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Breast

Is Topical Tranexamic Acid Effective in Reducing Hematoma and Seroma in Breast Surgery? A Systematic Review and Meta-analysis

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Background: Postoperative fluid-related complications, such as hematoma and seroma formation, are common concerns in breast surgery, adversely affecting surgical outcomes and patient recovery. Topical tranexamic acid (TXA) has emerged as a promising intervention to minimize bleeding while reducing systemic adverse effects linked to intravenous administration. However, evidence on the efficacy of topical TXA in breast surgery remains sparse.

Methods: This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. English-language databases were searched through April 2024 to identify randomized controlled trials and cohort studies assessing the effects of topical TXA on postoperative outcomes in breast surgery, including hematoma, seroma, infection rates, and drain output/duration.

Results: Six studies, encompassing 823 patients and 1477 breasts, were included. Subgroup meta-analysis demonstrated a statistically significant reduction in hematoma rates in patients who underwent mastectomy (risk ratio [RR] = 0.14; 95% confidence interval [CI], 0.03–0.78; $P = 0.02$), but not in patients who underwent breast reduction (RR = 0.76; 95% CI, 0.08–7.08; $P = 0.24$). No significant differences were found in overall hematoma rates (RR = 0.32; 95% CI, 0.08–1.195; $P = 0.09$), seroma formation (RR = 1.22; 95% CI, 0.99–1.51; $P = 0.07$), or infection rates (RR = 0.85; 95% CI, 0.46–1.56; $P = 0.59$).

Conclusions: Topical TXA significantly reduced hematoma rates in patients who underwent mastectomy but showed no significant effect on other outcomes. Larger studies with standardized methodologies are required to fully establish the role of topical TXA in optimizing breast surgery outcomes. *(Plast Reconstr Surg Glob Open 2025; 13:e6442; doi: 10.1097/GOX.0000000000006442; Published online 16 January 2025.)*

INTRODUCTION

Postoperative fluid-related complications, such as hematoma and seroma formation, are common concerns in breast surgery, impacting surgical outcomes and patient recovery.[1–3] The complications associated with postoperative fluid can lead to unplanned operations, blood transfusions due to acute blood loss anemia, infection, delayed wound healing, and an adverse effect on the overall surgical outcomes.[4]

Tranexamic acid (TXA) has gained popularity among plastic surgeons for its potential to reduce postoperative hematoma and seroma formation.[5–8] Since its introduction in the 1960s, TXA has been used to reduce intraoperative bleeding and subsequent complications across various surgical fields, including orthopedic, trauma, craniofacial, and cardiac surgery.[6,9–12] However, its widespread use is limited by concerns about potential systemic adverse effects, including myocardial infarction, deep vein thrombosis, and pulmonary embolism.[13,14] As a result, the topical application of TXA has emerged as a promising alternative. Studies have shown that topical TXA in breast surgery reduces seroma formation and overall blood loss without significant adverse effects.[15–19] Additionally, topical TXA offers a dual advantage by

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directly mitigating blood loss and indirectly reducing hospital expenses through lower postoperative complication rates and shortened hospital stays.[20]

Previous clinical investigations have demonstrated the comparable efficacy of topical TXA to IV TXA in reducing intraoperative blood loss, transfusion needs, and drainage volume in hip and knee surgery.[10,11,21–24] However, the literature on the efficacy of topical TXA in breast surgery is limited, with few studies possessing sufficient statistical power to draw definitive conclusions. To address this knowledge gap, we conducted a systematic review and meta-analysis to pool the available data and elucidate the role of topical TXA in influencing key postoperative outcomes, including hematoma rate, seroma rate, infection rates, and postoperative drain output and duration in breast surgery.

Takeaways

Question: How effective is topical tranexamic acid (TXA) in minimizing postoperative fluid-related complications in breast surgery?

Findings: This systematic review and meta-analysis evaluated 6 studies involving 823 patients and 1477 breasts. Overall, no significant reduction in postoperative complications was observed across all breast procedures. However, in the mastectomy subgroup, topical TXA significantly reduced postoperative hematoma rates. Such benefit was not observed in the breast reduction subgroup, as TXA showed no significant effect.

Meaning: Topical TXA could be effective in reducing postoperative complications in mastectomy patients but does not demonstrate similar benefits for breast reduction surgery.

MATERIALS AND METHODS

Search Strategy and Study Selection

This systematic review has been registered in the International Prospective Register of Systematic Reviews under the identifier (ID: CRD42023495427) and follows the Preferred Reporting Items for Systematic Review and Meta-analyses guidelines (Fig. 1). A comprehensive search of the English literature was conducted across Ovid MEDLINE, PubMed, Embase, Web of Science, and Central Register of Controlled Trials databases from inception through April 2024. The search strategy used specific terms as subjects and keywords, including "topical tranexamic acid," "antifibrinolytic," "breast surgery," "breast reduction," "reduction mammaplasty," "breast reconstruction," "breast augmentation," "breast implant," and "breast flap."

In the initial phase, studies were assessed for eligibility, and duplicates were removed. Two independent reviewers (A.S.A.H. and Z.H.A.) screened the articles based on the

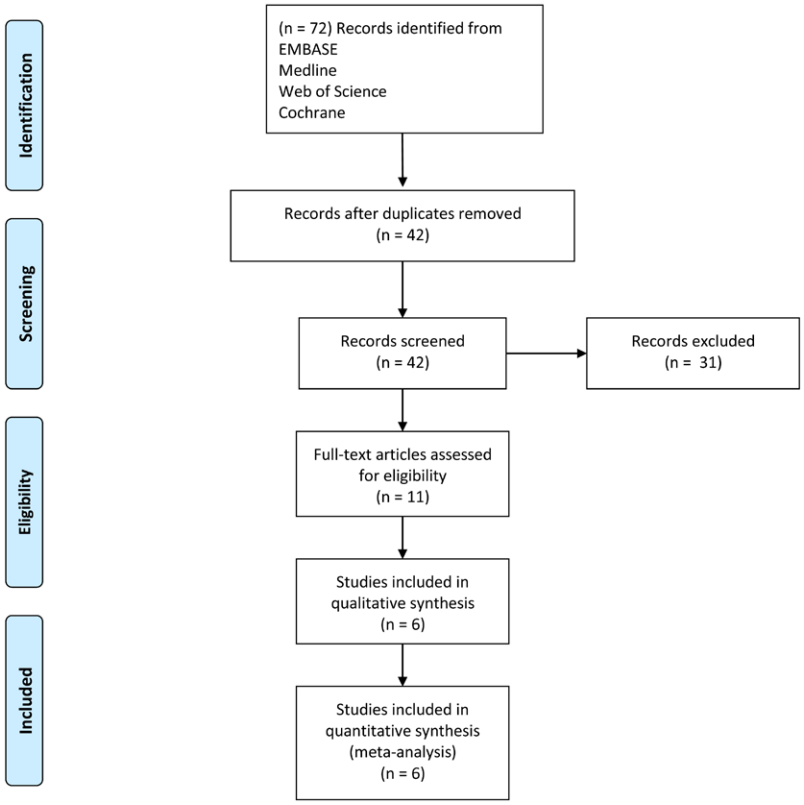

Fig. 1. Preferred Reporting Items for Systematic Review and Meta-analyses flowchart for the study.

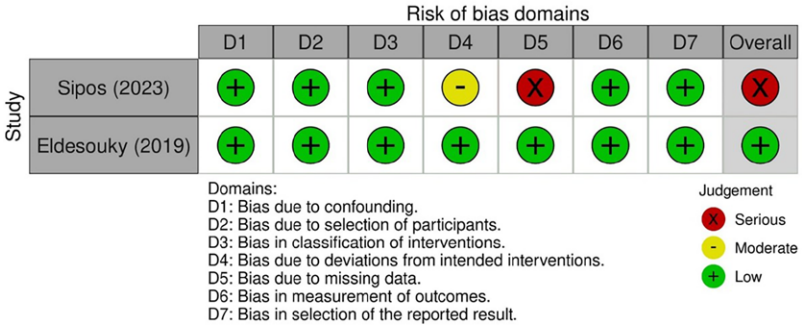

Fig. 2. Risk-of-bias assessment of RCTs using the Revised Cochrane Risk-of-bias tool for RCTs tool.

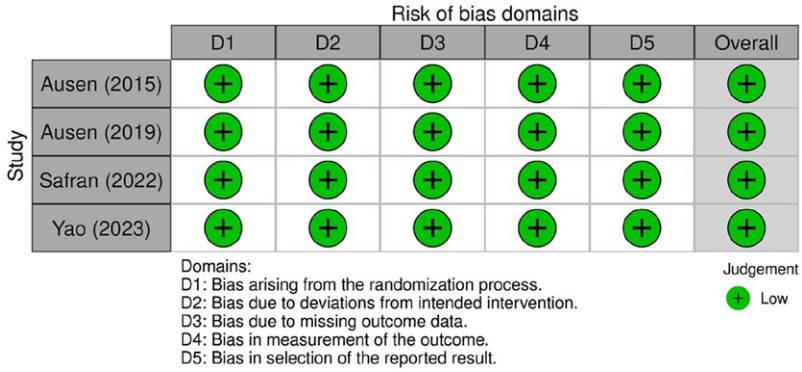

Fig. 3. Risk-of-bias assessment of non-RCTs using the Risk of Bias in Nonrandomized Studies of Interventions tool.

title and abstract. Disagreements were resolved by consensus or by consulting a third author (A.A.A.Q.). The inclusion criteria were (1) studies reporting data on patients older than 18 years undergoing any type of breast surgery who received topical TXA; (2) studies reporting relevant outcomes, including rates of hematoma, seroma formation, infection, and drain output and duration, along with other postoperative complications; and (3) randomized clinical trials and prospective/retrospective cohort studies. Articles not meeting these criteria, written in languages other than English, or with a high risk of bias or low methodological quality were excluded. Additionally, studies utilizing TXA administration routes other than the topical route were also ineligible. Our outcomes of interest included hematoma, seroma formation, infection, and drain output. Hematoma or postoperative bleeding was defined as bleeding that requires evacuation in the operating room[15,16] or at the bedside.[4] Seroma was defined as fluid accumulation requiring aspiration after drain removal.[16,19] The included studies did not provide a clear definition of infection.

Data Extraction and Quality Assessment

The data extraction process followed a standardized protocol using a data collection sheet, completed independently by the respective authors (A.S.A.H. and Z.H.A.) for each article. Any discrepancies were resolved through discussion or by consulting a third author A.A.A.Q.). The extracted data included demographic details (eg, age, sex, and smoking status), study design, procedural specifics, mean volume of excised breast tissue, patient outcomes, rate of postoperative complications, and follow-up duration.

For the risk-of-bias assessment, the authors utilized The Revised Cochrane Risk-of-Bias tool for randomized clinical trials and Risk of Bias in Nonrandomized Studies of Interventions tools (Figs. 2, 3). This was conducted independently by 2 authors, with disagreements resolved through consensus or consultation with a third author (A.A.A.Q.).

Statistical Analysis

The authors used descriptive statistics to characterize the research data and performed a weighted meta-analysis for the outcomes of interest. Comparative assessments of hematoma, seroma formation, and infection rates were conducted using risk ratios with a 95% confidence interval (CI), whereas drain output and duration were evaluated via mean differences. A Mantel-Haenszel random-effects model was applied for analysis and forest plot generation, using RevMan 5.4 software. Heterogeneity was assessed using I^2 statistics, categorized as low (I^2 = 0%–50%), moderate (I^2 = 50%–74%), or high (I^2 = 75%–100%). A P value of 0.05 was set as the threshold for statistical significance. Subgroup meta-analyses were conducted for all outcomes,

Table 1. Summary of Study Demographics

Study	Group	Age, y (Median ± SD, Unless Specified Otherwise)	Active Smoker (n)	BMI (kg/m²) (Mean ± SD)	Radiation (n)	Chemotherapy (n)	Follow-up
Ausen et al[18]	TXA	Median: 45, range: 18–67	—	—	—	—	3 mo
	Control						
Ausen et al[19]	TXA	66.2 ± 13.3	19	26.9 ± 4.9	14	32	3 mo
	Control	62.3 ± 12.8	13	27.1 ± 4.7	11	41	
Safran et al [16]	TXA	48, range: 30-70	0	24.2, range: 19.5–28.7	1	0	At least 6 mo
	Control						
Yao et al[4]	TXA	34.2 ± 12.87	4	31.5 ± 3.64	—	—	Mean: 30 d
	Control				—	—	
Sipos et al[15]	TXA	43 ± 15.2	8	—	—	—	—
	Control	46 ± 14.4	10	—	—	—	—
Eldesouky et al[17]	TXA	45.96 ± 7.06	—	32.4 ± 3.04	—	16	1 mo
	Control	47.87 ± 6.54	—	33.02 ± 2.39	—	11	

BMI, body mass index.

Table 2. Summary of Study Characteristics

Study	Design	Country	Group	No.		Procedure Performed	Mean Breast Size in g (SD)	Method of Topical TXA Administration	Concentration of TXA
				Patients	Breasts				
Ausen et al[18]	RCT	Norway	TXA	28 (split-breast technique)	28	Bilateral RM	415 ± 162	Surface moistened before closure	20 mL of 25 mg/mL of TXA
			Control		28				
Ausen et al[19]	RCT	Norway	TXA	101	101	Simple mastectomy, mastectomy with SNB, mastectomy with ALNC	780 ± 450	Surface moistened before closure	20 mL of 25 mg/mL of TXA
			Control	101	101		746 ± 359		
Safran et al[16]	RCT	Canada	TXA	53 (split-breast technique)	53	BNSM with immediate direct-to-implant breast reconstruction	—	Sponge soaked in TXA solution was placed over surgical breast pocket surface before closure	100 mL solution (70 mL of NS and 3 g of TXA), which is equivalent to 30 mg/mL concentration
			Control		53				
Yao et al[4]	RCT	United States	TXA	49 (split-breast technique)	49	Bilateral RM	773.6, range: 30–248	Surface moistened before closure	20 mL of 100 mg/mL of TXA
			Control		49				
Sipos et al[15]	Retrospective Cohort	Finland	TXA	168	785	RM	—	Rinsing the breast tissue before closure	25 mL of 20 mg/mL of TXA
			Control	208					
Eldesouky et al[17]	Prospective Cohort	Egypt	TXA	65	130	MRM (Patey or Madden)	—	Applied directly on the wound	20 mL of 25 mg/mL of TXA
			Control	50	100				

ALNC, axillary lymph node clearance; BNSM, bilateral nipple-sparing mastectomy; MRM, modified radical mastectomy; RM, reduction mammoplasty; SNB, sentinel node biopsy.

stratified into 2 groups based on the type of breast surgery performed: breast reduction versus mastectomy.

RESULTS

Search Strategy and Study Selection

The database search identified 42 unique articles, with 11 qualifying for full-text review. Of these, 6 articles met the inclusion criteria for this systematic review, which included 4 randomized controlled trials (RCTs), 1 retrospective cohort study, and 1 prospective cohort study.[4,15–19] Collectively, these studies involved 823 patients and 1477 breasts, as detailed in Tables 1 and 2. However, only 5 articles were included in the meta-analysis; as 1 retrospective cohort study[15] was excluded because it did not report the number of breasts per group separately, making it ineligible for meta-analysis (Fig. 1). The publication period of these studies spans from 2015 to 2023.

The analyzed data included 453 patients who underwent reduction mammaplasty and 370 patients who had mastectomy, with various techniques described (Table 2). Comprehensive demographic data, covering aspects such as age, smoking status, body mass index, radiation and chemotherapy exposure, and follow-up periods, are presented in Table 1. Additionally, Table 2 offers an in-depth overview of the study characteristics, including

Table 3. Summary of the Outcomes

Study	Group	Drain Output (Mean ± SD)	Drain Duration, d (Mean ± SD)	Hematoma (n)	Seroma (n)	Infection (n)	Other Complications (n)
Ausen et al[18]	TXA	Median: 12.9 (range: 0.0–47.0)	—	0	1	5	0
	Control	Median: 22 (range: 0.0–100.0)	—	2	1	5	0
Ausen et al[19]	TXA	Mean drain production in first 24 h: 110 mL (95% CI, 97–123) Mean total drain production: 189 mL (95% CI, 145–234)	—	1	87	10	Late hematoma or wound rupture: 3
	Control	Mean drain production in first 24 h: 144 mL (95% CI, 122–167) Mean total drain production: 214 mL (95% CI, 165–264)	—	7	84	8	Late hematoma or wound rupture:2
Safran et al[16]	TXA	—	—	0	1	1	Capsular contracture: 1
	Control	—	—	3	1	4	Capsular contracture: 7
Yao et al[4]	TXA	37.7 mL	6.7	2	0	3	Fat necrosis: 5 Delayed wound healing: 16
	Control	42.2 mL	6.9	1	0	8	Fat necrosis: 5 Delayed wound healing: 21
Sipos et al[15]	TXA	—	—	6	3	8	Minor skin problems: 76 Superficial mamilla necrosis: 3
	Control	—	—	25	5	19	Minor skin problems (eg, Suture fistulas): 96 Superficial mamilla necrosis: 6
Eldesouky et al[17]	TXA	798.06 ± 107.3	9.85 ± 1.66	0	8	3	—
	Control	1067.1 ± 188.6	11.67 ± 1.9	0	6	1	—

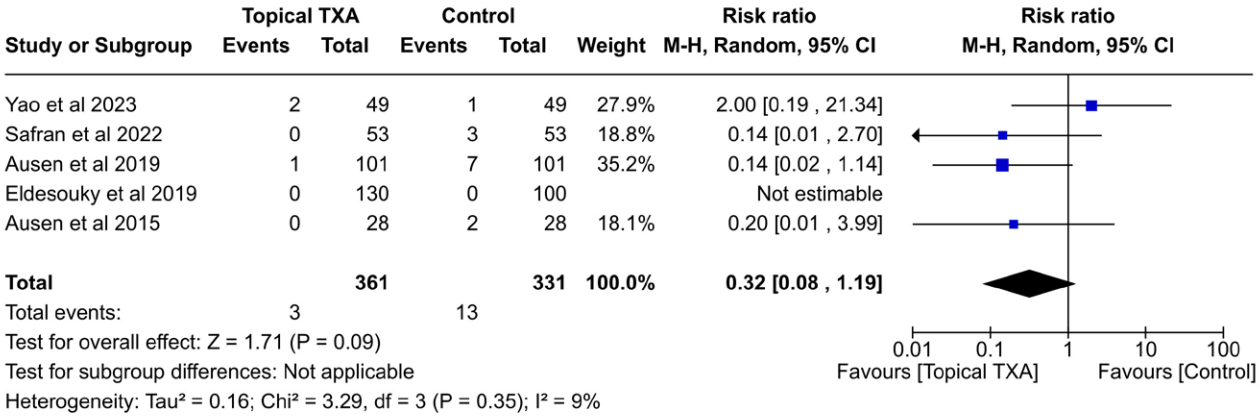

Fig. 4. Meta-analysis of total hematoma rates in breast surgery. M-H, Mantel-Haenszel.

group-specific details and the methods and concentrations of topical TXA administration used in each study. Various methods were used for administering topical TXA, such as surface moistening, rinsing, and sponge application. The concentrations of topical TXA used were variable and inconsistent (Table 2). The included studies reported no adverse reactions related to TXA. The outcomes discussed later are summarized in Table 3.

Rate of Hematoma or Rebleeding

Five studies reported hematoma rates in breast surgery (Fig. 4). The meta-analysis showed no significant statistical difference in hematoma or rebleeding rates between the topical TXA group and the control group (risk ratio [RR] = 0.32; 95% CI, 0.0.08–1.195; $P = 0.09$). The analysis indicated low heterogeneity, with an I^2 value of 9%. The incidence of hematoma in the topical TXA group was 0.83% (3 of 361 breasts), compared with 3.92% (13 of 331 breasts) in the control group. The subgroup meta-analysis revealed a statistically significant reduction in hematoma rates in the mastectomy group (RR=0.14; 95% CI, 0.03–0.78; $P = 0.02$) compared with the breast reduction group (RR = 0.76; 95% CI, 0.08–7.08; $P = 0.24$) (Fig. 5).

Rates of Seroma Formation

Five studies reported seroma formation rates in breast surgery (Fig. 6). The meta-analysis found no significant statistical difference in seroma formation rates between

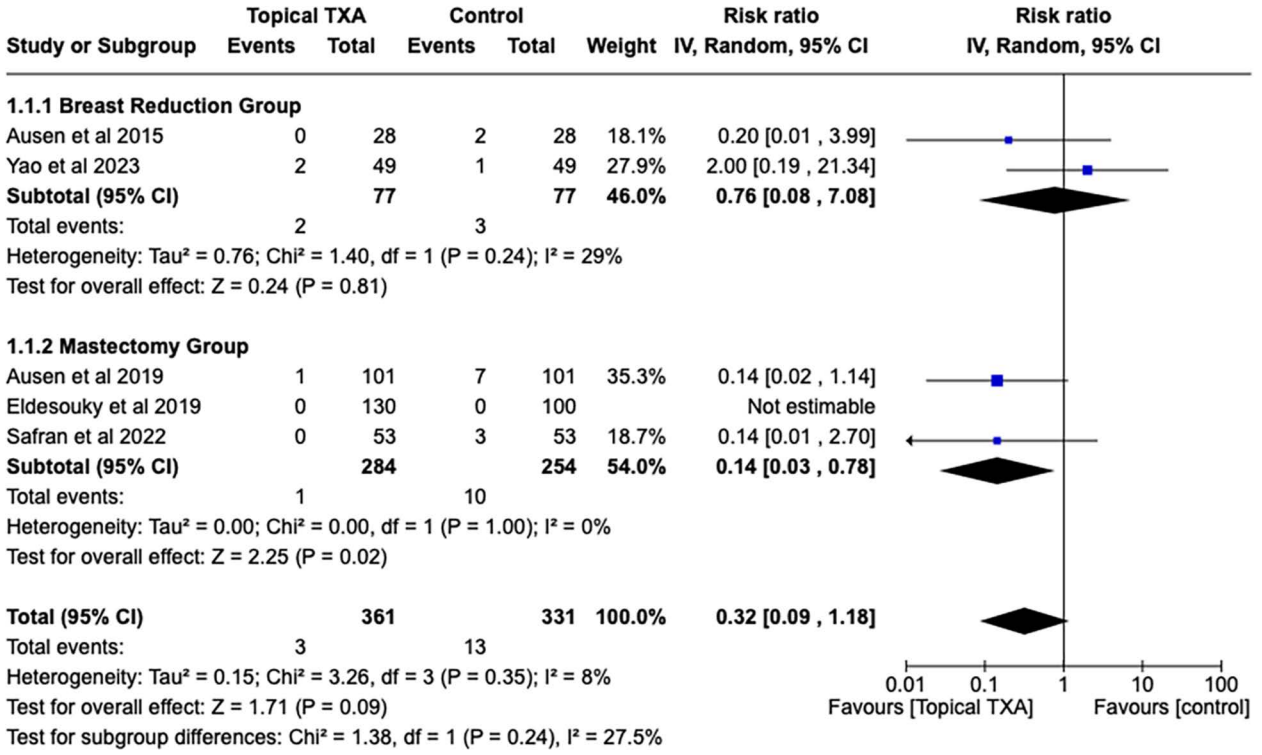

Fig. 5. Subgroup meta-analysis of total hematoma rates in breast surgery.

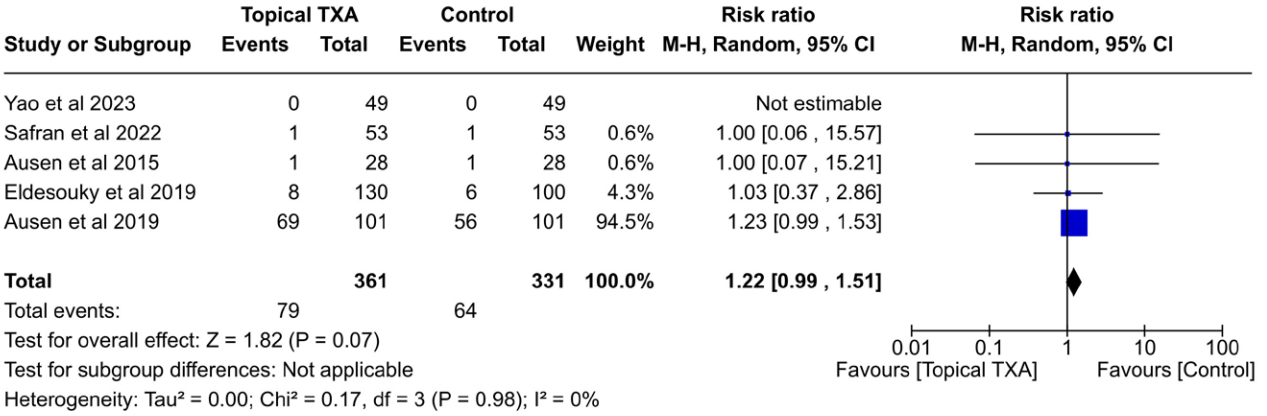

Fig. 6. Meta-analysis of total seroma rates in breast surgery. M-H, Mantel-Haenszel.

the topical TXA group and the control group (RR = 1.22; 95% CI, 0.99–1.51; $P = 0.07$). The analysis indicated low heterogeneity, with an I^2 value of 0%. The seroma incidence in the topical TXA group was 21.89% (79 of 361 breasts), compared with 19.34% (64 of 331 breasts) in the control group. The subgroup meta-analysis did not show a statistically significant difference in seroma rates between the breast reduction group (RR = 01.00; 95% CI, 0.07–15.21; $P = 1.00$) and the mastectomy group (RR = 1.22; 95% CI, 0.99–1.51; $P = 0.07$) (Fig. 7).

Rates of Infection

Five studies reported infection rates in breast surgery (Fig. 8). The meta-analysis found no significant statistical difference in infection rates between the topical TXA group and the control group (RR = 0.85; 95% CI, 0.46–1.56; $P = 0.59$). The heterogeneity among the studies was low, with an I^2 value of 10%. The infection rate in the topical TXA group was 6.10% (22 of 361 breasts), compared with a 7.85% infection rate (26 of 331 breasts) in the control group. The subgroup meta-analysis did not show any statistically significant difference in infection rates between the breast reduction group (RR = 0.64; 95% CI, 0.25–1.67; $P = 0.36$) and the mastectomy group (RR = 1.05; 95% CI, 0.42–2.64; $P = 0.91$) (Fig. 9).

Drain Output and Duration

None of the studies reported comparable measurements for the postoperative drain output and duration.

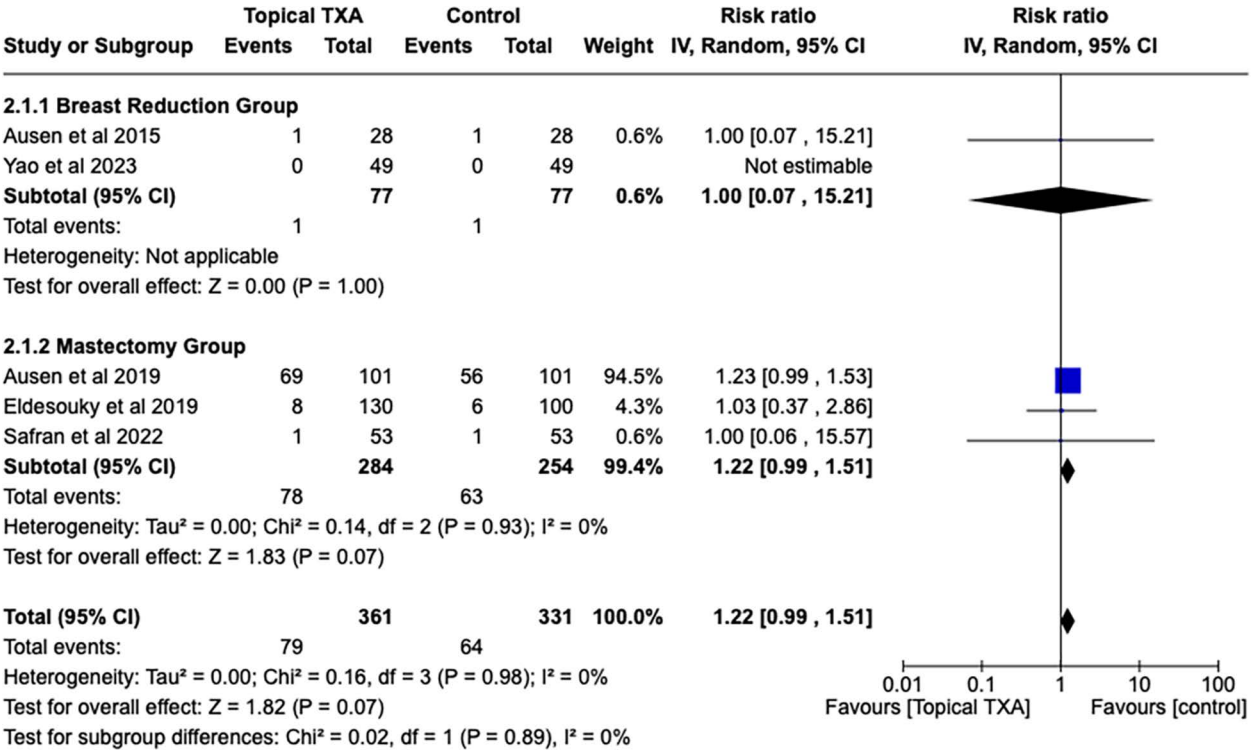

Fig. 7. Subgroup meta-analysis of total seroma rates in breast surgery.

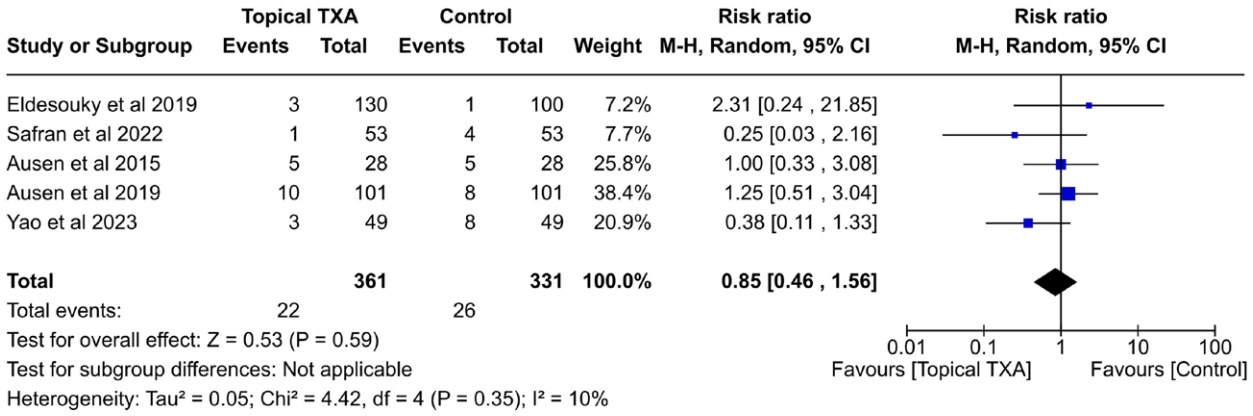

Fig. 8. Meta-analysis of total infection rates in breast surgery. M-H, Mantel-Haenszel.

DISCUSSION

This systematic review and meta-analysis provide an in-depth evaluation of the efficacy of topical TXA in reducing postoperative complications in various breast surgery indications. Among the 6 studies included, involving 823 patients and 1477 breasts, topical TXA showed no significant difference in hematoma, seroma formation, or infection rates between the topical TXA group and the control group. However, subgroup meta-analysis provided more nuanced insights, revealing that topical TXA significantly reduced hematoma rates in mastectomy patients, whereas no significant difference was observed in the breast reduction subgroup.

TXA is widely recognized for its role in hemostasis. It primarily works by inhibiting plasminogen activation through reversible binding to lysine receptors and preventing the degradation of fibrin.[5] Although TXA is a procoagulant, its mechanism of action involves stabilizing fibrin and reducing fibrinolysis rather than directly causing coagulation. However, the success of TXA may significantly depend on the timing and route of administration, the dosage used, and the characteristics of the patients.

The literature highlights the potential benefits of IV TXA in various surgical indications, including reduced rates of hematoma, seroma formation, infections, and drain outputs.[7,8] Early systematic reviews and

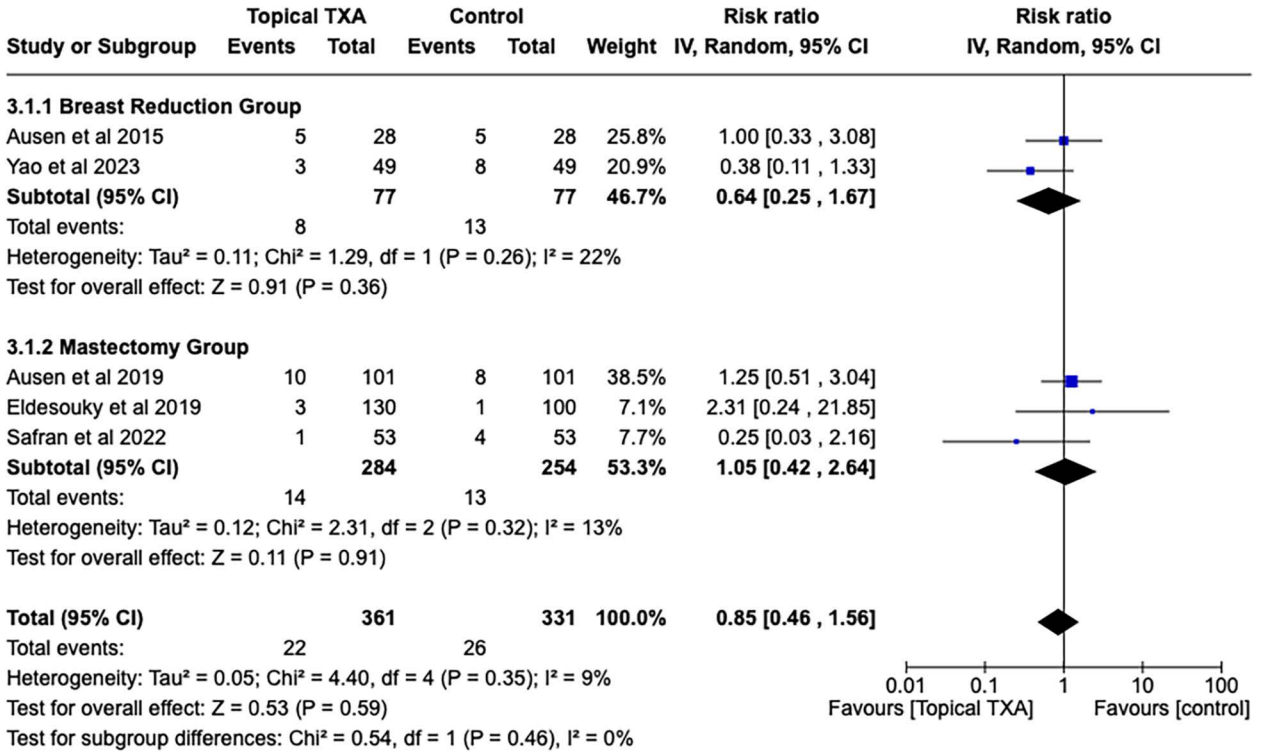

Fig. 9. Subgroup meta-analysis of total infection rates in breast surgery.

meta-analyses, such as one involving 129 clinical trials with 10,488 patients across various surgical interventions, found that IV TXA significantly reduced the need for blood transfusions.[25] However, the impact on other surgical complications remained uncertain. This has increased the interest in the application of TXA in plastic surgery for both aesthetic and reconstructive purposes.[4,15–19,26,27]

Although the IV route of TXA administration is widely studied and utilized, it has been associated with a few serious systemic complications, including thromboembolic events.[21–24,27] Whether these complications are directly associated with TXA or not, such risks have prompted the search for safer alternatives. As a result, the topical route has emerged as a promising off-label option, potentially mitigating systemic side effects and offering local anti-inflammatory benefits.[28] However, recent randomized trials and meta-analyses have shown less pronounced clinical benefits.[4,29] For instance, a recent double-blinded randomized clinical trial by Yao et al,[4] included in our current analysis, reported no statistically significant difference between the group that received topical TXA and the control group.

One possible explanation for the lack of pronounced effect on hematoma and complication rates could be the localized application of TXA, which may not achieve sufficient blood concentration to exert a systemic procoagulant effect. Additionally, meta-analyses have indicated that the reported benefits of TXA are supported by low-quality evidence, making its necessity as a standard of care debatable.

Another important consideration highlighted by our review is the variability in topical TXA concentration across different studies, which poses a significant challenge to the uniform interpretation of the results in clinical practice. Various studies utilized TXA concentrations ranging from 20 to 30 mg/mL, applied through methods such as surface moistening, rinsing, or sponge application. This inconsistency may have contributed to the heterogeneous outcomes observed in our analysis.

Hematoma

Evaluating both the IV and topical applications of TXA has shown that IV TXA significantly reduced the risk of hematomas by half in breast procedures.[30,31] Our review, which focused solely on topical TXA, found that it significantly decreased hematoma rates in mastectomy patients, whereas no significant difference was observed in patients who underwent breast reduction. This statistical difference could be attributed to the variance in the overall exposed surface area. Patients undergoing mastectomy have a larger exposed surface area postsurgery, including the pectoralis major muscle, which likely increases their risk of hematoma. These findings suggest that the effectiveness of topical TXA may be more pronounced in specific types of breast surgery, emphasizing the importance of tailoring its application based on surgical indications.[4,16,17,19]

Furthermore, a recent meta-analysis, which included 12 RCTs and other clinical studies involving 2045 patients, demonstrated that topical TXA significantly reduced perioperative blood loss in various spinal procedures, with the TXA group showing higher hemoglobin levels.[30] This suggests a trend toward reduced hematoma formation,

although the evidence varies depending on the procedure type and patient cohort.

Seroma Formation and Drain Output

TXA has shown inconsistent results regarding its effects on seroma formation and drain outputs. Our study found no significant difference in seroma formation between the TXA and control groups, despite the low heterogeneity of the pooled data. This is consistent with findings reported by Huynh et al,[31] who observed seroma rates of 23.5% in the TXA group versus 24% in the control group. However, there was a statistically nonsignificant trend favoring the topical TXA group in reducing the seroma formation rates. This highlights the need for future studies with a larger power to detect potentially significant findings.

Although placing drains may help reduce seroma rates,[32] the impact of TXA on this area has shown mixed results. Ausen et al[18,19] conducted a randomized clinical trial and reported that TXA significantly reduced drain output on the first day after surgery by an average of 34 mL compared with the control group ($P = 0.011$). Similarly, Safran et al reported a mean drain output reduction of 30.5% in TXA-treated breasts compared with the control group.[2] Conversely, Weissler et al[26] found that TXA did not affect the duration of drain placement in their study. The inconsistencies in reported findings on the duration of drain placement and postoperative output, coupled with the lack of standardized data reporting across the literature, make it difficult to pool data and draw definitive conclusions in this area.

Infection Rate

Recent reports from the National Surgical Quality Improvement Program database indicated that surgical site infection rates following breast surgery are low for benign indications.[33] In our review, the infection rate was 6.1% in the topical TXA group compared with 7.85% in the control group. The role of TXA in preventing infections is indirect, making it challenging to determine its exact effect on infection rates. This potential benefit could lead to the reduction in hospital stays as observed in some studies.[30] However, infection rates did not significantly differ between TXA-treated groups and controls. Our findings align with the reported data in the literature.[31]

Limitations

This study has several limitations, including heterogeneity in baseline characteristics and reported outcomes. Additionally, most of the included studies are observational, making retrospective validation of findings challenging. Although some findings were derived from randomized clinical trials, aligning these results with those from retrospective studies posed a challenge. Variations in the types of breast procedures and postoperative protocols in data collection introduced confounders that could impact the observed effects of topical TXA and reduce the power to detect significant outcomes. Additionally, the optimal TXA dosage and concentration for reducing postoperative complications in plastic surgery are not well-established. This study contributes to the understanding of TXA's effects and highlights the need for future research to determine the most effective concentration and administration method.

CONCLUSIONS

Topical TXA appears to be safe and effective in reducing hematoma in specific surgical procedures, such as mastectomy, while avoiding systemic adverse effects. This clinical observation highlights the complexities of using topical TXA as a universal hemostatic agent and emphasizes the need for context-specific application and thorough investigation in each surgical procedure. The lack of significant benefit in some studies may be attributed to variations in dosing, timing, method of use, and the types of complications reported. This study comprehensively assessed the role of topical TXA in breast surgery, focusing on its impact on postoperative complications and outcomes. More research with larger sample sizes and standardized protocols is needed to fully understand the potential benefits of topical TXA and outcomes in specific patient characteristics and surgical contexts. Future studies should also explore patient-reported outcomes and healthcare resource utilization to comprehensively assess the clinical and cost-effectiveness of topical TXA.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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