The use of 4F-PCC to correct direct oral anticoagulant-induced coagulopathy: An observational analysis

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With the approval of four-factor prothrombin complex concentrate (4F-PCC, Kcentra) for the reversal of haemorrhage in patients treated with vitamin K antagonists in the United States, it has become relatively common practice to use 4F-PCC "off-label" to correct coagulopathy caused by direct oral anticoagulants (DOACs). However, the efficacy and safety of 4F-PCC have not been well studied for coagulopathy reversal. For this reason, the authors of this study performed a retrospective observational study on the off-label use of 4F-PCC for reversing bleeding associated with DOACs in a level 1 trauma centre between November 2014 and February 2017. The authors collected international normalised ratio (INR) and haemoglobin data before and after 4F-PCC infusion, clinical outcome and onset of thromboembolic events within 24 hours and 45 days of 4F-PCC administration. In this article, 24 patients on DOACs who received 4F-PCC for severe haemorrhage and emergent surgeries were included. Most patients showed an improved clinical outcome based on stabilisation of the intracranial haemorrhage size and of haemoglobin levels. In the study, no thromboembolic events were identified within 24 hours of 4F-PCC administration; however, four (16.7%) patients experienced thromboembolic events 2–45 days after receiving 4F-PCC. With these data, the authors conclude that 4F-PCC was relatively efficient in correcting coagulopathy induced by DOACs. However, the authors note the fact that 16.7% of patients experienced some form of thromboembolic event in the days-to-weeks after administration of 4F-PCC, although the attribution of 4F-PCC to these processes (as opposed to the patient's underlying disease) is difficult to determine. In summary, this is an observational retrospective study and randomised prospective studies are needed to further evaluate the safety of 4F-PCC for the reversal of haemorrhage associated to DOACs.