

Efficacy of Systemic Versus Local Tranexamic Acid in Reducing Postoperative Bleeding Following Minor Oral Surgical and Periodontal Procedures

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Received: 16th August, 2026; Revised: 8th September 2026; Accepted: 19th September, 2026; Available Online: 20th September, 2026

ABSTRACT

Background: Tranexamic acid (TXA) is widely used to reduce perioperative bleeding; however, evidence directly comparing systemic and local administration in minor oral surgical and periodontal procedures remains limited.

Objective: To compare the efficacy and safety of systemic versus local TXA in reducing postoperative bleeding following minor oral surgical and periodontal procedures.

Materials and Methods: This prospective randomized comparative study included **220 patients**, allocated equally to systemic TXA (Group S, n=110) or local TXA (Group L, n=110). Group S received intravenous TXA 10 mg/kg before the procedure, while Group L received local application of 5% TXA-soaked gauze for 10 minutes after the procedure. The primary outcome was clinically significant postoperative bleeding within 24 hours. Intraoperative blood loss, time to haemostasis, postoperative bleeding, pain, wound healing, rescue haemostatic treatment, and adverse events were also evaluated.

Results: Baseline characteristics were comparable between groups. Time to haemostasis was significantly shorter with local TXA (**5.8 ± 2.1 vs 7.1 ± 2.7 minutes; p<0.001**), and bleeding/oozing at 1 hour was less frequent (**12.7% vs 22.7%; p=0.049**). Clinically significant bleeding within 24 hours occurred in **3.6%** of the local group compared with **10.0%** of the systemic group (RR 0.36, 95% CI 0.12–1.11; p=0.061). Postoperative pain and wound healing were comparable. Nausea was more frequent following systemic administration (8.2% vs 1.8%; p=0.030). No thromboembolic or serious adverse events occurred.

Conclusion: Both systemic and local TXA provided satisfactory haemostatic control. Local TXA achieved faster haemostasis and reduced early postoperative oozing, with comparable postoperative recovery and limited systemic adverse effects. Further adequately powered multicentre trials are required to determine whether local administration reduces clinically significant postoperative bleeding compared with systemic TXA.

Keywords: Tranexamic acid; local haemostasis; postoperative bleeding; oral surgery; periodontal surgery; dental extraction; antifibrinolytic therapy.

How to cite this article: Shreedevi Bhoi¹ Dr. Shilpa Kuravatti² Dr. Saba Shabbir Palekar³ Dr. Priyanka Razdan^{4*} Dr. Pooja Mittal⁵ Dr. Sumbul Saifi⁶. Efficacy of Systemic Versus Local Tranexamic Acid in Reducing Postoperative Bleeding Following Minor Oral Surgical and Periodontal Procedures. *Int J Drug Deliv Technol.* 2026;16(84s):669-676. DOI: 10.25258/ijddt.16.84s.73.

INTRODUCTION

Postoperative bleeding is an important concern following minor oral surgical and periodontal procedures because persistent or recurrent hemorrhage can cause patient discomfort, interfere with wound healing, and occasionally require additional haemostatic intervention. Tranexamic acid (TXA), a synthetic lysine analogue, inhibits fibrinolysis by blocking the interaction of plasminogen with fibrin and thereby promotes clot stability. Its haemostatic efficacy has been demonstrated across oral and maxillofacial surgical procedures [1].

TXA can be administered systemically or applied locally at the operative site. Systemic administration provides circulating antifibrinolytic activity and has been associated with reduced perioperative blood loss in maxillofacial surgery [2,3]. Recent evidence from orthognathic surgery has further demonstrated the potential of prophylactic TXA to reduce surgical blood loss and haemostatic requirements [4,5]. However, systemic administration may expose patients to unnecessary systemic drug exposure when bleeding originates from a relatively small and accessible surgical field.

Local application offers the advantage of achieving a high concentration of TXA directly at the bleeding site with limited systemic exposure. Evidence from oral and maxillofacial procedures supports the haemostatic effectiveness of TXA, although considerable variation exists regarding dose, route, and administration protocol [6,7]. Direct evidence comparing systemic and local administration in minor oral surgical and periodontal procedures remains limited. Therefore, the present study was undertaken to compare the efficacy and safety of systemic versus local TXA in reducing postoperative bleeding following minor oral surgical and periodontal procedures.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, parallel-group comparative clinical study was conducted in the Departments of Oral and Maxillofacial Surgery and Periodontology at a tertiary-care dental teaching

institution. Patients scheduled to undergo minor oral surgical or periodontal procedures were screened for eligibility and enrolled after obtaining written informed consent.

Study Population

Adult patients aged **18–65 years** undergoing minor oral surgical procedures, including uncomplicated or surgical dental extraction, minor soft-tissue surgery, or periodontal procedures associated with an anticipated risk of postoperative bleeding, were considered for inclusion.

Sample Size

The sample size was calculated for comparison of two independent proportions. Assuming clinically significant postoperative bleeding in **25%** of patients in one treatment group and **10%** in the other, with a two-sided α error of 5%, power of 80%, and 1:1 allocation, approximately **100 patients per group** were required. After allowing approximately 10% for attrition or protocol deviations, the final sample size was fixed at **220 patients**, with **110 patients in each group**.

Inclusion Criteria

Patients aged 18–65 years, belonging to **ASA physical status I or II**, scheduled for minor oral surgical or periodontal procedures, and willing to participate and comply with postoperative follow-up were included.

Exclusion Criteria

Patients with a known hypersensitivity to TXA, inherited or acquired bleeding disorders, active thromboembolic disease or previous thromboembolic events, severe renal or hepatic dysfunction, pregnancy or lactation, uncontrolled systemic disease, current therapeutic anticoagulation that could not be managed according to the institutional protocol, and those requiring major oral or maxillofacial surgery were excluded.

Randomization and Allocation

Eligible participants were randomly allocated in a **1:1 ratio** using a computer-generated random sequence into:

Group S (n=110): Systemic TXA group
Group L (n=110): Local TXA group

Allocation was concealed using sequentially numbered, opaque, sealed envelopes opened immediately before the procedure. Wherever feasible, the investigator assessing postoperative bleeding and wound healing was blinded to group allocation.

Intervention

Patients in **Group S** received **tranexamic acid 10 mg/kg intravenously**, administered slowly approximately **15 minutes before the surgical procedure**.

Patients in **Group L** received local TXA following completion of the procedure. A sterile gauze soaked with **5% tranexamic acid solution** was placed directly over the surgical site with firm pressure for **10 minutes**. No systemic TXA was administered to this group.

All surgical and periodontal procedures were performed using standardized operative techniques. Local anaesthetic technique, suturing where indicated, postoperative analgesia, and routine postoperative instructions were standardized as far as possible in both groups. Other local haemostatic agents were not routinely used unless required as rescue treatment.

Assessment of Bleeding

Intraoperative bleeding was evaluated using the amount of blood collected by suction after adjustment for irrigation fluid and the number/weight of blood-soaked gauzes, wherever applicable. **Time to haemostasis** was recorded from completion of the procedure until complete cessation of active bleeding.

Postoperative bleeding was assessed immediately after surgery and at **1, 6, and 24 hours**. Patients were instructed to report any episode of recurrent bleeding occurring between scheduled assessments.

Postoperative bleeding severity was categorized as:

- **Grade 0:** No bleeding.
- **Grade 1:** Mild oozing controlled by simple pressure.

- **Grade 2:** Bleeding requiring additional local haemostatic intervention.
- **Grade 3:** Persistent bleeding requiring resuturing, systemic intervention, or an unscheduled clinical visit.

Clinically significant postoperative bleeding was defined as Grade 2 or Grade 3 bleeding occurring within 24 hours and constituted the primary outcome.

Secondary Outcomes

Secondary outcomes included intraoperative blood loss, time required to achieve haemostasis, number and severity of postoperative bleeding episodes, need for rescue haemostatic treatment, and postoperative pain assessed using a **10-cm visual analogue scale (VAS)**. Wound healing and complications, including infection, hematoma, alveolar osteitis where applicable, nausea, vomiting, allergic reactions, and suspected thromboembolic events, were documented during follow-up.

Follow-up

Patients were reviewed at **24 hours and 7 days** following the procedure. The 24-hour assessment focused primarily on bleeding and early complications, while the 7-day visit assessed wound healing and delayed adverse events.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using **IBM SPSS Statistics**. Continuous variables were expressed as mean $\pm$ standard deviation or median with interquartile range according to their distribution, whereas categorical variables were expressed as frequencies and percentages.

Continuous variables were compared between groups using the **independent-samples t-test** or **Mann-Whitney U test**, as appropriate. Categorical variables, including the primary outcome of clinically significant postoperative bleeding, were compared using the **Chi-square test or Fisher's exact test**. Effect size for the primary outcome was reported as **relative risk (RR) with 95% confidence interval**, along with absolute risk difference.

Because the study included different types of oral surgical and periodontal procedures, **multivariable logistic regression** was performed to assess the association between route of TXA administration and clinically significant postoperative bleeding

after adjustment for potentially relevant variables such as age, sex, type of procedure, procedure duration, and baseline bleeding-risk factors. Adjusted odds ratios with 95% confidence intervals were reported. A **p-value <0.05** was considered statistically significant.

RESULTS

A total of **220 patients** undergoing minor oral surgical or periodontal procedures were included and randomized equally into the systemic TXA group (Group S, n=110) and local TXA group (Group L, n=110). Baseline demographic characteristics and distribution of procedures were comparable between the groups ($p>0.05$), indicating adequate comparability after randomization (Table 1).

Table 1. Baseline demographic and procedural characteristics

Variable	Group S: Systemic TXA (n=110)	Group L: Local TXA (n=110)	p- value
Age (years), mean $\pm$ SD	39.6 $\pm$ 12.1	40.2 $\pm$ 11.8	0.710
Male, n (%)	61 (55.5)	58 (52.7)	0.684
Female, n (%)	49 (44.5)	52 (47.3)	
ASA I, n (%)	72 (65.5)	75 (68.2)	0.669
ASA II, n (%)	38 (34.5)	35 (31.8)	
Minor oral surgical procedures, n (%)	67 (60.9)	65 (59.1)	0.784
Periodontal procedures, n (%)	43 (39.1)	45 (40.9)	
Procedure duration (min), mean $\pm$ SD	35.8 $\pm$ 10.6	36.5 $\pm$ 11.2	0.634

The mean intraoperative blood loss was **28.7 $\pm$ 11.4 mL** in Group S and **30.9 $\pm$ 12.3 mL** in Group L, with no statistically significant difference ($p=0.171$).

However, local TXA was associated with a significantly shorter mean time to haemostasis (**5.8 $\pm$ 2.1 vs 7.1 $\pm$ 2.7 minutes; $p<0.001$). Mild postoperative oozing was also less frequent in the local TXA group at the early postoperative assessments (Table 2).**

Table 2. Comparison of perioperative and postoperative bleeding parameters

Parameter	Group S (n=110)	Group L (n=110)	p- value
Intraoperative blood loss (mL), mean $\pm$ SD	28.7 $\pm$ 11.4	30.9 $\pm$ 12.3	0.171
Time to haemostasis (min), mean $\pm$ SD	7.1 $\pm$ 2.7	5.8 $\pm$ 2.1	<0.001
Any bleeding/oozing at 1 h, n (%)	25 (22.7)	14 (12.7)	0.049
Any bleeding/oozing at 6 h, n (%)	18 (16.4)	9 (8.2)	0.063
Any bleeding/oozing at 24 h, n (%)	12 (10.9)	6 (5.5)	0.141

The primary outcome, **clinically significant postoperative bleeding (Grade 2 or 3) within 24 hours**, occurred in **11 patients (10.0%)** in Group S compared with **4 patients (3.6%)** in Group L. Although clinically lower with local TXA, the difference did not reach conventional statistical significance ($p=0.061$). The relative risk was **0.36 (95% CI: 0.12–1.11)** for local compared with systemic TXA.

The overall severity distribution of postoperative bleeding was significantly more favorable in Group L ($p=0.047$). Rescue haemostatic intervention was required in 10.0% of patients receiving systemic TXA compared with 3.6% receiving local TXA (Table 3).

Table 3. Primary outcome, bleeding severity and rescue haemostatic intervention

Outcome	Group S (n=110)	Group L (n=110)	Effect estimate / p-value
Grade 0 – no bleeding, n (%)	78 (70.9)	90 (81.8)	
Grade 1 – mild oozing, n (%)	21 (19.1)	16 (14.5)	
Grade 2 – required local haemostatic intervention, n (%)	9 (8.2)	4 (3.6)	
Grade 3 – persistent/severe bleeding, n (%)	2 (1.8)	0 (0.0)	
Overall bleeding-grade distribution	—	—	p=0.047
Clinically significant bleeding (Grade 2/3), n (%)	11 (10.0)	4 (3.6)	RR=0.36 (95% CI: 0.12–1.11); p=0.061
Absolute risk difference	—	—	–6.4 percentage points
Rescue haemostatic intervention, n (%)	11 (10.0)	4 (3.6)	0.061
Resuturing required, n (%)	2 (1.8)	0 (0.0)	0.498

On multivariable logistic regression, local TXA showed a lower adjusted odds of clinically significant postoperative bleeding compared with systemic TXA (**adjusted OR 0.34; 95% CI: 0.10–1.10; p=0.071**), although the association did not reach statistical significance. Longer procedure duration was independently associated with an increased likelihood of postoperative bleeding (p=0.034). Procedure category was not independently associated with the primary outcome after adjustment (Table 4).

Postoperative pain scores and wound healing were comparable between groups. Nausea was more frequent following systemic TXA, whereas no thromboembolic event or serious treatment-related adverse event was observed in either group.

Table 4. Multivariable analysis and secondary clinical outcomes

Parameter	Group S	Group L	Effect estimate / p-value
Multivariable predictors of clinically significant bleeding			
Local vs systemic TXA	—	—	AOR 0.34 (95% CI: 0.10–1.10); p=0.071
Age, per year increase	—	—	AOR 1.01 (95% CI: 0.97–1.05); p=0.641
Male vs female	—	—	AOR 1.22 (95% CI: 0.42–3.54); p=0.715
Periodontal vs minor oral surgery	—	—	AOR 0.91 (95% CI: 0.30–2.75); p=0.866
Procedure duration, per 10-min increase	—	—	AOR 1.42 (95% CI: 1.03–1.97); p=0.034
Secondary outcomes			

Parameter	Group S	Group L	Effect estimate / p-value
VAS pain at 24 h, mean $\pm$ SD	3.2 $\pm$ 1.3	3.0 $\pm$ 1.2	0.236
Satisfactory wound healing at day 7, n (%)	103 (93.6)	106 (96.4)	0.352
Postoperative infection, n (%)	3 (2.7)	2 (1.8)	1.000
Nausea, n (%)	9 (8.2)	2 (1.8)	0.030
Vomiting, n (%)	3 (2.7)	1 (0.9)	0.622
Thromboembolic events, n (%)	0	0	—
Serious adverse events, n (%)	0	0	—

AOR: adjusted odds ratio; **CI:** confidence interval; **RR:** relative risk; **SD:** standard deviation; **TXA:** tranexamic acid; **VAS:** visual analogue scale.

Local TXA was associated with lower adjusted odds of clinically significant bleeding, although this was not statistically significant (AOR 0.34; $p=0.071$). Longer procedure duration was independently associated with increased bleeding risk ($p=0.034$). Pain scores, wound healing, infection, and vomiting were comparable between groups, while nausea was significantly more frequent with systemic TXA (8.2% vs 1.8%; $p=0.030$). No thromboembolic or serious adverse events occurred.

DISCUSSION

The present randomized comparative study evaluated systemic versus local tranexamic acid (TXA) for controlling postoperative bleeding following minor oral surgical and periodontal procedures. Both routes provided satisfactory haemostatic control; however, local TXA produced a significantly shorter time to haemostasis and less early postoperative oozing. Clinically significant bleeding within 24 hours occurred in 3.6% of patients receiving local TXA compared with 10.0% receiving systemic TXA, although this difference did not reach statistical significance.

The favorable local haemostatic effect observed in the present study is consistent with the randomized clinical trial by de Abreu de Vasconcellos et al., who demonstrated the usefulness of topical TXA for controlling bleeding following dental extraction in anticoagulated patients [8]. Local application can provide a high antifibrinolytic concentration directly at the surgical site, thereby stabilizing the fibrin clot during the early postoperative period. A systematic review and meta-analysis by Zaib et al. similarly supported local TXA as an effective strategy for reducing bleeding following dental and minor oral procedures in patients receiving anticoagulant therapy [9].

The EXTRACT-NOAC randomized trial evaluated TXA mouthwash following dental extraction in patients receiving non-vitamin K oral anticoagulants. Although TXA did not significantly reduce every bleeding endpoint, reductions were observed for some delayed and procedure-related bleeding outcomes, emphasizing that its clinical effect may vary according to the type and extent of the dental procedure [10]. Evidence synthesized by de Andrade et al. also indicates that local haemostatic interventions can effectively control post-extraction bleeding in patients receiving anticoagulant therapy [11].

The rationale for local administration is particularly relevant in minor oral and periodontal surgery because the operative field is readily accessible for direct drug application. The EXTRACT-NOAC study protocol highlighted the potential role of topical antifibrinolytic therapy in reducing oral bleeding while avoiding unnecessary modification of systemic anticoagulant treatment [12]. Similarly, the meta-analysis by Owattanapanich et al. demonstrated that local TXA contributes to postoperative haemostasis following dental procedures, particularly in patients at increased bleeding risk [13].

In the present study, local TXA also resulted in a shorter time to haemostasis than systemic administration. This may reflect rapid achievement of an effective TXA concentration directly within the surgical wound. Queiroz et al. reported favorable haemostatic outcomes with local TXA following dental extraction in patients receiving warfarin, further supporting direct application as a practical method for maintaining clot stability [14]. Earlier systematic evidence from randomized trials also demonstrated the effectiveness of topical TXA for haemostasis following minor oral surgery in anticoagulated patients [15-17].

Postoperative pain and wound healing were comparable between the groups, suggesting that the

route of TXA administration did not adversely affect early recovery. Nausea occurred more frequently in the systemic group, whereas no thromboembolic or serious adverse events were observed in either group. Although these findings favor the practicality of local administration, the study was not powered to establish differences in uncommon adverse events.

The study has certain limitations. It was conducted at a single centre and included different minor oral surgical and periodontal procedures, resulting in some procedural heterogeneity. Furthermore, relatively few clinically significant bleeding events limited the precision of the effect estimates. Larger multicentre trials with procedure-specific stratification and longer safety follow-up are required to establish whether local TXA is equivalent or superior to systemic administration for different categories of oral and periodontal procedures.

CONCLUSION

Both systemic and local tranexamic acid provided effective haemostatic control following minor oral surgical and periodontal procedures. Local TXA was associated with **faster haemostasis and less early postoperative oozing**, while clinically significant postoperative bleeding was numerically lower than with systemic TXA. Postoperative pain and wound healing were comparable, and no serious adverse events were observed. Local TXA therefore represents a useful haemostatic approach that provides direct antifibrinolytic activity at the surgical site with limited systemic exposure. Larger studies are required to confirm differences in clinically significant postoperative bleeding.

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