Bleeding news

Safety of Fibrinogen Concentrate in Non-Trauma and Non-Obstetric Adult Patients during Perioperative Care: Systematic Review and Meta-Analysis

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The use of fibrinogen concentrate as the first hemostatic factor in bleeding patients has been validated in different scenarios and by multiple studies. However, safety, even though very few complications have been reported in these years of pharmacovigilance, still leads to controversy, given it is difficult to homogenize results. This is the focus of this meta-analysis, which studies safety in adult patients, excluding cases of multiple trauma and obstetric hemorrhage, given the specificities of these patients, who received fibrinogen after perioperative bleeding.

For this meta-analysis, only 10 out of over 2,500 articles published met the inclusion criteria (randomized clinical trial, adult patient with perioperative bleeding, comparing the use of fibrinogen with another treatment or placebo, analysis of safety as and endpoint). The fibrinogen used was Octapharma's Fibryga® in 2 cases, and CSL Behring's Haemocomplettan®/RiaSTAP® in the 8 remaining cases. Thus, the meta-analysis included 1391 patients (702 in the treatment group and 689 in the control group), with a study sample between 10 and 372 patients.

The main result shown by this meta-analysis is a decrease in the combined incidence of thromboembolic events in the treatment group (OR 0.65, 95% CI 0.43 to 0.98, I2 = 0%), with no statistically significant differences found when studying different events separately. When the analysis is based on the use indication of fibrinogen (prophylactic vs therapeutic), no significant differences were found. In terms of mortality, the treatment group showed a slight increase in survival, but it was not statistically significant, and differences were not found either to this regard in any other subanalysis conducted.

Nevertheless, in order to properly interpret the results, both the limitations of the studies analyzed and the performance of the meta-analysis per se have to be considered. The definition of an adverse event, as well as the form of notification and the high number of factors involved, may impact the result.

All in all, while the authors acknowledge further studies are required with a high methodological quality, this is the first such analysis, and it provides relevant remarks for daily clinical practice.