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Evaluating The Efficacy And Safety Of Tranexamic Acid Applied By Combined Systemic And Local Application Vs. Single System Application In Pertrochanteric Hip Fracture In The Elderly Patient. Randomised, Placebo-Controlled Clinical Trial.

Trauma / Hip & Femur Trauma / Miscellaneous

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Keywords: Tranexamic Acid, Pertrochanteric Fracture Of The Elderly, Blood Loss

Background
There is currently a strong recommendation for the use of tranexamic acid in pertrochanteric hip fractures in the elderly, with the aim of minimising blood loss. However, there is wide controversy about which doses and routes of administration are optimal for this purpose.

Objectives
To determine whether the application of tranexamic acid intravenously, together with local application to the surgical site, offers a synergistic effect in minimising blood loss, compared to systemic application alone.

Study Design & Methods
We conducted a double-blind, randomised, placebo-controlled clinical trial, comparing 102 patients with pertrochanteric hip fracture in the elderly (>65 years) distributed in two arms:
-Treatment (n:51): They receive tranexamic acid by double route of administration; intravenous adjusted to the patient's serum creatinine levels (according to the technical data sheet), and local at the end of the intervention in a dose of 3g in the surgical site at the end of the intervention (in accordance with the usual recommended dosage).
-Control (n:51): They only receive the intravenous dose of tranexamic acid at the same dosage as the treatment group, with a placebo (saline solution, 3g) applied to the surgical bed at the end of the operation.
The main variables of our study were the differences in blood loss measured between the blood tests obtained on admission to the emergency department and those obtained in the postoperative period with respect to Haemoglobin, Haemoatocrit figures and the need or not for transfusion, and in what amounts.
Secondary variables studied were drug safety parameters evaluated in the form of recorded complications.

Results
Perioperative haemoglobin losses showed no significant differences between the two groups (2.53±1.39 in treatment group and 2.41±1.49 in control group, p=0.675), nor when assessing differences between haematocrit figures (loss of 7.347±4, 26 points in the treatment group compared to 6.67±4.42 in the control group, p=0.801), nor when evaluating the differences in the need or not for perioperative transfusion (18.6% required transfusion in the treatment group compared to 10.41% in the control group, p=0.265. 265.) On performing the analysis by subgroups according to the characteristics of the fracture and its treatment, with the aim of minimising bias (short nail vs. long nail without focus opening vs. long nail with focus opening), we found similar results, without showing significance.

The overall complication rate in the trial was 13.18%, showing no difference between the two groups (p=0.285). No thrombotic or ischaemic events were observed, even among patients who received the drug by both routes and had a history of thromboembolism.

Conclusions

:Although the administration of tranexamic acid in this group of patients is beneficial in itself, we cannot affirm that the synergic application by intravenous and local routes provides a therapeutic benefit with respect to the single systemic application, in relation to the reduction of perioperative blood loss. Our recommendation regarding the optimal route of administration would be single systemic use, given its simple administration and lower dosage requirements, offering the same therapeutic effect.