

Risk of hematoma and reoperation associated with pharmacologic thromboprophylaxis in breast reconstruction: a systematic review and meta-analysis

Risco de hematoma e reoperação associados à trombopprofilaxia farmacológica na reconstrução mamária: uma revisão sistemática e meta-análise

Riesgo de hematoma y reintervención asociado a la trombopprofilaxia farmacológica en la reconstrucción mamaria: una revisión sistemática y un metaanálisis

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ABSTRACT: Background: The role of pharmacologic thromboprophylaxis in breast reconstruction remains controversial due to the need to balance the prevention of venous thromboembolism (VTE) against the risk of bleeding complications. While anticoagulation may reduce thromboembolic events, it may also increase the incidence of hematoma and reoperation, potentially compromising surgical outcomes. Methods: A systematic review and meta-analysis was conducted in accordance with PRISMA 2020 guidelines. Electronic databases (PubMed/MEDLINE, Cochrane Library, and LILACS) were searched without date restrictions. Comparative studies evaluating pharmacologic thromboprophylaxis versus control in patients undergoing breast reconstruction were included. The primary outcome was hematoma, and the secondary outcome was reoperation. Risk ratios (RR) with 95% confidence intervals (CI) were calculated using a random-effects model. Results: Three studies involving 582 patients were included, with 379 receiving pharmacologic thromboprophylaxis and 203 serving as controls. Pooled analysis demonstrated a trend toward increased risk of hematoma (RR 2.19, 95% CI 0.87–5.51; $p = 0.095$) and reoperation (RR 3.31, 95% CI 0.87–12.57; $p = 0.079$) in the thromboprophylaxis group, although neither reached statistical significance. No statistical heterogeneity was observed ($I^2 = 0\%$) for either outcome. Conclusion: Pharmacologic thromboprophylaxis in breast reconstruction may be associated with an increased risk of bleeding complications without clear evidence of clinical benefit. These findings support a risk-adapted approach rather than routine use and highlight the need for high-quality prospective studies.

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1 INTRODUCTION

Venous thromboembolism (VTE), encompassing deep vein thrombosis and pulmonary embolism, remains a significant cause of preventable morbidity and mortality in the perioperative setting, particularly among patients undergoing oncologic surgery. The risk of VTE in this population is multifactorial, reflecting the prothrombotic state associated with malignancy, the inflammatory response to surgical trauma, and patient-related factors such as age, obesity, and comorbid conditions (Kakkar *et al.*, 2010; Keith *et al.*, 2013).

In plastic and reconstructive surgery, and especially in breast reconstruction following mastectomy, the risk-benefit profile of thromboprophylaxis presents unique challenges. These procedures often involve prolonged operative times and extensive tissue manipulation, and in the case of microsurgical reconstruction, delicate vascular anastomoses that may be adversely affected by both thrombotic and bleeding events. Consequently, patients undergoing breast reconstruction are frequently classified as moderate to high risk for VTE according to validated tools such as the Caprini risk assessment model (Panucci *et al.*, 2011; Falck-Ytter *et al.*, 2012).

Pharmacologic thromboprophylaxis, most commonly with low-molecular-weight heparin (LMWH), has been widely adopted across surgical specialties and is supported by international guidelines in high-risk oncologic populations (Falck-Ytter *et al.*, 2012; Key *et al.*, 2019). However, its routine use in breast reconstruction remains controversial. While anticoagulation may reduce thromboembolic risk, it may also increase the likelihood of postoperative bleeding complications, including hematoma formation. In this setting, even minor bleeding can compromise surgical outcomes, potentially leading to wound complications, reoperation, or, in autologous reconstruction, impaired flap perfusion (Panucci *et al.*, 2012; Keith *et al.*, 2013).

The available literature in this field is characterized by a predominance of observational studies, variability in prophylactic regimens, and relatively low event rates for VTE. Differences in timing of initiation, dosage, and duration of anticoagulation further limit the comparability of existing studies and hinder the development of clear, evidence-based recommendations. Moreover, the low incidence of thromboembolic events in some cohorts

raises questions regarding the net clinical benefit of routine chemoprophylaxis in this population (Pittelkow *et al.*, 2021; Hansdorfer *et al.*, 2023).

Given these uncertainties, there is increasing interest in evaluating not only the efficacy of thromboprophylaxis in preventing VTE but also its safety profile, particularly with respect to bleeding-related complications. Outcomes such as hematoma and reoperation are clinically relevant, as they occur more frequently than thromboembolic events and have a direct impact on postoperative recovery and surgical success.

Therefore, the aim of this systematic review and meta-analysis is to evaluate the association between pharmacologic thromboprophylaxis and the risk of hematoma and reoperation in patients undergoing breast reconstruction in the oncologic setting. By focusing on these safety outcomes, this study seeks to provide a more balanced assessment of the risks and benefits of anticoagulation and to support more individualized decision-making in clinical practice.

2 METHODS

This systematic review and meta-analysis were conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines. The study protocol was predefined, including eligibility criteria, search strategy, data extraction methods, and statistical analysis plan.

The research question was structured according to the PICOTT framework, including adult patients undergoing breast reconstruction in the oncologic setting (Population), receiving pharmacologic thromboprophylaxis with anticoagulants, primarily low-molecular-weight heparin (Intervention), compared with no pharmacologic prophylaxis or mechanical methods alone (Comparator), evaluating safety outcomes such as hematoma and reoperation (Outcomes), in observational studies or clinical trials (Type of studies), during the perioperative and postoperative follow-up period defined in each study (Time).

The search strategy was performed across PubMed/MEDLINE, Cochrane Library, and LILACS, without restrictions on publication date. Controlled vocabulary (MeSH terms) and free-text terms were combined using Boolean operators, including “venous thromboembolism,” “deep vein thrombosis,” “pulmonary embolism,” “breast reconstruction,” “plastic surgery,” “thromboprophylaxis,” “chemoprophylaxis,” “enoxaparin,” and “anticoagulation.” Additional strategies included manual screening of reference lists from selected studies to identify potentially eligible articles not captured in the initial search.

Studies were included if they met the following criteria: (1) population consisting of patients undergoing breast reconstruction after oncologic surgery; (2) comparison between pharmacologic thromboprophylaxis and a control group (no anticoagulation or mechanical prophylaxis alone); (3) reporting of at least one outcome of interest, including hematoma, reoperation, venous thromboembolism, or bleeding-related complications; and (4) comparative study design, including randomized controlled trials, prospective or retrospective cohort studies, and case-control studies. Case reports, case series without a comparator group, narrative reviews, editorials, and studies with mixed populations without extractable data specific to breast reconstruction were excluded.

Study selection was performed in two independent stages by two reviewers. Initially, titles and abstracts were screened to exclude clearly irrelevant studies. Subsequently, full-text articles of potentially eligible studies were assessed according to the inclusion criteria. Discrepancies were resolved by a third reviewer.

Data extraction was conducted independently by two reviewers using a standardized data collection form. Extracted variables included study characteristics (author, year, design), population data (sample size, age, type of reconstruction), intervention details (type of anticoagulant, dosage, timing of initiation, and duration of prophylaxis), comparator group, and clinical outcomes, including incidence of hematoma, reoperation, venous thromboembolism, and other postoperative complications, as summarized in Table 1.

Risk of bias was assessed using the ROBINS-I (Risk Of Bias In Non-randomized Studies of Interventions) tool, evaluating domains such as confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, outcome measurement, and selective reporting. The overall quality of evidence was interpreted narratively, considering methodological limitations, consistency of findings, and precision of estimates.

Statistical analysis was performed using R software (R Foundation for Statistical Computing), with the “meta” package. For dichotomous outcomes, risk ratios (RR) with 95% confidence intervals were calculated. Meta-analysis was conducted using the Mantel–Haenszel method, with a random-effects model as the primary analysis due to expected clinical heterogeneity, and a fixed-effect model as sensitivity analysis. A continuity correction of 0.5 was applied for studies with zero-event cells.

Heterogeneity among studies was assessed using the I^2 statistic and Cochran’s Q test, with I^2 values greater than 50% considered indicative of moderate to high heterogeneity. Sensitivity analyses were planned by excluding studies at higher risk of bias or with significant

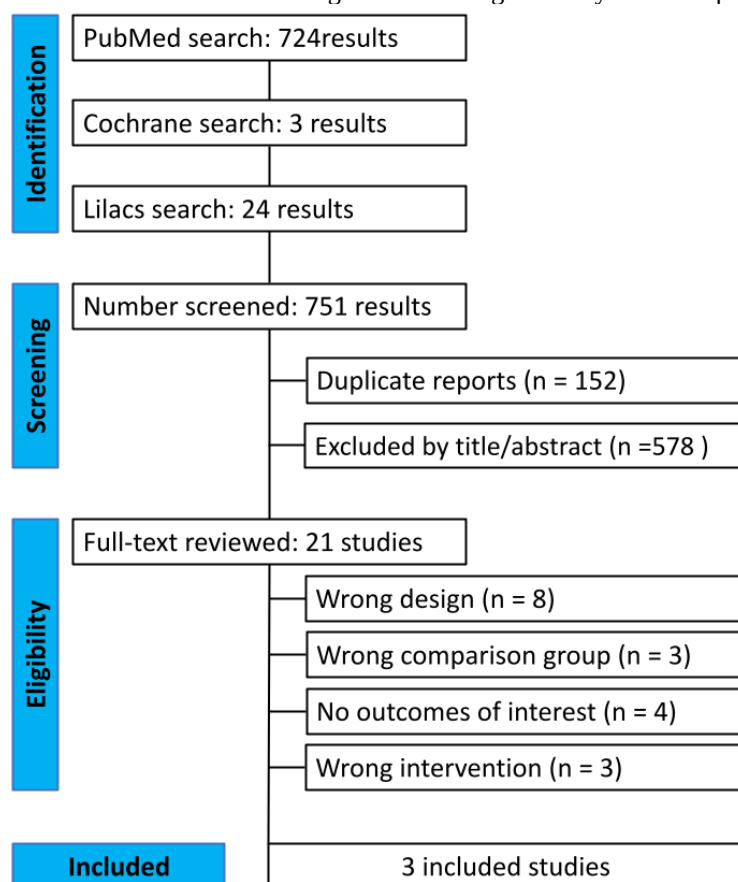
clinical differences, such as variations in reconstruction type (implant-based versus autologous). Due to the limited number of included studies, formal assessment of publication bias was not performed.

3 RESULTS

3.1 Study Selection

A total of 751 records were identified through database searching. After removal of 152 duplicate records, 599 studies remained for screening. Following title and abstract screening, 21 studies were considered potentially eligible and underwent full-text review. Of these, only three studies met the inclusion criteria and were included in the quantitative synthesis.

Figure 1. PRISMA 2020 - flow diagram illustrating the study selection process.



Source: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, *et al.* The PRISMA 2020 statement: an updated guideline for reporting systematic reviews.

3.2 Study Characteristics

The included studies comprised a total of 582 patients, of whom 379 received pharmacologic thromboprophylaxis and 203 were allocated to the control group. The studies evaluated patients undergoing breast reconstruction in the oncologic setting, with variability in surgical techniques, including microsurgical free flap reconstruction and implant-based procedures.

Pharmacologic thromboprophylaxis protocols varied across studies, particularly regarding timing of initiation (preoperative versus postoperative), duration of therapy (in-hospital only versus extended post-discharge), and indication criteria.

Detailed characteristics of the included studies, including study design, population, reconstruction type, and thromboprophylaxis regimens, are presented in Table 1. Event rates for hematoma and reoperation according to study groups are summarized in Table 2.

Table 1. Characteristics of the included studies

STUDY (YEAR)	DESIGN	N	RECONSTRUCTION TYPE	CHEMOPROPHYLAXIS	CONTROL	OUTCOMES
Keith <i>et al.</i> (2013)	Retrospective cohort	300	Implant + autologous	Preoperative enoxaparin (30 mg SC) + postoperative regimen	No preoperative anticoagulation	Hematoma, transfusion, bleeding complications
Pittelkow <i>et al.</i> (2021)	Retrospective cohort	103	Autologous (free flap)	Enoxaparin 40 mg daily (inpatient + 14 days post-discharge)	Inpatient-only prophylaxis	VTE, hematoma, reoperation, seroma, flap loss
Zinner <i>et al.</i> (2025)	Retrospective cohort	179	Implant-based	LMWH (enoxaparin 40 mg daily post-op)	Mechanical prophylaxis only	Hematoma, reoperation, seroma, VTE

Source: By authors, 2026. Characteristics of included studies evaluating pharmacologic thromboprophylaxis in breast reconstruction. Summary of study design, sample size, type of reconstruction, thromboprophylaxis protocols, control groups, and reported outcomes for each included study.

Table 2. Event rates of hematoma and reoperation in patients undergoing breast reconstruction with and without pharmacologic thromboprophylaxis.

STUDY (YEAR)	GROUP	N	HEMATOMA N (%)	REOPERATION N (%)
Pittelkow (2021)	Intervention	67	1 (1.5%)	1 (1.5%)
	Control	36	0 (0%)	0 (0%)
Zinner (2025)	Intervention	133	17 (12.8%)	15 (11.2%)
	Control	46	2 (4.4%)	1 (2.2%)
Keith (2013)	Intervention	179	8 (4.5%)	4 (2.2%)
	Control	121	3 (2.5%)	1 (0.8%)

Source: By authors, 2026. Data are presented as number of events and percentage within each group. Intervention refers to patients receiving pharmacologic thromboprophylaxis, while control refers to patients receiving no pharmacologic prophylaxis or mechanical methods only.

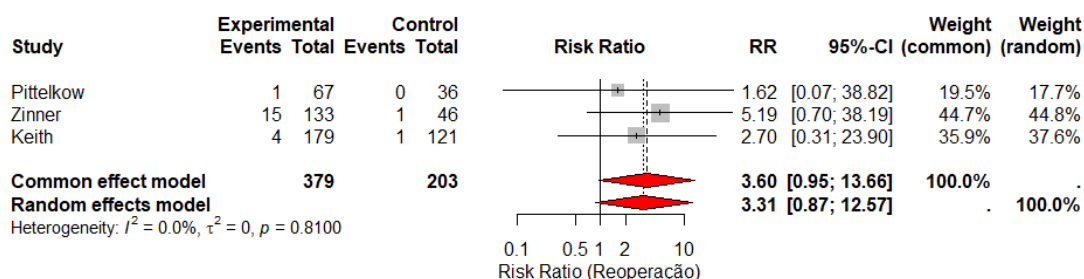
3.3 Quantitative Analysis

3.3.1 Reoperation

Pooled analysis demonstrated a trend toward a higher risk of reoperation in the thromboprophylaxis group; however, this did not reach statistical significance (random-effects model: RR 3.31, 95% CI 0.87–12.57; $p = 0.079$).

No statistical heterogeneity was observed among studies ($I^2 = 0\%$), although this finding should be interpreted with caution due to the limited number of included studies. The wide confidence intervals indicate substantial imprecision in the effect estimates. The corresponding forest plot is presented in Figure 2.

Figure 2. Forest plot of reoperation risk associated with pharmacologic thromboprophylaxis in breast reconstruction.



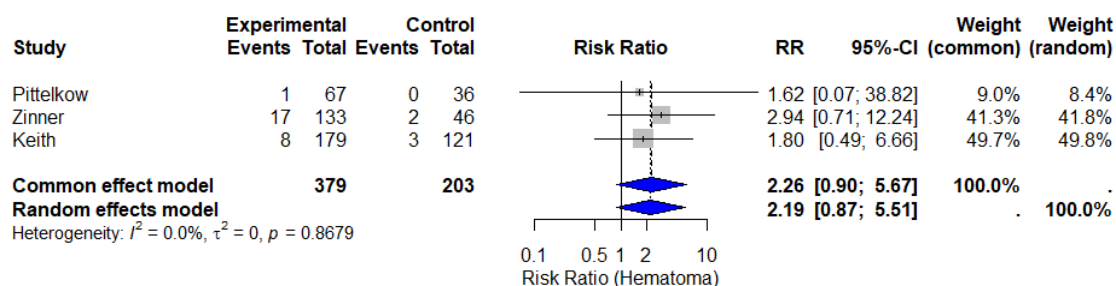
Source: By authors, 2026. Forest plot showing the pooled risk ratio (RR) for reoperation in patients undergoing breast reconstruction with versus without pharmacologic thromboprophylaxis. A random-effects model was used. The analysis demonstrated a trend toward increased risk of reoperation in the thromboprophylaxis group, although the result did not reach statistical significance (RR 3.31, 95% CI 0.87–12.57). No statistical heterogeneity was observed ($I^2 = 0\%$).

3.3.2 Hematoma

Similarly, pooled analysis for hematoma demonstrated a trend toward increased risk of bleeding complications in patients receiving pharmacologic thromboprophylaxis, without reaching statistical significance (random-effects model: RR 2.19, 95% CI 0.87–5.51; $p = 0.095$). The corresponding forest plot is shown in Figure 3.

No heterogeneity was detected among studies ($I^2 = 0\%$). However, the wide confidence intervals suggest limited statistical power and possible influence of the low number of events.

Figure 3. Forest plot showing the pooled risk ratio (RR) for hematoma in patients undergoing breast reconstruction with versus without pharmacologic thromboprophylaxis.



Source: By authors, 2026. A random-effects model was applied. The analysis demonstrated a trend toward increased hematoma risk in the thromboprophylaxis group, without statistical significance (RR 2.19, 95% CI 0.87–5.51). No heterogeneity was detected among studies ($I^2 = 0\%$).

Both analyzed outcomes demonstrated a consistent direction of effect, suggesting an increased risk of bleeding-related complications associated with pharmacologic thromboprophylaxis. However, the lack of statistical significance and the wide confidence intervals indicate uncertainty in the estimates and highlight the need for studies with larger sample sizes.

3.4 Risk of Bias Assessment

The risk of bias of the included studies was assessed using the ROBINS-I (Risk Of Bias In Non-randomized Studies of Interventions) tool. Overall, the included studies were judged to be at moderate risk of bias, primarily due to their retrospective design and potential confounding.

The main source of bias across studies was confounding, as the indication for pharmacologic thromboprophylaxis was not randomized and was likely influenced by clinical judgment, potentially leading to differences in baseline risk between groups. This introduces the possibility of confounding by indication, which may have affected the observed outcomes.

Regarding selection of participants, all studies included clearly defined populations undergoing breast reconstruction; however, the retrospective nature of the data collection may have introduced selection bias. In terms of classification of interventions, pharmacologic thromboprophylaxis was generally well defined across studies, although variations in timing, dosage, and duration were observed, which may have introduced some degree of misclassification.

No major concerns were identified in the domains of deviations from intended interventions and missing data, as outcomes were consistently reported and follow-up appeared adequate in the included studies. The measurement of outcomes was considered to be at low risk of bias, as clinically relevant endpoints such as hematoma and reoperation are objective and routinely documented in surgical practice.

Finally, selective reporting bias was judged to be low, as the outcomes of interest were consistently reported across studies. A graphical summary of the risk of bias assessment is presented in Figure 4.

Figure 4. Risk of bias assessment of included studies according to ROBINS-I domains

		Risk of bias domains							
		D1	D2	D3	D4	D5	D6	D7	Overall
Study	Keith et al. (2013)								
	Pittelkow et al. (2021)								
	Zinner et al. (2025)								
Domains:		Judgement							
D1: Bias due to confounding.		 Moderate							
D2: Bias due to selection of participants.		 Low							
D3: Bias in classification of interventions.									
D4: Bias due to deviations from intended interventions.									
D5: Bias due to missing data.									
D6: Bias in measurement of outcomes.									
D7: Bias in selection of the reported result.									

Source: By authors, 2026. CAPTION: Risk of bias was evaluated across seven domains: confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of reported results.

4 DISCUSSION

This systematic review and meta-analysis evaluated the association between pharmacologic thromboprophylaxis and bleeding-related complications in patients undergoing breast reconstruction in the oncologic setting. The findings demonstrated a consistent trend toward an increased risk of hematoma and reoperation in patients receiving pharmacologic prophylaxis, although these differences did not reach statistical significance. This lack of statistical significance should be interpreted cautiously, as the wide confidence intervals and low number of events suggest limited statistical power rather than absence of a clinically meaningful effect.

Balancing the prevention of thromboembolic events against the risk of bleeding complications represents a major challenge in plastic and reconstructive surgery. Unlike other surgical specialties, where the benefits of thromboprophylaxis are well established, breast reconstruction presents unique considerations. Even minor bleeding can significantly impact surgical outcomes. Hematomas, even when small, may compromise the surgical site, increase the risk of infection, and, in microsurgical reconstruction, exert pressure on vascular pedicles, potentially jeopardizing flap viability (Panucci *et al.*, 2012; Keith *et al.*, 2013).

The findings of this study are consistent with previous evidence suggesting a potential increase in bleeding risk associated with anticoagulation in plastic surgery. In one of the largest analyses in this field, Pannucci *et al.* demonstrated that enoxaparin reduces the incidence of venous thromboembolism in high-risk plastic surgery patients but may also be associated with an increased risk of clinically significant hematomas (Caprini *et al.*, 2005). Subsequent studies from the same group further emphasized that chemoprophylaxis is not without risk and should be carefully balanced against individual patient factors (Falck-Ytter *et al.*, 2012).

Conversely, large database studies have shown that the absolute incidence of thromboembolic events in breast reconstruction is relatively low compared to other oncologic procedures. In a recent population-based analysis, Hansdorfer *et al.* reported rates of deep vein thrombosis and pulmonary embolism below 3% in patients undergoing microsurgical breast reconstruction, even in settings with variable use of pharmacologic prophylaxis (Hansdorfer *et al.*, 2023). Additionally, these authors highlighted that most thromboembolic events occur after hospital discharge, raising the possibility of benefit from extended prophylaxis regimens, although current evidence remains inconclusive.

In the present study, the analysis of reoperation demonstrated a trend toward increased risk in the thromboprophylaxis group, which likely reflects the occurrence of hematomas requiring surgical intervention. This finding is clinically relevant, as reoperations are associated with increased morbidity, prolonged hospital stay, and negative impact on both aesthetic and functional outcomes in breast reconstruction (Pittelkow *et al.*, 2021; Zinner *et al.*, 2025).

The absence of statistical heterogeneity ($I^2 = 0\%$) should be interpreted with caution. Although it suggests consistency in the direction of effect, the small number of included studies limits the ability to detect true variability. From a clinical perspective, important differences exist among the included studies, including reconstruction type (implant-based versus autologous), anticoagulation protocols, timing of initiation, and duration of therapy, all of which may significantly influence outcomes (Keith *et al.*, 2013; Pittelkow *et al.*, 2021).

Another important consideration is the potential for confounding bias inherent to observational studies. In many cases, the decision to initiate chemoprophylaxis is influenced by the clinician's perception of higher thromboembolic risk, which may result in a greater proportion of higher-risk patients in the treatment group. This phenomenon, known as confounding by indication, may lead to an overestimation of complications in the anticoagulated group and limit causal inference (Sturmer *et al.*, 2014).

Furthermore, the low incidence of thromboembolic events in the included studies limits the ability to adequately assess the benefit of thromboprophylaxis for this outcome. Studies such as Pittelkow *et al.* report very low VTE rates, making it difficult to demonstrate statistically significant differences between groups (Pittelkow *et al.*, 2021). Therefore, the evaluation of more frequent outcomes, such as hematoma and reoperation, becomes particularly relevant for assessing the clinical impact of pharmacologic prophylaxis.

From a practical standpoint, the findings of this review suggest that the routine use of pharmacologic thromboprophylaxis in all patients undergoing breast reconstruction may not be justified. Instead, individualized strategies based on risk stratification, such as the Caprini score, appear more appropriate to guide clinical decision-making, allowing identification of patients who may benefit from anticoagulation while minimizing the risk of bleeding complications in lower-risk individuals (Caprini *et al.*, 2005; Panucci *et al.*, 2011).

This study has several limitations. The small number of included studies, the predominance of observational designs, clinical heterogeneity, and low event rates all limit the strength of the conclusions. Additionally, variability in outcome definitions, particularly for hematoma and reoperation, may affect comparability across studies. The lack of high-quality randomized controlled trials in this field represents a significant gap in the current literature.

Future research should focus on well-designed prospective studies with larger sample sizes and standardized thromboprophylaxis protocols, including type of anticoagulant, dosing, timing, and duration. The incorporation of clinically meaningful outcomes, such as hematoma requiring intervention, reconstructive failure, and symptomatic thromboembolic events, will be essential to better define the role of pharmacologic thromboprophylaxis in this setting.

5 CONCLUSION

Pharmacologic thromboprophylaxis in breast reconstruction may increase the risk of bleeding complications without clear evidence of clinical benefit. These findings challenge the

routine use of anticoagulation and support a risk-adapted strategy, highlighting the need for high-quality prospective studies to guide clinical decision-making.

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