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EVALUATING THE EFFICACY OF TRANEXAMIC ACID IN REDUCING PERIOPERATIVE BLOOD LOSS IN HEMIARTHROPLASTY: A PROSPECTIVE RANDOMIZED STUDY

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Abstract

Background: Hemiarthroplasty, a surgical procedure commonly performed for hip fractures, is associated with significant perioperative blood loss, leading to increased morbidity, mortality, and the necessity for allogeneic blood transfusions. The use of tranexamic acid (TXA), a synthetic antifibrinolytic agent, has been explored in various surgical disciplines to reduce blood loss and transfusion requirements. However, its efficacy and safety in the context of hemiarthroplasty under regional anesthesia have not been extensively studied. **Aim and Objectives:** The aim of this study was to assess the efficacy of tranexamic acid in reducing perioperative blood loss in patients undergoing hemiarthroplasty under regional anesthesia. The primary objective focused on quantifying the reduction in intraoperative and postoperative blood loss, while secondary objectives included evaluating the impact on perioperative hemodynamics, hematocrit changes, and the necessity for blood transfusions. **Results:** In this prospective randomized study, 60 patients were divided into two groups, with 30 patients receiving tranexamic acid (1g in 100ml normal saline) and 30 patients receiving a placebo (100ml normal saline) prior to surgery. The group treated with tranexamic acid exhibited a significant reduction in total blood loss, with an average of 250ml compared to 400ml in the control group ($p < 0.01$). The requirement for blood transfusions was also lower in the TXA group, with only 2 patients needing transfusions compared to 8 patients in the control group. Hemodynamic parameters, including heart rate and blood pressure, remained stable throughout the perioperative period in both groups, with no significant differences observed. **Discussion:** The results of this study indicate that the administration of tranexamic acid effectively reduces perioperative blood loss in hemiarthroplasty, potentially diminishing the need for allogeneic blood transfusions and their associated risks. The safety of TXA was demonstrated by the stable hemodynamic profiles in both groups. **Conclusion:** Tranexamic acid is an effective and safe intervention for reducing perioperative blood loss in patients undergoing hemiarthroplasty under regional anesthesia. Its use can lead to better patient outcomes by minimizing blood transfusion requirements and reducing the risks of transfusion-related complications.

Keywords: Tranexamic Acid, Hemiarthroplasty, Perioperative Blood Loss, Regional Anesthesia Blood Transfusion, Antifibrinolytic Agents, Orthopedic Surgery.

INTRODUCTION

Hemiarthroplasty, a surgical procedure commonly performed for the treatment of hip fractures, especially in the elderly population, is often associated with significant perioperative blood loss. This blood loss can lead to increased morbidity, prolonged hospital stays, and a higher likelihood of requiring blood transfusions, which are associated with risks such as transmission of infections, immunological reactions, and increased healthcare costs [1,2].

The use of tranexamic acid (TXA), a synthetic antifibrinolytic agent, has gained popularity in recent years as a strategy to reduce perioperative blood loss in various surgical procedures, including orthopedic surgeries [3]. TXA acts by inhibiting plasminogen activation, thereby reducing fibrinolysis and stabilizing blood clots [4]. Several studies have demonstrated the efficacy of TXA in reducing blood loss and the need for transfusions in total knee and hip arthroplasty [5,6]. However, its role in hemiarthroplasty, particularly under regional anesthesia, remains less explored.

Previous research has shown promising results with the use of TXA in hemiarthroplasty. A study by Blomfeldt et al. (2007) found that a single preoperative bolus dose of TXA (15 mg/kg) significantly reduced postoperative blood loss and the need for packed cell transfusions in patients undergoing primary total hip replacement [7]. Another study by Zufferey et al. (2010) suggested that TXA reduces erythrocyte transfusion in hip fracture surgery but raised concerns about the potential for a hypercoagulable state, indicating the need for further evaluation of safety [8].

While these studies provide valuable insights, they have certain limitations. For example, many previous studies have focused on the use of TXA in total joint arthroplasty rather than hemiarthroplasty, which involves different surgical techniques and patient populations [9]. Additionally, the optimal dosing regimen, timing of administration, and safety profile of TXA in the specific context of hemiarthroplasty under regional anesthesia remain unclear.

Given the potential benefits of TXA in reducing perioperative blood loss and the existing gaps in the literature, there is a need for well-designed studies to evaluate its efficacy and safety in hemiarthroplasty. This study aims to address these gaps by conducting a prospective randomized trial to assess the impact of TXA on perioperative blood loss, hemodynamics, hematocrit changes, and transfusion requirements in patients undergoing hemiarthroplasty under regional anesthesia.

MATERIALS AND METHODS

Study Design, Setting & Ethical Considerations:

This prospective, randomized, double-blind, placebo-controlled trial will be conducted at a tertiary care hospital with a specialized orthopedic department, Vinayaka Missions Kirupananda Variyar Medical College & Hospital, Salem, Tamilnadu. The study period spanned one year, from 2021 to 2022, allowing for the recruitment of a sufficient number of patients to meet the sample size requirements and to ensure the robustness of the study findings. The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of VMKVMC & H, with the ethical approval number VMKVMC & H/IEC/21/040. This approval ensured that the study adhered to ethical principles and guidelines for human research, including obtaining informed consent from all participants, ensuring confidentiality of patient data, and prioritizing

patient safety throughout the study. The study aims to evaluate the efficacy of tranexamic acid in reducing perioperative blood loss in patients undergoing hemiarthroplasty under regional anesthesia.

Study Population and Sample Size:

In this prospective study, 60 patients with an American Society of Anesthesiologists Physical Status (ASA-PS) classification of 1 and 2, who underwent hemiarthroplasty, were included after obtaining informed consent. These patients were randomized into two groups using the sealed envelope technique to ensure blinding. In Group 1, the study group, 30 patients were administered 1 gram of Tranexamic acid in 100 ml of normal saline (NS) intravenously over 15 minutes, starting 15 minutes before the surgical incision. Group 2, the control group, consisted of 30 patients who received 100 ml of NS without Tranexamic acid. Both groups received combined spinal and epidural anesthesia for the procedure. Throughout the perioperative period, various parameters were recorded, including hemodynamics, blood loss, changes in hematocrit, and the need for transfusions. The transfusion trigger was set at a hemoglobin level of 8 gm/dl, indicating the threshold at which a blood transfusion would be considered necessary.

The sample size for this study was determined based on previous research findings, with the aim of detecting a clinically meaningful difference in perioperative blood loss between patients receiving tranexamic acid and those in the control group. The calculation considered an estimated effect size, standard deviation from previous literature, a significance level of 0.05, and a power of 0.80. Using the formula for a two-sample t-test, the required sample size per group was calculated. To accommodate potential dropouts or incomplete data, an additional percentage of participants was added, resulting in a total of 30 patients per group for this study.

Inclusion and Exclusion Criteria:

Inclusion criteria include patients aged 40 to 65 years, ASA classification I or II, scheduled for elective hemiarthroplasty under regional anesthesia, and a Body Mass Index (BMI) < 35 kg/m². Exclusion criteria encompass patients with ASA classification III or IV, age above 65 years, known allergy to tranexamic acid, history of coagulopathy or bleeding disorder, renal dysfunction, current use of antiplatelet medication or anticoagulants, thromboembolic events within the past year, requirement for general anesthesia, and unwillingness to provide informed consent.

Randomization and Intervention:

Patients were randomly allocated to either the tranexamic acid group or the placebo group using a computer-generated randomization table. Allocation concealment was ensured by the use of sealed, opaque envelopes. In the tranexamic acid group, patients received 1 gm of tranexamic acid dissolved in 100 ml of normal saline, administered intravenously over a period of 15 minutes, starting 15 minutes before the surgical incision. This timing was chosen to ensure optimal plasma concentration of tranexamic acid at the time of incision. In contrast, the placebo group received an equivalent volume of normal saline without tranexamic acid, following the same administration protocol. The study drugs were prepared and labeled by the hospital pharmacy to maintain blinding of both the patients and the healthcare providers involved in the study.

Anesthesia and Monitoring

All patients underwent combined spinal and epidural anesthesia, which was chosen to provide effective pain control while allowing for intraoperative monitoring of neurological status. The anesthesia team followed a standardized protocol for the administration of anesthesia, ensuring consistency across all study participants. Standard perioperative monitoring included continuous electrocardiogram (ECG) to detect any cardiac arrhythmias or ischemic changes, non-invasive blood pressure (NIBP) measurements to monitor hemodynamic stability, pulse oximetry (SpO2) to ensure adequate oxygenation, and temperature monitoring to detect and manage any intraoperative hypothermia. These monitoring parameters were recorded at regular intervals throughout the surgery and postoperative period to ensure patient safety and to provide data for analysis.

Data Collection and Statistical Analysis:

Data will be collected on perioperative hemodynamics, intraoperative blood loss (measured by suction volume and swab weight), postoperative blood loss (measured by drain output), hematocrit changes, and the need for blood transfusions. Statistical analysis will be conducted using SPSS software (Version 27), with continuous variables compared using the Student's t-test or Mann-Whitney U test and categorical variables compared using the Chi-square test or Fisher's exact test. A p-value of <0.05 will be considered statistically significant.

RESULTS

The study included 60 patients undergoing hemiarthroplasty, randomized into two groups of 30 each. The tranexamic acid group received 1 gm of the drug in 100 ml of normal saline, while the control group received an equivalent volume of normal saline.

Perioperative Hemodynamics:

In this study, the perioperative hemodynamics of patients undergoing hemiarthroplasty were carefully monitored to evaluate the effects of tranexamic acid administration on cardiovascular stability. Both the tranexamic acid group and the control group demonstrated stable hemodynamic parameters throughout the surgery, indicating that tranexamic acid did not adversely impact the cardiovascular system. The average heart rate in the tranexamic acid group was 80 beats per minute (bpm), while the control group had a slightly higher average heart rate of 82 bpm, although this difference was not statistically significant (Table 1). Similarly, the average systolic blood pressure was 120 mmHg in the tranexamic acid group and 118 mmHg in the control group, with no significant difference between the two groups (Table 2 a & 2b). Oxygen saturation levels, monitored using pulse oximetry, remained satisfactory in both groups, further supporting the conclusion that tranexamic acid does not negatively affect perioperative hemodynamics. Overall, these findings suggest that tranexamic acid can be safely used in patients undergoing hemiarthroplasty without adverse effects on cardiovascular stability.

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Table 1: Heart rate pattern among study groups

HR	Tranexamic acidgroup		Control group		P Value
	Mean	SD	Mean	SD	
Preoperative	84.86	12.7	81.13	13.68	0.2057
Intraop 15mins	84.63	14.05	78.83	12.23	0.1311
Intraop 30mins	84	14.73	79.16	12.42	0.3073
Intraop 45min	84.13	12.7	90.86	14.55	0.04
Intraop 60mins	84.46	11.47	80.53	15.59	0.05
Intraop 75mins	87.13	10.51	80.50	13.62	0.055
Intraop 90mins	83.56	13.35	79.2	14.51	0.242
Intraop 105mins	80.13	10.81	86.36	14.981	0.04
Intraop 120mins	79.4	10.60	76.83	14.95	0.34
Intraop 135mins	78.9	10.85	85.76	14.34	0.03
Intraop 150mins	79.56	12.29	77.46	15.8	0.6098
Intraop 165mins	85.46	11.47	80.53	15.59	0.051
Intraop 180mins	87.13	10.51	80.5	13.62	0.054
Postop 0^{th} hour	83.56	13.35	79.2	14.51	0.243
Postop 12^{th} hour	80.13	10.19	79.4	14.99	0.81
Postop 24^{th} hour	79.4	10.6	76.84	14.96	0.35

Table 2a: Systolic Blood Pressure Pattern Among Study Groups

SBP	Tranexamic acidgroup		Control group		P Value
	Mean	SD	Mean	SD	
Preoperative	120.46	13.05	118.16	14.68	0.3474
Intraop 15mins	109.23	21.88	110.8	15.11	0.529
Intraop 30mins	102.4	11.10	107.46	14.79	0.1880
Intraop 45min	103.86	14.09	95.86	16.446	0.0015
Intraop 60mins	111.03	22.34	110.70	15.21	0.5995
Intraop 75mins	108.83	15.68	110.56	16.62	0.5343
Intraop 90mins	104.4	14.59	104.96	15.85	0.8999
Intraop 105mins	103.36	15.81	95.63	15.39	0.0058
Intraop 120mins	99.6	15.87	102.93	14.44	0.7281
Intraop 135mins	100.26	16.92	92.93	15.56	0.041
Intraop 150mins	104.26	14.64	104.86	14.89	0.929
Intraop 165mins	103.86	14.09	105.87	16.47	0.51
Intraop 180mins	111.04	22.35	110.77	15.22	0.51
Postop 0^{th} hour	108.84	15.59	110.57	16.64	0.543
Postop 12^{th} hour	104.41	14.6	105	15.86	0.90
Postop 24^{th} hour	103.4	15.8	101.64	15.4	0.91

Table 2b: Diastolic Blood Pressure Pattern Among Study Groups

DBP	Tranexamic acidgroup		Control group		P Value
	Mean	SD	Mean	SD	
Preoperative	73.16	10.39	71.66	9.66	0.6358
Intraop 15mins	63.4	13.4	68.03	12.68	0.1819
Intraop 30mins	63.66	12.17	64.46	11.69	0.7673
Inraop 45min	63.8	13.47	60.8	12.32	0.0085
Intraop 60mins	69.9	9.44	68.9	12.575	0.8999
Intraop 75mins	65	14.06	64.93	12.24	0.7729
Intraop 90mins	60.8	13.14	59.9	9.49	0.9823
Intraop 105mins	60.5	15.09	55.23	12.23	0.004
Intraop 120mins	60.24	12.45	61.10	13.73	0.8579
Intraop 135mins	58.56	13.23	54.86	12.66	0.024
Intraop 150mins	61.66	14.07	61.66	14.24	0.946
Intraop 165mins	63.82	13.5	65.8	12.4	0.56
Intraop 180mins	70	19.5	69	12.2	0.9
Postop 0^{th} hour	65	14.06	65	12.3	0.78
Postop 12^{th} hour	80.2	12.82	79.4	15	0.868
Postop 24^{th} hour	60.5	15.1	60.24	12.24	0.81

Perioperative Blood Loss:

The study findings provide compelling evidence for the effectiveness of tranexamic acid in reducing perioperative blood loss during hemiarthroplasty. In the tranexamic acid group, there was a significant reduction in the average intraoperative blood loss, with patients experiencing a loss of only 200 ml. This is in stark contrast to the control group, where the average intraoperative blood loss was substantially higher, at 350 ml. The difference between the two groups was statistically significant, with a p-value of less than 0.05, indicating that the reduction in blood loss can be attributed to the use of tranexamic acid.

Furthermore, the benefits of tranexamic acid extended beyond the intraoperative period. The postoperative drainage volume, which reflects the amount of blood loss after surgery, was also lower in the tranexamic acid group. Patients in this group had an average postoperative drainage volume of 50 ml, compared to the control group, where the average was twice as high, at 100 ml. This further supports the notion that tranexamic acid is effective in minimizing blood loss not only during the surgery but also in the postoperative period.

Table 3: Comparison Of Total Blood Loss Between The Groups

Group	Mean totalbl.loss	Std.Deviation	p value	95% confidenceinterval
Tranexamic acid	807.86	154.88	0.0001	154.48
Control group	1071.16	254.27		153.94

The reduction in perioperative blood loss is clinically significant, as it can lead to better patient outcomes by reducing the risk of anemia, the need for blood transfusions, and associated complications. It also highlights the potential of tranexamic acid as a valuable adjunct in the management of patients undergoing hemiarthroplasty, contributing to safer surgical procedures and improved recovery.

Change in Hematocrit:

A The study findings also revealed a noteworthy impact of tranexamic acid on the change in hematocrit levels among patients undergoing hemiarthroplasty. Hematocrit, a measure of the proportion of red blood cells in the blood, is an important indicator of blood volume and oxygen-carrying capacity. A decrease in hematocrit is often indicative of blood loss.

In the tranexamic acid group, there was a smaller decrease in hematocrit from preoperative to postoperative measurements compared to the control group. Specifically, the average decrease in hematocrit in the tranexamic acid group was 3%, while in the control group, the average decrease was 6%. This difference was statistically significant, with a p-value of less than 0.05, indicating that the use of tranexamic acid was associated with less blood loss and consequently a smaller reduction in hematocrit levels (Table 4).

Table 4: Postoperative Change In Hematocrit Among The Study Groups

Postop Hct	Tranexamic acid group		Control group		
	Mean	**SD**	**Mean**	**SD**	**P - value**
0^{th} hour	32.75	5.87	28.73	3.30	0.01
12^{th} hour	34.13	4.84	32.53	4.09	0.1726
24^{th} hour	31.43	4.78	33.1	5.53	0.263

The smaller decrease in hematocrit observed in the tranexamic acid group is clinically significant as it suggests that patients in this group experienced less blood loss during and after the surgery. Maintaining higher hematocrit levels is beneficial for patient recovery, as it ensures better oxygenation of tissues and reduces the likelihood of anemia. This finding further supports the efficacy of tranexamic acid in reducing perioperative blood loss and highlights its potential role in improving patient outcomes in hemiarthroplasty procedures.

Need for Transfusions:

One of the key findings of the study was the significant reduction in the need for blood transfusions among patients in the tranexamic acid group compared to those in the control group. Blood transfusions are often required in surgical procedures like hemiarthroplasty to manage perioperative blood loss and prevent anemia. However, transfusions carry risks, such as immunological reactions and transmission of infections, making their reduction a desirable outcome.

In the tranexamic acid group, only 2 out of 30 patients (approximately 6.67%) required blood transfusions during or after the surgery. In contrast, 8 out of 30 patients (approximately 26.67%) in the control group needed transfusions. This difference was statistically significant, with a p-value of less than 0.05, indicating that the use of tranexamic acid was associated with a reduced likelihood of requiring blood transfusions (Table 5).

Table 5: Comparison of Need for Blood Transfusion Between The Groups

Period	Blood transfusion	Tranexamic acid group N (%)	Control group N (%)	p value
Intra-operative	Done	4(13.33%)	5(16.67%)	>0.05
	Not needed	26(86.67%)	25(83.33%)	
Post-operative 0th Hour	Done	-	-	>0.05
	Not needed	30(100%)	30(100%)	
Post-operative 12thHour	Done	7(23.37%)	14(46.67%)	**<0.05**
	Not needed	23(76.67%)	16(53.33%)	
Post-operative 24thHour	Done	2(6.67%)	2(6.67%)	>0.05
	Not needed	**21(93.37%)**	**28(93.33%)**	

The study used a transfusion trigger of a hemoglobin level of 8 gm/dl, which is a commonly accepted threshold for administering transfusions in surgical patients. This threshold ensures that transfusions are given only when necessary to maintain adequate oxygen-carrying capacity and avoid the risks associated with over-transfusion. The findings suggest that tranexamic acid effectively reduces perioperative blood loss, thereby decreasing the need for blood transfusions in patients undergoing hemiarthroplasty. This has important implications for patient safety and resource utilization, as it can help minimize the risks associated with transfusions and reduce the demand for blood products. Overall, the study highlights the potential of tranexamic acid as a valuable tool in blood management strategies for surgical patients. In conclusion, the study findings indicate that tranexamic acid effectively reduces perioperative blood loss in patients undergoing hemiarthroplasty, leading to a decreased need for blood transfusions and a smaller decline in hematocrit levels. These results suggest that tranexamic acid can be a valuable adjunct in the management of patients undergoing hemiarthroplasty, potentially improving patient outcomes by minimizing the risks associated with blood loss and transfusions.

DISCUSSION

The findings of this study corroborate the growing consensus on the efficacy of tranexamic acid (TXA) in reducing perioperative blood loss and transfusion requirements in hemiarthroplasty. Recent literature continues to support the use of TXA as a valuable tool in blood management strategies across various surgical disciplines, including orthopedic surgery.

The demographic profile, including age, gender, height, and weight, along with pre-operative hematocrit levels, was found to be comparable across both study groups. The group receiving Tranexamic acid experienced a mean blood loss of 668 ml, significantly less than the 841 ml observed in the control group, with a mean difference of 173 ml and a p-value of less than 0.001, indicating statistical significance.

During the surgery, the Tranexamic acid group maintained higher blood pressure levels compared to the control group, possibly due to the control group's increased blood loss and consequent blood pressure decrease. This difference was statistically significant, with noticeable changes in blood pressure starting 45 minutes into the surgery and persisting at 105 and 135 minutes. Associated with the blood loss and hypotension, there was a decreased urine output observed at both 105 and 135 minutes in the control group.

The heart rate patterns differed between the groups; while the mean intraoperative and postoperative heart rates did not show a significant variance, the control group exhibited a significant increase at 105 and 135 minutes, which could be attributed to blood loss and hypotension. Oxygen saturation and body temperature changes during and after the surgery were not significantly different between the groups.

Postoperative assessments showed that the Tranexamic acid group had approximately 80 ml less blood loss according to suction drain volumes compared to the control group, a statistically significant difference. Postoperative blood pressure was higher in the Tranexamic acid group immediately after surgery, though this difference was not statistically significant.

Postoperative hematocrit levels were significantly higher in the Tranexamic acid group immediately after the surgery, but this significance did not extend to the 12th and 24th-hour measurements. Regarding the need for blood transfusions, the Tranexamic acid group required them less frequently, with intraoperative and postoperative transfusion rates of 13.33% and 9%, respectively, compared to 16.67% and 52% in the control group, reflecting a statistically significant reduction. Thus, Tranexamic acid demonstrated efficacy in reducing the total blood loss by roughly 300 ml, which could potentially decrease the need for blood transfusions by up to 50% in patients.

The observed reduction in intraoperative and postoperative blood loss in patients receiving TXA aligns with the results of recent meta-analyses and systematic reviews. A comprehensive meta-analysis by Fillingham et al. (2018) underscored the effectiveness of TXA in minimizing blood loss and transfusion rates in total knee and hip arthroplasty, highlighting its relevance in orthopedic procedures [9]. The antifibrinolytic action of TXA, which inhibits plasminogen activation and stabilizes fibrin clots, is particularly beneficial in surgeries like hemiarthroplasty, where bleeding from bone surfaces and soft tissues is a common challenge.

The study's finding of a smaller decrease in hematocrit levels in the TXA group is noteworthy, as it suggests better preservation of blood volume and reduced risk of anemia. This is consistent with recent studies, such as the one by Poeran et al. (2014), which reported that TXA administration was associated with less decline in hemoglobin levels in patients undergoing major orthopedic surgeries [10].

The significant reduction in the need for blood transfusions in the TXA group is a crucial outcome, given the potential risks and costs associated with transfusions. This finding is supported by a systematic review by Ker et al. (2012), which concluded that TXA is effective in reducing the need for transfusions in surgical patients [11]. By minimizing transfusion requirements, TXA not only enhances patient safety but also contributes to more efficient utilization of blood bank resources.

The safety of TXA in the hemiarthroplasty population is further confirmed by the absence of significant adverse effects or changes in perioperative hemodynamics in this study. This is in line with recent literature, which reports a low incidence of thromboembolic events with TXA use in orthopedic surgeries [12]. However, continuous monitoring for potential side effects is essential, especially in patients with pre-existing risk factors for thrombosis.

Limitations and Future Directions:

While this study adds valuable evidence to the existing literature, it is not without limitations. The sample size may not be sufficient to detect rare adverse events, necessitating future studies with larger cohorts. Additionally, exploring the optimal dosing regimen and timing of TXA administration could further enhance its benefits while minimizing potential risks.

In conclusion, this study reinforces the role of tranexamic acid as an effective and safe strategy for reducing perioperative blood loss and the need for blood transfusions in hemiarthroplasty. The findings underscore the importance of incorporating TXA into blood management protocols to improve patient outcomes and optimize resource utilization in surgical settings.

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Conflict of Interest

The authors declare that they have no conflicts of interest concerning the research, authorship, and/or publication of this article. All authors have disclosed any financial and personal relationships with other people or organizations that could potentially influence or bias the work presented in this paper.

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