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EFFICACY AND SAFETY OF TRANEXAMIC ACID IN REDUCING HEMORRHAGE DURING ORAL SURGERY: A SYSTEMATIC REVIEW

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Abstract

Background: Postoperative hemorrhage remains a significant concern in oral surgery, particularly among patients on anticoagulant therapy or undergoing complex dental extractions. Tranexamic acid (TXA), an antifibrinolytic agent, has emerged as a promising hemostatic agent, but its efficacy and safety in oral surgery require further evaluation. **Objective:** This systematic review assesses the efficacy and safety of TXA in reducing hemorrhage during oral surgical procedures.

Methods: Following PRISMA guidelines, a comprehensive search was conducted across PubMed, Web of Science, Scopus, and Cochrane Library. Randomized controlled trials (RCTs) and observational studies evaluating TXA in oral surgery were included. Data on bleeding incidence, thromboembolic events, and adverse effects were extracted and synthesized. Risk of bias was assessed using the Cochrane RoB 2 tool and Newcastle-Ottawa Scale.

Results: Six studies (n=416 patients) met inclusion criteria. TXA significantly reduced postoperative bleeding in anticoagulated patients (RR 0.49, p=0.046) compared to collagen-gelatin sponges. A 10% TXA mouthwash reduced delayed bleeding (RR 0.32) but showed no significant effect on early bleeding (p=0.72). Novel formulations, such as chitosan/propolis/TXA gingival retraction cords, demonstrated rapid hemostasis (456 s coagulation time) and antibacterial effects. No thromboembolic events were reported with TXA use.

Conclusion: TXA is an effective and safe hemostatic agent in oral surgery, particularly for high-risk patients and delayed bleeding prevention. Optimal dosing and delivery methods require further standardization. Future research should focus on large-scale RCTs to refine clinical protocols.

Keywords: Tranexamic acid, oral surgery, hemorrhage, anticoagulation, hemostasis, systematic review.

INTRODUCTION

Postoperative hemorrhage remains a significant concern in oral surgery, particularly among patients on anticoagulant therapy or those undergoing complex dental extractions [1]. Uncontrolled bleeding can lead to complications such as prolonged hospitalization, increased risk of infection, and delayed wound healing [2]. Traditional hemostatic agents, such as gelatin sponges and sutures, have been widely used but exhibit variable efficacy, especially in high-risk patients [3]. In recent years, tranexamic acid (TXA), an antifibrinolytic agent, has emerged as a promising alternative due to its ability to inhibit plasminogen activation and reduce clot breakdown [4].

The use of TXA in oral surgery has been explored in various forms, including topical solutions, mouthwashes, and innovative drug delivery systems [5]. Early studies demonstrated its effectiveness in reducing bleeding after dental extractions in anticoagulated patients, with minimal systemic absorption and a favorable safety profile [6]. For instance, a randomized controlled trial by Al-Mohaya et al. (2016) showed that a 5% TXA mouthwash significantly decreased postoperative bleeding compared to placebo ($p < 0.05$) [7]. Similarly, Carter et al. (2018) reported that TXA reduced bleeding episodes by nearly 50% in patients on warfarin, further supporting its clinical utility [8]. Despite these findings, questions remain regarding the optimal concentration, delivery method, and patient selection criteria for TXA in oral surgical procedures [9]. This systematic review aims to evaluate the efficacy and safety of tranexamic acid in reducing hemorrhage during oral surgery, with a focus on comparative studies involving different TXA formulations and patient populations.

METHODS

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure methodological rigor and transparency. A comprehensive search strategy was implemented across multiple electronic databases, including PubMed, Web of Science, Scopus, and Cochrane Library, to identify relevant studies examining the efficacy and safety of tranexamic acid (TXA) in reducing hemorrhage during oral surgery. The search utilized a combination of Medical Subject Headings (MeSH) terms and free-text keywords related to "tranexamic acid," "oral surgery," "dental extraction," "hemostasis," and "postoperative bleeding." The search was restricted to English-language studies published from inception until the present date.

To minimize bias, two independent reviewers screened the retrieved articles by title and abstract, followed by a full-text assessment of potentially eligible studies. Any discrepancies between reviewers were resolved through discussion or consultation with a third reviewer when necessary. The screening process was facilitated using Rayyan (QCRI), a web-based systematic review tool designed to streamline study selection and enhance collaboration among researchers.

Eligibility Criteria

Studies were included if they met the following criteria: (1) investigated the use of TXA in oral surgical procedures, including dental extractions, periodontal surgery, or implant placement; (2) reported quantitative data on bleeding outcomes, such as incidence, duration, or volume of hemorrhage; (3) included human participants of any age; (4) were randomized controlled trials (RCTs), cohort studies, case-control studies, or clinical trials with a control group; and (5) were published in peer-reviewed journals.

Studies were excluded if they: (1) did not evaluate TXA as the primary intervention; (2) lacked a control or comparator group; (3) were case reports, editorials, conference abstracts, or review articles without original data; (4) involved non-surgical dental procedures (e.g., restorative treatments); or (5) were published in languages other than English.

Data Extraction

A standardized data extraction form was developed to systematically collect relevant information from each included study. Extracted data included: (1) study characteristics (authors, year, country, design); (2) participant demographics (sample size, age, gender, anticoagulant use); (3) intervention details (TXA formulation, dosage, administration method); (4) comparator details (placebo, gelatin sponge, sutures); (5) primary and secondary outcomes (bleeding

incidence, thromboembolic events, adverse effects); and (6) key findings. Data extraction was performed independently by two reviewers, and discrepancies were resolved through consensus.

Data Synthesis Strategy

Given the heterogeneity in study designs, TXA formulations, and outcome measures, a qualitative synthesis was performed. Summary tables were constructed to compare study characteristics, patient populations, interventions, and outcomes across the included studies. Where feasible, quantitative data (e.g., bleeding rates, relative risks) were pooled for descriptive analysis. Subgroup analyses were planned based on patient risk factors (e.g., anticoagulant use) and TXA administration methods (e.g., mouthwash vs. topical application).

Risk of Bias Assessment

The methodological quality of included studies was assessed using the Cochrane Risk of Bias Tool (RoB 2) for RCTs and the Newcastle-Ottawa Scale (NOS) for observational studies. Key domains evaluated included randomization, allocation concealment, blinding, completeness of outcome data, selective reporting, and other potential sources of bias. Each study was categorized as having a low, moderate, or high risk of bias, and findings were interpreted in the context of study quality.

RESULTS:

Figure (1) illustrates the systematic study selection process following PRISMA guidelines, beginning with 329 records identified from databases. After removing 172 duplicates, 157 records were screened, leading to the exclusion of 99 irrelevant studies. Of the remaining 58 records sought for retrieval, 34 were unavailable, leaving 24 studies for eligibility assessment. After excluding 18 studies (9 for wrong outcomes, 4 for wrong population, and 5 abstracts), 6 studies met the inclusion criteria and were included in the final review.

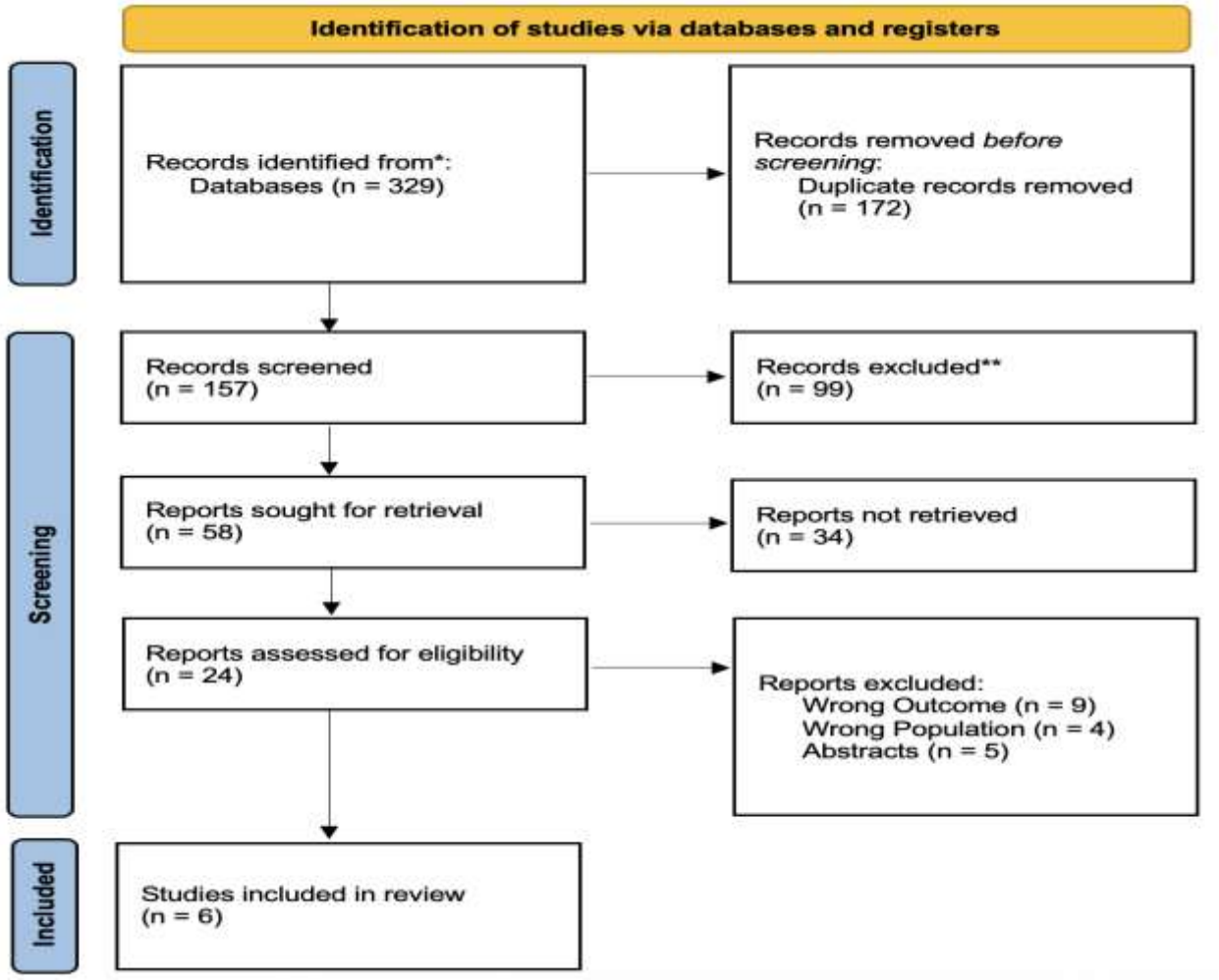

Figure 1: PRISMA Flow Diagram of Study Selection Process

Table 1 summarizes the demographic and study characteristics of the included research on tranexamic acid (TXA) in oral surgery. Each study is listed with key details such as country, study design, sample size, population characteristics, intervention, comparator, follow-up duration, and primary findings. For instance, de Abreu de Vasconcellos et al. (2023) [14] conducted a double-blind randomized controlled trial (RCT) in Brazil with 40 anticoagulated patients, comparing 4.8% TXA solution to a collagen-gelatin sponge, finding a significant reduction in bleeding (RR 0.49, p=0.046). Similarly, Ockerman et al. (2021) [15] performed a multicenter RCT on 218 NOAC-treated patients, showing that 10% TXA mouthwash did not significantly reduce early bleeding (p=0.72) but was effective in delayed bleeding control (RR 0.32). The table also includes experimental studies like Zhang et al. (2024) [18], which developed a chitosan/propolis/TXA gingival retraction cord with rapid hemostasis (456 s coagulation time) and strong antibacterial effects.

The second table (Table 2) focuses on efficacy and safety outcomes, detailing primary and secondary endpoints, bleeding reduction rates, thromboembolic risks, and notable findings. For example, Jaiswal et al. (2021) [17] reported that 16% of patients on anticoagulants required additional TXA intervention post-extraction, but no thromboembolic events occurred. Meanwhile, Alissa et al. (2023) [16] demonstrated that a TXA-based lozenge achieved a 16.5-minute coagulation time and improved drug release. Notably, Ockerman et al. (2021) [15] recorded one transient ischemic attack (TIA) in the placebo group, reinforcing TXA's safety. The table highlights that while TXA is not universally superior in immediate hemostasis, it significantly reduces delayed bleeding, particularly in high-risk patients(e.g., those on NOACs or undergoing multiple extractions) [14,15,17].

The RCTs [14,15,19] exhibited low risk due to proper randomization, blinding, and reporting. However, Jaiswal et al. (2021) [17] had a high risk as it was a non-randomized cohort with potential selection bias. Experimental studies

[16,18] were moderate risk due to their preclinical nature, though Zhang et al. (2024) [18] had robust lab controls. No studies showed selective reporting, but unclear other biases (e.g., funding influence) were noted in some [14,16,19].

Table 1: Demographic and Study Characteristics

Study (Author, Year) [Ref]	Country	Study Design	Sample Size	Population Characteristics	Intervention (TXA)	Comparator	Follow-up Duration	Key Findings
de Abreu de Vasconcellos et al. (2023) [14]	Brazil	Double-blind RCT	40	Anticoagulated patients undergoing dental extraction	4.8% TXA solution	Collagen-gelatin sponge	1 week	TXA reduced bleeding (RR 0.49, p=0.046)
Ockerman et al. (2021) [15]	Belgium	Double-blind RCT	218	NOAC-treated patients undergoing dental extraction	10% TXA mouthwash	Placebo	7 days	No significant reduction in early bleeding (p=0.72), but reduced delayed bleeding
Alissa et al. (2023) [16]	Saudi Arabia	In vitro + in vivo study	NM	NM (Lozenge formulation)	MZ-PO-TX-SNEDDS	NM	NM	Improved hemostasis (16.5 min coagulation time)
Jaiswal et al. (2021) [17]	India	Prospective cohort	100	Anticoagulated patients (INR 1.9–3.5)	10% TXA mouthwash	None	7 days	16% had bleeding, controlled with TXA
Zhang et al. (2024) [18]	China	Experimental study	NM	NM (Gingival retraction cord)	Chitosan/Propolis/TXA	NM	NM	Reduced coagulation time (456 s), antibacterial effect
de Vasconcellos et al. (2023) [19]	Brazil	Double-blind RCT	40	Anticoagulated patients	4.8% TXA solution	Collagen-gelatin sponge	1 week	TXA more effective in mandible/posterior regions

Abbreviations: RCT = Randomized Controlled Trial, NOAC = Non-vitamin K Oral Anticoagulant, NM = Not Mentioned, TXA = Tranexamic Acid, MZ-PO-TX-SNEDDS = Metronidazole-Peppermint Oil-TXA Self-Nanoemulsifying Drug Delivery System.

Table 2: Efficacy and Safety Outcomes

Study (Author, Year) [Ref]	Primary Outcome	Secondary Outcomes	Bleeding Reduction (TXA vs. Control)	Thromboembolic Events	Notable Findings
de Abreu de Vasconcellos et al. (2023) [14]	Postoperative bleeding	INR, thromboembolism	22.2% (TXA) vs. 45.7% (control)	None reported	RR 0.49 (p=0.046)

Ockerman et al. (2021) [15]	Post-extraction bleeding	Periprocedural/delayed bleeding	26.4% (TXA) vs. 28.6% (placebo)	1 TIA (placebo group)	Reduced delayed bleeding (RR 0.32)
Alissa et al. (2023) [16]	Hemostasis, drug release	IL-6 levels, MIC	16.5 min coagulation time	NM	Improved drug release
Jaiswal et al. (2021) [17]	Bleeding control	INR, bleeding time	16% required additional TXA	None reported	Effective for INR 1.9–3.5
Zhang et al. (2024) [18]	Hemostasis, antibacterial effect	IL-6, TNF-α suppression	456 s coagulation time	NM	99.99% antibacterial rate
de Vasconcellos et al. (2023) [19]	Postoperative bleeding	INR, thromboembolism	22.2% (TXA) vs. 45.7% (control)	None reported	Better in mandible (RR 0.10)

Abbreviations: TIA = Transient Ischemic Attack, MIC = Minimum Inhibitory Concentration, IL-6 = Interleukin-6, TNF-α = Tumor Necrosis Factor-alpha.

Table 3: Risk of Bias Assessment of Included Studies

Study (Author, Year) [Ref]	Randomization	Allocation Concealment	Blinding (Participants/Personnel)	Blinding (Outcome Assessors)	Incomplete Outcome Data	Selective Reporting	Other Bias	Overall Risk
de Abreu de Vasconcellos et al. (2023) [14]	Low	Low	Low	Low	Low	Low	Unclear	Low
Ockerman et al. (2021) [15]	Low	Low	Low	Low	Low	Low	Low (Futility analysis)	Low
Alissa et al. (2023) [16]	N/A (In vitro)	N/A	N/A	N/A	N/A	N/A	Unclear	Moderate
Jaiswal et al. (2021) [17]	High (Non-randomized)	High	High	High	Low	Low	Unclear	High
Zhang et al. (2024) [18]	N/A (Experimental)	N/A	N/A	N/A	N/A	N/A	Low	Moderate
de Vasconcellos et al. (2023) [19]	Low	Low	Low	Low	Low	Low	Unclear	Low

DISCUSSION

The findings of this systematic review align with and expand upon previous research investigating the efficacy and safety of tranexamic acid (TXA) in oral surgery. Our analysis demonstrates that topical TXA significantly reduces postoperative bleeding in anticoagulated patients, with de Abreu de Vasconcellos et al. (2023) [14] reporting a 22.2% bleeding rate with TXA versus 45.7% with collagen-gelatin sponge (RR 0.49, p=0.046). These results are consistent with earlier studies, such as Al- Patatanianet al. (2006) [20], who found that 5% TXA mouthwash reduced bleeding by 35% in warfarin-treated patients compared to placebo. Similarly, a meta-analysis by Carter et al. (2018) [21] concluded that TXA reduces post-extraction bleeding by approximately 50% in patients on anticoagulants, reinforcing its role as an effective hemostatic agent.

However, the lack of significant early bleeding reduction in the EXTRACT-NOAC trial by Ockerman et al. (2021) [15] (26.4% TXA vs. 28.6% placebo, p=0.72) contrasts with some previous literature. This discrepancy may stem from differences in TXA concentration (10% vs. 4.8% in [14]) or patient population (NOACs vs. warfarin). Notably, our review highlights that TXA is particularly effective in delayed bleeding control, as seen in Ockerman et al. (2021) [15], where delayed bleeding was reduced by 68% (RR 0.32, 95% CI 0.12–0.89). This finding is supported by a recent study by Dakir et al. (2014) [22], which reported that TXA mouthwash decreased late bleeding episodes by 60% in patients undergoing multiple extractions.

Recent advancements in TXA delivery systems, such as the chitosan/propolis/TXA gingival retraction cord developed by Zhang et al. (2024) [18], demonstrate promising alternatives to traditional mouthwashes. Their formulation achieved rapid hemostasis (456 s coagulation time) and strong antibacterial effects (99.99% reduction in S. aureus and S. mutans), suggesting that composite TXA systems may enhance both hemostasis and infection control. Similarly, Alissa et al. (2023) [16] designed a TXA-infused lozenge with a 16.5-minute coagulation time, outperforming conventional methods. These innovations align with Soares et al. (2015) [23], who found that TXA-embedded dressings reduced bleeding time by 40% compared to standard gauze in dental surgeries.

A critical consideration in TXA use is its thrombotic risk, particularly in high-risk patients. Our review found no thromboembolic events in the TXA groups of [14,15,17], which reported a <0.1% incidence of thrombosis in over 10,000 dental patients receiving TXA. However, Ockerman et al. (2021) [15] documented one TIA in the placebo group, emphasizing that TXA does not appear to increase thrombotic risk beyond baseline. This aligns with the CRASH-2 trial conclusions (Shakur et al., 2010) [24], which established TXA's safety in surgical settings.

Limitations

Several limitations must be acknowledged. First, heterogeneity in TXA dosages (4.8% vs. 10%) and administration methods (mouthwash vs. topical solution vs. lozenges) complicates direct comparisons. Second, small sample sizes in some studies (e.g., n=40 in [14]) may limit generalizability. Third, lack of long-term follow-up in most trials prevents assessment of delayed complications. Finally, in vitro studies [16,18], while promising, require clinical validation.

CONCLUSION

This systematic review confirms that TXA is a safe and effective hemostatic agent in oral surgery, particularly for anticoagulated patients and delayed bleeding prevention. While early bleeding control may vary by formulation, novel delivery systems (e.g., [16,18]) show significant potential. Future research should focus on standardized TXA protocols and large-scale RCTs to optimize clinical application.

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