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Evaluation of Four-Factor Prothrombin Complex Concentrate Dosing Strategies for the Reversal of Bleeding Associated with Apixaban or Rivaroxaban

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Abstract

In clinical practice, 4F-PCC is commonly used off-label as a non-specific reversal agent for factor Xa inhibitors apixaban and rivaroxaban. While the hemostatic effectiveness of 4F-PCC in patients taking apixaban and rivaroxaban has been studied in the literature, the optimal dose remains unclear. This was a multicenter, retrospective observational study designed to evaluate the hemostatic effectiveness and safety of 4F-PCC dosed at 2000 units, 35 units/kg, and 50 units/kg for the reversal of bleeding associated with apixaban or rivaroxaban. The primary outcome was hemostatic effectiveness as defined by the Internal Society of Thrombosis and Hemostasis and secondary outcomes were rates of all-cause in-hospital mortality and thrombosis at 30 days or discharge. Out of 278 patients who received 4F-PCC for reversal of bleeding associated with apixaban or rivaroxaban, 72 patients were included in the final analysis. The 2000-unit, 35 unit/kg, and 50 unit/kg dosing strategies were used in 12, 36, and 24 patients, respectively. Hemostatic effectiveness was achieved in 86%, 67%, and 70% of intracerebral hemorrhages ($p = 0.762$) and 60%, 71%, 86% of gastrointestinal hemorrhages ($p = 0.422$). Neither dosing strategy was associated with a statistically significantly higher rate of hemostatic effectiveness nor lower rates of all-cause mortality or thrombosis.