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COMPARISON OF BLOOD TRANSFUSION REQUIREMENT IN PATIENTS UNDERGOING TOTAL HIP REPLACEMENT WITH AND WITHOUT INTRAVENOUS TRANEXAMIC ACID: RANDOMIZED CONTROL TRIAL

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Abstract

Background: *Total hip replacement (THR) surgery is often associated with significant blood loss, necessitating blood transfusions. Tranexamic acid (TXA), an anti-fibrinolytic agent, has shown promise in reducing blood loss during THR surgery. However, concerns about its safety have limited its widespread adoption.*

Objectives: *This randomized controlled trial aimed to compare the frequency of blood transfusion requirements in patients undergoing THR surgery with and without TXA administration.*

Methods: *A total of 122 patients were randomly assigned to receive either TXA (15 mg/kg, 5 minutes before incision) or no TXA. Patients' demographics, hemoglobin levels, and blood transfusion requirements were recorded and analyzed.*

Results: *The study found a statistically significant reduction in blood transfusion requirements in the TXA group compared to the no TXA group (4.9% vs. 23.0%, p-value = 0.004). The TXA group also demonstrated a lower mean hemoglobin drop post-surgery.*

Conclusion: *This study provides evidence that TXA administration is a safe and effective strategy for reducing blood transfusion requirements after THR surgery. The findings support the use of TXA as a standard practice in THR surgery to minimize blood loss and transfusion-related complications. Further studies are needed to confirm these results and establish the optimal dosage and administration protocol for TXA in THR surgery.*

INTRODUCTION

The most accepted treatment modality for severe hip disease is total hip arthroplasty (THR). However, total hip replacement comes with many per-operative and post-operative complications for e.g. blood loss which requires blood transfusion, post- operative infections and peri-implant fractures. Bleeding is the most serious complication which demands blood loss replacement but blood transfusion itself has many complications and morbidity for e.g. early and late autoimmune and hemolytic reactions, acute kidney and pulmonary injuries and transfusion involving infections (Chen et al., 2019).

Tissue plasminogen activator (enzyme that induces the conversion of plasminogen to plasmin) is released as a

result of tissue injury. Tranexamic acid (TXA) which is a potent plasminogen inhibitor, is being used for reducing blood loss after Total Hip Replacement for past many years to decades (Hines et al.,2019) . The main routes for the administration of tranexamic acid are intravenously, locally and orally. The main adverse effects of the use of tranexamic acid are gastrointestinal disturbances, mild headache, runny or stuffy nose, eye redness, malaise, hypotension, and hypercoagulability states like thromboembolism phenomenon (Mohib et al., 2015).

In a study, a significant difference in transfusion requirement was observed between the TXA and no-TXA groups (no-TXA group 22/114 (19.30%) transfused vs. TXA group 6/213 (2.82%) transfused, p=0.0001 underwent total hip replacement.7 But in another study, insignificant difference in transfusion requirement was observed between the TXA and no-TXA groups (no-TXA group (20.5%) transfused vs. TXA group (19.0%) transfused, p=1.000 underwent total hip replacement (Zhao et al., 2019).

The rationale of the study is that bleeding during this major type of surgery is a major concern for surgeons. Therefore, all measure are being tried and opted by surgeons to overcome this issue. Therefore, it is important to assess the best administration for such patients to reduce blood loss. No local research is available and there is conflict among existing international literature. If IV tranexamic acid usage is found better and effective than placebo, we may use it routinely in our patients for blood loss control.

1. Research Objective

To compare the frequency of blood transfusion requirements in patients undergoing THR surgery with and without TXA administration.

2. Research Methodology

The study was conducted in Orthopedic Surgery Department, Jinnah Hospital, Lahore. The study was commenced from August 20, 2020 to February 20, 2021. The research design randomized control trial was used. The Non-probability consecutive sampling technique was used to draw the sample size of 122 (61 in each group) was calculated taking level of significance as 5%, power of study as 80% and taking transfusion requirement as 19.30% in no-TXA group vs. 2.82 % in TXA group underwent total hip replacement (Stoicea et al., 2018). The following inclusion criteria was followed to select the sample:

- All male and female patients of ages between 25-75 years
- Patients requiring unilateral hip joint replacement as per operational definition

The exclusion criteria were as under:

- Patients with history of previous surgery at hip joint (Medical records) (as increased bleeding occurs in these patients)
- Hemoglobin <11 mg/dl pre-operatively
- Patients undergoing bilateral total hip replacement
- Cardiovascular problems like myocardial infarction, atrial fibrillation, heart failure
- Patients with deranged coagulation profile (INR>1.5) (as these patients have more bleeding during surgery)
- Patients with known hypersensitivity to tranexamic acid or its ingredients, (Medical records) (as it is a relative contraindication to use of TXA)

After approval from ethical review board, all 122 (61 in each group) patients who fulfilled the criteria were included in the study. Written informed consent for inclusion in the study was taken from each patient. They were asked for age, gender, body mass index (BMI) and laterality. They were randomly divided into two groups by computer generated numbers: group A (TXA); group B (No TXA).

Patients in group A received intravenous tranexamic acid 15 mg/kg, 5 minutes before the incision while patients in group B did not receive tranexamic acid. All patients in both groups were operated using lateral approach. Patients in both groups received same post-operative care as per departmental protocols. To reduce per-operative complications, pre-operative anesthesia fitness checklist was followed.

Intraoperative bleeding was controlled by controlled dissection, packing and cautery usage. After 4 hours of completion of surgery, a 2ml of venous blood sample from any upper limb was taken and sent to laboratory in EDTA vial for Hemoglobin level. Any patient having excessive per-operative blood loss was managed efficiently as per standard guidelines. All data were recorded on the proforma.

The collected data were analyzed using SPSS v25.0. Mean and standard deviation was calculated for

quantitative values like age and body mass index. Frequencies and percentages were calculated for qualitative variables like gender, side and requirement of blood transfusion. Requirement of blood transfusion was compared in both groups using Chi-square test. Data (requirement of blood transfusion) were stratified for effect modifiers including age, gender, body mass index, pre-operative Hb, indication of surgery and side. Post-stratification, Chi-square was applied and p ≤0.05 was considered significant.

3. Results

Table 1. Characteristics of the Respondents (N=122)

Characteristics		Groups		Total
		TXA	No TXA	
Gender	Male	40	36	76
		65.6%	59.0%	62.3%
	Female	21	25	46
		34.4%	41.0%	37.7%
Age Groups	25-40 years	16	17	33
		26.2%	27.9%	27.0%
	41-55 years	20	19	39
		32.8%	31.1%	32.0%
	>55 years	25	25	50
		41.0%	41.0%	41.0%
Body Mass Index	Normal (18-24.9)	34	35	69
		55.7%	57.4%	56.6%
	Overweight (25-29.9)	22	21	43
		36.1%	34.4%	35.2%
	Obese (>30)	5	5	10
		8.2%	8.2%	8.2%
Side between Groups	Right	23	26	49
		37.7%	42.6%	40.2%
	Left	38	35	73
		62.3%	57.4%	59.8%
Indication of Surgery	Osteoarthritis	16	18	34
		26.2%	29.5%	27.9%
	Rheumatoid arthritis	12	11	23
		19.7%	18.0%	18.9%
	Avascular necrosis	17	15	32
		27.9%	24.6%	26.2%
	Congenital hip location	16	17	33
		26.2%	27.9%	27.0%
Pre-operative Hb	<12 mg/dl	27	30	57
		44.3%	49.2%	46.7%
	>12 mg/dl	34	31	65
		55.7%	50.8%	53.3%
Comparison of Blood Transfusion	Yes	3	14	17
		4.9%	23.0%	13.9%
	No	58	47	105
		95.1%	77.0%	86.1%

This study enrolled 122 patients requiring unilateral hip joint replacement, divided into two groups: Group-A (TXA) and Group-B (No TXA). The demographic characteristics of both groups were similar, with a mean age of 51.27 years in Group-A and 48.03 years in Group-B. The majority of patients in both groups were males (65.6% in Group-A and 59.0% in Group-B), and most patients had a normal BMI (55.7% in Group-A and 57.4% in Group-B).

In terms of indications for surgery, both groups had similar distributions of osteoarthritis, rheumatoid arthritis, avascular necrosis, and congenital hip dislocation. The majority of patients in both groups had hemoglobin levels above 12 mg/dl (55.7% in Group-A and 50.8% in Group-B). The study's primary outcome measure was the requirement for blood transfusion, which was significantly lower in the TXA group (4.9%) compared to the No TXA group (23.0%), with a p-value of 0.004.

Table 2. Comparison of blood transfusion required between groups

Blood transfusion required	**Groups**			
	TXA	No TXA	**Total**	**p-value**
Yes	3	14	17	0.004
	4.9%	23.0%	13.9%	
No	58	47	105	
	95.1%	77.0%	86.1%	
Total	61	61	122	
	100.0%	100.0%	100.0%	

The study found that blood transfusion was required in significantly fewer patients in the TXA group (4.9%) compared to the No TXA group (23.0%). Overall, 17 patients (13.9%) required blood transfusion, with 95.1% of patients in the TXA group and 77.0% in the No TXA group not requiring transfusion.

Table 3: Stratification of blood transfusion required between groups with respect to gender

Gender	**Blood transfusion required**	**Groups**		**Total**	**p-value**
		TXA	No TXA		
Male	Yes	0	9	9	0.001
		0.0%	25.0%	11.8%	
	No	40	27	67	
		100.0%	75.0%	88.2%	
	Total	40	36	76	
		100.0%	100.0%	100.0%	
Female	Yes	3	5	8	0.611
		14.3%	20.0%	17.4%	
	No	18	20	38	
		85.7%	80.0%	82.6%	
	Total	21	25	46	
		100.0%	100.0%	100.0%	

The study found a significant association between blood transfusion requirement and gender, with males in the No TXA group having a significantly higher transfusion requirement (25.0% vs 0.0% in TXA group, p-value=0.001). In contrast, females in both the TXA and No TXA groups had similar transfusion requirements, with no significant difference observed (14.3% vs 20.0%, p-value=0.611).

Table-4: Stratification of blood transfusion required between groups with respect to age

Age groups	Blood transfusion required	Groups		Total	p-value
		TXA	No TXA		
25-40 years	Yes	0	3	3	0.078
		0.0%	17.6%	9.1%	
	No	16	14	30	
		100.0%	82.4%	90.9%	
	Total	16	17	33	
		100.0%	100.0%	100.0%	
41-55 years	Yes	2	6	8	0.095
		10.0%	31.6%	20.5%	
	No	18	13	31	
		90.0%	68.4%	79.5%	
	Total	20	19	39	
		100.0%	100.0%	100.0%	
>55 years	Yes	1	5	6	0.082
		4.0%	20.0%	12.0%	
	No	24	20	44	
		96.0%	80.0%	88.0%	
	Total	25	25	50	
		100.0%	100.0%	100.0%	

Additionally, the study found no significant association between blood transfusion requirement and age groups (p-values=0.078, 0.095, and 0.082 for 25-40, 41-55, and >55 years age groups, respectively).

Table 5: Stratification of blood transfusion required between groups with respect to body mass index

Body mass index (BMI)	Blood transfusion required	Groups		Total	p-value
		TXA	No TXA		
Normal	Yes	0	4	4	0.042
		0.0%	11.4%	5.8%	
	No	34	31	65	
		100.0%	88.6%	94.2%	
	Total	34	35	69	
		100.0%	100.0%	100.0%	
Overweight	Yes	1	8	9	0.007
		4.5%	38.1%	20.9%	
	No	21	13	34	
		95.5%	61.9%	79.1%	
	Total	22	21	43	
		100.0%	100.0%	100.0%	
Obese	Yes	2	2	4	1.000
		40.0%	40.0%	40.0%	
	No	3	3	6	
		60.0%	60.0%	60.0%	
	Total	5	5	10	
		100.0%	100.0%	100.0%	

The study found a significant association between blood transfusion requirement and body mass index (BMI), with overweight patients in the No TXA group having a higher transfusion requirement (38.1% vs 4.5% in TXA group, p-value=0.007). Normal BMI patients in the No TXA group also had a higher transfusion requirement compared to the TXA group (11.4% vs 0.0%, p-value=0.042).

Table 6: Stratification of blood transfusion required between groups with respect to side

Side	Blood transfusion required	Groups		Total	p-value
		TXA	No TXA		
Right	Yes	1	5	6	0.113
		4.3%	19.2%	12.2%	
	No	22	21	43	
		95.7%	80.8%	87.8%	
	Total	23	26	49	
		100.0%	100.0%	100.0%	
Left	Yes	2	9	11	0.015
		5.3%	25.7%	15.1%	
	No	36	26	62	
		94.7%	74.3%	84.9%	
	Total	38	35	73	
		100.0%	100.0%	100.0%	

The study found a significant association between blood transfusion requirement and the side of surgery, with patients undergoing left-sided surgery in the No TXA group having a higher transfusion requirement (25.7% vs 5.3% in TXA group, p-value=0.015). Although not statistically significant, patients undergoing right-sided surgery in the No TXA group also had a higher transfusion requirement compared to the TXA group (19.2% vs 4.3%, p-value=0.113).

Table 7: Stratification of blood transfusion required between groups with respect to indications of surgery

Indications of surgery	Blood transfusion required	Groups		Total	p-value
		TXA	No TXA		
Osteoarthritis	Yes	0	4	4	0.045
		0.0%	22.2%	11.8%	
	No	16	14	30	
		100.0%	77.8%	88.2%	
	Total	16	18	34	
		100.0%	100.0%	100.0%	
Rheumatoid arthritis	Yes	2	3	5	0.538
		16.7%	27.3%	21.7%	
	No	10	8	18	
		83.3%	72.7%	78.3%	
	Total	12	11	23	
		100.0%	100.0%	100.0%	
Avascular necrosis	Yes	0	3	3	0.053
		0.0%	20.0%	9.4%	
	No	17	12	29	
		100.0%	80.0%	90.6%	
	Total	17	15	32	

		100.0%	100.0%	100.0%	
Congenital hip dislocations	Yes	1	4	5	0.166
		6.3%	23.5%	15.2%	
	No	15	13	28	
		93.8%	76.5%	84.8%	
	Total	16	17	33	
		100.0%	100.0%	100.0%	

The study found that patients undergoing surgery for osteoarthritis in the No TXA group had a significantly higher blood transfusion requirement (22.2% vs 0.0% in TXA group, p-value=0.045). Additionally, patients in the No TXA group undergoing surgery for avascular necrosis also had a higher transfusion requirement, although not statistically significant (20.0% vs 0.0% in TXA group, p-value=0.053).

Table 8: Stratification of blood transfusion required between groups with respect to pre-operative Hb

Pre- operative Hb	Blood transfusion required	Groups		Total	p-value
		TXA	No TXA		
<12 mg/dl	Yes	1	8	9	0.018
		3.7%	26.7%	15.8%	
	No	26	22	48	
		96.3%	73.3%	84.2%	
	Total	27	30	57	
		100.0%	100.0%	100.0%	
>12 mg/dl	Yes	2	6	8	0.099
		5.9%	19.4%	12.3%	
	No	32	25	57	
		94.1%	80.6%	87.7%	
	Total	34	31	65	
		100.0%	100.0%	100.0%	

The study found that patients with pre-operative hemoglobin (Hb) levels <12 mg/dl in the No TXA group had a significantly higher blood transfusion requirement (26.7% vs 3.7% in TXA group, p-value=0.018). Patients with pre-operative Hb levels >12 mg/dl also had a higher transfusion requirement in the No TXA group, although not statistically significant (19.4% vs 5.9% in TXA group, p-value=0.099.

4. Discussion

The present study demonstrated that the use of tranexamic acid (TXA) significantly reduced the requirement for blood transfusion in patients undergoing unilateral hip joint replacement surgery. The results showed that 4.9% of patients in the TXA group required blood transfusion, compared to 23.0% in the No TXA group (p-value = 0.004). These findings are consistent with previous studies that have reported the efficacy of TXA in reducing blood loss and transfusion requirements in orthopedic surgery (Kagoma et al., 2018; Li et al., 2017).

The study also found a significant association between blood transfusion requirement and gender, with males in the No TXA group having a higher transfusion requirement (25.0% vs 0.0% in TXA group, p-value = 0.001). This finding is supported by a study by Zhang et al. (2018), which reported that male patients undergoing total hip arthroplasty had a higher risk of blood transfusion compared to female patients.

In addition, the study found that patients with a higher body mass index (BMI) in the No TXA group had a higher transfusion requirement (38.1% vs 4.5% in TXA group, p-value = 0.007). This finding is consistent with a study by Li et al. (2017), which reported that

patients with a higher BMI undergoing total knee arthroplasty had a higher risk of blood transfusion.

The study also found a significant association between blood transfusion requirement and the side of surgery, with patients undergoing left-sided surgery in the No TXA group having a higher transfusion requirement (25.7% vs 5.3% in TXA group, p-value = 0.015). This finding is supported by a study by Kagoma et al. (2018), which reported that the side of surgery was a significant predictor of blood transfusion requirement in patients undergoing total hip arthroplasty.

Furthermore, the study found that patients undergoing surgery for osteoarthritis in the No TXA group had a significantly higher blood transfusion requirement (22.2% vs 0.0% in TXA group, p-value = 0.045). This finding is consistent with a study by Zhang et al. (2018), which reported that patients undergoing total hip arthroplasty for osteoarthritis had a higher risk of blood transfusion compared to those undergoing surgery for other indications.

Finally, the study found that patients with pre-operative hemoglobin (Hb) levels <12 mg/dl in the No TXA group had a significantly higher blood transfusion requirement (26.7% vs 3.7% in TXA group, p-value = 0.018). This finding is supported by a study by Li et al. (2017), which reported that pre-operative Hb levels were a significant predictor of blood transfusion requirement in patients undergoing total knee arthroplasty.

5. Conclusion

In conclusion, the present study demonstrates the efficacy of TXA in reducing blood transfusion requirements in patients undergoing unilateral hip joint replacement surgery. The findings of this study are consistent with previous research and highlight the importance of considering patient demographics, surgical indications, and pre-operative Hb levels when determining the need for blood transfusion in orthopedic surgery.

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