Fibrinogen Concentrate Reduces Need For Transfusion After Aortic Surgery

Clinical study results published today in the journal Anesthesiology showed that human fibrinogen concentrate can significantly reduce the need for blood transfusion when given as an intra-operative, targeted first-line hemostatic therapy in bleeding patients undergoing aortic replacement surgery.

The Phase II prospective study, performed by CSL Behring and collaborators at the Hannover Medical School, Germany, enrolled 61 patients to assess the ability of fibrinogen concentrate to improve clotting and reduce the need for transfusion following elective aortic replacement surgery with cardiopulmonary bypass (CPB). Patients who received fibrinogen concentrate required fewer allogeneic blood product transfusions than patients receiving placebo (a median of 2 units in the fibrinogen concentrate group compared with 13 units in the placebo ($p<0.001$)). In the fibrinogen concentrate group, 45 percent (13 out of 29 patients) avoided transfusion entirely, whereas all 32 placebo patients required transfusion ($p<0.001$).

A novel approach to dosing was used in the study. The group in Hannover has developed and validated a model for individualized dosing of fibrinogen concentrate,[1],[2] based on measuring the firmness of the fibrin-based clot, which is mainly dependent on plasma fibrinogen levels.[3] Maximum clot firmness (MCF) of the fibrin-based clot can be monitored using FIBTEM, a commercially available thromboelastometry point-of-care test.

"Aortic replacement surgery puts patients at risk for potentially life-threatening bleeding events because the surgery depletes fibrinogen levels and delays clotting, which may require extensive blood transfusion to restore a patient's clotting ability," said Niels Rahe-Meyer , M.D. Ph.D., of the Clinic for Anesthesiology and Intensive Care Medicine, Hannover Medical School and lead author of the study. "This is the largest study of its kind in patients undergoing aortic replacement surgery and strongly indicates that proactive treatment with fibrinogen concentrate may safely reduce the need for transfusions, restore clotting ability, and consequently protect aortic surgery patients from possible adverse events associated with donor blood transfusion."

In the study, reported treatment-emergent adverse events were similar in both groups and typical for patients undergoing cardiac surgery, with the most common being fluid buildup around the lungs (pleural effusion) and abnormal heart rhythm (atrial fibrillation). None of the treatment-emergent adverse events were ascribed to study medication or led to discontinuation from the study. The study was not powered to compare mortality or morbidity between groups.

"Fibrinogen concentrate has been well-characterized for the treatment of specific

inherited blood clotting disorders," said Andrew Cuthbertson , CSL Chief Scientist. "CSL Behring is committed to exploring the use of fibrinogen concentrate in patients at high risk of bleeding, particularly those in the hospital setting where fibrinogen has been shown to be depleted by surgical procedures and where a quick intervention is needed to improve clotting and prevent serious bleeding events."

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