

Introduction

- 4-factor PCC is a single agent indicated for the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist therapy, such as warfarin, in adult patients with need for urgent surgery, invasive procedure or acute major bleeding. It is also used off-label with limited data for the reversal of life-threatening hemorrhage associated with non-vitamin K antagonist anticoagulation
- Currently at our hospital, there is an established protocol for 4-factor PCC in the setting of warfarin reversal, but not for non-warfarin reversal
- The purpose of this study was to evaluate appropriate usage of 4-factor PCC based on indication and dosage in patients requiring urgent anticoagulation reversal

Methods

Inclusion Criteria:

- All patients who received 4-factor PCC at the study institution

Dates:

- March 1, 2018 to August 31, 2018

Data Collected:

- Patient demographics: (sex, age, height, weight, BMI)
- Drug reversed
- Indication for anticoagulation
- Location of bleed
- Dose administered
- Baseline and follow-up INR, PT and PTT as appropriate
- Other factors or blood products utilized
- Surgical or procedural interventions required

Results

Table 1. Patient Demographics

| | Gender | Average Age | Average BMI | Anticoagulation Indication | Agent Reversed | Location of Bleed |
|--|------------------------|---------------------|-------------------------|---|---------------------------------|--|
| Warfarin Reversal Group (n=6) | Male 67% Female 33% | 78 (Range 62-97) | 25 (Range 22.8-27.7) | Atrial fibrillation 50% Clotting disorder 17% History of stroke 17% Mechanical valve 17% | Warfarin 100% | ICH 67% GIB 0% Other 33% (1 CSF, 1 rectal) |
| Non-warfarin Reversal Group (n=7) | Male 43% Female 57% | 81 (Range 67-96) | 31 (Range 23.2-42.9) | Atrial fibrillation 71% DVT 14% PE 14% | Apixaban 43% Rivaroxaban 57% | ICH 57% GIB 0% Other 43% (1 vaginal, 1 rectal, 1 pelvic) |

Table 2. Summary of Coagulation Assays

| | Pre-Treatment INR | Post-Treatment INR | Average Pre-Treatment PT | Average Post-Treatment PT | Average Pre-Treatment PTT | Average Post-Treatment PTT |
|--|---|--------------------------------|---|---|---|----------------------------|
| Warfarin Reversal Group (n=6) | <2 (17%) 2 to <4 (67%) 4 to 6 (0%) >6 (17%) | <2 (100%) | 43.2 (Range 19.7-120) | 15.2 (Range 13.5-19.6) | 63.7 (Range 30-183) | 29 (5 not reported) |
| Non-warfarin Reversal Group (n=7) | <2 (57%) 2 to <4 (29%) 4 to 6 (0%) >6 (0%) Not reported (14%) | <2 (57%) Not reported (43%) | 21.8 (Range 16.9-29.1) (1 not reported) | 15.9 (Range 15.2-17.3) (3 not reported) | 42.4 (Range 35-60) (2 not reported) | None reported |

Table 3. Other Treatment Received

| | Vitamin K Given | Blood Products Given | Surgery/Procedure |
|--|-------------------|----------------------|-------------------|
| Warfarin Reversal Group (n=6) | Yes 100% No 0% | Yes 0% No 100% | Yes 17% No 83% |
| Non-warfarin Reversal Group (n=7) | Yes 14% No 86% | Yes 43% No 57% | Yes 29% No 71% |

Summary and Conclusions

Based on the results, we conclude that 4-factor PCC was appropriately indicated in 100% of the cases between March 1, 2018 to August 31, 2018.

4-factor PCC was correctly dosed in 54% of total patients included in the review

- 83% of warfarin reversals
- 29% of non-warfarin reversals

4-factor PCC was mostly used for the reversal of non-warfarin agents, such as direct oral anticoagulants (DOACs) with the exception of dabigatran

- 54% of the cases involved DOACs
- 46% of the cases involved warfarin

Comparison of baseline, post treatment, and average levels show an improvement of INR for warfarin

- Minimal changes in PT and PTT for apixaban and rivaroxaban

The overall mortality rate of patients receiving 4-factor PCC in our sample was 15%

Overall, we see the need for developing a protocol for non-warfarin reversal at our institution to facilitate choosing the correct dosages in life-threatening bleeds. We also recommend adding reversal agents for individual DOACs as they become available.

References

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