

## Retrospective Analysis: INR and Vitamin K-Dependent Factor Levels After Vitamin K Antagonist Reversal With 4F-PCC or Plasma

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### HIGHLIGHTS

- INR  $\leq 1.5$**  ~86% of 4F-PCC-treated patients had an INR  $\leq 1.5$  after infusion compared to ~39% of plasma-treated patients
- Fill and FX levels** After 4F-PCC treatment, >89% of patients had Fill and FX levels >50% compared to ~10% to ~15% of plasma-treated patients
- All VKDF levels were significantly higher in patients treated with 4F-PCC** compared to plasma, irrespective of achieving a post-infusion INR of  $\leq 1.5$  or  $>1.5$

### INTRODUCTION

Vitamin K antagonist (VKA) reversal is needed in cases of acute major bleeding or before urgent surgical procedures, and **4F-PCC has been used as an effective alternative to plasma for rapid VKA reversal**

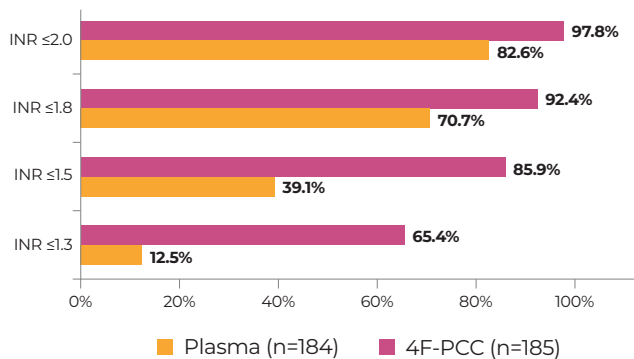
This study evaluates the impact of **4F-PCC or plasma on INR correction and vitamin K-dependent factor (VKDF) restoration in VKA-treated patients** with acute bleeding or requiring urgent surgeries

### STUDY CHARACTERISTICS

- Objective**  
Efficacy comparison of 4F-PCC and plasma for VKA reversal in acute major bleeding or urgent surgery
- Study design**  
Retrospective exploratory analysis of 2 prospective Phase 3b randomized controlled trials
- Patient population**  
VKA-treated patients  $\geq 18$  years of age; elevated INR; 4F-PCC or plasma treatment after major bleeding or requiring an urgent surgical or invasive procedure within 24 hours

### RESULTS

Figure. Cumulative frequency distribution of INR values at 30 minutes after infusion



**INR  $\leq 1.5$**  85.9% of 4F-PCC-treated patients had a post-infusion INR  $\leq 1.5$  at 30 minutes, compared to only 39.1% in the plasma group



Post-infusion INR correction was rapid with 4F-PCC, from a median baseline value of 2.9 (IQR, 2.3-3.8) to a median of 1.3 (IQR, 1.2-1.6) at 30 minutes

#### Time to surgery



Median time to surgery in 4F-PCC group was **~5 hours faster** (median, 3.6 hours vs 8.8 hours for those receiving plasma;  $P=0.04$ )



Mean activity levels of all VKDFs\* in the 4F-PCC-treated group were >50% at 30 minutes post-infusion, irrespective of whether the patient achieved a post-infusion INR  $\leq 1.5$  or  $>1.5$



~45% of patients in 4F-PCC group were able to start surgery within 3 hours post-infusion (vs ~28% of patients in plasma group;  $P=0.027$ )

\*VKDFs included FII, FVII, FIX, and FX

#### Abbreviations

4F-PCC: four-factor prothrombin complex concentrate; FII: factor II; FVII: factor VII; FIX: factor IX; FX: factor X; INR: international normalized ratio; IQR: interquartile range; VKA: vitamin K antagonist; VKDF: vitamin K-dependent factor.

#### Reference

Hood C, Goldstein JN, Milling TJ, et al. *Blood Adv.* 2023;7(10):2206-2213.



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