INPLASY PROTOCOL

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Effectiveness of Tranexamic Acid for Reducing Blood Loss in Myomectomy: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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Review question / Objective: Does intravenous tranexamic acid have positive effect during myomectomy?

Condition being studied: Uterine fibroids are benign tumors which are common in gynecological clinics. Approximately 25% to 30% of women have had uterine fibroids in their lifetime. To women need to undergoing surgery but have fertility requirements, myomectomy is the best option which can preserve uterine. However, intraoperative and postoperative blood loss, which may lead to death for patients, has always been a major problem that bother doctors during myomectomy. Meanwhile, there are many methods to reduce blood loss, including mechanical tourniquets, administration of different hemostatic drugs, and autologous blood transfusion. Tranexamic acid (TXA), as a plasminogen inhibitor, has been widely used in various clinical hemostatic treatments. But the effect of TXA in uterine fibroids is unclear. The objective of this review is to determine the effectiveness of intravenous tranexamic acid in reducing blood loss during myomectomy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 February 2021 and was last updated on 08 February 2021 (registration number INPLASY202120030).

INTRODUCTION

Review question / Objective: Does intravenous tranexamic acid have positive effect during myomectomy? **Rationale:** Tranexamic acid (TXA) is a plasminogen inhibitor that has been widely used in various clinical hemostatic treatments. But the effectiveness of Tranexamic Acid for Reducing Blood Loss in Myomectomy.

Condition being studied: Uterine fibroids are benign tumors which are common in gynecological clinics. Approximately 25% to 30% of women have had uterine fibroids in their lifetime. To women need to undergoing surgery but have fertility requirements, myomectomy is the best option which can preserve uterine. However, intraoperative and postoperative blood loss, which may lead to death for patients, has always been a major problem that bother doctors during myomectomy. Meanwhile, there are many methods to reduce blood loss, including mechanical tourniquets, administration of different hemostatic drugs, and autologous blood transfusion. Tranexamic acid (TXA), as a plasminogen inhibitor, has been widely used in various clinical hemostatic treatments. But the effect of TXA in uterine fibroids is unclear. The objective of this review is to determine the effectiveness of intravenous tranexamic acid in reducing blood loss during myomectomy.

METHODS

Search strategy: The search terms used were (myomectomy) OR (leiomyoma)) OR (uterine fibroid) AND (tranexamic acid). All relevant articles were included, and no restrictions were imposed on date and region.

Participant or population: Inclusion: women scheduled to undergo myomectomy (including transabdominal, robotic or laparoscopic myomectomy). Exclusion: women with malignant tumors, pregnant women, and patients with a history of thrombosis; women with hemorrhage caused by diseases other than fibroids.

Intervention: TXA group - Intravenous tranexamic acid.

Comparator: Control group - Intravenous placebo or no treatment.

Study designs to be included: Randomized Controlled Trials.

Eligibility criteria: Inclusion criteria: (1) clinical RCT; (2) women scheduled to

undergo myomectomy (including transabdominal, robotic or laparoscopic myomectomy); (3) the intervention in the TXA group was intravenous injection of TXA during the perioperative period; (4) the control group received a placebo or no treatment; (5) outcomes such as blood loss or blood transfusion rate were reported.

Information sources: (1) clinical RCT; (2) w o m e n s c h e d u l e d t o u n d e r g o myomectomy (including transabdominal, robotic or laparoscopic myomectomy); (3) the intervention in the TXA group was intravenous injection of TXA during the perioperative period; (4) the control group received a placebo or no treatment; (5) outcomes such as blood loss or blood transfusion rate were reported.

Main outcome(s): Total blood loss, transfusion rate.

Additional outcome(s): Intraoperative blood loss, duration of surgery.

Data management: Using a standardized form for data extraction, two authors independently and in duplicate extracted relevant data from the studies included. The data that needed to be extracted included: first author name, publication year, sample size, blinding, inclusion criteria, intervention method, volume of blood loss, blood transfusion rate and calculation method of blood loss. The final extracted data was jointly decided by the two authors. When disagreements occurred, a more advanced review was required, and the third author participated in and made the final decision.

Quality assessment / Risk of bias analysis: We used the Cochrane collaboration's tool for assessing risk of bias. Its methodology bias assessment includes six items: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias. The evaluation level of each item includes "high risk", "low risk" or "unclear".

Strategy of data synthesis: We integrated all data and performed this meta-analysis using Review Manager 5.3 software. The integrated data included the primary outcome (total blood loss and intraoperative blood loss) and secondary outcomes (blood transfusion rate and operation duration).For continuous variable, we used the means and standard deviations to calculate their standard mean differences (SMDs) with a 95% confidence interval(CI). For dichotomous variables, we used the numbers and sample size of events to calculate the risk difference (RD) and the 95% CIs. Using Chi-square test for heterogeneity test, I²>50% or P<0.1 was considered to be significant heterogeneity, and the random effects model was used. otherwise the fixed effects model was applied.

Subgroup analysis: None.

Sensitivity analysis: Sensitivity analysis will be done if needed.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Tranexamic acid, myomectomy, intravenous, blood loss, and meta-analysis.

Dissemination plans: None.

Contributions of each author:

Author 1 - Zixian Wan - Raise clinical questions and design this meta-analysis, find the relevant literature, and determine the inclusion and exclusion criteria of the literature, search the literature and screen the required literature, evaluate the quality of the research, extract data, meta analysis was performed and writing of the article. Email: wanzixain6@163.com

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