Reduction Of Blood Loss In Spine Surgery By Large Doses Of Tranexamic Acid: A Prospective Blinded, Randomized Controlled Study

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Patients & Methods

- **This study is a *prospective double blinded randomized placebo-controlled study*.**
- The study was carried out at King Khalid University Hospital (Riyadh, Saudi Arabia) *during the period; June 2005 to December 2006.*

- **<u>Inclusion criteria;</u>**

  All patients undergoing major spinal operation where significant blood loss is expected were included in the study.

- **<u>Exclusion criteria;</u>**

1. Patients undergoing microdiscectomy.
2. Patients with coagulopathy.
3. Using anticoagulation therapy.
4. History of deep venous thrombosis or pulmonary embolism.
5. Those who have contraindication to use of antifibrinolytic

- An informed written consent was obtained from all the patients.
- Patients undergoing spinal surgery were ***randomly assigned*** to receive placebo or tranexamic acid by a random number generated table.
- The medicine bags were prepared and labelled by the pharmacy staff.
- **The placebo bags contained** normal saline (0.9%) of similar volume and in a similar bag as the tranexamic acid bags.
- Both the anesthetist and surgeon were unaware of the contents of the bag.
- At the end of the study the code was disclosed for statistical analysis.

The data collected:

1. Pre-, intra-, and postoperative (48 hours after the operation) hemoglobin and hematocrite values.
2. Blood loss both intraoperatively and postoperative amount of blood in drains.
3. Any blood or blood substitutes transfused intra- or postoperatively.

- **Data were analysed using SPSS** (Statistical Package for the Social Science) version 12.0.
- **Independent t-test** was used to compare the two groups, results were presented as mean ± SD.
- Differences were considered significant ***if P-value was less than 0.05.***

Results

The study included 64 patients who were distributed equally between both groups (32 patients for each of the placebo and the tranexamic acid groups).

	Tranexamic acid group	Placebo group	P-value
Duration of surgery (minutes)	178.48 ± 72.04	195.69 ± 74.08	.09
Hospital stay	8.45 ± 5.79	10.69 ± 8.27	.21

Insignificant differences between both groups

	Tranexamic acid	*Placebo*	*P- value*
Preoperative Hb (Average, gm/dl)	13.37	13.42	0.87
Intraoperative Hb (Average, gm/dl)	9.77	10.76	0.06
Postoperative Hb (Average, gm/dl)	12.39	11.35	0.006

Significant reduction in the Hb level in the placebo group

	Tranexamic acid	*Placebo*	*P- value*
Preoperative Hct (Average, in %)	39.73	39.19	0.64
Intraoperative Hct (Average, in %)	28.15	26.7	0.74
Postoperative Hct (Average, in %)	35.98	32.79	0.003

Significant reduction in the Hct level in the placebo group

	Tranexamic acid	Placebo	P- value
Intraoperative blood loss (Average, in ml)	311.25	584.69	0.03
Postoperative blood in drains (Average, in ml)	97.94	215.31	0.004
Amount of blood transfusion (Average, in ml)	93.97	531.25	0.008

Significant blood loss in the placebo group

Discussion

- The use of pharmacological therapies to reduce blood loss and blood transfusions in surgery is restricted to a few drugs
  - Aprotinin (Trasylol)
  - Tranexamic acid (Cyklocapron)
  - Aminocaproic acid
  - Desmopressin
  - Recombinant factor VIIa
- However only very few clinical trials have been performed and scientific evidence supporting their use is still limited.

- A recent systematic review of randomized controlled trials of antifibrinolytic agents *(mainly aprotinin)* in elective surgical patients identified 89 trials including 8,850 randomized patients *(74 trials in cardiac, 8 in orthopaedic including 2 trials in spinal surgery, 4 in liver, three in vascular).*

- The results has shown that aprotinin reduced the number of patients requiring blood transfusion, and reduced the need for further surgery to control bleeding by about 50 percent.

- ***These differences were all highly statistically significant*.**

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- **The present study is probably the first randomized trial on the effect of tranexamic acid on blood loss during spinal operations.**
- Aprotinin is an expensive drug *(costs 200 £ for a complete course)* and may elicit an anaphylactic reaction.
- On the other and TA is a very cheap drug and the whole dose used *costs only 20 £**, and its use was not associated with allergic reactions.

*(BNF September 2000)

Conclusion

1. This study has convincingly shown that tranexmic acid has significant beneficial haemostatic and blood conservation effects in spine surgery.

2. Tranexamic acid is a safe and very cheap drug.

3. Its use in large dose was not associated with increased risk of complications particularly thromboembolism.

4. We recommend its use in the same regimen for all spine operations as well as other surgical specialities where significant blood loss is

THANK YOU