

# THE IMPACT OF TRANEXAMIC ACID ON HEMATOMA AND SEROMA FORMATION IN BREAST CONSERVATION SURGERY

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## ABSTRACT

**Objective:** This study was conducted to evaluate the effect of perioperative tranexamic acid on postoperative hematoma and subsequent seroma formation in patients undergoing breast-conserving surgery (BCS).

**Methods:** This quasi-experimental study was conducted at the Breast Unit, Khyber Teaching Hospital, Peshawar. Sixty-two patients undergoing BCS with axillary dissection were included and equally divided into two groups (n=31 each). In the intervention group, tranexamic acid (TXA) at 1 g, diluted in 100 mL of saline, was administered intravenously at wound closure, whereas no TXA was given in the control group. Patients were monitored for hematoma formation, seroma, drain output, duration of drainage, and any other postoperative complications.

**Results:** Hematoma occurred in 3 patients (9.7%) in the TXA group and 6 patients (19.4%) in the control group. Seroma formation was observed in 1 patient (3.2%) in the TXA group, while 2 patients (6.5%) in the controls. Neither of these differences was statistically significant. The mean drain output was comparable between the two groups (i.e.,  $92.1 \pm 43.5$  ml vs.  $95.9 \pm 40.5$  ml;  $p=0.73$ ). However, drain removal occurred earlier in the TXA group (4.7 days vs. 6.2 days). No thromboembolic events were reported.

**Conclusion:** Peri-operative Tranexamic Acid appears safe and may reduce postoperative bleeding and shorten drainage duration, although larger randomized trials are needed to strengthen the results of this study.

**Keywords:** Tranexamic acid, Breast-conserving surgery, Hematoma, Seroma, Drain output, Breast cancer surgery

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## INTRODUCTION

The management of breast cancer has evolved over the years from surgery as the stand-alone modality to an evidence-based, multidisciplinary specialty approach.<sup>1, 2</sup> While radical and modified radical procedures have been gradually de-escalated to oncoplastic breast-conserving surgery in many patients, postoperative complications remain.

Postoperative complications after breast surgery include hematoma, seroma, wound infection, dehiscence, and flap necrosis. After breast cancer surgery, the rate of hematoma formation ranges from 1-5%, while that of seroma varies between 2.5-85%.<sup>3</sup> Seroma formation remains an unforeseeable sequela rather than a complication, resulting in additional treatment, a prolonged hospital stay, and a delay in the commencement of adjuvant treatment.<sup>4</sup>

The use of Tranexamic acid (TXA) to reduce intra- and postoperative bleeding and seroma formation has been widely practiced across a broad spectrum of surgical procedures.<sup>4, 5</sup> Its use has even been explored in cardiothoracic surgery, where it has been associated with decreased blood loss during open-heart surgery. With the increasing trend of day surgery, more and more disciplines are encouraging its use.<sup>6</sup> The use of Tranexamic acid to reduce hematoma and seroma formation has recently been studied in breast surgeries with mixed results, with some showing a significant decrease in hematoma and seroma formation while other studies didn't show any benefit at all.<sup>7</sup> Plastic surgical procedures, on the other hand, have shown promising results, attracting significant attention from plastic surgeons. Knowledge of Tranexamic acid use in our population and data on its impact in breast surgery are even more limited; therefore, this study is planned to determine the impact of Tranexamic acid in breast-conserving surgeries, which could lead to the establishment of local protocols for the prevention of hematoma and seroma formation.

## MATERIALS AND METHODS

This quasi-experimental study was conducted at the Breast Unit, Department of Surgery, Khyber Teaching Hospital, Peshawar, Pakistan, over six months (from 22<sup>nd</sup>

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The sample size was determined using the WHO sample size calculator to be 31 patients per group, based on a 95% confidence interval and 80% power, with hematoma frequencies of 7.3% and 12.9% in those given TXA, as reported in a recent meta-analysis using a consecutive non-probability sampling technique.

Patients aged over 20 years with invasive breast cancer undergoing breast-conserving surgery, either upfront or after neoadjuvant chemotherapy, with axillary lymph node dissection, were included in the study. Patients undergoing mastectomy, those who had previous breast surgery of any type, patients with known bleeding disorders, and those with a documented history of allergy to tranexamic acid were excluded.

The study was conducted after obtaining approval from the institution's ethics and research board. All eligible patients were admitted, and routine baseline investigations were performed. After the purpose of the study was explained, written informed consent was obtained for participation. Randomization was performed using the lottery method to assign patients to two groups.

Patients were kept "Nil Per Oral" for 6 hours prior to surgery. In the intervention group, 1 g of tranexamic acid, diluted in 100 mL of normal saline, was administered intravenously over 20 minutes during wound closure. The control group did not receive tranexamic acid. Postoperatively, patients were monitored for hematoma formation, daily drain output, and other complications, with follow-up visits scheduled at 7, 14, and 21 days in the outpatient department.

Drains were removed when the output was less than 25 mL in 24 hours. Data were analyzed using SPSS version 28.0. Mean and standard deviation were calculated for quantitative variables, including age, tumor size, and drain output, while frequencies and percentages were calculated for qualitative variables, including receipt of neoadjuvant chemotherapy, menstrual status, and seroma formation in both groups. These variables were compared between the groups using a t-test for the former and

a chi-square test for the latter, with a p-value of less than 0.05 considered statistically significant.

## RESULTS

A total of 62 patients were included in this study, equally divided into two groups. One group received tranexamic acid at the time of surgical closure, and the second group did not receive tranexamic acid (control). The mean age was  $48.7 \pm 10.2$  years in the tranexamic acid group and  $49.5 \pm 11$  years in the control group. Most patients were premenopausal in both groups, and the majority had T2-stage disease at the time of surgery. Twenty patients in the tranexamic acid group and 18 in the control group had received neoadjuvant chemotherapy. Baseline demographics and tumor characteristics were statistically similar between the two groups, as shown in Table 1.

Post-operative hematoma formation occurred in 3 patients receiving Tranexamic acid, while 6 patients in the control group had hematoma postoperatively, as depicted in chart 1. Post-operative seroma formation was observed in 1 patient receiving Tranexamic acid and in 2 patients in the control group, with a p-value of 1% (not significant), as shown in Table 2.

The mean postoperative drain output was  $92.1 \pm 43.5$  mL in the tranexamic acid group and  $95.9 \pm 40.5$  mL in the control group. However, this difference was not statistically significant ( $p = 0.73$ ). In the study, 2 patients had their drains removed on the first postoperative day because the drains contained only 30 mL of blood, and 1 patient had the drain inadvertently removed in the evening after surgery, as shown in Table 3.

The mean drain output was slightly lower in the tranexamic acid group than in the control group; however, the difference was not statistically significant ( $p=0.732$ ). In the tranexamic acid group, the mean time to drain removal was 4.7 days, compared with 6.2 days in the control group. Tranexamic acid didn't affect the rate of complications in either group. No thromboembolic events were observed in either group. The frequency of wound infection was also comparable between the two groups.

**Table No 1: Baseline Demographic and Clinical Characteristics of the Study Population (n = 62)**

Variable		Tranexamic acid group	Control group
Age	Mean +/- SD	48.7 +/- 10.2	49.5 +/- 11
	Range	35-67	36-68
Menopausal Status	Premenopausal	19 (61.3%)	18 (58.1%)
	Postmenopausal	12 (38.7%)	13 (41.9%)
Tumor size (mm)	Mean +/- SD	26.1 +/- 6.4	26.7 +/- 6.8
	T1	9 (29%)	8 (25.8%)
	T2	22 (71%)	23 (74.2%)
Neo Adjuvant chemotherapy	Yes	20 (64.5%)	18 (58.1%)
	No	11 (35.5%)	13 (41.9%)

**Table No 2: Effect of Tranexamic acid on Seroma formation**

	Seroma Formation		p = 1.00 (Not significant)
	YES	NO	
TXA Group	1 (3.2%)	30 (96.8%)	
Control Group	2 (6.5%)	29 (93.5%)	

**Table No 3: Effect of Tranexamic Acid on Drain Output**

Drain Output	TXA group	Control group	p-value
Mean drain output +/- SD, ml	85.3 +/- 43.5	95.9 +/- 40.5	0.732
Mean duration of drain placement, days	4.7	6.2	0.685

**DISCUSSION**

This study aimed to assess the efficacy of tranexamic acid in reducing hematoma and seroma formation in patients undergoing breast-conserving surgery with axillary dissection. Although no statistically significant difference was observed between the two groups in hematoma and seroma formation, several clinically relevant trends were noted, including a lower incidence of hematoma and earlier drain removal in patients receiving tranexamic acid. The lack of statistical significance is likely due to a small sample size rather than the absence of a clinical effect.

TXA has many beneficial properties, including reducing bleeding, transfusion requirements, hematoma formation, and the duration of drain use.<sup>10</sup> Its anti-inflammatory effect has also been demonstrated in several studies.<sup>11,12</sup> Its effectiveness has been widely studied in cardiac, obstetric, orthopedic, and trauma settings, with many trials reporting its long-term benefits and potential risks.<sup>13</sup>

Our findings are consistent with previously published studies that report mixed outcomes regarding TXA use in breast surgery. Buheiri et al. conducted a meta-analysis of tranexamic acid use in breast cancer surgery and concluded that both topical and IV tranexamic acid use in breast surgery leads to a decreased rate of hematoma and seroma formation, with no impact on infection rate or thromboembolic events.<sup>14</sup> Liechti et al. also reported a reduction in hematoma and seroma formation after perioperative intravenous administration of tranexamic acid in breast-conserving and free-flap surgery, with a mean difference of 132 mL in drain output.<sup>15</sup>

Fung et al. conducted a meta-analysis examining the use of tranexamic acid in patients undergoing mastectomy with or without breast reconstruction, assessing outcomes including hematoma formation, seroma formation, infection, drain output, and drain duration. They reported a 60% decrease in hematoma formation with tranexamic acid use, and drain duration was only 1.2 days, with no impact on seroma formation or surgical site infection.<sup>16</sup> In contrast, Yao et al. found no effect on hematoma formation when assessing the role of tranexamic acid in breast reduction mammoplasties.<sup>17</sup> Similarly, Weissler et

al. did not observe a significant reduction in hematoma or seroma formation after perioperative tranexamic acid administration.<sup>18</sup> As in our observations, these studies have failed to demonstrate statistically significant benefits, often attributing this to small sample sizes or heterogeneity in TXA administration methods.

In our study, Post-operative hematoma formation was observed in 3 patients (9.7%) in the Tranexamic acid (TXA) group compared to 6 patients (19.4%) in the control group. Although this difference was not statistically significant, patients who did not receive TXA had nearly a two-fold higher incidence of hematoma, suggesting peri-operative tranexamic acid may be associated with a clinically meaningful decrease in bleeding complications. Hematoma formation after breast-conserving surgery can result in patient discomfort, wound tension, increased risk of infection, need for re-intervention, and potential delay in adjuvant therapy. The lack of statistical significance is likely related to the relatively small sample size rather than the absence of a therapeutic effect. These findings are in accordance with previously published literature demonstrating a reduction in postoperative bleeding complications with TXA use in breast and plastic surgical procedures.<sup>19, 20, 21</sup>

Postoperative seroma formation was observed in 1 patient (3.2%) in the tranexamic acid (TXA) group, compared with 2 patients (6.5%) in the control group. Although the incidence was lower in the TXA group, the difference was not statistically significant. The overall seroma rate in both groups was low, which may have limited the ability to detect a meaningful statistical difference. Compared with hematoma, which primarily reflects bleeding, seroma formation primarily results from lymphatic disruption, dead space, and the inflammatory response after axillary dissection.<sup>22, 23</sup> Larger studies with greater statistical power are required to clarify whether TXA plays a significant role in reducing seroma formation after breast-conserving surgery.

The average time to drain removal was shorter in the Tranexamic acid (TXA) group (4.7 days) than in the control group (6.2 days), suggesting a potential clinical benefit of TXA administration. Although mean drain output

did not differ significantly between the two groups, earlier drain removal in the TXA group may reflect improved hemostasis and reduced postoperative oozing. Prolonged drain placement is associated with increased patient discomfort, a higher risk of ascending infection, delayed mobilization, and an extended hospital stay.<sup>24, 25</sup> Therefore, even a modest reduction in drain duration can translate into meaningful improvements in postoperative recovery and patient satisfaction.

No increase in wound infection, flap-related complications, or other adverse surgical outcomes was observed with TXA administration. Importantly, no thromboembolic events were reported in either group, reinforcing the safety profile of peri-operative TXA in breast-conserving surgery.

This study has several limitations. The relatively small sample size may have reduced statistical power to detect significant differences between groups. As a single-center, quasi-experimental study, it may not be broadly applicable to other populations or surgical settings. Additionally, variations in TXA administration methods and the short follow-up period may have affected the assessment of postoperative outcomes. Larger, multicenter randomized controlled trials are needed to validate these findings and establish standardized protocols.

## CONCLUSION

Peri-operative administration of tranexamic acid in patients undergoing breast-conserving surgery with axillary dissection appears to be safe and may offer clinically meaningful benefits. Although the reductions in hematoma and seroma formation did not reach statistical significance in this study, a lower incidence of hematoma and earlier drain removal were observed in the TXA group. Importantly, no increase in wound complications or thromboembolic events was noted, reinforcing its favorable safety profile.

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**Authors Contribution:**

Following authors have made substantial contributions to the manuscript as under

Authors	Conceived & designed the analysis	Collected the data	Contributed data or analysis tools	Performed the analysis	Wrote the paper	Other contribution
Wahid A	✓	✓	✗	✗	✓	✗
Ali IS	✓	✗	✓	✓	✓	✗
Saeed F	✓	✓	✗	✗	✗	✓
Ahmad Z	✓	✗	✓	✓	✓	✗
Jehanzeb A	✓	✓	✗	✗	✗	✓
Afridi A	✓	✗	✓	✓	✓	✗
Khan MM	✓	✗	✓	✓	✓	✗

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**Ethical Approval:**

**This Manuscript was approved by the Ethical Review Board of Khyber Teaching Hospital, Peshawar. Vide No. 273/DME/KMC.**

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