EFFECT OF TOPICAL TRANEXAMIC ACID ON WOUND DRAINAGE AND SEROMA FORMATION FOLLOWING MODIFIED RADICAL MASTECTOMY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Introduction: Modified radical mastectomy (MRM) is a standard surgical procedure for breast cancer, but postoperative wound drainage and seroma formation remain common complications that delay recovery. Topical tranexamic acid (TXA) has been proposed as a simple and safe method to reduce postoperative bleeding and related complications.

Method: This Randomized Controlled Trial done at in tertiary care hospital, Nagpur. 60 patients undergoing MRM for biopsy-proven breast carcinoma were allocated into two groups (30 each). Group A received topical tranexamic acid (1 g), while Group B received an equal volume of normal saline before wound closure. Postoperative drain output, drain removal time, seroma formation, wound complications, and follow-up outcomes were compared.

Result: Group A showed significantly lower drain output and drain removal occurred significantly earlier in Group A. Seroma formation was significantly lower in the TXA group while wound complications and two-week follow-up outcomes were comparable.

Conclusion: Topical application of tranexamic acid during MRM effectively reduced postoperative wound drainage, facilitated earlier drain removal, and significantly decreased seroma formation without increasing postoperative complications.

Keywords: Breast Cancer, Modified Radical Mastectomy, Seroma, Wound Drainage.

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and remains a major cause of cancer-related morbidity and mortality [1]. As reported by Vijaykumar et al., breast cancer incidence in India is expected to increase by approximately 5.6% per year, contributing to an estimated 50,000 additional new cases annually[2]. Modified radical mastectomy (MRM) is one of the standard surgical procedures for the management of operable breast cancer [3].

www.ajmrhs.com
eISSN: 2583-7761

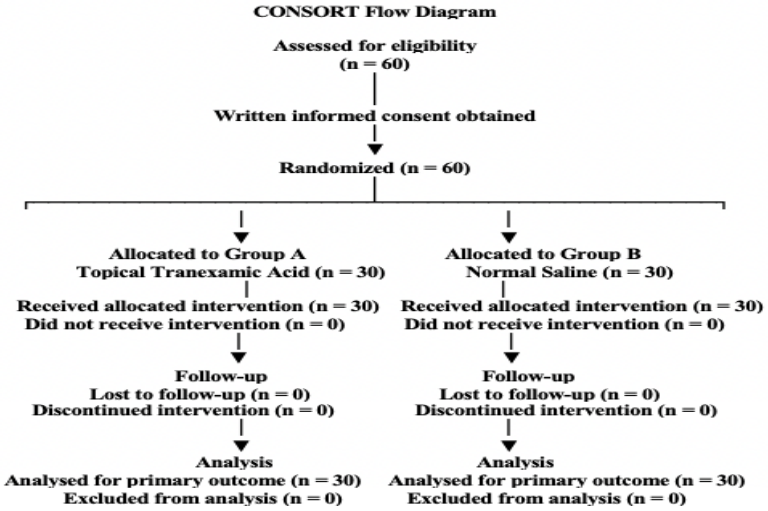
Date of Received: 30-06 2026
Date Acceptance: 09-07-2026
Date of Publication: 08-08-2026

Despite advances in surgical techniques, postoperative wound drainage and seroma formation remain the most frequent complications following MRM, leading to prolonged drain duration, delayed wound healing, increased risk of infection, patient discomfort, and extended hospital stay [4].

Tranexamic acid (TXA), a synthetic antifibrinolytic agent, inhibits plasminogen activation and stabilizes fibrin clots, thereby reducing postoperative bleeding. While the efficacy of intravenous TXA has been established in various surgical specialties, topical application offers the advantage of achieving a high local concentration with minimal systemic absorption and reduced risk of thromboembolic complications [5]. However, evidence regarding its effectiveness in reducing wound drainage and seroma formation after MRM remains limited.

Therefore, this study aimed to compare the effect of topical application of tranexamic acid on postoperative wound drainage and seroma formation following modified radical mastectomy [6].

METHOD



This prospective randomized controlled trial was conducted in the Department of General Surgery, Government Medical College, Nagpur, over a period of 24 months from July 2023 to July 2025. The study was initiated after obtaining approval from the Institutional Ethics Committee (IEC), Maharashtra University of Health Sciences (MUHS), vide Reference No. MUHS/Medical/MUHS-070586/2019, dated 17 January 2025.

The study population comprised patients with biopsy-confirmed carcinoma of the breast who were admitted to the Department of General Surgery and scheduled to undergo MRM or Radical Mastectomy during the study period. Patients aged 18 years or older with biopsy-proven breast carcinoma who were willing to provide written informed consent were considered eligible for inclusion. Patients younger than 18 years of age, those with known congenital or acquired bleeding disorders, patients receiving anticoagulant therapy, immunocompromised individuals, patients with infected or contaminated surgical wounds, those with a recent history of systemic infection, patients diagnosed with benign breast disease, and those unwilling to participate in the study were excluded.

The sample size was estimated using G*Power software (version 3.0.1) for comparison of two independent groups. Considering a two-sided significance level of 5%, study power of 80%, an effect size of 0.75, and an allocation ratio of 1:1, the minimum required sample size was calculated to be 58 participants. To compensate for possible dropouts and to ensure equal allocation between the study groups, the sample size was rounded to 60 participants, with 30 patients included in each group.

After enrolment, participants were randomized into two equal groups based on their inpatient department (IPD) registration number. Patients with even IPD registration numbers were assigned to Group A (tranexamic acid group), whereas those with odd IPD registration numbers were assigned to Group B (control group).

Patients allocated to Group A received a single intraoperative topical application of 1 g tranexamic acid prepared by diluting 10 mL of tranexamic acid with 10 mL of normal saline to obtain a total volume of 20 mL. Immediately before wound closure, 5 mL of the solution was infiltrated beneath the upper skin flap, 5 mL beneath the lower skin flap, and the remaining 10 mL into the axillary dissection bed. Patients in Group B received an equal volume (20 mL) of normal saline infiltrated in an identical manner before wound closure. All patients underwent standard surgical procedures and received routine perioperative management according to departmental protocol.

Baseline demographic and clinical characteristics including age, sex, and body mass index, laterality of the disease, histopathological diagnosis, and type of surgery performed, and associated comorbidities were recorded for all participants. The primary study parameters included postoperative drain output and the incidence of seroma formation. Secondary outcome measures included daily wound drainage, total drain output, duration until drain removal, postoperative wound complications, and

the need for seroma aspiration during follow-up. Patients were monitored throughout their hospital stay and during the postoperative follow-up period until drain removal and subsequent evaluation for seroma formation.

All clinical information was recorded in a predesigned case record form. Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics version 27.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Comparisons between the two groups for continuous variables were performed using the independent sample *t*-test, whereas categorical variables were analysed using the Chi-square test or Fisher's exact test whenever appropriate. A two-tailed *p*-value of less than 0.05 was considered statistically significant.

RESULT

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A (n=30)	Group B (n=30)	P value
Age (years), Mean ± SD	50.67 ± 12.35	52.87 ± 11.59	0.480
BMI (kg/m²), Mean ± SD	21.47 ± 2.16	22.07 ± 2.83	0.360
Right-sided disease, n (%)	19 (63.3)	17 (56.7)	0.598
No comorbidity, n (%)	28 (93.3)	25 (83.3)	0.342
Received neoadjuvant therapy, n (%)	4 (13.3)	4 (13.3)	1.000
Cautery dissection, n (%)	25 (83.3)	26 (86.7)	0.718

As shown in table 1 the mean age of patients was comparable between Group A and Group B (50.67 ± 12.35 vs. 52.87 ± 11.59 years; p=0.480). Similarly, the mean BMI did not differ significantly between the two groups (21.47 ± 2.16 vs. 22.07 ± 2.83 kg/m²; p=0.360). Right-sided breast disease was observed in 19 (63.3%) patients in Group A and 17 (56.7%) patients in Group B (p=0.598). The majority of participants had no comorbidities, accounting for 28 (93.3%) patients in Group A and 25 (83.3%) patients in Group B (p=0.342). Neoadjuvant therapy had been administered to 4 (13.3%) patients in each group (p=1.000). Cautery dissection was the predominant surgical technique, performed in 25 (83.3%) patients in Group A and 26 (86.7%) patients in Group B (p=0.718). Overall, no statistically significant differences were observed in baseline characteristics, indicating good comparability between the two groups.

Table 2. Comparison of Drain Output and Drain Removal between the Groups

Variable	Group A (n=30)	Group B (n=30)	P value
Drain output Day 1 (mL)	112.00 ± 28.45	134.67 ± 45.39	0.024*
Drain output Day 5 (mL)	33.17 ± 10.30	51.33 ± 14.56	<0.0001*
Total drain output (mL)	353.33 ± 69.91	505.33 ± 96.23	<0.0001*
Drain removal (days)	6.20 ± 1.38	8.40 ± 1.19	<0.0001*

Table 2 shows that the mean drain output on postoperative Day 1 was significantly lower in Group A than in Group B (112.00 ± 28.45 mL vs. 134.67 ± 45.39 mL; p=0.024). Similarly, the mean drain output on Day 5 was significantly lower in Group A (33.17 ± 10.30 mL) compared with Group B (51.33 ± 14.56 mL; p<0.0001). The total postoperative drain output was also markedly reduced in Group A (353.33 ± 69.91 mL) compared with Group B (505.33 ± 96.23 mL; p<0.0001). Furthermore, drains were removed significantly earlier in Group A than in Group B (6.20 ± 1.38 vs. 8.40 ± 1.19 days; p<0.0001).

Table 3. Effect of Clinical Variables on Total Drain Output

Variable		Group A Mean ± SD (mL)	P value	Group B Mean ± SD (mL)	P value
Age	≤40 years	353.33 ± 53.97	0.329	460.00 ± 80.31	0.252
	41–50 years	335.00 ± 70.86		518.75 ± 75.86	
	51–60 years	394.29 ± 94.84		536.25 ± 114.14	
	61–70 years	360.00 ± 52.92		521.43 ± 98.90	
	71–80 years	300.00 ± 17.32		385.00 ± 49.50	
Comorbidity	No	344.29 ± 56.87	0.0057*	493.60 ± 99.58	0.138
	Yes	480.00 ± 141.42		564.00 ± 49.80	

BMI	Normal	342.12 ± 58.54	0.022*	498.52 ± 98.91	0.480
	Overweight/Obese	426.25 ± 102.50		583.33 ± 35.36	

As shown in Table 3 Age did not significantly influence total drain output in either Group A (p=0.329) or Group B (p=0.252). In Group A, patients with comorbidities had significantly higher drain output than those without comorbidities (480.00 ± 141.42 mL vs. 344.29 ± 56.87 mL; p=0.0057). Patients with overweight or obesity also exhibited significantly greater drain output compared with those having normal BMI (426.25 ± 102.50 mL vs. 342.12 ± 58.54 mL; p=0.022). In contrast, neither comorbidity (p=0.138) nor BMI category (p=0.480) showed a statistically significant association with drain output in Group B.

Table 4. Effect of Surgical Factors on Total Drain Output

Variable		Group A Mean ± SD (mL)	P value	Group B Mean ± SD (mL)	P value
Neoadjuvant therapy	No	348.85 ± 73.84	0.379	515.39 ± 97.66	0.148
	Yes	382.50 ± 22.17		440.00 ± 58.88	
Method of dissection	Cautery	341.60 ± 59.23	0.037*	505.00 ± 99.37	0.962
	Scissor	412.00 ± 96.02		507.50 ± 85.00	

As seen in Table 4 Neoadjuvant therapy did not significantly affect drain output in either Group A (348.85 ± 73.84 mL without therapy vs. 382.50 ± 22.17 mL with therapy; p=0.379) or Group B (515.39 ± 97.66 mL vs. 440.00 ± 58.88 mL; p=0.148). However, in Group A, patients undergoing scissor dissection had significantly higher drain output than those undergoing cautery dissection (412.00 ± 96.02 mL vs. 341.60 ± 59.23 mL; p=0.037). No significant difference according to the method of dissection was observed in Group B (p=0.962).

Table 5. Postoperative Outcomes

Outcome	Group A (n=30)	Group B (n=30)	P value
Seroma formation, n (%)	1 (3.3)	7 (23.3)	0.023*
Seroma aspiration volume (mL)	180	155.71 ± 47.21	0.647
Wound complications, n (%)	4 (13.3)	6 (20.0)	0.353
No wound complications, n (%)	26 (86.7)	24 (80.0)	

As shown in Table 5 Seroma formation occurred in only 1 (3.3%) patient in Group A compared with 7 (23.3%) patients in Group B, demonstrating a statistically significant reduction in the tranexamic acid group (p=0.023). Among patients who developed seroma, the mean aspiration volume was comparable between the groups (180.00 mL in Group A vs. 155.71 ± 47.21 mL in Group B; p=0.647). Postoperative wound complications were observed in 4 (13.3%) patients in Group A and 6 (20.0%) patients in Group B (p=0.353), while the majority of patients had no wound-related complications (26 [86.7%] vs. 24 [80.0%], respectively).

Table 6. Follow-Up Outcomes at Two Weeks

Follow-up Status	Group A (n=30)	Group B (n=30)	P value
No complaints	27 (90.0)	28 (93.3)	0.640
Resolving raw area	3 (10.0)	2 (6.7)	

Table 6 shows that most patients in both groups had no postoperative complaints, accounting for 27 (90.0%) patients in Group A and 28 (93.3%) patients in Group B. A resolving raw area was noted in 3 (10.0%) patients in Group A and 2 (6.7%) patients in Group B. The distribution of follow-up outcomes was similar in both groups, with no statistically significant difference (p=0.640).

DISCUSSION

The present study showed that the administration of tranexamic acid (TXA) in Group A significantly reduced postoperative drain output compared to the control Group B. Consequently, the time to drain removal was also significantly shorter in the TXA group (6.20 ± 1.38 days vs. 8.40 ± 1.19 days, p<0.0001).

These findings are similar to existing literature on the blood-conserving effects of TXA in orthopedic procedures, particularly total knee arthroplasty (TKA), where TXA consistently reduces

postoperative drainage and facilitates earlier drain removal. For instance, Yogesh et al. reported a marked reduction in total drain output with TXA (185.00 ± 38.92 mL in the TXA group vs. 298.33 ± 62.45 mL in controls, p<0.001), along with lower 24-hour (115.00 ± 28.45 mL vs. 178.33 ± 42.67 mL) and 48-hour outputs, representing approximately a 38% reduction in total drainage—comparable to the ~30% reduction observed in our study [7].

Similarly, Choudhury et al. (2024) found that additional peri-articular TXA led to significantly lower drain output at 24 hours (181.71 ± 64.26 mL vs. 208.67 ± 68.81 mL, p=0.0247) and 48 hours (117.65 ± 36.04 mL vs. 145.31 ± 78.18 mL, p=0.0119), with total drain output of 299.37 ± 86.39 mL versus 353.98 ± 120.50 mL (p=0.0041). Our total drain volumes in the TXA group (353 mL) are consistent with these values, though our control group showed higher output, possibly due to differences in surgical technique, patient demographics, or TXA dosing regimen [8].

A large meta-analysis of topical TXA by Tantavisut et al. (2025) reported a substantial reduction in drainage volume compared to placebo (mean difference -239.8 mL, 95% CI: -298.7 to -180.9 mL, p<0.001 across 74 study arms), supporting the robust antifibrinolytic effect of TXA on postoperative bleeding. This is in line with our observed differences in both early (Day 1) and later (Day 5) drain outputs. Other studies, such as those evaluating systemic TXA, have shown similar benefits in reducing drainage volume and drain duration [9,10].

Regarding drain removal timing, our finding of earlier removal by approximately 2.2 days in the TXA group corroborates evidence from broader TXA literature, where reduced cumulative output allows for safer and earlier discontinuation of drains without increasing complications. This is clinically relevant, as prolonged drain use can increase infection risk, patient discomfort, and hospital stay [7,9].

In the present study, age did not significantly influence total drain output in either group (Group A: p=0.329; Group B: p=0.252), with outputs remaining relatively stable across age strata (e.g., 353.33 ± 53.97 mL in ≤40 years and 300.00 ± 17.32 mL in 71–80 years in Group A). In contrast, the presence of comorbidities significantly increased total drain output in the TXA group, while the difference was not statistically significant in the control group (p=0.138). Similarly, higher BMI (overweight/obese) was associated with greater drain output in Group A) but not in Group B (p=0.480) [10].

These findings partially are similar to broader orthopedic literature on factors affecting perioperative blood loss and drainage in total knee arthroplasty (TKA). Consistent with our observation that age had no significant impact, several studies have reported that patient age does not independently correlate strongly with drain output or total blood loss when TXA is used, likely due to the overriding antifibrinolytic effect of TXA across age groups [11].

Regarding comorbidities, our results showing significantly higher drain output in patients with comorbidities within the TXA group (an increase of ~136 mL) echo reports showing that higher comorbidity burden is linked to increased bleeding risk and disruptive perioperative bleeding in TKA. Hu et al. identified obesity, hypertension, and diabetes as independent risk factors for excessive perioperative bleeding. Ng et al. further noted that disruptive bleeding in TKA is associated with higher comorbidity burden, leading to prolonged hospitalizations and other adverse outcomes. The attenuated effect in our control group may show already elevated baseline bleeding, masking subgroup differences [12].

For BMI, our study found a significant association with increased drain output in the TXA group (approximately 84 mL higher in overweight/obese patients, p=0.022). This is consistent with evidence that higher BMI contributes to greater surgical complexity, soft tissue dissection, and potential for increased blood loss. Studies have shown obesity is associated with higher rates of wound complications and overall perioperative challenges in TKA, though specific drain output data varies. Some reports, however, note that while higher BMI correlates with certain complications, the relative benefit of TXA in reducing blood loss may still be preserved, as seen in our overall group comparison [11,13].

The present study evaluated the influence of surgical factors on total drain output. Neoadjuvant therapy did not significantly affect total drain output in either group (p=0.379). However, the method of dissection in Obermeier et al. (2023) study showed a significant impact in the TXA group, with cautery dissection associated with lower total drain output (341.60 ± 59.23 mL) compared to scissor dissection). No such difference was observed in the control group (p=0.962) [14].

These results are consistent with literature comparing dissection techniques. In various surgical fields, electrocautery (cautery) is often linked to reduced intraoperative blood loss and postoperative drainage due to its hemostatic properties, though outcomes vary by procedure. Obermeier et al. (2023) reported that monopolar electrocautery in neck dissection led to significantly lower blood loss and shorter operative times compared to traditional scalpel and scissors. Similarly, studies in modified radical mastectomy

have shown reduced drain output and shorter hospital stays with electrocautery versus scissors dissection [14,15].

In the context of total knee arthroplasty (TKA), findings are more nuanced. Tammachote et al. (2018) done a double-blinded RCT and found no significant difference in total blood loss between electric cautery and scalpel-only techniques in primary TKA. Lin et al. (2020) also compared scalpel and electric cautery in primary TKA, reporting comparable clinical outcomes, though specific drain volumes were not always differentiated. Our study's observation of significantly lower drain output with cautery in the TXA group (a reduction of approximately 70 mL, p=0.037) suggests a potential synergistic effect when combined with TXA's antifibrinolytic action, which may not be as evident in non-TXA controls. This shows the importance of surgical technique as a modifiable factor in blood management protocols [16,17].

Regarding neoadjuvant therapy, limited orthopedic-specific data exists, as this factor is more commonly studied in oncologic surgeries. Our non-significant findings are similar to the general understanding that while neoadjuvant treatments can affect tissue quality and healing, they did not substantially alter drain output in this cohort, possibly due to the standardized use of TXA or patient selection [18].

The present study showed a statistically significant reduction in seroma formation in the TXA group (Group A: 3.3%, n=1/30) compared to the control group (p=0.023). This finding is similar to several studies in the literature supporting the role of TXA in mitigating seroma after breast and reconstructive surgeries. For instance, Ahmed et al. (2024) reported that TXA significantly reduced seroma formation, facilitated earlier drain removal, and lowered wound infection rates in patients undergoing MRM. Similarly, in gender-affirming mastectomy, patients receiving intraoperative TXA showed markedly lower seroma rates (20.5% vs. 33.0% in controls; p<0.001) [6,19].

Weissler et al. (2020) also observed that topical TXA was associated with a decreased risk of postoperative seroma and shorter time to drain removal following implant-based breast reconstruction. These results suggest that TXA's antifibrinolytic action helps stabilize clots and reduce fluid accumulation in the dead space, consistent with the mechanism observed in our cohort where seroma incidence was substantially lower with TXA administration [6,20].

In contrast to our finding Weissler et al. (2022), in a large series of 385 patients undergoing reduction mammaplasty, found no significant reduction in seroma or hematoma with TXA (P > 0.05), attributing seroma risk more strongly to factors like BMI and drain use. A systematic review by Fung et al. (2025) similarly concluded that while TXA significantly reduced hematoma formation, drain duration, and 24-hour output, it did not significantly impact seroma rates or surgical site infections, though trends toward reduction were noted [21,22].

In our study, the volume of seroma aspiration showed no significant difference between groups (180 mL in Group A vs. 155.71 ± 47.21 mL in Group B; p=0.647). This is comparable to findings where TXA reduced incidence but had variable effects on aspirated volume or drain output in some cohorts. MadhuBabu et al. (2025) noted that TXA significantly reduced intraoperative blood loss and late postoperative drain output in MRM but did not achieve a statistically significant reduction in overall seroma formation or wound complications [23].

Regarding wound complications, our study showed a lower but non-significant rate in the TXA group (13.3% vs. 20.0%; p=0.353). This is similar to many studies report no increase in adverse events with TXA and occasional reductions in infection or other complications, with no elevated thromboembolic risk [24,25].

At the two-week follow-up, the present study showed comparable outcomes between the TXA group (Group A) and the control group (Group B). The majority of patients in both groups were complaint-free, with a small proportion showing resolving raw areas (10.0% vs. 6.7%; p=0.640). This lack of significant difference shows that TXA administration does not adversely affect short-term wound healing or increase minor wound issues, supporting its safety profile in the early postoperative period.

These findings are consistent with broader literature on TXA in breast surgery, which generally reports no negative impact on wound healing parameters. Systematic reviews and meta-analyses, such as that by Fung et al. (2025), showed that TXA significantly reduced hematoma formation and drain-related metrics without impacting surgical site infection (SSI) rates or seroma formation, with similar safety observed in follow-up assessments. Hashemi et al. (2025) similarly found no significant differences in infection rates or other complications with topical TXA (RR = 0.85 for infection; p=0.59), reinforcing that TXA does not compromise wound healing trajectories [21,24].

In a retrospective study of autologous breast reconstruction, Rose et al. (2024) reported fewer wound healing complications in the TXA group (22% vs. 49% in controls; p=0.01), along with earlier drain removal, showing potential benefits or at least neutrality in healing outcomes. MadhuBabu et al. (2025) observed no statistically significant increase in wound complications with TXA in

modified radical mastectomy patients, similar to our non-significant p-value for resolving raw areas [23,26].

The high rates of "no complaints" in both arms of our study (over 90%) show effective overall surgical management and are comparable to short-term follow-up data in TXA trials, where most patients achieve uneventful recovery by the second week when major bleeding complications are controlled. The minor, non-significant difference in resolving raw areas may relate to individual healing variations rather than TXA exposure, consistent with reports showing that TXA's antifibrinolytic effects do not impair tissue repair or increase dehiscence risks [27].

The present study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Additionally, the follow-up period was short and focused primarily on early postoperative outcomes, precluding assessment of long-term complications and recurrence of seroma.

CONCLUSION

Topical application of tranexamic acid during modified radical mastectomy significantly reduced postoperative wound drainage, total drain output, and duration of drain placement compared with normal saline. It also resulted in a significantly lower incidence of seroma formation, while baseline characteristics and postoperative wound complications remained comparable between the two groups. These findings suggest that topical tranexamic acid is a safe, simple, and effective adjunct for reducing postoperative fluid collection following breast cancer surgery. Its use may facilitate earlier drain removal, improve postoperative recovery, and decrease seroma-related morbidity without increasing adverse postoperative outcomes.

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How to cite this article: Dr. Gaurav Jitendra Nighot, Dr. Sanjay Dakhore, Dr. Unmed Chandak, Dr. Shweta Gupta, Dr. Brajesh Gupta, Dr. Chetankumar Sonewane, Dr. Rahul Uikey, Dr. Sanskruti Akulwar, Dr. Ashlesha Ganorkar, Dr. Ramesh S Tatti, Dr. Shivadev M, Dr. Shikha Tolani, Dr. Subodh Behera, Dr. Neel Mehta, EFFECT OF TOPICAL TRANEXAMIC ACID ON WOUND DRAINAGE AND SEROMA FORMATION FOLLOWING MODIFIED RADICAL MASTECTOMY: A RANDOMIZED CONTROLLED TRIAL , Asian J. Med. Res. Health Sci., 2026; 4 (2): 2674-2682. **Source of Support:** Nil, Conflicts of Interest: None declared.