Comparison of the Hemostatic Efficacy of Pathogen-Reduced Platelets vs Untreated Platelets in Patients With Thrombocytopenia and Malignant Hematologic Diseases: A Randomized Clinical Trial

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Résumé en anglais	Importance: Pathogen reduction of platelet concentrates may reduce transfusion-transmitted infections but is associated with qualitative impairment, which could have clinical significance with regard to platelet hemostatic capacity. Objective: To compare the effectiveness of platelets in additive solution treated with amotosalen-UV-A vs untreated platelets in plasma or in additive solution in patients with thrombocytopenia and hematologic malignancies. Design, Setting, and Participants: The Evaluation of the Efficacy of Platelets Treated With Pathogen Reduction Process (EFFIPAP) study was a randomized, noninferiority, 3-arm clinical trial performed from May 16, 2013, through January 21, 2016, at 13 French tertiary university hospitals. Clinical signs of bleeding were assessed daily until the end of aplasia, transfer to another department, need for a specific platelet product, or 30 days after enrollment. Consecutive adult patients with bone marrow aplasia, expected hospital stay of more than 10 days, and expected need of platelet transfusions were included. Interventions: At least 1 transfusion of platelets in additive solution with amotosalen-UV-A treatment, in plasma, or in additive solution. Main Outcomes and Measures: The proportion of patients with grade 2 or higher bleeding as defined by World Health Organization criteria. Results: Among 790 evaluable patients (mean [SD] age, 55 [13.4] years; 458 men [58.0%]), the primary end point was observed in 126 receiving pathogen-reduced platelets in additive solution (47.9%; 95% CI, 41.9%-54.0%), 114 receiving platelets in plasma (43.5%; 95% CI, 37.5%-49.5%), and 120 receiving platelets in additive solution (45.3%; 95% CI, 39.3%-51.3%). With a per-protocol population with a prespecified margin of 12.5%, noninferiority was not achieved when pathogen-reduced platelets in additive solution were compared with platelets in plasma (4.4%; 95% CI, -4.1% to 12.9%) but was achieved when the pathogen-reduced platelets were compared with platelets in additive solution (2.6%; 95% CI, -5.9% to 11.1%). The proportion of patients with grade 3 or 4 bleeding was not different among treatment arms. Conclusions and Relevance: Although the hemostatic efficacy of pathogen-reduced platelets in thrombopenic patients with hematologic malignancies was noninferior to platelets in additive solution, such noninferiority was not achieved when comparing pathogen-reduced platelets with platelets in plasma. Trial Registration: clinicaltrials.gov Identifier: NCT01789762.
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