Original Research Paper

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COMPARATIVE STUDY TO EVALUATE THE EFFICACY AND SYSTEMIC COMPLICATIONS OF INTRAVENOUS VERSUS TOPICAL TRANEXAMIC ACID IN REDUCING PERI-OPERATIVE BLOOD LOSS IN TOTAL KNEE ARTHROPLASTY

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ABSTRACT **Background:** Total knee arthroplasty (TKA) is a cost-effective treatment for end-stage knee osteoarthritis when conservative methods fail, but it can cause significant blood loss, leading to transfusions in 10-38% of patients, with associated risks. Tranexamic acid (TXA), available in intravenous, topical, and oral forms, is effective in reducing blood loss. Recent studies, have investigated combining topical and intravenous TXA to improve efficacy in TKA. **Aims And Objective:** This study compared IV tranexamic acid alone to topical tranexamic acid in total knee arthroplasty with 20 patients. The topical group showed better post-operative hemoglobin levels (11.39 vs. 10.51 mg/dl), no transfusions and fewer complications indicating hematological advantages of topical therapy. **Materials And Methods:** We conducted a prospective, randomized study at MMIMSR, Mullana, from December 2022 to March 2024, involving patients scheduled for total knee replacement (TKR). Patients were divided into two groups: Group 1 received intravenous tranexamic acid (1g) before and after surgery; Group 2 received intraoperative topical tranexamic acid. **Result:** Our study compared intravenous (IV) tranexamic acid (TXA) alone versus topical TXA in total knee replacement patients. The topical group showed similar hemoglobin levels at 6 hours, 2 days, and 6 days post-surgery, a lower likelihood of requiring blood transfusions, and reduced 48-hour drain volume and less systemic complications of tranexamic acid. These findings suggest that topical TXA may offer greater hematological benefits and effectively reduce blood loss than IV TXA alone. **Conclusion:** Adding topical tranexamic acid intra-operatively improves hematological outcomes and reduces transfusion risk in total knee replacement. Larger studies are needed to confirm these preliminary findings and support standardized use.

KEYWORDS : Tranexamic acid (TXA), Topical, Intravenous (IV), Total knee arthroplasty (TKA), Blood loss, Hemoglobin levels, Transfusion, Randomized study, Hematological outcomes, Drain volume

INTRODUCTION

Total knee arthroplasty (TKA) is considered the most effective and economical treatment for patients with end-stage knee osteoarthritis, particularly in those with severe pain and limited mobility where conservative measures have failed. TKA is one of the most frequently performed major orthopedic surgeries worldwide. However, it is often associated with significant blood loss due to extensive soft tissue dissection and bone cuts, which can lead to increased hospital stays, higher treatment costs, and a greater risk of requiring blood transfusions, with blood loss volumes reaching up to 1500 mL. Blood transfusions carry risks such as mismatched reactions and transmission of infections like HIV.

To mitigate these complications, multiple blood-conservation techniques have been employed, including preoperative autologous blood donation (PAD), acute normovolemic hemodilution (ANH), hypotensive epidural anesthesia, pneumatic tourniquet application, use of antifibrinolytic agents like tranexamic acid (TXA), autologous blood transfusion (ABT), intraoperative cell savers, and drain clamping. TXA is a synthetic antifibrinolytic agent originally developed to reduce bleeding in hemophilia patients post dental procedures. It is available in intravenous, topical, and oral forms, each reaching peak plasma concentrations at different times.

Its cost-effectiveness and safety have led to widespread use in orthopedic procedures. While both systemic and topical TXA are popular, topical TXA—proven effective in dental and cardiac surgery—has recently gained traction in TKA for its promising outcomes.

AIM

To compare the efficacy and safety of intravenous versus topical tranexamic acid (TXA) in reducing perioperative blood loss and transfusion requirements in patients undergoing total knee arthroplasty (TKA), and to evaluate their impact on postoperative hemoglobin levels and drain output.

MATERIALS AND METHODS

This was a prospective, randomized control trial conducted at the Department of Orthopaedics, Maharshi Markandeshwar Institute of Medical Sciences and Research (MMIMSR), Mullana, from February 2023 to April 2024.

Inclusion Criteria:

- Adult patients scheduled for total knee arthroplasty (TKA).
- Patients with unilateral or bilateral advanced knee arthritis undergoing TKA.
- Able to follow post-op rehabilitation protocol

Exclusion Criteria:

- History of allergic reactions to tranexamic acid (TXA).
- History of thrombotic events (e.g., deep vein thrombosis, pulmonary embolism).
- Patients with acute renal failure.

Informed consent was obtained from all participants prior to their inclusion in the study, ensuring ethical compliance and voluntary participation.

Randomization And Group Allocation

Patients were randomly assigned into two groups:

Group 1 (Intravenous TXA Group): Received 1 gram of intravenous tranexamic acid 20 minutes prior to tourniquet inflation, followed by a second dose 3 hours postoperatively.

Group 2 (Topical TXA Group): Received 3 grams of tranexamic acid diluted in 50 ml of normal saline, applied topically at the surgical site for five minutes before wound closure.

Data Collection Parameters

Data collected from both groups included:

Patient Demographics: Age, gender, body mass index (BMI), diagnosis, type of procedure, heart rate, and blood pressure.

Operative Details: Duration of surgery.

Peri-operative Measures:

- o Drain output at 48 hours post-surgery.
- o Requirement for blood transfusions.
- o Hemoglobin levels measured at 6 hours, 2 days, and 6 days postoperatively.

All the above variables were systematically compared between the two groups to assess the efficacy and safety of intravenous versus topical administration of tranexamic acid in total knee arthroplasty.

RESULTS

This prospective study was conducted to compare the efficacy of intravenous versus topical tranexamic acid in reducing blood loss during total knee arthroplasty. A total of 20 patients were randomly assigned into two equal groups. Clinical, hematological, and perioperative parameters were assessed and compared over a 6-day postoperative period, with all patients followed for short-term outcomes related to blood loss, hemoglobin levels, drain output, and transfusion requirements.

Demographic Profile

The study included 20 patients, evenly divided into two groups of 10 each. The mean age was 59.3 years in the intravenous (IV) group and 61.8 years in the topical group, indicating a similar age distribution across groups. Female predominance was noted in both groups, with females comprising 80% of the IV group and 90% of the topical group.

Clinical Profile

In terms of diagnosis, bilateral osteoarthritis was more common in the IV group (60%) compared to 40% in the topical group, while unilateral osteoarthritis was more frequent in the topical group (60%) than in the IV group (40%).

Surgical Observations

The average duration of surgery was slightly shorter in the intravenous (IV) group (87.6 ± 12.52 minutes) compared to the topical group (90.00 ± 14.06 minutes), though this difference was not statistically significant.

Table 1: Baseline Characteristics and Surgical Parameters Between IV and Topical Groups

Parameters	IV (n = 10)	Topical (n = 10)	p value
Age (Years)	59.30 ± 9.03	61.80 ± 8.74	0.622[t]
Gender			0.361[f]
Male	2 (20.0%)	1 (10.0%)	
Female	8 (80.0%)	9 (90.0%)	
Diagnosis***			0.009[f]
Bil. Osteoarthritis Knee	6 (60.0%)	4 (40.0%)	
Left OA Knee	0 (0.0%)	6 (60.0%)	
Right Knee OA	4 (40.0%)	0 (0.0%)	
Surgery			0.653[f]
L. Total Knee Replacement	4 (40.0%)	5 (50.0%)	
R. Total Knee Replacement	6 (60.0%)	5 (50.0%)	
Heart Rate (BPM)	90.00 ± 4.32	85.00 ± 10.08	0.445[t]
Systolic BP (mmHg)	133.60 ± 17.17	130.80 ± 12.44	0.969[M]
Diastolic BP (mmHg)	85.80 ± 7.07	81.60 ± 6.72	0.301[t]
Duration of Surgery (Minutes)	87.60 ± 12.60	90.00 ± 14.06	0.879[M]
Drain Collection in 48 Hours (mL)***	216.5 ± 21.6	160.0 ± 41.7	0.002[t]

Hematological Observations

Preoperative hemoglobin values were similar between the two groups. Postoperative hemoglobin levels measured at 6 hours, 2 days, and 6 days were consistently higher in the topical group, but the differences between groups were not statistically significant. Within each group, the decrease in hemoglobin over time was statistically significant. The IV group experienced a greater absolute and percentage reduction in hemoglobin, indicating more blood loss, although this was not statistically significant.

Drain Output

A significant difference was observed in the 48-hour postoperative drain output between the groups. The median drain volume was higher in the intravenous (IV) group at 217.5 mL compared to 172.5 mL in the topical group. This difference was statistically significant ($p = 0.002$), indicating reduced blood loss with topical tranexamic acid (TXA).

Table 2: Hemoglobin Levels at Different Timepoints in IV vs. Topical Groups

Timepoint	IV Mean (SD)	IV Median (IQR)	Topical Mean (SD)	Topical Median (IQR)	p value
Pre-Operative	11.75 (1.27)	11.60 (10.55-13.23)	12.24 (1.65)	12.20 (10.75-13.85)	0.472
6 Hours Post-Operative	10.79 (1.56)	10.80 (9.43-12.38)	11.50 (1.48)	11.30 (10.20-12.40)	0.325
Day 2 Post-Operative	10.28 (1.78)	10.75 (8.30-12.00)	11.31 (1.24)	11.00 (10.23-12.38)	0.184
Day 6 Post-Operative	10.50 (1.29)	10.30 (9.18-11.55)	11.37 (1.25)	11.30 (10.23-12.45)	0.139

Transfusion Requirements

Regarding blood transfusion needs, 3 patients (30%) in the IV group required one unit of whole blood each, while no patients in the topical group required transfusion. Although this difference did not reach statistical significance, the trend favored topical TXA, suggesting its potential to reduce transfusion-related complications.

DISCUSSION

Our findings indicate that topical tranexamic acid (TXA) resulted in higher postoperative hemoglobin values and significantly reduced drain outputs compared to intravenous TXA. Additionally, fewer patients in the topical group required blood transfusions, suggesting a clinical advantage of topical administration in total knee arthroplasty (TKA).

The mean preoperative hemoglobin levels in our cohort were 11.75 g/dL in the intravenous (IV) group and 12.24 g/dL in the topical group, which is consistent with similar studies conducted on the Indian population. These values are notably lower than averages reported in Western populations, likely reflecting the higher prevalence of anemia in India. The mean postoperative hemoglobin levels were 10.51 g/dL for the IV group and 11.39 g/dL for the topical group, aligning with findings from Aggarwal et al (9.96 g/dL), Gautam et al (11.1 g/dL), Yuan et al (10.33 g/dL), and Adravanti et al (10.8 g/dL) in their studies on intravenous TXA.

The smaller hemoglobin drop (0.85 g/dL) observed in the topical group in our study compares favorably to previous research. For example, Adravanti et al reported a 3% drop in the IV group and 1.3% in the combined topical and IV group. Differences between studies may be attributed to factors such as the inclusion of patellar resurfacing and the postoperative use of low molecular weight heparin in other protocols, which were not part of ours.

Our mean drain volumes were 216.5 mL for the IV group and 160 mL for the topical group, which are comparatively lower than volumes reported by Adravanti et al (328.8 mL and 277.6 mL), Agarwal et al (335 mL and 168 mL), and Good et al (385 mL). The relatively low drain outputs in our study might reflect smaller knee sizes, fewer deformities, shorter surgery durations, or limited synovectomies. These results emphasize the potential benefits of tailoring TXA use based on patient-specific factors.

While our study supports the efficacy and safety of topical TXA in reducing perioperative blood loss in TKA, limitations include a small sample size and a short follow-up period. Further studies involving larger patient populations and longer-term outcomes are warranted to validate these findings and optimize TXA dosing protocols.

CONCLUSION

Overall, we found that topical Tranexamic acid provides additional benefits in terms of a better hematological profile and decreased risk for the need of transfusion.

We believe our analysis was limited by our limited sample size and additional studies with larger study cohorts could further validate our findings.

Though our findings are early, it is an indication for care teams to

potentially in future to standardize the use of Tranexemic acid Topical and intravenous, simultaneously for patients undergoing Total Knee Replacement.

LIMITATION:

The small sample size of this study limited the ability to detect statistically significant differences between groups. Additionally, the routine use of a tourniquet during surgery, which inherently reduces blood loss, may have influenced the overall assessment of tranexamic acid's effectiveness in controlling perioperative bleeding.

Image 1: For 'Intravenous Group' 1g of TXA was given 20 minutes before inflation of tourniquet and a repeat dose 3 hours post surgery

Image 2: For Group ('I.V + Topical')
3 g of TXA (1 vial contains 500mg TXA) was used for topical application + 1g I.V TXA 20 minutes before inflation of tourniquet and a repeat dose 3 hours post operatively.

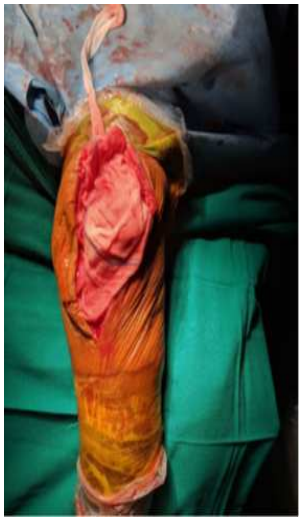

Image 3: Sterile gauge placed at operative sit for a duration of 5 minutes before closure and insertion of drain.

Limitation –

The study's limited sample size hindered statistically significant findings. The use of a tourniquet during surgery, a method to limit blood loss, could be seen as influencing blood loss control.

Conflict Of Interest – there is no conflict of interest.

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