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Meta-Analysis of Topical Tranexamic Acid in Posterior Lumbar Surgery for Patients with Lumbar Degenerative Diseases

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Abstract

Objective: The present meta-analysis aimed to evaluate the efficacy and safety of topical tranexamic acid on reducing perioperative blood loss for posterior lumbar surgery in patients with lumbar degenerative diseases.

Methods: Online databases were systematically searched to identify relevant studies published before May 2019. Randomized controlled trials (RCTs) and retrospective studies were included in this study. The mean difference of drainage volume, total blood loss (TBL), hidden blood loss (HBL), hospital stay, and risk ratios of blood transfusion in the topical tranexamic acid (tTXA) treated group was compared to the placebo group and analyzed.

Results: Four RCTs and two retrospective studies with a total of 451 patients were included. tTXA can significantly decrease postoperative drainage volume, TBL, HBL, hospital stay, and the requirement of blood transfusion. Moreover, patients with tTXA had a high level of hemoglobin 24 hours after surgery and hematocrit 72 hours after surgery when compared to the placebo group. However, hematocrit 24 hours after surgery showed no statistical significance between the groups. Five studies were included to assess the safety of tTXA and no patient on tTXA had thromboembolic complications.

Conclusion: This meta-analysis indicated that tTXA could significantly reduce postoperative drainage volume, TBL, HBL, blood transfusion rates, and hospital stay in patients undergoing posterior lumbar surgery. Moreover, topical administration of TXA is safe and does not increase the risk of thromboembolic complications. However, more high-quality and large-sample RCTs are required to confirm these pooled results.

Keywords: Tranexamic acid; Posterior lumbar surgery; Blood loss; Topical use; Meta-analysis

Introduction

Posterior lumbar surgery often entails laminectomy, decompression, fusion, and instrumentation, which may contribute to significant blood loss during the perioperative period. Excessive blood loss may increase the need for blood transfusion and the incidence of transfusion-related complications such as infections, allergic reactions, and acute lung injury [1]. Moreover, significant postoperative blood loss can prolong the duration of tube drainage and hospital stay [2]. Thus, ensuring an effective and safe management of blood loss during posterior lumbar surgery has become an important issue for spinal surgeons.

It is well established that fibrinolysis increases transiently, and results in perioperative blood loss during spinal surgery [3,4]. Tranexamic acid (TXA), an anti-fibrinolytic agent, is able to retard fibrinolysis by impairing plasminogen activation and blood clot degradation [5,6]. Currently, TXA is used to manage perioperative blood management in spinal surgeries such as scoliosis surgery [7], thoracic spine fixation [8], and posterior lumbar surgery [9]. Intravenous use and topical application are the two common routes for posterior lumbar surgery [6]. Numerous individual studies and meta-analyses have demonstrated that intravenous TXA (iTXA) can reduce perioperative blood loss and hospital stay duration without an increase in thrombotic complications [10-12]. However, the efficacy of iTXA in ameliorating the requirements of blood transfusion remains controversial.

Similar to iTXA, several studies have shown that topical TXA (tTXA) can also reduce postoperative blood loss, hospital stay,

and even blood transfusion rates [9,13]. To date, few studies have evaluated the role of tTXA in reducing blood loss in patients who undergo posterior lumbar surgery. Currently, there is no consensus on whether to adopt tTXA during posterior lumbar surgery. Therefore, we conducted a meta-analysis to investigate the efficacy and safety of tTXA in reducing postoperative blood loss, blood transfusion, and hospital stay during posterior lumbar surgery.

Materials and Methods

Literature search

We systematically searched online databases, including PubMed, EMBASE, Web of science, and the Cochrane library from their dates of inception up to May 2019. The search key words included 'tranexamic acid,' 'topical,' 'blood loss,' and 'lumbar surgery.' In addition, the reference lists of relevant articles were manually searched to find other potentially eligible studies. Two reviewers (Weibang Ma, Xue Wen) independently screened the database by title and abstract. If either reviewer observed a title or abstract that qualified the eligibility criteria, a full text of the study was retrieved.

Inclusion and exclusion criteria

Studies were included if they met the following criteria: randomized controlled trial (RCT) or retrospective case-controlled study on posterior lumbar surgery for patients with lumbar degenerative diseases including, lumbar disc herniation, lumbar spinal stenosis, or lumbar spondylolysis, in which tTXA was compared to placebo. The study should include at least one of the following outcomes: drainage volume, total blood loss, hidden blood loss, hematocrit (Hct), hemoglobin (Hb), hospital stay, and blood transfusion. In vitro or animal studies, case reports, reviews, meta-analyses, and letters to the editor were excluded.

Data extraction

Two reviewers (Weibang Ma, Xue Wen) independently extracted the following data from the included literature: surname of the first author, publication year, sample size, sex ratio, age, and detailed methodology for each study. The primary outcomes included were postoperative drainage volume, total blood loss (TBL), hidden blood loss (HBL), and blood transfusion rate. Secondary outcomes included Hb at 24 hours after surgery, Hb at 24 hours and 72 hours after surgery, and duration of hospital stay. Thrombotic events including deep vein thrombosis, pulmonary embolism, and other tTXA related side effects, such as hematoma and wound infection were extracted to evaluate the safety of tTXA in posterior lumbar surgery. All data were extracted from article texts, tables, and figures. If necessary, we contacted the corresponding authors for original data. Any disagreement between investigators was resolved by discussion. When necessary, a third investigator (Hong Sun) would help reach a consensus between all investigators.

Quality assessment and statistical analysis

We adopted a standard method to evaluate the RCTs and retrospective case-controlled studies. The quality of RCTs was assessed via the Cochrane Collaboration Risk of Bias tool15. The retrospective case-controlled studies were assessed using a methodological index for non-randomized studies (MINORS) [14]. All statistical analyses were conducted by Review Manager 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). Continuous data (drainage volume, TBL, HBL, Hb, Hct, Hospital Stay) were assessed using the mean difference (MD) with a corresponding 95 % confidence interval (CI). Dichotomous data (blood transfusion rate) were calculated using relative risk at 95 % CIs. P <0.05 was considered statistically significant. The statistics and quantity of heterogeneity were estimated depending on the P value of the Q test (PQ) and I^2 using the standard Chi-square test and I2 statistic respectively. When I^2>50 % and PQ<0.1, the heterogeneity was considered to be significant and subsequently, a random effects model was used. Otherwise, a fixed effects model was chosen.

Results

Study Identification and Selection

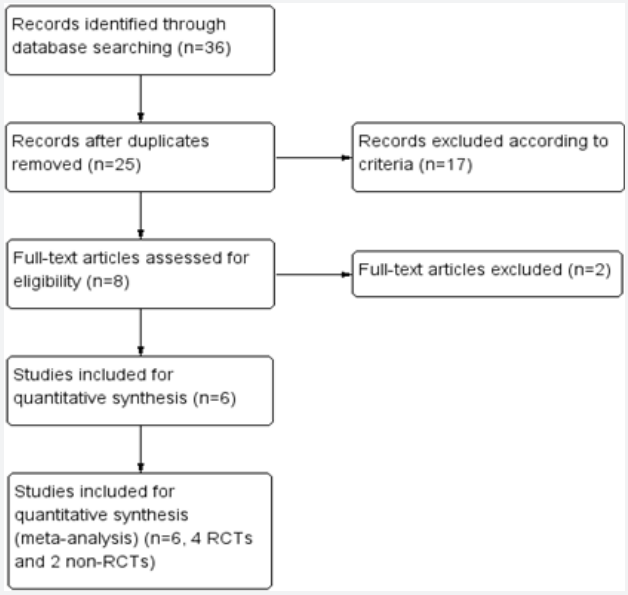

Figure 1: Flowchart of study selection

(Figure 1) shows the flow chart for enrolling eligible studies. We identified a total of 36 citations as potentially relevant studies. After removing duplicates, 25 citations were included for scanning of the title and abstract. Next, 8 full texts of the citations were screened according to the inclusion and exclusion criteria. Ultimately, 6 eligible studies were included for the meta-analysis.

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Characteristics and Quality Assessment

Six studies published in China between 2003 and 2018 with a total of 451 patients were included [9, 13, 18-20]. The demographic characteristics are summarized in (Table 1). The patients in the studies suffered from lumbar degenerative diseases and underwent posterior lumbar surgery. The baseline characteristics including sample size, age, and sex ratio showed no statistical difference between groups. The quality assessment results of the RCTs are illustrated in (Figure 2). The two non-RCTs scored ≥18 according to the MINORS score criteria and therefore considered as high quality.

Table 1: The characteristics of included studies. T/P, tranexamic acid group/placebo group; F/M, female/male; MINORS, methodological index for non-randomized studies; TXA, tranexamic acid.

Study	Type	Country	Sample Size (T/P)	Mean Age (T/P)	Gender(F/M) (T/P)	Transfusion Indication	MINORS Score	Usage and Dosage of Ttxa
Krohn 2003	RCT	Norway	16/14	51	9/7	<80 g/L	-	Wound irrigated with TXA for 2-5mins (0.5g in 50mL saline solution)
				54	9/5			
Liang 2016	RCT	China	30/30	51.13	15/15	<80 g/L	-	TXA soaked Gelfoam in wound (2g in 20 ml saline solution)
				54	16/14			
Xu 2017	RCT	China	40/40	53.1	21/19	<80 g/L	-	Soaking wound with TXA for 5mins (1g in 100mL saline solution)
				57.4	27/13			
Ren 2017	Case-controlled	China	50/50	55.2	30/20	<70g/L	20	Soaking wound with TXA for 5mins (1g in 100mL saline solution)
				58.7	31/29			
Ren ZN 2017	Case-controlled	China	50/50	55.2	30/20	<70g/L	18	Soaking wound with TXA for 5mins (1g in 100mL saline solution)
				58.7	31/19			
Mu 2018	RCT	China	39/42	51.77	17/22	<70g/L	-	TXA soaked Gelfoam in wound (1g in 50mL saline solution)
				52.57	19/23			

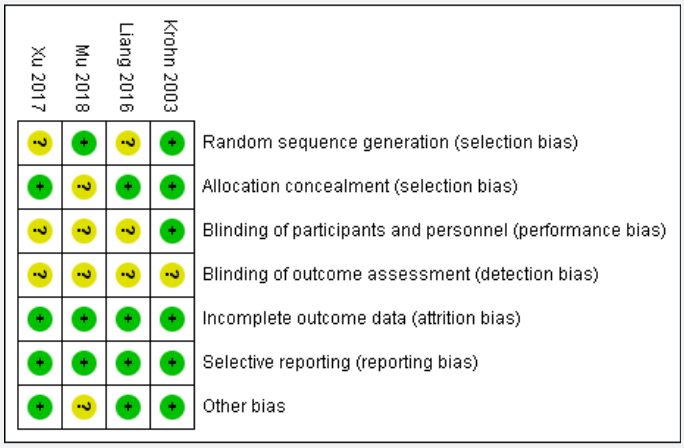

Figure 2: The quality of the randomized controlled trials. Review authors' judgments about each risk of bias item for each included study. + is "yes", - is "no"? is "unclear".

Analysis of outcomes

Blood loss and transfusion

All included literature with a total of 451 patients reported postoperative drainage volume data (9,14,15-17). The pooled results showed that tTXA in posterior lumbar surgery could significantly reduce postoperative drainage volume (MD= -145.23, 95%CI= -186.07 to -104.40, P<0.00001, (Figure 3). However, there was significant heterogeneity among the studies (I^2=85%, PQ <0.00001). Subgroup analysis on the usage of tTXA was performed to observe the potential source of heterogeneity. The amount of postoperative drainage volume was significantly

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decreased in both the TXA soaked Gelfoam in wound group and the soaking wound with TXA group. Nevertheless, the I2 of each group still remained >50%. The heterogeneity may have been caused by differences of dosage, lumbar levels, and the method of calculating postoperative blood loss.

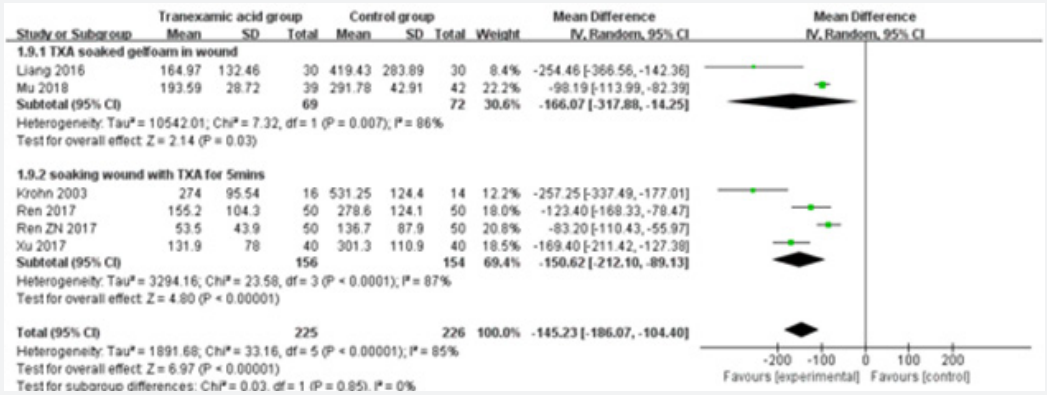

Figure 3: Forest plot for the meta-analysis of postoperative drainage volume.

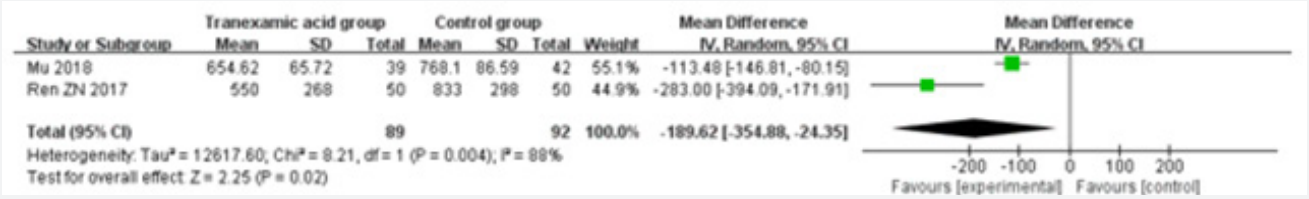

Figure 4: Forest plot for the meta-analysis of total blood loss.

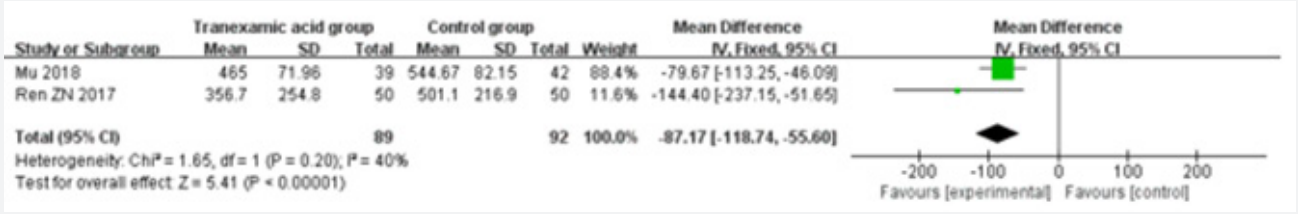

Figure 5: Forest plot for the meta-analysis of hidden blood loss.

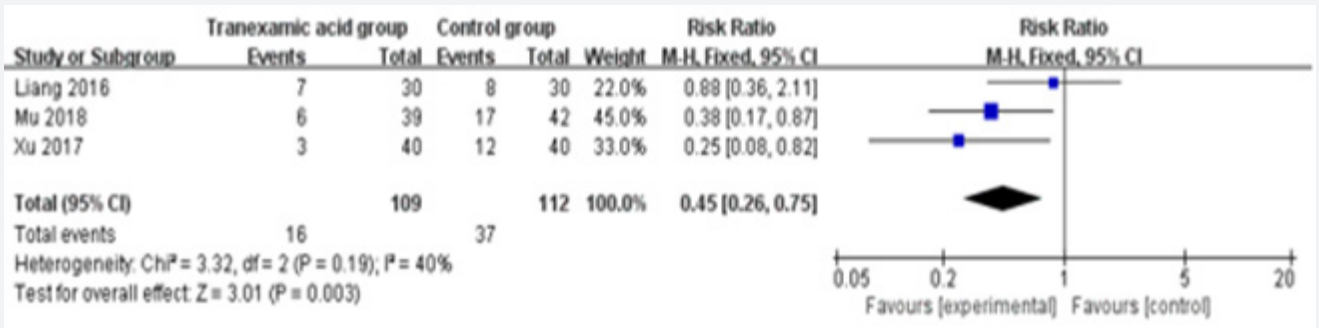

Figure 6: Forest plot for the meta-analysis of blood transfusion rates.

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TBL data were available in two studies with a total of 181 patients [15,17]. The pooled results showed that the tTXA treated group had reduced TBL when compared to the placebo group (MD= -189.62, 95%CI=-354.88 to -24.35, P=0.02, (Figure 4). However, there was significant heterogeneity between studies (I^2=88%, PQ=0.004). HBL data was also available in two studies with a total of 181 patients18, 20. The pooled results showed that tTXA could significantly reduce HBL (MD=-87.17, 95%CI=-118.74 to -55.60, P<0.00001, (Figure 5), with no significant heterogeneity (I^2=40%, PQ =0.20). Three studies with 221 patients investigated the blood transfusion rates [9,13,15]. The pooled results revealed that patients with tTXA had decreased blood transfusion rates (RR=0.45, 95%CI= 0.26 to 0.75, P=0.003, (Figure 6) when compared to the placebo group with no significant heterogeneity (I^2=40%, PQ =0.19).

Postoperative Hb, Hct and hospital stay

Table 2: Meta-analysis of postoperative Hb, Hct and hospital stay.

Outcome	Studies number	Sample size		Std. Mean Difference IV.Random.95%CI	*p*-Value	Heterogeneity	
		tTXA	PG			I^2	P_Q
Hb at 24h after surgery	2	80	80	0.92(0.40, 1.43)	0.005	2%	0.31
Hct at 24h after surgery	2	70	70	-3.28(-10.57, 4.01)	0.38	94%	<0.0001
Hct at 72h after surgery	3	109	112	-0.09(-2.34, 2.15)	0.94	90%	<0.0001
Hospital stay	4	159	162	-1.40(-1.71, -1.08)	<0.00001	10%	0.34

tTXA, topical tranexamic acid group; PG, placebo group: P_Q, *P* value of heterogeneity

(Table 2) summarizes the pooled results of postoperative Hb, Hct, and hospital stay. The Hb at 24 hours after surgery was reported in 2 studies with 160 patients14, 19. A fixed-effects model was used to analyze the pooled data. The level of Hb at 24 hours after surgery in the tTXA group was higher than the placebo group (MD= 0.92, 95%CI= 0.40 to 1.43, P=0.0005). The Hct at 24 hours after surgery was reported in 2 studies with 140 patients [9,13] and Hct at 72 hours after surgery was reported in 3 studies with 221 patients [9,13,15]. A random-effects model was used to calculate the pooled results. No significant differences were found between Hct at 24 hours after surgery (MD= -3.28, 95%CI= -10.57 to 4.01, P=0.38) and Hct at 72 hours after surgery groups (MD=-0.09, 95%CI= -2.34 to 2.15, P=0.94). Hospital stay data were reported in 4 studies with 321 patients [9,14,18,19]. A fixed-effects model was used to explore the pooled data. The hospital stay in tTXA group was shorter than that in placebo group (MD= -1.40, 95%CI= -1.71 to -1.08, P<0.00001).

Complications

The complications associated with tTXA were documented in five studies [9,13,15-17]. No thromboembolic events such as DVT or PE were reported. No patients were found with epidural hematoma. One study by Mu et al18 reported 1 case of wound infection in the tTXA group and 2 cases in the placebo group but no significant difference was found between the groups.

Discussion

Given the rich blood supply of spongy vertebra and canal venous plexus, a posterior lumbar surgery is always associated with massive blood loss. Moreover, posterior lumbar surgery often results in a transient enhancement of endogenous fibrinolytic activity [3]. It has been reported that surgical wounds are associated with the most severe degree of fibrinolysis [18], which may exacerbate postoperative blood loss. The prolonged duration of drainage followed by excessive postoperative blood loss can increase the hospital stay of patients and influence the clinical outcomes. Some studies have demonstrated that iTXA can significantly reduce the intraoperative blood loss (IBL) and TBL in posterior lumbar surgery [12,19]. However, we still found massive postoperative blood loss in iTXA treated patients in these studies. Notably, a study by Ou et al. [13] reported that iTXA combined with tTXA could effectively decrease postoperative blood loss in patients with posterior lumbar fusion surgery [20]. These findings indicated that tTXA seemed to show a synergistic effect with iTXA in the management of postoperative blood loss.

Recently, few studies have investigated the role of tTXA on reducing postoperative blood loss in posterior lumbar surgery for patients with lumbar degenerative diseases [9,13,16,17,21]. The efficacy of tTXA in decreasing perioperative blood loss is still largely unknown. This meta-analysis revealed that tTXA in posterior lumbar surgery could significantly reduce postoperative drainage volume, TBL, and shorten the hospital stay. In general, iTXA was used before stitching the wound and did not show significance in the management of IBL [9]. Therefore, the IBL was not included for overall analysis in the present study [22].

HBL, an important part of TBL, is always disregarded by surgeons in clinical practice. The underlying mechanisms of HBL involve blood infiltration into tissue compartments, red blood cell hemolysis, and ongoing blood loss in the wound25. It is shown that HBL was 429 ± 223 milliliters (ml) in total hip arthroplasty, which was 35.4 % ± 11.0% of the TBL26. Smorgick et al. reported that the HBL during posterior spine fusion surgery was 600–631ml and 39 %–42 % of the TBL27. As for lumbar surgery, it has been demonstrated that the amount of HBL was 588 ml, 39 % of TBL [28,29]. Significant HBL can negatively influence patients'

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outcomes, such as increased risk of blood transfusion and prolonged hospital stay 27. Therefore, HBL management should be considered during the perioperative period. To our knowledge, this is the first meta-analysis to evaluate the efficacy of tTXA in reducing HBL during posterior lumbar surgery [23]. The pooled results indicated that tTXA could significantly ameliorate HBL. Nevertheless, only 2 studies were included in this meta-analysis. More high-quality RCTs are necessary to confirm this result.

There is still a lack of consensus regarding the role of tTXA in reducing blood transfusion requirements during a posterior lumbar surgery. Ren et al. reported that tTXA failed to reduce blood transfusion rates in patients undergoing posterior lumbar spinal fusions [16]. Conversely, Liang et al. found that a TXA-soaked gelatin sponge was effective in ameliorating blood transfusion demands [13]. hether the use of tTXA decreases blood transfusion requirements is still controversial. A previous meta-analysis showed no significant differences in transfusion rates between tTXA group and the placebo group in patients undergoing lumbar surgery [30]. Interestingly, the pooled results in this meta-analysis revealed that tTXA could effectively reduce blood transfusion requirements. The reason may be that tTXA can provide high concentrations of TXA at the bleeding site and thus inhibit the activation of fibrinolysis in the surgical wound, which eventually attenuate HBL and TBL. Notably, it has been shown that iTXA was unable to reduce blood transfusion rates [11]. Compared to iTXA, tTXA seems to be more effective in the management of blood transfusions.

We also explored the influence of tTXA in postoperative Hb and Hct levels. The requirements for blood transfusion are based on postoperative Hb levels. An overall analysis suggested that the decline of Hb at 24 hours after surgery in tTXA treated patients was lower than that the placebo group. However, there was no significant difference in Hct at 24 hours and 72 hours after surgery between the groups. The heterogeneity of Hct at 24 hours at 72 hours after surgery was large. Due to the limited scope of included studies, a subgroup analysis could not be performed to identify the source of heterogeneity.

Theoretically, the use of TXA may increase the risk of thromboembolic complications by inhibiting fibrinolysis. A potential high risk of thrombosis and related side effects are the biggest concerns in the clinical application of TXA. Our previous study indicated that prophylactic iTXA at 30 min before skin incision during posterior lumbar fusion surgery (PLIF) did not increase the risk of TXA related complications [30]. A meta-analysis by Gong et al. also demonstrated that iTXA was safe and did not increase the incidence of thromboembolic events or epidural hematoma formation [11]. In this meta-analysis, most studies investigated the TXA related complications and no case in tTXA group was reported among studies. We did not find any significant increased risks of DVT and PE in patients undergoing posterior lumbar surgery, which was consistent with a previous meta-analysis [30]. The reason could be that tTXA is localized in surgical wounds with little or no TXA in the circulatory system and does not influence systematic fibrinolysis. The blocked ongoing blood loss after wound closed may decrease the incidence of wound hematoma and infection. These findings revealed that tTXA is safe in posterior lumbar surgery [24-26].

Nevertheless, the present meta-analysis has several potential limitations. First, only 4 RCTs and 2 retrospective case-controlled studies were included. Due to the small sample size, a subgroup analysis was not conducted, and the strength of pooled results might be attenuated. Second, there were differences in drug dosage, indications for transfusion, and methods for calculating blood loss between the studies, which may have caused heterogeneity. In addition, most of included studies were from China and the results should be interpreted with great caution when applying the results to other ethnic populations [27-29].

Conclusion

The current study indicated that tTXA was able to reduce postoperative drainage volume, TBL, HBL, blood transfusion rates, and hospital stay in patients undergoing posterior lumbar surgery without increasing TXA related complications. Considering the remarkable heterogeneity and limited scope of the included studies, larger sample sizes and well-designed RCTs are required to validate the efficacy and safety of topical TXA in posterior lumbar surgery.

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