Efficacy and Safety of Prophylactic Large Dose of Tranexamic Acid in adolescent with idiopathic scoliosis Surgery: A Prospective, Randomized, Double-Blind, Placebo-Controlled Study

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Blood loss associated with spinal operations is a common potential cause of morbidity and often requires blood transfusion which subject patients to the known risks of blood transfusion including transmission of diseases.

TA is used routinely to reduce bleeding in cardiac, orthopaedic, and hepatic surgery, however, its use in neurosurgery is uncommon and only few studies reported the use of antifibrinolytic drugs in spine surgery.
How to choose a secure hemostasis medicine?

Study Design

To evaluate efficacy and safety of large doses of TA on blood loss during spinal operations.
METHODS

- Outcome measures included total (i.e., intraoperative and postoperative) blood loss, amount of blood transfusion, as well as postoperative hemoglobin, and hematocrite levels.
- The data were analyzed by means of Statistical Package for the Social Science Version 12.0. The results were presented as mean +/- SD. Independent Student t test was used to compare the 2 groups and differences were considered significant if the P-value was <0.05.
This is a double blind randomized placebo controlled study, after obtaining approval of ethics committee in the hospital and informed written consent, 391 patients were randomized equally into 2 groups (tranexamic acid (TA) and placebo).
 Shortly after the induction of anesthesia, patients received either TA or placebo as a loading dose of 2 g (for teenagers) or 30 mg/kg (for children).

Followed immediately by continuous infusion of 100 mg/h (for adults) or 1 mg/kg/h (for children) during surgery.

Use scenarios

- Preoperative
- During operation
- After operation
- Attention

For 5 hours after the operation

control of the dripping rate
Body can be adjusted under certain conditions via the feedback; stop the abnormal increase of fibrin; prevent thrombus formation.
Three major effects

one
Anti-fibrinolysis

two
Platelets
Functional protection

three
Anti-inflammatory
RESULTS

- There were 201 males and 190 females, ranging in age from 4 to 14 years with a mean of 10 and median of 9 years. Statistical analysis showed no significant differences between the 2 study groups with regard to age, sex, weight, preoperative hemoglobin, and hematocrit levels, type of surgery, as well as operative time.
- In contrast, patients who received TA had 49% reduction of blood loss ($P < 0.007$) and required 80% less blood transfusion ($P < 0.008$) than patients who received placebo.
The combination seems to achieve best results and was more efficient than either of the two drugs alone. No apparent adverse events were found in these groups.

- **Total amount of blood loss**
  - Blank: 43 ml/kg
  - TA group: 24 ml/kg

- **Red blood cell volume**
  - Blank: 32 ml/kg
  - TA group: 24 ml/kg

- **Non-RBC total amount**
  - Blank: 1.9 Unit
  - TA group: 0.7 Unit

- **TA group**: dose of 2 g (for teenagers) or 30 mg/kg (for children)
Statistical analysis showed no significant differences between the 2 study groups with regard to age, sex, weight, preoperative hemoglobin, and hematocrite levels, type of surgery, as well as operative time.

During operation, the number of blood transfusions:
- Placebo group: 27
- TA group: 6

After the surgery, the number of blood transfusions:
- Placebo group: 13
- TA group: 2
CONCLUSIONS

1. Prophylactic use of large doses of TA provides an effective, safe, and cheap method for reducing blood loss during and after spinal operations.

2. Hence, TA may help in reducing not only transfusion related complications but also operative expenses.

3. Does not increase the risk of arterial or venous thrombosis.
Incompatibility

Blood

Incompatibility

Penicillin

Incompatibility
Female hormones, birth control pills

TA contraindication
We conclude that tranexamic acid clearly reduces blood loss, requirement for blood transfusion, and the risk of reoperation for bleeding.

In our study, Reptilase and TA can markedly reduce the blood loss and transfusion requirements equivalently.

TA in multidisciplinary is a safe and effective!

TA significantly reduced blood loss; reduce transfusion needs while reducing the risk of reoperation for bleeding.
Thank you!