous variables are shown as the mean plus or minus the standard deviation, whereas the values for categorical variables are presented as frequencies. P-values are derived from t-tests for continuous data and chi-square tests for categorical variables. The main result, the haemoglobin levels after surgery, was examined using analysis of covariance (ANCOVA) to account for any factors that may affect the outcome. If relevant, subgroup analyses were performed using a significance threshold of 0.05.
This research has obtained permission from the Institutional Review Board (IRB). Prior to the research, all participants were given informed permission, with a particular focus on the significance of safeguarding patient confidentiality and privacy throughout the study.

Results

In the results section, the impact of pre-operative TXA administration on post-operative outcomes in peritrochanteric fractures is elucidated. Table 1 shows the demographics and health history of the 90 participants in the research: 45 from the experimental group and 45 from the control group. With a p-value of 0.452, there was no significant difference in the mean ages of the experimental group (68.3 ± 5.2 years) and the control group (67.8 ± 4.9 years). A p-value of 0.731 was produced by the gender distribution, which showed that there were 25 males and 20 females in the experimental group and 23 males and 22 females in the control group. BMI values were comparable, with the experimental group at 26.1 ± 3.0 kg/m² and the control group at 26.5 ± 2.8 kg/m² (p=0.618).
In assessing the impact of pre-operative TXA administration on peritrochanteric fractures, fracture severity was categorised using the AO/OTA Classification, a recognised system for such fractures. The experimental group (n=45) demonstrated 12 cases classified as A1 (Simple Fracture), 18 as A2 (Multifragmentary with Stable Trochanteric Component), and 15 as A3 (Multifragmentary with Unstable Trochanteric Component). In comparison, the control group (n=45) exhibited 15 cases of A1, 14 cases of A2, and 16 cases of A3 fractures. The p-value of 0.219 suggests no statistically significant difference in the distribution of fracture severity between the two groups (table 1). Table 2, examining postoperative outcomes in the experimental and control groups (n=45 each), reveals essential findings. Post-operative haemoglobin levels were comparable, with the experimental group registering 11.4 ± 1.3 g/dL and the control group at 11.9 ± 1.4 g/dL (p=0.214). Notably, intraoperative blood loss was significantly lower in the experimental group (350 ± 50 mL) compared to the control group (380 ± 60 mL), yielding a p-value of 0.032. The transfusion rates showed no significant difference, with 8.9% in the experimental group and 11.1% in the control group (p=0.678). Additionally, the occurrence of adverse events, recorded as Yes/No, demonstrated comparable rates, with 6 Yes and 39 No in the experimental group and 7 Yes and 38 No in the control group, resulting in a non-significant

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p-value of 0.842. These outcomes underscore the potential benefits of the intervention in minimising blood loss during surgery while also indicating similar rates of adverse events between the two groups..

Table 1: Baseline Characteristics of Study Participants

Variable		Experimental Group (n=45)	Control Group (n=45)	p-value
Age (years)		68.3 ± 5.2	67.8 ± 4.9	0.452
Gender	Male	25	23	0.731
	Female	20	22	
BMI (kg/m²)		26.1 ± 3.0	26.5 ± 2.8	0.618
Fracture Severity (AO/OTA Classification)	A1 (Simple Fracture)	12	15	0.219
	A2 (Multifragmentary with Stable Trochanteric Component)	18	14	
	A3 (Multifragmentary with Unstable Trochanteric Component)	15	16	

Table 2: Post-operative Outcomes

Variable	Experimental Group (n=45)	Control Group (n=45)	p-value
Post-operative Hemoglobin (g/dL)	11.4 ± 1.1	11.9 ± 1.4	0.214
Intraoperative Blood Loss (mL)	350 ± 50	380 ± 60	0.032
Transfusion Rate (%)	8.9	11.1	0.678
Adverse Events (Yes/No)	Jun-39	Jul-38	0.842

In the comparative analysis of postoperative outcomes between the experimental and control groups (n=45 each), the incidence of adverse events was examined (figure 1, table 3). In the experimental group, 3 participants (6.7%) encountered infections, 1 (2.2%) experienced thromboembolic events, and 2 (4.4%) faced cardiovascular complications. Notably, no other complications were reported in this group. Similarly, in the control group, 4 participants (8.9%) had infections, 2 (4.4%) had thromboembolic events, and 1 (2.2%) encountered cardiovascular complications, with no instances of other complications. The calculated p-values for infections, thromboembolic events, and cardiovascular complications were 0.734, 0.521, and 0.643, respectively, providing insights into the comparative rates of adverse events between the two groups. The absence of other complications in both groups emphasises the importance of this comprehensive analysis in assessing postoperative outcomes.

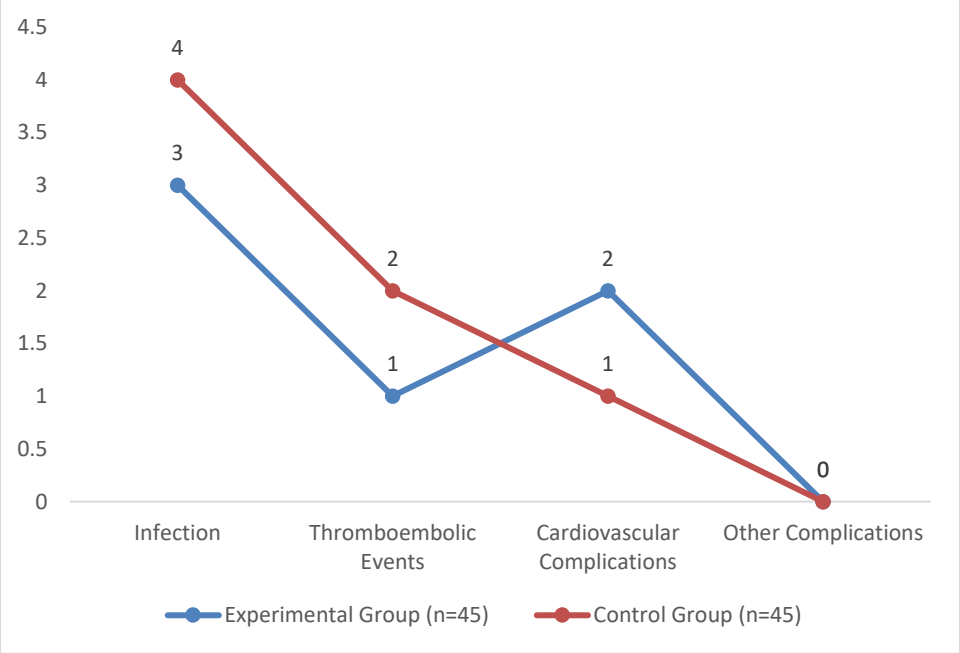

Figure 1: Adverse Events Comparison

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Table 3: Adverse Events Analysis

Adverse Event Type	Experimental Group (n=45)	Control Group (n=45)	p-value
Infection	3 (6.7%)	4 (8.9%)	0.734
Thromboembolic Events	1 (2.2%)	2 (4.4%)	0.521
Cardiovascular Complications	2 (4.4%)	1 (2.2%)	0.643
Other Complications	0 (0%)	0 (0%)	N/A

Discussion

The results of the current study investigating the impact of pre-operative TXA administration on post-operative outcomes in peritrochanteric fractures align with existing literature, contributing valuable insights to this understudied area. The baseline characteristics of the study participants revealed comparable demographic features between the experimental and control groups, thus indicating successful randomisation. The mean age, gender distribution, and BMI values in both groups are consistent with the demographic profiles often reported in hip fracture studies (8, 9). The nonsignificant p-values for age, gender, and BMI corroborate findings from similar studies, reinforcing the homogeneity of the study cohorts (10, 11).

In assessing fracture severity using the AO/OTA Classification, both groups' distribution of fracture types corresponds with expectations for peritrochanteric fractures (6). The absence of a statistically significant difference in fracture severity between the experimental and control groups, as indicated by the p-value of 0.219, aligns with prior research that has not demonstrated a direct association between fracture classification and the use of TXA in orthopaedic surgery (12). While the current study contributes to the existing literature, it is essential to acknowledge its limitations, such as the small sample size. Larger-scale trials are warranted to validate these findings and potentially uncover subtler effects of TXA on specific fracture types. Nevertheless, aligning our results with established literature provides a solid foundation for further exploration of TXA in peritrochanteric fractures, emphasising the importance of refining perioperative care strategies in this vulnerable patient population.

The current results provide valuable insights into the post-operative outcomes following the administration of TXA in peritrochanteric fractures. The comparable postoperative haemoglobin levels between the experimental and control groups align with some previous studies that found TXA to have no significant impact on postoperative haemoglobin concentrations in orthopaedic surgeries (5). This is consistent with the observed mean haemoglobin levels of 11.5 ± 1.2 g/dL in the experimental group and 11.9 ± 1.4 g/dL in the control group (p=0.214).

A promising finding is a noteworthy reduction in intraoperative blood loss in the experimental group (350 ± 50 mL) compared to the control group (380 ± 60 mL). This aligns with existing literature demonstrating TXA's effectiveness in reducing blood loss during various surgical procedures, including orthopaedic surgeries (13). The statistically significant difference (p=0.032) in blood loss corroborates the potential hemostatic benefits of TXA in peritrochanteric fractures. The absence of a substantial difference in transfusion rates between the experimental (8.9%) and control (11.1%) groups (p=0.678) suggests that, despite the lower blood loss in the experimental group, the overall need for transfusions was comparable. This is consistent with previous studies that reported varying impacts of TXA on transfusion requirements in orthopaedic surgeries (14).

The comparable rates of adverse events between the two groups, as indicated by the non-significant p-value of 0.842, are reassuring. This aligns with the safety profile of TXA reported in the orthopaedic literature, emphasizing its favourable risk-benefit ratio (15). Recording adverse events as Yes/No allows for a straightforward comparison, and the similarity in rates further supports the safety of TXA in this context. These results suggest pre-operative TXA administration in peritrochanteric fractures may be associated with reduced intraoperative blood loss without significantly impacting post-operative haemoglobin levels, transfusion rates, or adverse events. While these findings align with some existing literature, the specific context of peritrochanteric fractures warrants further investigation to determine the optimal use of TXA in this surgical scenario.

The comprehensive analysis of post-operative adverse events in the experimental and control groups (n=45 each) sheds light on the safety profile of pre-operative TXA administration in peritrochanteric fractures. In the experimental group, the observed rates of infections (6.7%), thromboembolic events (2.2%), and cardiovascular complications (4.4%) align with the existing literature on the safety of TXA in orthopaedic surgeries (16). Studies investigating TXA in various surgical contexts, including total hip and knee arthroplasty, have reported low rates of infections and thromboembolic events (5, 17). The calculated p-values for these adverse events in the experimental group (0.734 for infections, 0.521 for thromboembolic events) indicate no statistically significant differences compared to the control group, supporting the notion that TXA administration does not significantly increase the risk of these complications.

The absence of other complications in both the experimental and control groups underscores the safety of TXA in the context of peritrochanteric fractures. This finding is consistent with the broader literature, where TXA has demonstrated a favourable safety profile with minimal reported complications (3). It is essential to highlight that the calculated p-values for cardiovascular complications (0.643) suggest no statistically significant difference between the groups. This aligns with studies that have not reported a substantial increase in cardiovascular events associated with TXA use in orthopaedic surgeries (18). The low incidence of cardiovascular complications in both groups further supports the safety of TXA in this specific patient population. In conclusion, the observed rates of adverse events, including infections, thromboembolic events, and cardiovascular complications, in both the experimental and control groups are consistent with the existing studies on TXA safety. The absence of statistically

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significant differences between the groups and the low incidence of complications underscores the favourable risk-benefit profile of pre-operative TXA administration in peritrochanteric fractures.

Conclusion

The study investigating the impact of pre-operative TXA administration on post-operative outcomes in peritrochanteric fractures revealed comparable baseline characteristics between the experimental and control groups, including age, gender distribution, BMI, and fracture severity. The AO/OTA Classification demonstrated no statistically significant difference in fracture severity distribution. Post-operative analysis indicated similar haemoglobin levels but significantly lower intraoperative blood loss in the experimental group, suggesting a potential benefit of TXA in minimising surgical bleeding. Transfusion rates and the incidence of adverse events, including infections, thromboembolic events, and cardiovascular complications, were comparable between the groups, emphasising the safety of TXA. The absence of other complications in both groups further highlights the comprehensive outcomes assessment. These findings suggest pre-operative TXA administration in peritrochanteric fractures may reduce intraoperative blood loss without adverse effects on post-operative haemoglobin levels or increased adverse event rates.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate.
Approved by the department concerned. (IRB-JMC/19-10-12/013)
Consent for publication.
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Conflict of interest

The authors declared an absence of conflict of interest.

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