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### Analysis of Treatment Strategies Utilized in Non-Intracranial Hemorrhage Secondary to Oral Anticoagulation Therapy

Allison Vargas

*Baptist Hospital of Miami*, [allison.vargas@baptisthealth.net](mailto:allison.vargas@baptisthealth.net)

Manny Alfonso

*Baptist Hospital of Miami*, [manny.alfonso@baptisthealth.net](mailto:manny.alfonso@baptisthealth.net)

Erika Dittmar

*Baptist Hospital of Miami*, [ErikaDi@baptisthealth.net](mailto:ErikaDi@baptisthealth.net)

Heidi Clarke

*Baptist Hospital of Miami*, [heidic@baptisthealth.net](mailto:heidic@baptisthealth.net)

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## BACKGROUND

- There are three FDA-approved reversal agents: 4-factor prothrombin complex concentrates (4F-PCCs, KCentra) for warfarin, idarucizumab for dabigatran, and andexanet alfa for apixaban and rivaroxaban
- Despite andexanet alfa's and idarucizumab's indication, there is considerable controversy surrounding reversal strategies for the factor Xa inhibitors due to the limited data and high cost of the antidote
- Clinicians frequently use non-specific agents such as 4F-PCC off-label to reverse factor Xa inhibitors based on limited data
- Vitamin K antagonists are associated with a more than a 3-fold increase in odds of gastrointestinal (GI) bleeding compared with placebo or control
- Among patients with atrial fibrillation, dabigatran has an increased rate of GI bleeding relative to warfarin
- Apixaban is associated with significantly lower odds of major GI bleeding compared to warfarin
- Dabigatran and rivaroxaban may be associated with increased odds of major GI bleeding

## OBJECTIVES

- Analyze the safety and efficacy of reversal agents used within Baptist Hospital of Miami to manage acute non-ICH major bleeds secondary to oral anticoagulation
- Identify opportunities to optimize the management of non-ICH major bleeds secondary to oral anticoagulation

## METHODS

- Study design:** Single center, retrospective chart review of patients admitted within Baptist Hospital of Miami with a major non-ICH bleed secondary to oral anticoagulation between January 1, 2019 and December 31, 2020
- Inclusion criteria:** Individuals ≥ 18 years old, major non-ICH bleed, home oral anticoagulant
- Exclusion criteria:** Pregnant, ICH bleed
- Primary outcomes:** In-hospital mortality
- Secondary outcomes:** Treatment strategies used and the percentage of patients achieving hemostasis within 24 hours, incidence of thromboembolic events, and length of stay
- Major bleeding was defined as:
  - Bleeding in a critical area or organ\*
  - Fall in hemoglobin of 2g/dL
  - Transfusion of 2 or more units of whole blood or red cells
- Hemostasis was defined as:
  - Achievement of post-infusion INR <2
  - No administration of blood products past 24 hours

\*Critical sites: intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome

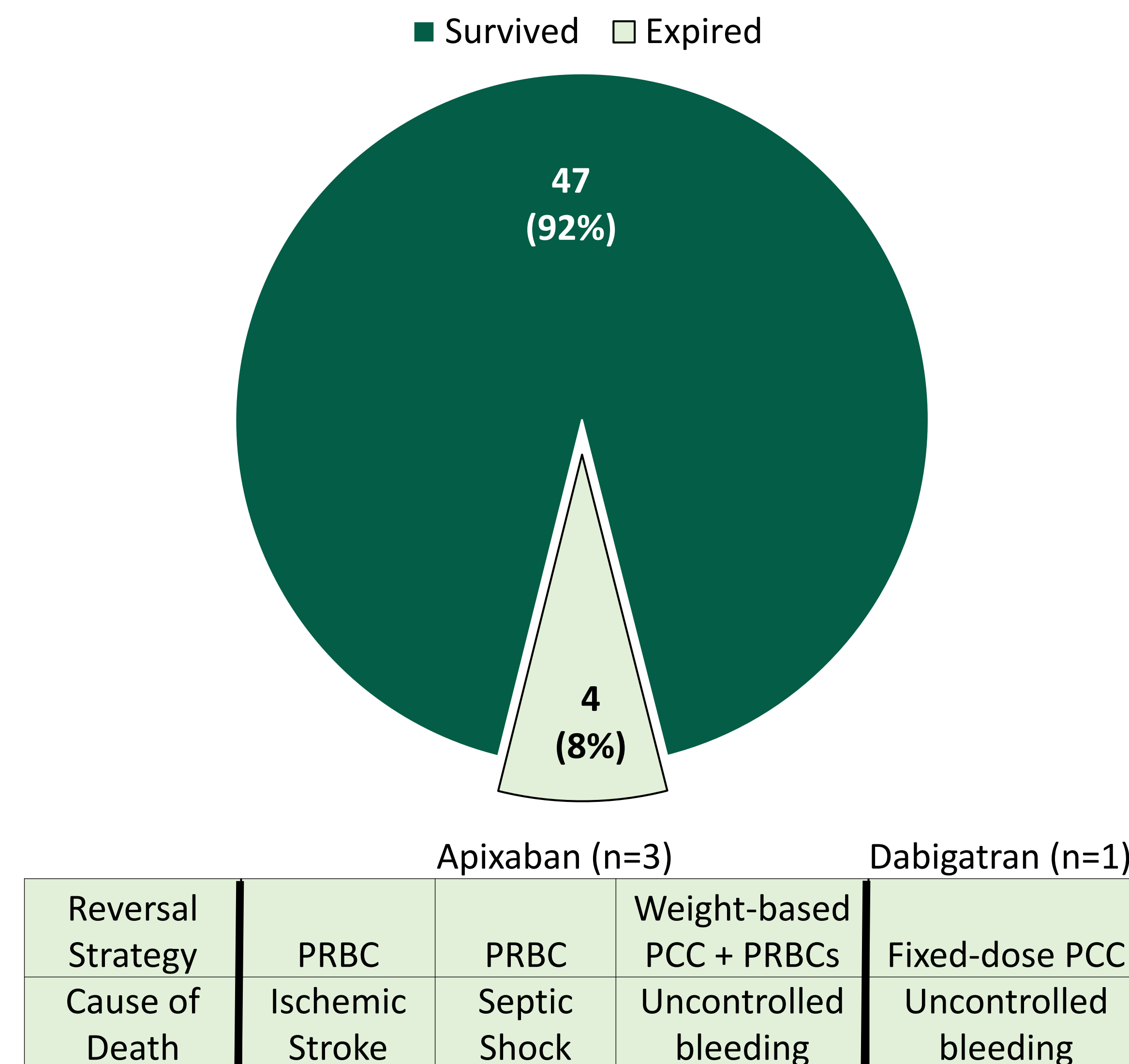
## RESULTS

Baseline Characteristics	n=51
<b>Bleed type, n (%):</b>	
GI	44 (86%)
Retroperitoneal	2 (4%)
Other	5 (10%)
<b>Home Oral Anticoagulant, n (%)</b>	
Apixaban	27 (53%)
Rivaroxaban	14 (27%)
Warfarin	8 (16%)
Dabigatran	2 (4%)
<b>Indication for Oral Anticoagulation, n (%)</b>	
Atrial Fibrillation	39 (76%)
Venous Thromboembolism	8 (16%)
Other	4 (8%)
<b>Concomitant drugs that increase bleeding risk, n (%):</b>	29 (57%)

Secondary Outcomes	n=51
Mean length of stay (days)	12
Incidence of thromboembolic events	1

Agent	Reversal Strategy Used (n)					
	Fixed-dose PCC	Weight-based PCC	Vitamin K	Tranexamic Acid	FFP	PRBC
Apixaban/Rivaroxaban	2	8	2	1	1	33
Dabigatran	1	-	-	-	-	1
Warfarin	2	3	5	-	1	5

## In-hospital Mortality



## Treatment Strategies and Hemostasis



## CONCLUSION

- The overall mortality rate was 8% in major non-ICH bleeds
- Average length of stay was 12 days
- Majority (86%) of the bleeds were GI
- Anti-Xa inhibitors were the most common (80%) oral anticoagulants used, where a majority of patients were taking apixaban (53%)
- 26 patients did not receive a reversal agent, and 7 patients only received supportive care
- 13 patients did not achieve hemostasis within 24 hours of bleeding onset
- 1 patient experienced a thromboembolic event due to holding anticoagulation

## LIMITATIONS

- Small sample size
- Last administration time of oral anticoagulant was mostly unknown
- Baseline hemoglobin not available for all patients
- Majority of patients were not scoped to confirm exact location and severity of bleed
- Difficult to draw conclusions based on comparative data between patients with different major bleeds of varying severity

## DISCUSSION

- Blood products are the most frequently utilized management strategy of major non-ICH bleeds
- Decision making regarding ideal management strategy depends on patient specific factors including oral anticoagulant, hemoglobin, platelets, INR, and hemodynamic stability
- Prospective studies with larger sample sizes should be conducted to establish the most appropriate management strategy for major non-ICH bleeds
- In general, use of off-label reversal agents is safe and effective

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## DISCLOSURES

All authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have direct or indirect interest in the subject matter of this presentation