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Original Article

Application of Tranexamic Acid in Proximal Humerus Fracture

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ABSTRACT

Background: Tranexamic acid [TXA] represents an antifbrinolytic agent that binds to plasminogen's lysine-binding sites, delaying fibrinolysis, and can be administered via intravenous, local, or intraarticular routes during joint surgery.

Aim of the work: The study aimed to compare between blood loss in patients with local administration of TXA and the patient without local administration of TXA in proximal humeral fracture.

Patients and methods: This comparative, prospective case control study was conducted on 30 patients with proximal humerus fracture who underwent fixed with plate and screws in the period from April 2023 to March 2024. Cases were divided into two groups [15 patients each], first group was injected with 30 ml TXA subcutaneous and intramuscular [case group], while the second group didn't receive TXA [control group]. Intra operative blood loss was estimated using the gauze and suction system. Also, post-operative blood loss was calculated in the drainage bag. A 24-hour period thereafter, post-operative CBC was done.

Results: The outcomes revealed that there was no significant difference concerning the intraoperative blood loss [p-value = 0.174], which was decreased in the first group [average 295±109.3] compared to the second one [346±128.8]. Postoperative blood loss was decreased in first group [mean 38±20.42], while was 68.67±19.86 in the second one with a significant difference between the two groups [p-value = 0.001]. A significant drop in Hemoglobin [Hb] level was noticed [p-value = 0.027], which was less in the first group than in the second one.

Conclusion: The local application of TXA in proximal humerus fracture has good clinical effectiveness and safety.

Keywords: Humerus; Tranexamic; Fractures; Blood loss; Hemoglobin.

INTRODUCTION

Blood loss in Orthopedic Trauma Surgery is a source of morbidity and mortality. It usually needs blood transfusion, which associated with an increased risk for bacterial infection and long hospital stay duration [1]. Tranexamic acid [TXA] is a laboratory-created counterpart of the naturally occurring amino acid lysine that was discovered in 1962 [2]. Tranexamic acid exerts its effect by reversibly binding to lysine receptor sites on plasminogen, blocking the latter from binding to tissue plasminogen activator in the process [tPA]. Once this binding is inhibited, there will be no formation of plasmin, which will prevent fibrinolysis [3].

TXA is administered by different routes [e.g., intravenous, topical and intraarticular administration] in the case of joint surgery. In addition, different doses been used [for example bolus versus continuous, and single versus multiple doses], as well as variations in the timing of administration [e.g., in the preoperative, intraoperative, or postoperative period] [4]. Local application of TXA was equally or more effective than intravenously TXA administration [5]. Local dose of TXA range from 0.5 to 3 g [6].

Fractures of the proximal humerus are frequent in adults, with an estimated prevalence of 5.7% of all fractures [7]. Humerus fractures may result in approximately 800 mL of blood loss [8]. Tranexamic acid was effective in reduction of the total blood loss. Consequently, it led to a smaller pre-to-postoperative reduction of hemoglobin concentrations in patients undergoing surgical treatment for humeral fractures [9].

The estimation of intraoperative blood loss was determined by different methods [e.g., gravimetric, photometry, and visual estimation]. However, the visual method is the most used method is the visual estimation [10]. Hence, the current research was carried out to evaluate the effect of local TXA injection on decreasing the amount of intra operative and postoperative blood loss.

PATIENT AND METHODS

The present cohort study was performed on 30 patients attending at Emergency Room of Al-Azhar university hospital complying with following inclusion and exclusion criteria. Patients were divided into two groups [15 patients each]: Group 1 [case group] in which patients with Proximal humerus fracture received TXA and Group 2 [control group], who didn't receive TXA.

The research was approved from Ethical committee of Al Azhar university. The data that were obtained from participants are confidential. All participants were not identified by name in any report or publication concerning this study. Before the participants were admitted in this study, the purpose and nature of the study, as well as the risk–benefit assessment were explained to them. An informed consent was obtained. Inclusion criteria involved; age above 18 years, and cases with recent closed unilateral proximal humerus fracture. While exclusion traits comprised; patients with shaft or distal humerus fracture, pathological fracture, neurovascular injury, or cases with coagulopathy disorder.

A complete history was taken from each case, followed by physical and local examinations, and routine laboratory investigations. Radiological investigation was conducted involving a standard X-rays shoulder and computed tomography [CT scan].

Intra operative evaluation: All patients were operated under general anesthesia in Beach - chair position and subjected to deltopectoral approach, Figure [1]. 30 ml of tranexamic acid [6 ampoules] were injected subcutaneously and intramuscularly. Intra operative blood loss was calculated as follows:

Volume of blood was collected by the suction system: Direct measurements of blood volume loss were performed as the total volume was contained in the canister and measured after the end of surgery, as showed in Figure [2].

Volume of blood on surgical gauze used: The absorption of the blood into mops, pads or gauzes was used during the surgery, as illustrated in Figure [3]. The dry mops/pads were used during surgery absorbed blood depending on their sizes. ⌉ 4 X 4 cm = 10 ml ⌉ 30 X 30 cm = 100 ml. Based on this the amount of blood loss that could be allowed for the patient was calculated and determined.

Volume of irrigation fluid subtracted from this value.

Postoperative evaluation:

Blood loss was measure at 24 hours by the volume of blood collected in the drainage bag. Total amount of drained fluids was calculated over 24 hours, as illustrated in Figure [4]. In addition, post-operative complete blood picture [CBC] was done after 24 hours to evaluate HB level.

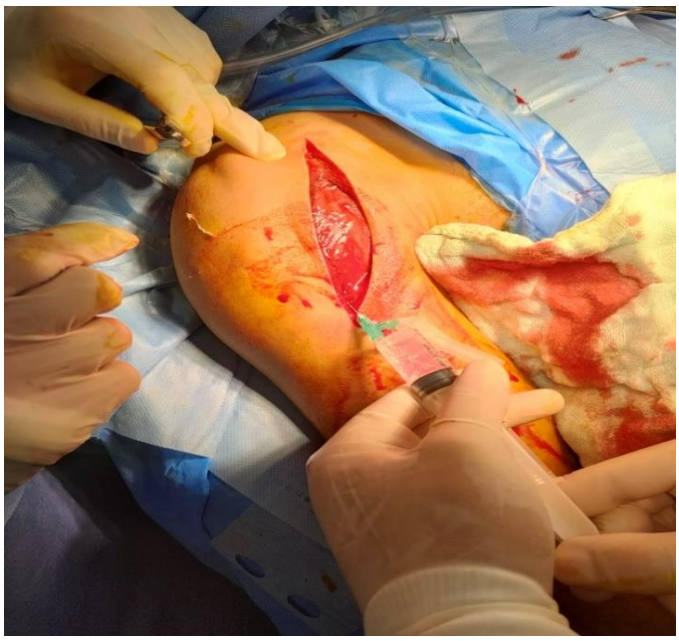

Figure [1]: Deltopectoral Approach.

Figure [2]: Blood collected in canister by suction system

Figure [3]: Surgical gauze with absorbed blood.

Figure [4]: Post-operative drain after 24 hours

Statistical analysis: The normality of data was evaluated by Shapiro–Wilk test. Quantitative data were expressed by their means and standard deviation, while frequencies and percentage were used to summarize the qualitative data. The SPSS Version 22.0 [IBM Corp, Armonk, NY] was used to calculate different measures. In order to compare between groups, Chi-square test was used for categorical variables, while independent sample t-test was used for numerical variables. P-value less than 0.05 was considered to declare statistical significance.

RESULTS

Based on data presented in Table 1, the mean intraoperative blood loss was 295.3 ± 109.3 ml in the TXA group, and 364 ± 128.8 ml in the control group. The mean postoperative blood loss was 38 ± 20.42 ml in the TXA group and 68.67 ± 19.86 ml in the control group. The mean total blood loss was 333.33 ± 105.47 ml, and 432.67 ± 124.48 ml in the TXA and control groups, respectively. Accordingly, the amount of postoperative and total blood loss was significantly larger in the control group than the TXA group [P < 0.001, and 0.026, respectively].

The postoperative Hb ranged from 8.50 to 13.50 g/dl in the TXA group and from 8.0 to 12.50 g/dl in the control group. The mean postoperative Hb was 10.91 ± 1.42 g/dl, and 9.83 ± 1.10 g/dl in the TXA and control groups, respectively. Accordingly, a significant difference was observed among the studied cases regarding the postoperative Hb [p=0.027]. Concerning the postoperative complications between the studied groups, only one case [6.7%] in each group [A & B] exhibited hematoma, as illustrated in Table 2. No statistically significant difference was found between groups as regards wound complications [Hematoma], and vascular side effects of TXA [p=1.000].

Table [1]: Comparing Perioperative Outcomes between Groups [N = 30]

	Variables	TXA Group [n=15]		Control [n=15]		*P* value
		No.	%	No.	%	
Gauze	Min. – Max.	120.0 – 500.0		120.0 – 600.0		0.088
	Mean ± SD.	242.0 ± 95.71		304.0 ± 149.8		
Suction	Min. – Max.	0.0 – 100.0		0.0 – 150.0		0.775
	Mean ± SD.	53.33 ± 44.19		60.0 ± 47.06		
Total intraoperative blood loss [ml]	Min. – Max.	150.0 – 600.0		200.0 – 600.0		0.174
	Mean ± SD.	295.3 ± 109.3		364.0 ± 128.8		
Postoperative Blood Loss [ml]	Min. – Max.	10.0 – 70.0		30.0 – 100.0		**< 0.001***
	Mean ± SD.	38.0 ± 20.42		68.67 ± 19.86		
Total Blood Loss [ml]	Min. – Max.	200.0 – 610.0		260.0 – 650.0		**0.026***
	Mean ± SD.	333.33 ± 105.47		432.67 ± 124.48		
Postoperative Hb	Min. – Max.	8.50 – 13.50		8.0 – 12.50		**0.027***
	Mean ± SD.	10.91 ± 1.42		9.83 ± 1.10		
Blood Transfusion	No	14	93.3	12	80.0	0.598
	Yes	1	6.7	3	20.0	

SD: Standard deviation; p: p value for comparing between the two studied groups; *: Statistically significant at p ≤ 0.05

Table [2]: Wound Complications and TXA Side Effects [N = 30]

Variables		Group A [n=15]		Group B [n=15]		*P* value*
		No.	%	No.	%	
Wound complications	Hematoma	1	6.7	1	6.7	^{FE}p=1.000
Vascular side effects	Acute Coronary Syndrome	0	0	0	0	-
	Deep Venous Thrombosis	0	0	0	0	-
	Cerebrovascular Accident	0	0	0	0	-

*: Statistically significant at p ≤ 0.05 FE: **Fisher Exact** p: p value for comparing between the two studied groups.

DISCUSSION

The study showed the amount of postoperative and total blood loss was significantly larger in the control group than the TXA group [$P < 0.001$, and 0.026, respectively]. These outcomes were supported by **Yang *et al.*** [11] who reported that there was highly statistically significant difference between the studied groups regarding amount of postoperative blood loss [0–24 h] which was significantly larger in the control group than the TXA group. Similarly, **Cuff *et al.*** [9] who reported that the TXA group had less average intraoperative blood loss, less postoperative drain output and less total blood loss [$P < 0.001$] compared to the control group. Our results agree with **Zhao *et al.*** [12] who reported that there was no statistically significant difference between the two studied groups regarding intraoperative blood loss.

The study showed that the mean postoperative hemoglobin level ranged from 8.50 to 13.50 g/dl in the TXA group and from 8.0 to 12.50 g/dl in the control group. The mean postoperative Hb was 10.91±1.42 g/dl, and 9.83±1.10 g/dl in the TXA and control groups, respectively. Accordingly, a significant difference was observed among the studied cases regarding the postoperative Hb [p=0.027]. These findings agreed with **Yang *et al.*** [11] who reported that there was statistically significant difference between the studied groups regarding postoperative HB. Furthermore, **Beyth *et al.*** [13] who reported that TXA administration was associated with a significant decrease in postoperative hemoglobin concentration reduction.

The study showed blood transfusion was required in one [6.7%] patients in the TXA group, and three [20%] patients in the control group. No statistically significant difference was observed between the studied groups regarding blood transfusion. These results supported by **Yang *et al.*** [11] who reported that there was no statistically significant difference between the studied groups regarding blood transfusion, P= 0.972. In the same line, our results agreed with **Zhao *et al.*** [12] who reported that there was no statistically significant difference between the two studied groups regarding blood transfusion. Furthermore, **Cuff *et al.*** [9] who reported that no patients in either treatment arm of the study required an intraoperative or postoperative blood transfusion. On the other hand, our results disagree with **Beyth *et al.*** [13] who reported that there was statistically significant difference between the nonTXA and TXA groups regarding postoperative blood transfusion, P<0.001.

Regarding postoperative complications between the studied groups, our results showed that there was no statistically significant difference between the studied groups concerning wound complications [Hematoma], and vascular side effects of TXA. These outcomes were supported by **Yang *et al.*** [11] who declared that there was no statistically significant difference among the studied groups as regard wound complications [P= 0.972], and adverse side effects **[**P= 0.628]. In the same line, the study agreed with **Zhao *et al.*** [12] who confirmed that there was no statistically significant difference between the two studied groups regarding deep vein thrombosis. Furthermore, **Cuff *et al.*** [9]**,** demonstrated that there was no identifiable intraoperative or postoperative thromboembolic events or complications associated with the use of TXA occurred in any patient. Conversely, our findings disagreed with **Pauzenberger *et al.*** [14] who recorded that the occurrence of hematomas was significantly more frequent in the control than in the TXA group.

Conclusion: Within the limitations of our study, it was concluded that: The local application of Tranexamic Acid in proximal humerus fracture has good clinical effectiveness and safety. Intraoperative blood loss was slightly lower in TXA group, but without any statistically significant difference. Postoperative blood loss was statistically significant in TXA group. There was highly statistically significant difference between the studied groups regarding postoperative Hemoglobin.

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