INPLASY PROTOCOL

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None.

Different dose regimens of Intravenous Tranexamic Acid in Spinal Deformity Surgery: A Systematic Review and Meta-Analysis

Xiong, ZC[1]; Deng, Z[2]; Leng, DL[3]; Tu, CQ[4]; Tan, MS.[5].

Review question / Objective: **To evaluate the efficacy and safety of different dose regimens of intravenous (IV) tranexamic acid (TXA) in spinal deformity surgery.**
Condition being studied: **TXA, a synthetic lysine analogue, exerts an antifibrinolytic effect through binding to the lysine-binding sites on plasminogen molecules and inhibiting fibrinolysis. There are many clinical studies and meta-analyses that show that intravenous (IV) TXA can reduce blood loss and allogeneic blood transfusion without the high risk of complications such as deep vein thrombosis (DVT), pulmonary embolism (PE), or other. For IV TXA in spinal deformity surgery, high-dose and low-dose stratification can be performed. The optimal dosage scheme of TXA in spinal deformity surgery is still controversial. Therefore, we conducted this meta-analysis to evaluate the efficacy and safety of different dose regimens of IV TXA in spinal deformity surgery.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2020 and was last updated on 23 April 2020 (registration number INPLASY202040151).

INTRODUCTION

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METHODS

Participant or population: Patients undergo spinal deformity surgery.

Intervention: This meta-analysis sets the definition of high-dose IV TXA to include any dose ≥ 20 mg/kg or > 1 g. On the contrary, it is a low-dose regimen. We divided the studies that met the criteria into a high-dose group and a low-dose group, and conducted a subgroup analysis of the dose for the same outcome measurements.

Comparator: Equal amount of normal saline or blank control group.

Study designs to be included: Randomized controlled trials (RCTs) or non-RCTs.

Eligibility criteria: All studies involved the comparison of the effect of IV TXA versus a placebo or control group in patients undergoing spinal deformity surgery.Study population with diagnosis of spinal deformities, such as AIS, post-traumatic kyphosis and degenerative lumbar scoliosis. Study population all had spinal instrumentation and fusion surgery in professional medical institutions due to spinal deformities.

Information sources: Two researchers independently searched multiple databases according to Cochrane Collaboration guidelines, such as PubMed (1966 to April 1, 2020), Embase (1980 to April 1, 2020), Cochrane library (1980 to April 1, 2020), and Web of Science (1965 to April 1, 2020). Literature was searched with the MeSH terms and corresponding keywords (connecting via Boolean operators "AND or OR"), including "tranexamic acid or TXA", "intravenous", "spine deformity", "spine surgery", "scoliosis", and "spinal deformity surgery".

Main outcome(s): Total blood loss (TBL) and intraoperative blood loss (IBL) are the primary outcome measurements. We conducted subgroup analysis according to different dosage regimens. In order to analyze the difference between the high-dose group and the low-dose group.

Additional outcome(s): Operative time and blood transfusion rate are the secondary outcome measurement.

Quality assessment / Risk of bias analysis: Two researchers independently conducted a quality assessment of each included RCT according to the Cochrane Handbook for Systematic Reviews. The Newcastle-Ottawa scale (NOS) was used to assess the quality of included non-RCTs.

Strategy of data synthesis: The continuous data was analyzed by using weighted mean difference (WMD) and 95% confidence interval (CI). The dichotomous data was analyzed by using risk ratio (RR) and their 95% CI, such as blood transfusion rate. The heterogeneity of the included studies was evaluated using the $\chi 2$ test and I2 test. When the value of I2 is 25%, 50% and 75%, it is regarded as low, medium and high heterogeneity. When I2> 50%, P<0.1, we performed a random-effect model; otherwise, a fixed-effect model was performed.

Subgroup analysis: This meta-analysis sets the definition of high-dose IV TXA to include any dose ≥ 20 mg/kg or > 1 g. On the contrary, it is a low-dose regimen. We divided the studies that met the criteria into a high-dose group and a low-dose group, and conducted a subgroup analysis of the dose for the same outcome measurements.

Sensibility analysis: Sensitivity analysis was conducted to assess the stability of the pooled result. We use Stata software for sensitivity analysis. We found that when excluding any study, the results did not find significant changes, thus confirming the robustness and reliability of the results of this meta-analysis.

Language: English database.

Country(ies) involved: China.

Keywords: Tranexamic acid, Blood loss, Spinal deformity, Scoliosis, Dose regimen.