

A retrospective chart review of patients receiving Four-Factor Prothrombin Complex Concentrate (4F-PCC) for anti-factor Xa related bleeding

ABSTRACT

*Introduction:* Since FDA approval of rivaroxaban in 2011 and apixaban in 2012, factor Xa inhibitors have grown more popular for anticoagulation. As all anticoagulants carry a risk for bleeding, it is important to have reversal agents readily available for patients who experience bleeding while taking these medications. In 2018, andexanet alfa was approved by the FDA for reversing bleeds in patients taking apixaban or rivaroxaban. The initial data regarding andexanet alfa has limited efficacy and safety data, and it may pose a significant financial burden on healthcare systems. Historically, four-factor prothrombin complex concentrate (4F-PCC) has been used off label to reverse these bleeds. This observational, retrospective chart review was conducted to evaluate the safety and efficacy of 4F-PCC in managing factor Xa inhibitor-related bleeds.

*Methods:* This observational, retrospective study reviewed the use of 4F-PCC for reversing bleeding in patients taking rivaroxaban or apixaban from May 2014 to December 2018 at a community hospital. Assessment criteria outlined by Sarode et al. were used to evaluate hemostatic efficacy. Thromboembolic events, length of stay, mortality, and discharge disposition were analyzed as secondary outcomes.

*Results:* Of fifty-nine patient charts that were reviewed, forty-eight patients were included in the study analysis. As determined by Sarode et al. criteria, effective hemostasis was achieved in thirty-three patients (68%) who were given 4F-PCC to reverse bleeding associated with factor Xa inhibitors. Of these patients, twelve patients (86%) with intracranial hemorrhage achieved effective hemostasis without surgical intervention. Four patients (8.3%) experienced thromboembolic events within 30 days of receiving 4F-PCC. Most patients (85.4%) returned to home or went to long-term care following hospital discharge. Seven patients (14.6%) deceased in the hospital.

*Conclusion:* Most patients who received 4F-PCC for factor Xa inhibitor-associated bleeding achieved effective hemostasis.

Learning objective: Evaluate the off-label use of 4F-PCC for reversing bleeds associated with factor Xa inhibitor use.