CSL Behring

Thromboembolism After Treatment With Four-Factor Prothrombin Complex Concentrate or Plasma for Warfarin-Related Bleeding

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HIGHLIGHTS



No significant adjusted difference in the 45-day risk of thromboembolism was observed posttreatment with 4F-PCC compared to plasma



4F-PCC-mediated reversal was associated with a similar short-term risk of thromboembolic complications as plasma



treated cohort had a lower adjusted risk of death within 45 days post-treatment compared with a historical plasmatreated cohort

INTRODUCTION



Long-term VKAtreated patients may be predisposed to thromboembolic events (TEEs)



Acute VKA reversal in these patients may increase short-term TEE risk, which can vary with the treatment strategy

STUDY CHARACTERISTICS

Objective

45-day risk of thromboembolic events in 4F-PCC vs plasma-treated adults with warfarin-associated major bleeding

Study design

Multicenter observational study

Primary outcome

Occurrence of acute TEE

Patient population

Matched adults ≥18 years of age

Exposure

4F-PCC or plasma treatment for acute VKA reversal

RESULTS

Figure 1. Primary analysis: Risk of TEE among patients with no recent TEE history

Multivariable association of 4F-PCC vs plasma therapy with risk of thromboembolism at 7, 14, and 45 days post-treatment

Model	aHR (95% CI)
Confirmed TEE at 45 days	0.76 (0.49-1.16)
Confirmed TEE at 7 days	1.42 (0.66-2.97)
Confirmed TEE at 14 days	1.23 (0.69-2.17)

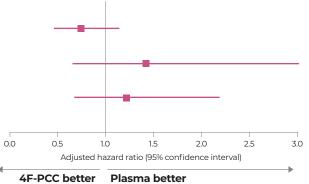
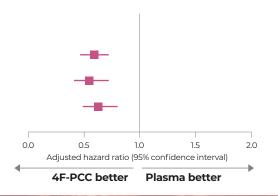


Figure 2. Secondary analyses: Mortality risk among patients with no recent TEE history

Multivariable association of 4F-PCC vs plasma therapy with risk of death at 7, 14, and 45 days post-treatment

Model	aHR (95% CI)
Death at 45 days	0.59 (0.47-0.73)
Death at 7 days	0.55 (0.41-0.73)
Death at 14 days	0.63 (0.49-0.81)





Among 1119 4F-PCC treated patients, the **overall** risk of TEEs was 3.5%



45-day risk of thromboembolic events was similar in both groups



Lower adjusted risk of all-cause death at 45 days post-treatment with 4F-PCC was reported (aHR 0.59 [95% CI, 0.47-0.73])



144 deaths and 206 deaths were identified among 4F-PCC and plasma patients, respectively

Reference

Go AS, Leong TK, Sung SH, et al. *J Thromb Thrombolysis*. 2022;54(3):470-479.

Abbreviation

4F-PCC: four-factor prothrombin complex concentrate; aHR: adjusted hazard ratio; TEE: thromboembolic event; VKA: vitamin K antagonist



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