

Investigating the Prophylactic Use of 4F-PCC for Urgent FXa Inhibitor Reversal

BACKGROUND

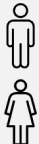


FXa inhibitors are commonly prescribed to prevent or treat blood clots but can potentially increase bleeding risk in high-risk settings, e.g., during surgery or following trauma



Due to the lack of data for 4F-PCC in prophylactic FXa inhibitor reversal, most guidelines recommend the 'wait and see' strategy

POPULATION



n=10 (50%)



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25% on rivaroxaban

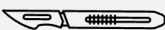
75% on apixaban

FXa inhibitor concentration range

Min: 77 ng/mL

Max: 497 ng/mL

Median: 128 ng/mL



All patients (n=20) underwent emergency surgery with >50 mL expected blood loss

OBJECTIVE

The PROXY trial aimed to evaluate the efficacy and safety of 2,000 IU 4F-PCC for controlling hemostasis in patients with FXa inhibitor levels ≥ 75 ng/mL who require urgent major surgery



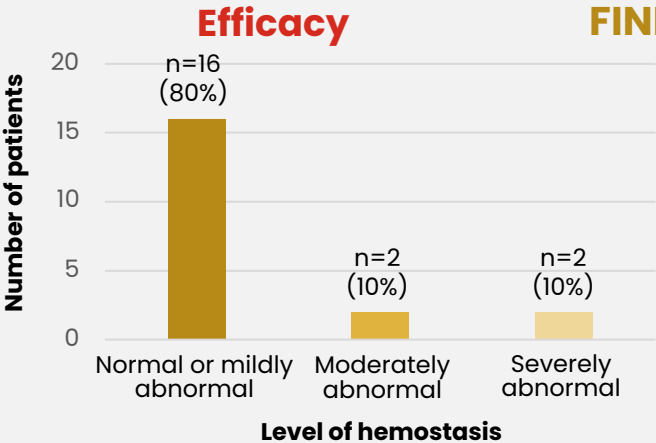
OUTCOMES



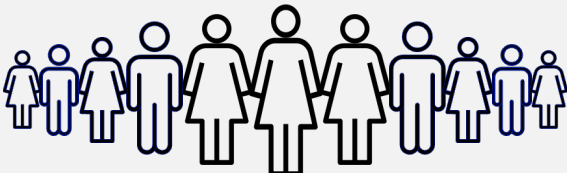
Primary efficacy outcome:
incidence of normal or mildly abnormal hemostasis

Primary safety outcome:
incidence of thromboembolic events within 7 days

FINDINGS



Safety



1/20

Only one asymptomatic thrombotic event reported in one patient (5%), 5 days post-operative; unclear if related to 4F-PCC



CENTERS

3 hospitals in Canada



CONCLUSION

4F-PCC was effective and well tolerated for improving hemostasis in patients on FXa inhibitors requiring urgent major surgery; more data is required to confirm this finding



4F-PCC, four-factor prothrombin complex concentrate; FXa, factor Xa; IU, international units, n, number of patients.
Schulman S, Bhagirath V, Chan C, et al. Prothrombin complex concentrate for emergency surgery in patients on oral Xa-inhibitors.
J Thromb Haemost. 2024;S1538-7836(24)00386-6. doi: 10.1016/j.jth.2024.07.002