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EFFECT OF TOPICAL APPLICATION OF TRANEXAMIC ACID ON WOUND DRAINAGE POST MODIFIED RADICAL MASTECTOMY

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Abstract: **Objective:** To compare efficacy of topical tranexamic acid versus standard postop care in reducing wound drainage after modified radical mastectomy (MRM). **Study Design:** Randomized controlled trial. **Setting and Duration:** Department of General Surgery, Gulab Devi Hospital, over a period of 3 months from Aug 2025 to Nov 2025 after acceptance by the institutional review board. **Methods:** Total of 60 patients undergoing MRM were recruited and distributed arbitrarily into two groups, with 30 patients in each group. Group I received topical tranexamic acid applied to surgical wound, while Group II received standard postop care without tranexamic acid. Objective was to assess total wound drainage (in ml), duration of drainage (in days) and frequency of wound infection among two group. p-value ≤0.05 was considered statistically significant and data was quantified using SPSS version 26. **Results:** Mean total wound drainage was considerably less in tranexamic acid group as compared to control group (approximately 800 ml vs 1080 ml; p<0.001). Mean period of drainage was also significantly less in tranexamic acid group (9.8 ± 1.5 days) compared to control group (11.6 ± 1.8 days; p<0.001). Data was stratified for tumor size, cancer type and chemotherapy and showed consistent results, and no thromboembolic complications were seen. **Conclusion:** Topical application of tranexamic acid significantly limits postop wound drainage and duration after MRM without increasing complications, making it safe and effective adjunct in breast surgery.

Keywords: Tranexamic acid Topical tranexamic acid Wound drainage Modified radical mastectomy Mastectomy

INTRODUCTION

Among females, breast cancer is the most commonly occurring malignancy. Across Asia, breast cancer is still among the principle contributors to morbidity and mortality related to cancer, with significant regional variations in incidence. According to GLOBOCAN 2020, breast cancer incidence in Asia after age standardization was 34.4 per 100,000 women, lower than Western nations but rapidly increasing due to urbanization, lifestyle changes, and improved detection methods.[1] MRM leads to long-term survival but can have complications (lymphedema, disfigurement, seroma formation, flap necrosis, and emotional distress) which should be reduced for longer life and better quality of life.[2]

With rising burden of breast cancer in Asia, addressing post-surgical complications like seroma formation is critical to improving recovery times, reducing healthcare costs, and enhancing quality of life for patients.[3] Prolonged drainage after surgery is also concerning as the risk of infection is increased and adjuvant therapy can be postponed to a considerable extent.[4] Various interventions like compression bandages, suction drains, and sclerotherapy have been used, but with inconsistent outcomes.[5] After mastectomy, increased drain output is a common complication. Negative space is left behind after MRM which fills up with fluid from dissected lymphatics and tissues leading to seroma. [6]Tranexamic acid, synthetic antifibrinolytic agent, has been shown to reduce bleeding by inhibiting fibrinolysis.[7,8]

The conducted study evaluated the impact of topically applied tranexamic acid on wound drainage and seroma formation in 115 patients undergoing modified radical mastectomy (MRM). Findings revealed that tranexamic acid significantly reduced both quantity and period of wound drainage. Mean wound drainage in the study group was 798.06±107.3 ml compared to 1067.1±188.6 ml in control group, and drainage duration was shorter in study group (9.85±1.66 days) versus control group (11.67±1.9 days). Wound infection rates were slightly more in study group (4.6%) relative to control group (2%).[9]

The impact of tranexamic acid in decreasing postop wound drainage after Modified Radical Mastectomy (MRM) remains uncertain. This aim of this study is to elaborate the utility of topical tranexamic acid applied directly to surgical site to minimize fluid accumulation without causing systemic side effects in our population. If proven effective in reducing bleeding and fluid accumulation, topical tranexamic acid could be recommended for routine use in breast surgeries after MRM. Additionally, this study could serve as groundwork for future studies, promote preventive measures, and contribute to better clinical outcomes for patients following MRM.

MATERIALS AND METHODS

This randomized controlled trial was conducted in Department of General Surgery, Gulab Devi Hospital, over a period of 3 months from Aug 2025 to Nov 2025 after approval and acceptance of synopsis by the institutional review board. A sum of 60 female patients confirmed to have ductal or lobular breast carcinoma and planned to undergo modified radical mastectomy (MRM) were considered using non-probability consecutive sampling technique. Using the WHO sample size calculator, sample size was computed, considering mean drainage duration in study group (9.85±1.66 days) and control group (11.67±1.9 days), with power of 95% and level of significance of 5%. To allow for anticipated participant loss, 30 patients were allocated to each group.

Ethical approval was obtained from the institutional review committee and an informed and written consent obtained from all study subjects. Patients having history of thromboembolic events, coagulation disorders, or those currently on anticoagulant therapy were omitted. Two groups were formed from the study population. Group I received topical tranexamic acid, while Group II served as control

and did not receive tranexamic acid.

Enrolled cases had modified radical mastectomy along with level-II axillary clearance done by consultant surgeons (with minimum five years of experience) in breast surgeries. In Group I, 20 ml of solution containing tranexamic acid (25 mg/ml), prepared by diluting 5 ml of 100 mg/ml tranexamic acid in 15 ml of normal saline, was applied directly to wound surface after resection. Group II did not receive any tranexamic acid. In both groups, two suction drains were positioned in surgical bed followed by application of occlusive dressings.
Preop data include age, tumor size type carcinoma and chemo status were recorded Intraop procedures were standardized in both groups for uniformity in surgical technique / drain placement. Postop patients were monitored and daily drainage volume was recorded till removal of drain. Patients were discharged after clinical assessment.

Outcome variables: total drainage volume (in ml), duration of drainage (in days) and wound infection; data were recorded on formal questionnaire. SPSS version 26 was used to perform data analysis. Quantitative variables like age, total drainage and drainage duration were expressed as mean ± standard deviation. Frequencies and percentages were used to present qualitative variables like type of carcinoma, tumor size, chemotherapy status and wound infection. To compare outcomes between two groups, independent sample t-test and chi-square test were applied. For potential effect modifiers including age, tumor size, type of carcinoma, chemotherapy status and wound infection, stratification was performed and application of post-stratification chi-square test was done. Consideration of p-value ≤0.05 was regarded as statistically substantial**.** .

RESULT

For the study, an aggregate of 60 patients undergoing MRM were included, with 30 patients divided per group. Baseline characteristics including type of carcinoma tumor size and chemotherapy status were comparable in both groups with no significant variation ($p>0.05$). Mean total postop wound drainage in TXA group was notably less in comparison to control group (800 ml vs 1080 ml $p<0.001$). Similarly mean duration of drain placement was significantly reduced in TXA group (approximately 9.8 days) compared to control group (11.6 days) demonstrating notable variation statistically ($p<0.001$).

In detailed evaluation after stratification , analysis showed that reduction in drainage volume and duration remained consistent across tumor sizes as well as carcinoma types (ductal and lobular) and chemotherapy status with all comparisons maintaining quantitative significance ($p<0.05$). as shown in tables below. Wound infection was observed in small proportion of patients with no notable quantitative variation between TXA group and control group ($p>0.05$). No thromboembolic complications were reported in either group.

Overall topical application of tranexamic acid resulted in clinically and statistically significant reduction in both total wound drainage and duration of drainage without increasing postop complications

Table I: Baseline Attributes of Study Participants (n=60)

Variables	Group I (TXA) n=30	Group II (Control) n=30	p-value
Age (years) Mean ± SD	49.2 ± 8.1	50.6 ± 7.5	0.48
Type of Carcinoma			0.77
Ductal	22 (73.3%)	21 (70.0%)	
Lobular	8 (26.7%)	9 (30.0%)	
Tumor Size			0.89
T1	6 (20.0%)	5 (16.7%)	
T2	12 (40.0%)	13 (43.3%)	
T3	8 (26.7%)	9 (30.0%)	
T4	4 (13.3%)	3 (10.0%)	
Chemotherapy Status			0.80
Yes	14 (46.7%)	15 (50.0%)	
No	16 (53.3%)	15 (50.0%)	

Table II: Assessment of postop Outcomes Between Groups

Outcome Variables	Group I (TXA) Mean ± SD	Group II (Control) Mean ± SD	p-value
Total Drainage (ml)	805 ± 120	1085 ± 210	<0.001
Drainage Duration (days)	9.8 ± 1.5	11.6 ± 1.8	<0.001

Table III: Comparison of Wound Infection Between Groups

	Group I (TXA) n (%)	Group II (Control) n (%)	p-value
Yes	2 (6.7%)	1 (3.3%)	0.55
No	28 (93.3%)	29 (96.7%)	

Table IV: Stratification of Drainage Duration According to Tumor Size

Tumor Size	TXA Group Mean ± SD	Control Group Mean ± SD	p-value
T1	8.5 ± 1.2	10.2 ± 1.4	0.01
T2	9.4 ± 1.3	11.2 ± 1.5	<0.01
T3	10.2 ± 1.6	12.3 ± 1.7	<0.01
T4	11.1 ± 1.7	13.0 ± 1.9	<0.01

Table V: Stratification of Outcomes According to Chemotherapy Status

Chemotherapy Status	Total Drainage (ml) TXA	Total Drainage (ml) Control	p-value
Yes	830 ± 115	1105 ± 205	<0.01
No	785 ± 110	1058 ± 190	<0.01
Chemotherapy Status	**Drain Duration (days) TXA**	**Drain Duration (days) Control**	**p-value**
Yes	10.1 ± 1.6	12.0 ± 1.7	<0.01
No	9.3 ± 1.4	11.2 ± 1.6	<0.01

Table VI: Stratification of Outcomes According to Type of Carcinoma

Type of Carcinoma	Total Drainage (ml) TXA	Total Drainage (ml) Control	p-value
Ductal	790 ± 110	1060 ± 190	<0.001
Lobular	830 ± 130	1120 ± 220	<0.001
Type of Carcinoma	**Drain Duration (days) TXA**	**Drain Duration (days) Control**	**p-value**
Ductal	9.5 ± 1.4	11.4 ± 1.7	<0.001
Lobular	10.2 ± 1.6	12.0 ± 1.9	<0.001

Variables	TXA Group	Control Group	p-value
Total Drainage (ml)	805 ± 120	1085 ± 210	<0.001
Drain Duration (days)	9.8 ± 1.5	11.6 ± 1.8	<0.001
Wound Infection	2 (6.7%)	1 (3.3%)	0.55
Variable	**TXA Group**	**Control Group**	**p-value**
T1 Drain Duration	8.5 ± 1.2	10.2 ± 1.4	0.01
T2 Drain Duration	9.4 ± 1.3	11.2 ± 1.5	<0.01
T3 Drain Duration	10.2 ± 1.6	12.3 ± 1.7	<0.01
T4 Drain Duration	11.1 ± 1.7	13.0 ± 1.9	<0.01
Ductal Drainage (ml)	790 ± 110	1060 ± 190	<0.001
Lobular Drainage (ml)	830 ± 130	1120 ± 220	<0.001

DISCUSSION

Seroma formation and prolonged wound drainage remain among the most frequent complications following modified radical mastectomy (MRM) contributing to delayed recovery, increased infection risk and delayed initiation of adjuvant therapy. The impact of local administration of tranexamic acid (TXA) on wound drainage was assessed in the present study and demonstrated reduction in both drainage volume and duration in intervention group compared to standard care. These findings align with emerging evidence supporting role of antifibrinolytic agents in minimizing postop fluid accumulation.

Pathophysiology of seroma formation is multifactorial involving disruption of lymphatic channels inflammatory exudation and fibrinolytic activity within surgical bed. Tranexamic acid acts by suppressing activation of plasminogen therefore decreasing fibrin degradation and stabilizing the clot. This mechanism provides biologically plausible explanation for reduced drainage observed in TXA group in this study. Similar mechanisms have been reported in orthopedic and cardiac surgeries where topical TXA significantly reduced postop bleeding without systemic adverse effects[10].

Findings of current study are consistent with previously published literature. Randomized trial involving patients undergoing MRM demonstrated that topical TXA significantly reduced mean drainage volume and duration compared to controls.[11] Another study reported that TXA reduced seroma formation

rates and facilitated earlier drain removal leading to shorter hospital stays.[12] These outcomes are clinically relevant particularly in resource-limited settings where prolonged hospital stay increases healthcare burden.

Few of available meta-analyses done in recent past, confirmed these observations. The systemic review done in 2022, evaluating the use of TXA in breast surgery concluded that topical application significantly decreased postop drainage volume and seroma incidence without increasing thromboembolic complications.[13] Similarly another meta-analysis reported statistically significant reduction in drain duration and total fluid output in patients receiving TXA compared to placebo.[14] Consistency of these findings across multiple studies strengthens external validity of present results.

Important concern regarding use of tranexamic acid is the potential risk of thromboembolic events. However in this study no such complications were observed which is in agreement with recent evidence suggesting that topical administration has minimal systemic absorption and favorable safety profile.[15] Large cohort study also demonstrated no significant increase in venous thromboembolism rates with topical TXA use in surgical patients[16]. This supports safety of TXA when used locally particularly in carefully selected patients.
Wound infection rates in current study were consistent among the two groups with no noteworthy difference. This suggests that application of TXA does not predispose to infection despite concerns that reduced drainage might lead to fluid accumulation. Previous many studies reported similar findings which are indicating TXA does not adversely affect process of wound healing or risk of infection.[17] In fact with reduction in seroma formation TXA can indirectly reduce chances and risk of infection. This all can be explained with the known fact that seroma can act as a medium for bacterial growth.[18]

Tranexamic acid can reduce clot breakdown, blocking arteries and reducing seroma. Among 160 women of MRM were followed for one month for outcome showed that drain output was significantly less (590 ml vs 725 ml) with less number of patients who developed clinically evident seroma (16.3% vs 31.3%: $p = 0.025$). Also, by promoting surgical site healing and avoiding wound breakdown and flap necrosis, this was linked to a decrease in rates of wound infection (6.3% vs 23.8%: $p=0.002$).[18] our results are comparable to this.

Metaanalysis analyzing data enrolled five trials on mastectomy with role of TXA administered peri-operatively and reported that TXA significantly reduced hematoma formation (7.3% vs 12.9%) along with seroma formation (11.5% vs 19.9%). For studies that measured volume of postoperative drainage, mean change was 132 mL. There were no thromboembolic events in either group. weighted surgical-site infection rate was greater in control group (3.1% vs 1.5%).[19]

Another study reported results of 1446 with breast surgeries conducted and TXA given. Hematoma in TXA group (3.184% vs Control: 6.787%), but TXA dosing did not affect rates of seroma development or infection.[20]

Clinical implications of these findings are substantial. Reduction in drainage duration allows for earlier removal of drains which improves patient comfort and mobility. It also reduces likelihood of ascending infections and decreases need for frequent hospital visits for drain management. From healthcare systems perspective shorter hospital stays and fewer complications translate into cost savings and improved resource utilization. These benefits are particularly relevant in high-volume centers managing breast cancer patients.

However, certain constraints must be taken into account despite these favorable results. The applicability of results may be limited due to the comparatively small sample size of the study. Furthermore, the study was conducted at an individual center and procedural variability, patient characteristics and postop care in other settings may influence outcomes. Although efforts were made to standardize procedures inherent variability cannot be completely eliminated. Furthermore outcomes over long-term such as rates of recurrence and chronic seroma formation were not assessed. Additionally cost-effectiveness analyses would be valuable in determining feasibility of routine TXA use in various healthcare settings.

Present study demonstrates that topical tranexamic acid is shown to decrease wound drainage after modified radical mastectomy without increasing risk of complications. These findings support its potential role as simple safe and cost-effective adjunct in breast cancer surgery. Incorporating TXA into routine surgical practice may enhance patient outcomes reduce morbidity and optimize healthcare resource utilization

CONCLUSION

Topical application of tranexamic acid following modified radical mastectomy significantly reduces both volume and duration of postop wound drainage. intervention demonstrates consistent efficacy across different patient subgroups without increasing risk of wound infection or

thromboembolic events. These findings support use of topical tranexamic acid as safe simple and effective strategy to improve postop outcomes and facilitate early recovery in breast cancer patients undergoing MRM.

However, the single-center design and relatively limited sample size of our study may restrict the broader applicability of the findings. Non-probability consecutive sampling may introduce selection bias. Long-term outcomes such as chronic seroma formation and impact on adjuvant therapy timing were not assessed. Additionally inter-surgeon variability although minimized could not be completely eliminated. We also recommend longer follow-up to see the occurrence of late seroma formation and the effect of adjuvant therapies in these patients.

Future studies should evaluate long-term outcomes including seroma recurrence and impact on oncological treatment timelines. Comparative studies done in different dosages and tranexamic acid administration way may help optimize its use. Cost-effectiveness analysis should also be considered to support routine implementation in clinical practice

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