

Evaluation of Adverse Events Following Change in Dosing Protocol and Implementation of Bedside Reconstitution of 4-Factor Prothrombin Complex Concentrate

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Background:

Hematoma expansion is a major cause of mortality related to vitamin K antagonist (VKA) associated intracranial hemorrhage. Prothrombin complex concentrate (PCC) is a first line recommendation for initial reversal of VKA-associated intracranial hemorrhage. Current literature has shown implementation of a PCC administration protocol has improved rates of time to administration of PCC and INR reduction. Our institution implemented a protocol in May 2018 allowing for bedside reconstitution of PCC for reversal of anticoagulation in the emergency department. The objective of this study is to evaluate thrombotic and bleeding events following administration of PCC after a change in dosing protocol and implementation of bedside reconstitution.

Methods:

This is a single center retrospective study that includes adult patients in the emergency department who received 4-Factor PCC. This study will compare patients who received PCC for indications including but not limited to gastrointestinal bleed or intracranial hemorrhage before and after protocol change for the administration of PCC. Patients who received PCC outside of the emergency department will be excluded. Pre-protocol data will be collected for 72 patients and post-protocol data will be collected for 46 patients. The primary outcome is the composite of thrombotic and bleeding events within 30 days of 4-Factor PCC administration. Secondary outcomes include: total thrombotic events, total bleeding events, mortality, time to administration, and reduction in INR. Categorical data will be analyzed using the Chi-square test and nominal data analysis will utilize the T-test.

Results:

Primary Endpoint	Pre-pilot (n=72)	Post-pilot (n=46)
Total number of adverse events, n (%)	26 (36%)	9 (20%)

Secondary Endpoint	Pre-pilot (n=72)	Post-pilot (n=46)
Thrombotic event n, (%)	7 (10%)	2 (4%)
MI/ACS n, (%)	1 (1%)	0 (0%)
DVT/PE n, (%)	5 (7%)	2 (4%)
Stroke n, (%)	2 (3%)	0 (0%)
Bleeding n, (%)	23 (32%)	8 (16%)
Time to Administration, median (minutes)	31	16
Mortality, n (%)	16 (22%)	5 (11%)

Conclusions:

This evaluation will be used as a quality initiative to promote system-wide implementation of bedside reconstitution of PCC at Lahey Hospital & Medical Center.