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Affordable Excellence: A Meta-Analysis on the Efficacy of Topical Tranexamic Acid in Reducing Blood Loss in Thoracolumbar Spinal Surgery

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ABSTRACT

AIM: To evaluate the efficacy and safety of topical tranexamic acid (tTXA) in thoracolumbar fusion surgery.

MATERIAL and METHODS: A systematic review was conducted per PRISMA guidelines. Studies from January 1970 to August 2024 were retrieved from PubMed, Cochrane, EMBASE, Medline, and Google Scholar. Randomized controlled trials, non-RCTs, and cohort studies comparing tTXA with placebo or standard care in thoracolumbar surgery were included.

RESULTS: Eleven studies with 986 patients met the criteria. tTXA significantly reduced intraoperative blood loss (MD: -25.85 mL, $p = 0.002$), postoperative drain output (MD: -84.82 mL, $p < 0.00001$), transfusion rates (OR: 0.33, $p = 0.0004$), and hospital stay (MD: -0.67 days, $p < 0.00001$). It also increased postoperative hemoglobin (MD: 0.39 g/dL, $p < 0.00001$) but slightly prolonged operative time (MD: 3.73 minutes, $p < 0.00001$). No significant difference was found in complication rates ($p = 0.36$).

CONCLUSION: tTXA is effective in reducing blood loss and transfusion needs in thoracolumbar surgery, with minimal risk. Slightly increased operative time is clinically acceptable.

KEYWORDS: Topical tranexamic acid, Thoracolumbar surgery, Blood loss management, Cost-effective hemostasis, Meta-analysis

INTRODUCTION

Intervertebral disc herniation and degenerative spinal diseases represent increasingly common clinical challenges. Over the past century, advances including antibiotic development and implant material improvement, have facilitated spinal fusion surgery evolution. Despite these advances, intraoperative bleeding remains a significant concern that requires further investigation. The key steps in thoracolumbar fusion, including paraspinal muscle dissection, laminectomy, flavectomy, and discectomy, require wide exposure. Paraspinal muscle bleeding can be effectively managed using monopolar electrocautery, gauze compression, or muscle retraction. Bone bleeding encountered during laminectomy is typically controlled effectively with bone wax application. However, after flavectomy and discectomy, profuse hemorrhage may occur from the Batson venous plexus, which poses challenges for hemostatic control. This complication is especially pronounced during ligamentum flavum resection near the lateral recess or in cases involving inadvertent vertebral body erosion. Significant blood loss increases the risk of severe complications such as cardiopulmonary events, renal failure, and cerebral infarction, particularly in patients > 60 years (8). Although allogeneic blood transfusions can mitigate these life-threatening risks, their use is often by limited blood availability and potential complications, including immunologic reactions and infectious disease transmission. In modern

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medicine, various techniques such as bipolar electrocautery, hypotensive anesthesia (2), normovolemic hemodilution, and blood salvage (11) have been used to control intraoperative bleeding during thoracolumbar spinal fusion surgery. However, these methods have demonstrated suboptimal efficacy. Hemostatic agents, such as Floseal® or Surgiflo®, provide excellent hemostatic control but are often prohibitively expensive, limiting their accessibility for many patients.

Tranexamic acid (TXA), a synthetic lysine derivative, acts as an antifibrinolytic agent by competitive binding to lysine sites on plasminogen, thereby inhibiting its attachment to fibrin. This mechanism prevents plasminogen activation into plasmin, promoting clot stabilization and reducing excessive bleeding. TXA was initially synthesized in 1962 by Japanese researchers Shosuke and Utako Okamoto for postpartum hemorrhage management. Systemically TXA is widely used in orthopedic (10) cardiovascular and spinal surgeries. However, it may induce side effects, including thromboembolic events, seizures (19), and cardiovascular complications. Prolonged surgical duration, particularly in spinal procedures, correlates with increased complication rates. Recently, strategies to minimize perioperative blood loss, reduce drain output, and decrease transfusion requirements in spinal surgery have gained attention. Numerous studies (15,26) have assessed the efficacy of topical TXA (tTXA) application at surgical sites. This approach offers the advantage of achieving a concentrated effect directly at the bleeding site while circumventing the potential adverse effects associated with systemic administration. The therapeutic efficacy and safety profile of tTXA have been well established in various surgical disciplines, including orthopedic (24), hepatic, and cardiac surgeries (7). Although some studies have explored tTXA use in spinal surgery, no consensus exists regarding its optimal application in this field.

MATERIAL and METHODS

Data Search and Extraction Strategies

Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (18), a systematic literature search was conducted.

Two independent reviewers performed the meta-analysis using electronic databases, including PubMed, Cochrane, EMBASE, MEDLINE, and Google Scholar, to identify relevant studies published between January 1, 1970, and August 30, 2024. The year 1970 was selected to ensure consistency in database indexing, thereby capturing early literature comprehensively. Although tTXA has only recently gained widespread use, this extended timeframe helps avoid missing earlier studies under different terminologies and early exploratory or pioneering studies. The search strategy incorporated Medical Subject Headings (MeSH) terms combined with the Boolean operators “AND” and “OR.”

Keywords comprised “Interbody fusion,” “Lumbar fusion surgery,” “Spine fusion,” “Spine instrument,” “Spine surgery,” “Spine,” “thoracolumbar degenerative disease,” “Tranexamic acid,” “TXA,” and “topical.” Only English-language publications were included. This review protocol was not registered in PROSPERO or other public registries.

Eligibility Criteria

The inclusion criteria for this study were as follows: 1) Patients undergoing lumbar or thoracic spinal fusion surgery; 2) Use of TXA as an intervention, with the experimental group receiving tTXA and the control group receiving either placebo or standard treatment alternatives; 3) Reported outcome including intraoperative blood loss or postoperative measures, including drain output, postoperative hemoglobin levels, hospital stay duration, operative time, adverse effects and complications; 4) Study designs limited to randomized controlled trials (RCTs), non-RCTs, or comparative cohort studies; and 5) Publications in English.

Exclusion criteria comprised: 1) Case reports or case series; 2) Surgical procedures other than lumbar or thoracic fusion surgery; 3) interventions not utilizing tTXA; 4) Patients with dural tears or intradural procedures; and 5) Unavailable full-text articles.

Data Collection and Assessment of Outcome Measures

Two authors, JYH and JNC, independently extracted data using a structured template based on the Cochrane Consumers and Communication Group(CCCG) guidelines. This study was performed according to the criteria established by the CCCG for systematic reviews and meta-analyses. Discrepancies in data extraction were resolved by consensus. The extracted data included:

1. Basic personal profiles, including age, sex, and body mass index (BMI);

2. Clinical and surgical profile;

3. Intervention method, particularly topical tranexamic acid (tTXA) vs. placebo;

4. Intervention details including TXA dosage;

5. Parameters used to evaluate the intervention impact included intraoperative blood loss, surgical time, length of hospital stay, transfusion rates, postoperative drain output, postoperative hemoglobin levels, and any complications reported.

This methodology ensured that all pertinent data were systematically and accurately gathered for subsequent analyses.

Statistical Analysis

Statistical analysis was performed using the Review Manager (RevMan Web) software. Continuous variables were assessed using pooled weighted mean differences (MD), while dichotomous variables were analyzed using odds ratios (OR). Results are presented as MD or OR, with 95% confidence intervals (CI). A fixed-effects model was employed for data synthesis, assuming a common effect size across studies.

Study heterogeneity was assessed using the I^2 statistic to determine the proportion of variation due to between-study differences rather than random variations. Statistical tests were performed with the significance set at $p < 0.05$.

RESULTS

Study Selection

A total of 153 articles were identifies after a comprehensive search of the electronic databases. Following the initial abstract screening, nine duplicates were eliminated, and 127 articles were excluded due to their irrelevance to spinal surgery. Subsequently, 17 full-text articles were assessed for eligibility. Six articles were excluded based on the predefined criteria, yielding 11 studies fulfilled the criteria and were subsequently included in our review; more information is in Figure 1.

Overall Characteristics

The analysis included 986 patients, with 439 allocated to the control group and 547 to the intervention group receiving tTXA treatment. The comprehensive details of the studies included in the analysis, including basic characteristics, clinical features, and study designs, are presented in Table I.

Intraoperative Blood Loss (cc)

The tTXA group demonstrated lower intraoperative blood loss (mean 372.39 ± 326.59 mL) compared to controls (431.03 ± 384.60 mL), with a mean difference (MD) of -25.85 (95% CI: -42.45 to -9.26, *p*-value = 0.002) (Figure 2).

Operative Time

The average operative duration for the tTXA group was 146.58 ± 52.41 minutes, compared to 139.95 ± 49.34 minutes observed in the control group (MD: 3.73 minutes; 95% CI 0.65–6.81; *p*-value < 0.00001) (Figure 3).

The Length of Hospital Stay

The mean length of hospital stay was notably reduced for the tTXA group, averaging 4.96 ± 3.29 days, compared to 6.81 ± 5.09 days in the control group (MD -0.67 days; 95% CI -0.85 to -0.50; *p*-value < 0.00001) (Figure 4).

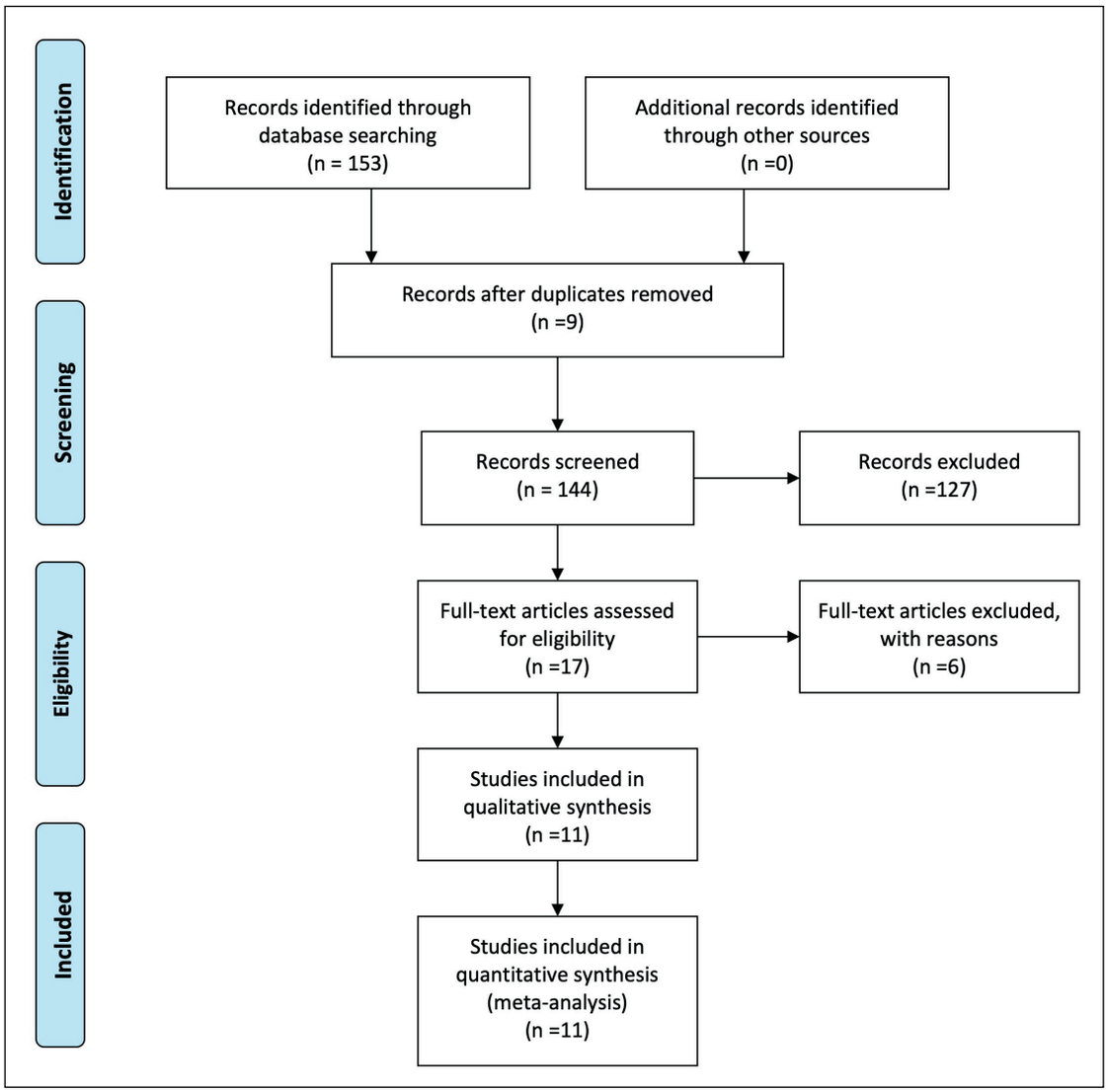

Figure 1: PRISMA diagram of study screening and selection.

Table I: Characteristics of All the Included Studies

Study	Type	Clinical status	Surgery	Control	Intervention	Number of pts	Gender (M/F)	Age(yrs)	BMI(Kg/m^2)	Country
Mallepally et al. (2020), (17)	CCS	Degenerated lumbar spinal disease	Single-level TLIF	Normal saline	1 g tTXA in 100cc normal saline was poured into the surgical wound for 5 minutes following muscle dissection and final discectomy, and prior to closure	Control: 75 Intervention: 175	Control: 39/36 Intervention: 85/90	Control: 56.9±13.4 Intervention: 55.3±12.8	Control: 24.3±2.09 Intervention: 24.4±2.31	India
Arun-Kumar and Naresh-Babu (2021), (1)	RCT	Degenerative grade 1 or 2 spondylolisthesis	Single or dual level lumbar fixation with interbody fusions	10 ml of 2% lignocaine with adrenaline (1 in 200000 dilution) mixed in 10 ml normal saline	1 g of tTXA in 100 mL normal saline was poured into surgical wound followed by a wait time of 5 minutes	Control: 26 Intervention: 26	Control: 14/12 Intervention: 13/13	Control: 50.8±3.4 Intervention: 51.9±2.8	Control: 27.6±1.4 Intervention: 25.6±2.1	India
Xu et al. (2017), (25)	RCT	Degenerated lumbar spinal disease	Total laminectomy with transpedicular screw fixation	Gelatin sponge	tTXA 1000 mg diluted in 100 ml of normal saline was irrigated over the surgical field for 3 minutes and subsequently aspirated prior to wound closure	Control: 40 Intervention: 40	Control: 13/27 Intervention: 19/21	Control: 57.4±10.7 Intervention: 53.1±12	Control: 24.9±3.9 Intervention: 25.6±2.8	China
Li et al. (2020), (12)	RCT	Degenerated lumbar spinal disease	Lumbar spinal fusion surgery	Normal saline	tTXA saline (2 g in 20 mL normal saline) was injected into the incision by the drainage after the incision closure	Control: 70 Intervention: 70	Control: 23/47 Intervention: 25/45	Control: 65.61±3.17 Intervention: 65.61±4.81	Control: 22.75±2.39 Intervention: 22.24±2.78	China
Liang et al. (2016), (13)	RCT	Degenerated lumbar spinal disease	Lumbar decompression surgery ± discectomy	Normal Saline soaked gelatin compressed Gelfoam applied to wound	tTXA 2g in 20cc normal saline soaked gelatin compressed Gelfoam applied to wound	Control: 30 Intervention: 30	Control: 14/16 Intervention: 15/15	Control: 53.5±10.26 Intervention: 51.13±10.72	Control: 25.3±5.2 Intervention: 26.2±4.1	China
Emrah et al. (2021), (4)	Cross-sectional comparative study	Thoracolumbar spinal stenosis or spondylolisthesis	Posterior thoracolumbar spinal fusion surgery	Nothing	tTXA 1g in 20cc normal saline was poured into wound for 3 to 5 minutes	Control: 30 Intervention: 30	Control: 13/17 Intervention: 14/16	Control: 63.5(53.5-67.0) Intervention: 63.0(59.0-68.3)	Control: 30.0(28.4-33.8) Intervention: 29.6(27.2-31.4)	Turkey

Table I: Cont.

Ren et al. (2017), (20)	Non-RCT	Lumbar disc herniation or spinal stenosis	Primary PLIF	Normal saline	1 g tTXA in 100cc normal saline was poured into the surgical wound for 5 minutes prior to closure followed by negative pressure suction drain	Control: 50 Intervention: 50	Control: 19/31 Intervention: 20/30	Control: 58.7±12.9 Intervention: 55.2±13.0	Control: 25.1±3.1 Intervention: 25.7±2.8	China
El-Sharkawi et al. (2016), (3)	RCT	Spinal deformities	Underwent correction (in the form of multiple Ponte osteotomies, PSO, PVCR) and posterior spinal fusion for spinal deformity	Normal saline	tTXA	Control: 23 Intervention: 31	34/49	17±4	Body weight: 49±6	Egypt
Farzanegan et al. (2022), (5)	RCT	Disk herniation, spinal canal stenosis, or both.	Posterior lumbar spinal surgery	Normal saline	3 g tTXA in 100cc normal saline was poured into the surgical wound for 5 minutes following muscle dissection and final discectomy, and prior to closure	Control: 50 Intervention: 54	Control: 27/23 Intervention: 26/28	Control: 54.8±14.04 Intervention: 51.39±12.77	Control: 26.56±5.44 Intervention: 26.57±4.18	Iran
Sudpraset et al. (2019), (23)	RCT	Thoracolumbar spine trauma	Long segment posterior fixation	Normal saline	tTXA saline 1 g in 100 mL normal saline was applied directly to the surgical field, followed by the placement of a drain. The drain was clamped and kept closed for 2 hours.	Control: 28 Intervention: 29	Control: 15/13 Intervention: 20/9	Control: 51.5 (33.5-58.0) Intervention: 52.0 (33.5-55.5)	Control: 22.3±3.2 Intervention: 22.2±3.3	Thailand
Wood (2016), (27)	RCT	Thoracolumbar spinal stenosis	Posterior approach	Normal saline	tTXA 3g was irrigated in the wound prior to closure, and aspirated it after 5 minutes. Drains were placed after the study drug was aspirated.	Control: 17 Intervention: 12	Control: 5/12 Intervention: 4/8	Control: 66(50-73) Intervention: 69(62-72)	NA	United States

RCT: *Randomized controlled study,* ***CCS:*** *Case controlled study,* ***TLIF:*** *Transforaminal lumbar interbody fusion,* ***tTXA:*** *topical tranexamic acid,* ***pts:*** *Patients.*

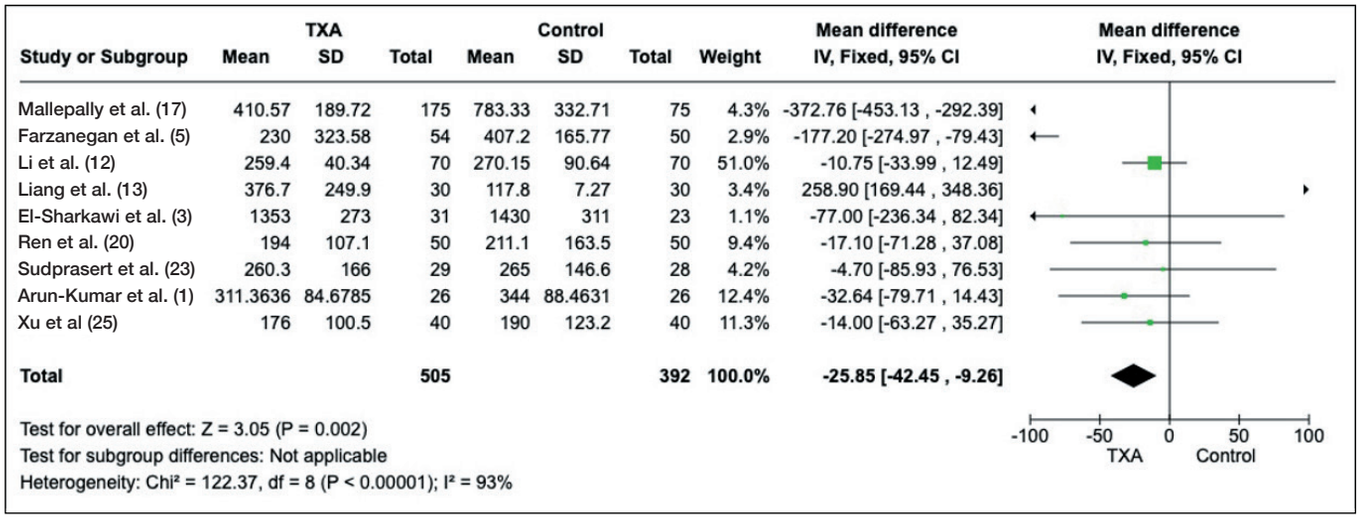

Figure 2: Forest plot of intraoperative blood loss (cc).

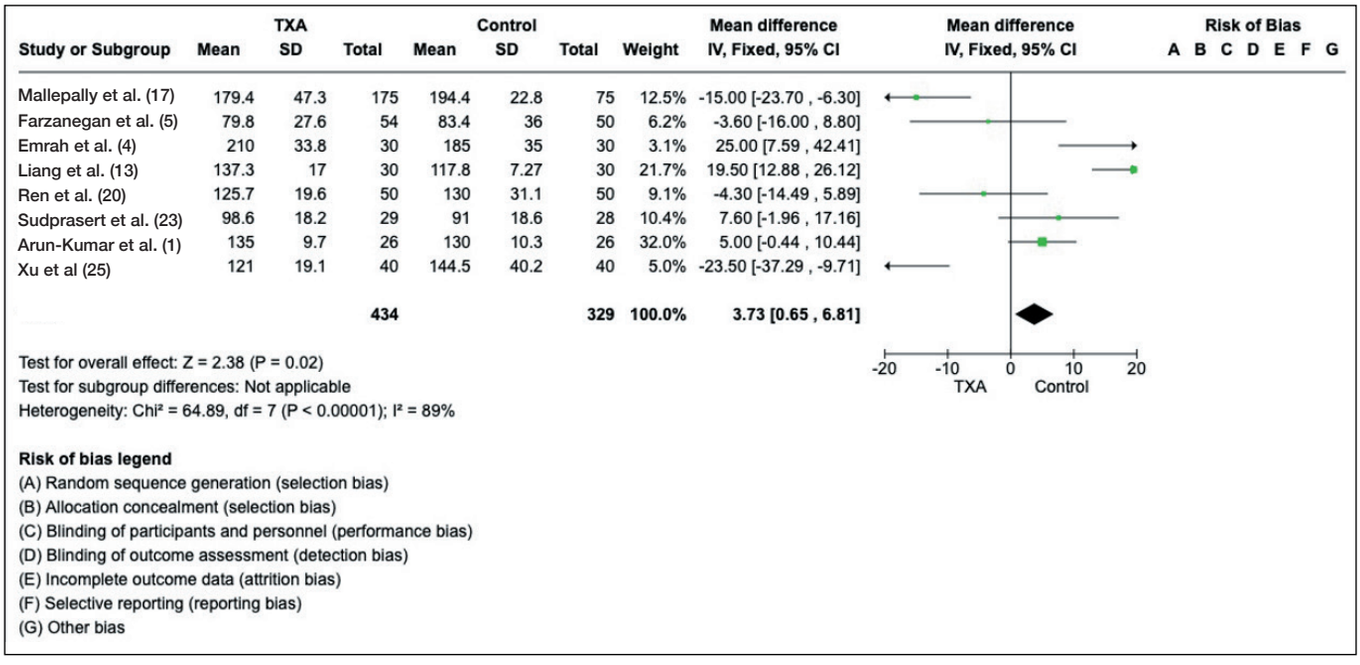

Figure 3: Forest plot of operative time (minutes).

Postoperative Drain Output (cc)

The average postoperative drain output for the tTXA group was measured as 149.70 ± 97.80 cc, compared to 285.74 ± 164.57 cc observed in the control group (MD: -84.82; 95%, CI: -95.55 to -74.10; *p*-value < 0.00001) (Figure 5).

Postoperative Hemoglobin Concentration (Hb, measured in grams per deciliter or g/dL)

The average postoperative Hb concentration in the tTXA group was recorded at 10.64 ± 1.92 g/dl, compared to 9.97 ± 2.09 g/dl observed in the control group (MD: 0.39; 95% CI: 0.21–0.58; *p*-value < 0.00001) (Figure 6).

Transfusion Rate

When compared to control group, the administration of tTXA led to a 67% decrease in the necessity for blood transfusions with an odds ratio of 0.33 (95% CI: 0.18–0.61; $p = 0.0004$) (Figure 7). This notable reduction underscores the favorable safety characteristics of tTXA by reducing the need for allogeneic blood transfusions.

Complications Rate

When compared to control group, odds ratio was 0.71 (95% CI: 0.33–1.49; $p = 0.36$) (Figure 8). No significant differences were found between the two groups.

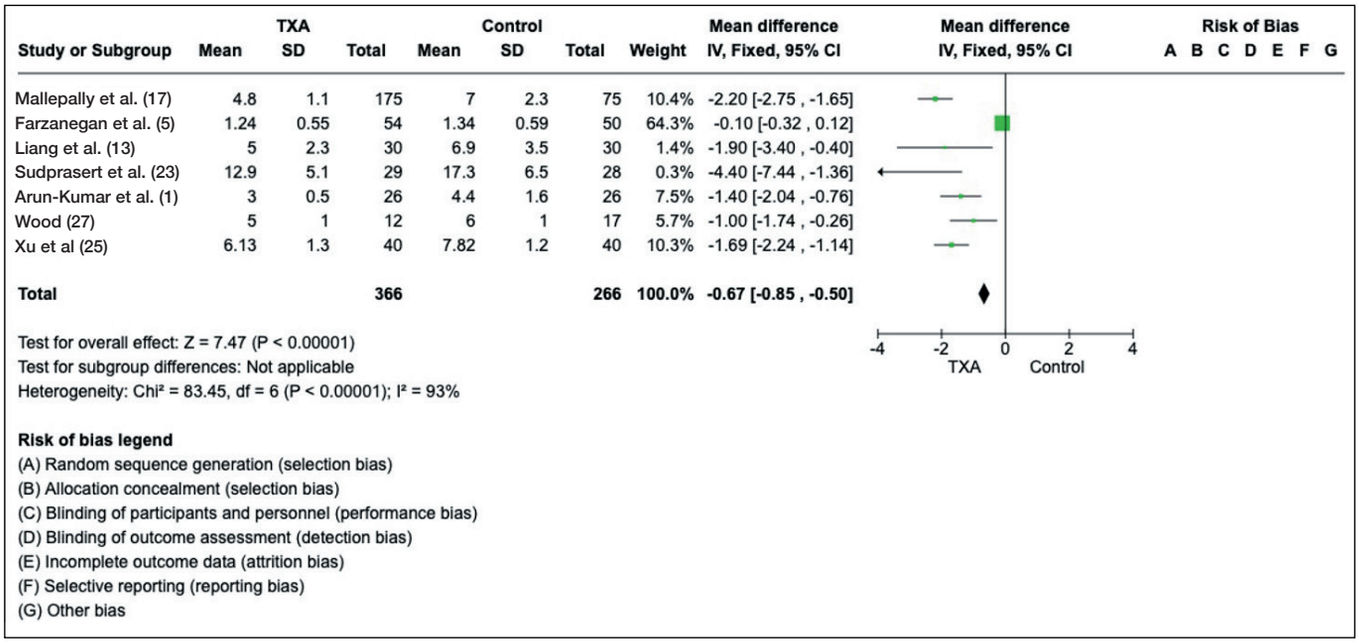

Figure 4: Forest plot of length of hospital stay (days).

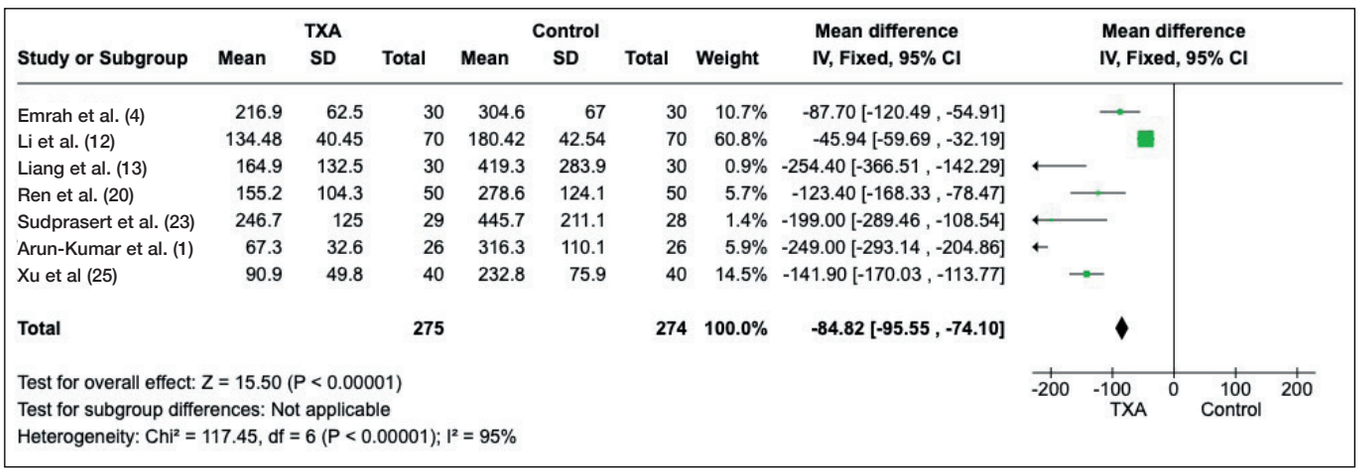

Figure 5: Forest plot of postoperative drain output (cc).

DISCUSSION

This meta-analysis demonstrated that tTXA administration in thoracolumbar surgery significantly reduced intraoperative bleeding, postoperative drain output, transfusion rates, and hospital length of stay compared to controls. While the tTXA group also demonstrated a significantly higher postoperative hemoglobin level, they experienced longer operative times. No statistical difference in complication rates were observed.

This is a highly subjective result; TXA local administration reduced intraoperative blood loss, which subsequently lowered transfusion rates, postoperative drain output, and hospital length of stay. However, because time is required for TXA to diffuse into the surgical wound, the tTXA group had a longer operative time. The slight increase in operative time observed in the tTXA group was potentially due to the additional time required for tTXA application and absorption. However, this minor prolongation is clinically acceptable and does not outweigh the substantial benefits of reduced blood loss, lower transfusion rates, and shorter hospital length of stay. Therefore, the advantages of tTXA remain significant despite the marginal increase in surgical duration.

Blood loss during thoracolumbar surgery has been a significant challenge for over a century. In modern medicine, various techniques such as bipolar electrocautery, hypotensive anesthesia, normovolemic hemodilution, and blood salvage are commonly used to manage intraoperative bleeding in thoracolumbar spinal surgery. Although these methods are effective, their outcomes can be suboptimal. Hemostatic agents,

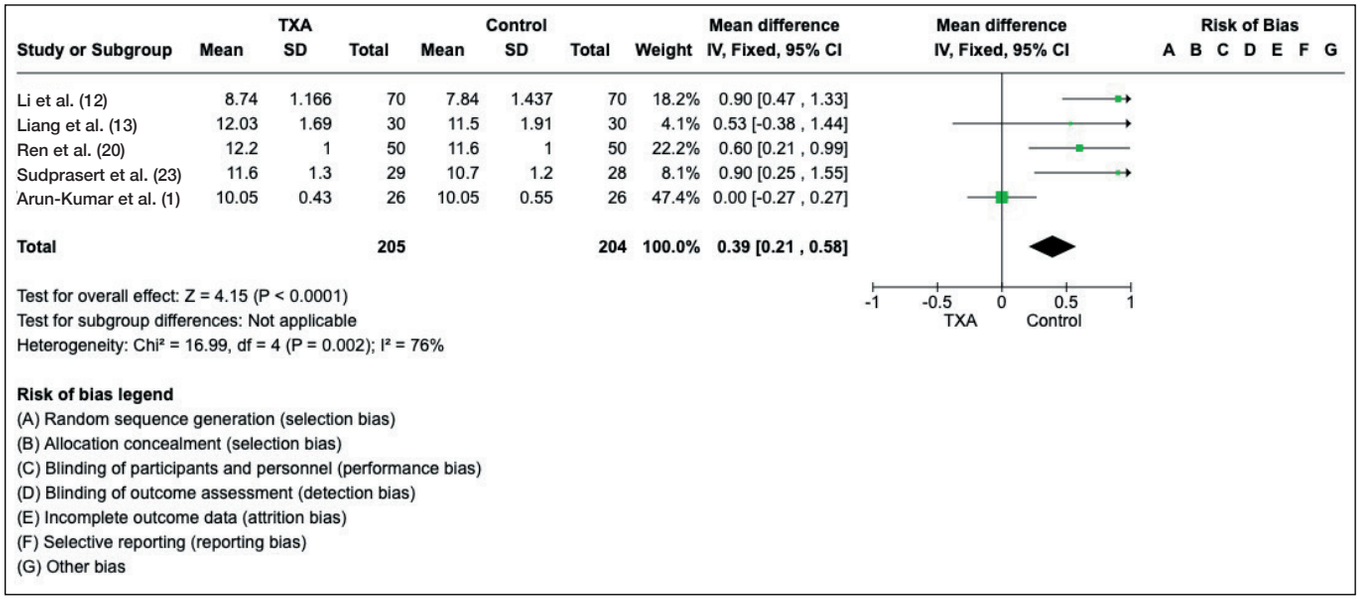

Figure 6: Forest plot of postoperative hemoglobin concentration(g/dl).

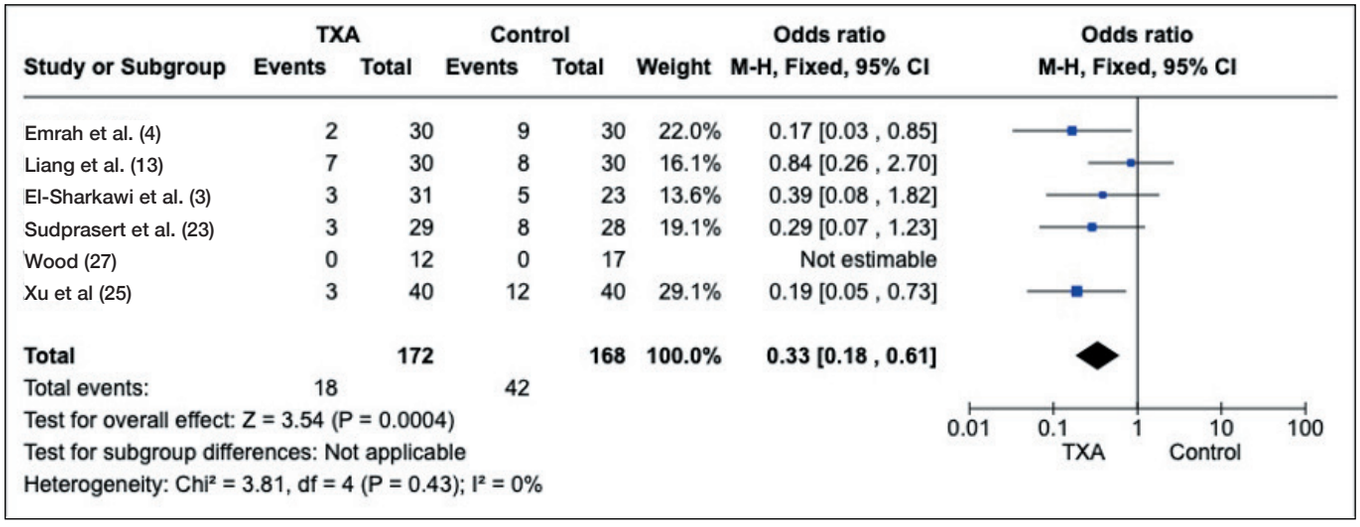

Figure 7: Forest plot of transfusion rate.

including Floseal® and Surgiflo®, offer excellent hemostatic efficacy; however, their high-cost limits accessibility for many patients. For instance, a 10 mL of Floseal® costs approximately $1,000 in Taiwan. In contrast, one 5 mL ampule of TXA costs only $0.50, making it an affordable option. Globally, tTXA is widely regarded as a cost-effective alternative, particularly compared to commercial hemostatic agents, which are often expensive and have limited availability.

In 1962, Japanese scientists Shosuke and Utako Okamoto first synthesized TXA for managing postpartum hemorrhages. Currently, TXA is widely used in trauma care, orthopedic and cardiovascular procedures. Studies have shown that intravenous TXA reduce intraoperative blood loss effectively, although concerns regarding thromboembolic events remain. Consequently, many studies investigated tTXA in thoracolumbar surgery to reduce thromboembolic complications while maintaining effective blood loss control (21,22).

Luo et al. (14) evaluated three RCTs and one non-RCT, reporting several statistically significant benefits in the tTXA group compared to the control group: 1) significantly reduced total intraoperative blood loss, 2) decreased drainage volume, 3) increased postoperative hemoglobin levels, and 4) shorter hospital length of stay. In contrast, they found no significant differences in transfusion requirements, thromboembolism events, hematoma formation, or infection rates. These findings align with the results of this study.

Fatima et al. (6) analyzed data from eight studies involving 609 patients, including 258 (42.4 %) who received tTXA. Their

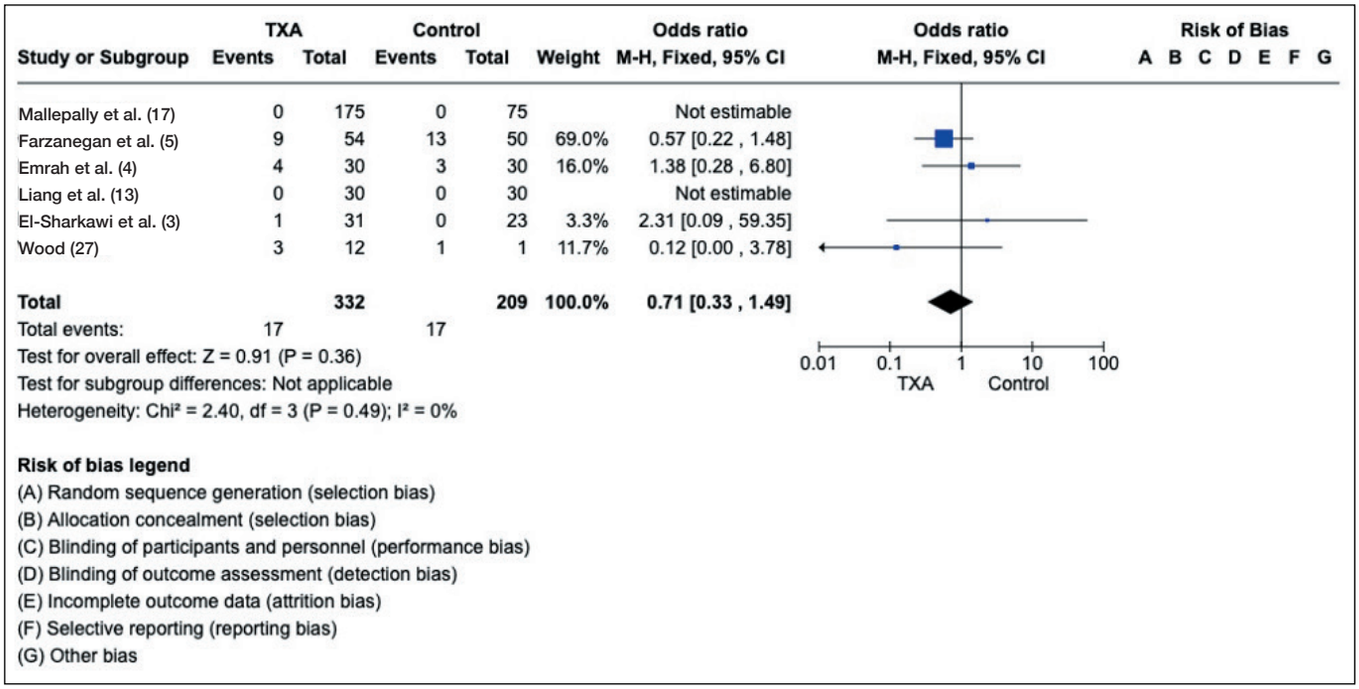

Figure 8: Forest plot of complications rate.

analysis revealed statistically significant improvements in several postoperative outcomes in the tTXA group, including 1) reduced postoperative blood loss, 2) increased postoperative hemoglobin levels, 3) shorter operative time, 4) lower postoperative transfusion rate, 5) decreased postoperative drain volume, and 6) shorter hospital length of stay. These findings highlighted the significant benefits of tTXA therapy compared with control treatments. However, in contrast to our study, they reported no significant differences in intraoperative blood loss (p=0.13) or complication rates (p=0.23) between groups. Additionally, Fatima et al. found that low-dose tTXA (250–500 mg) was more effective in reducing postoperative blood loss (p<0.00001) than high-dose tTXA (1–3 g, p=0.001). This dose-dependent effect offers further insights into the optimal use of tTXA in clinical practice.

At our institution, the standard protocol for tTXA administration involves applying 1 g of TXA diluted in 100 mL of normal saline to the surgical wound for 3–5 minutes on three points during surgery. The first application occurred following complete muscle dissection, exposure of the lamina, and placement of pedicle guide pins. After applying tTXA to the surgical field, a mobile C-arm fluoroscope was used to confirm pedicle guide pin placement, a process requiring approximately 3 minutes. The solution was then suctioned before proceeding with surgery. The second application was performed after discectomy and interbody fusion cage placement. comparably, tTXA was applied to the surgical field, followed by fluoroscopic confirmation of the interbody fusion cage depth, which required approximately 3 minutes. The solution was then suctioned and the procedure was continued. The final tTXA application was administered immediately before wound closure. However, tTXA is contraindicated in cases of dural tear. Several reports have demonstrated that the accidental TXA injection into the dural sac may induce generalized tonic-clonic convulsions, which should strictly be avoided (9,16).

This meta-analysis demonstrated that tTXA is an effective and safe intervention for improving hemostasis during spinal deformity surgery. However, several limitations warrant consideration:, including: 1) small sample sizes in the RCTs, 2) inconsistent reporting of surgical indications and patient comorbidities, 3) insufficient details regarding various surgical techniques and vertebral levels operated, 4) short follow-up periods for complication assessment, 5) heterogeneity in tTXA concentrations, administration methods and timing, which may introduce sampling bias and underestimating tTXA's effect on intraoperative blood loss, and 6) lack of direct comparison between topical and intravenous TXA in this analysis. Additionally, most studies failed to report comprehensive baseline characteristics related to patient-specific bleeding risks, such as anticoagulant use, obesity status, and systemic comorbidities, limiting our ability to assess potential confounding factors and perform subgroup analyses. To address these limitations, future prospective randomized controlled studies are needed to assess the influence of alternative tTXA dosage regimens on perioperative blood loss in spinal surgery and compare its efficacy with intravenous TXA.

CONCLUSION

This study provides strong evidence supporting the benefits of tTXA in thoracolumbar surgery. tTXA significantly reduces intraoperative blood loss, decreases postoperative drain volume, lowers complication rate, and shortens hospital length of stay. Furthermore, patients receiving tTXA maintained high-

er postoperative hemoglobin levels, consequently reducing transfusion rates. Although tTXA may prolong operative times, which we believe is acceptable, as it requires time for the medication to take effect after application. Further research comparing intravenous and topical tranexamic will be our next objective.

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Declarations

Funding: This research received no external funding.

Availability of data and materials: All data analyzed during this study are included in the published articles cited in the reference list. The extracted dataset used for the meta-analysis is available from the corresponding author upon reasonable request.

Disclosure: The authors declare that they have no conflicts of interest related to this study.

Ethics approval and consent to participate: This study is a systematic review and meta-analysis based solely on previously published studies. No new human participants were enrolled, and no individual patient data were collected. Therefore, ethical approval and informed consent were not required.

AUTHORSHIP CONTRIBUTION

Study conception and design: PYC
Data collection: TNC, JYH
Analysis and interpretation of results: HKW
Draft manuscript preparation: JYH, MJL
Critical revision of the article: YYW
Other (study supervision, fundings, materials, etc...): KL
All authors (JYH, TNC, PYC, HKW, KL, JSC, YYW, MJL, TJH) reviewed the results and approved the final version of the manuscript.

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