INTRODUCTION

• Apixaban is an oral direct factor Xa inhibitor FDA-approved for stroke prophylaxis and systemic embolism prevention in patients with non-valvular atrial fibrillation
• Apixaban has a favorable safety profile in ARISTOTLE trial compared to warfarin with a reduction in major bleeding, intracranial hemorrhage and all-cause mortality
• Limited data are available which evaluate the safety of apixaban in clinical practice where use occurs in a population more broad than that studied and with less-structured follow-up
• Apixaban was associated with nearly 500 hemorrhage adverse events that were reported to the FDA in 2014

OBJECTIVES

• To assess characteristics, management and outcomes in patients with atrial fibrillation who experience a major bleeding event while taking apixaban
• To identify opportunities for improving apixaban safety at our institution

METHODS

• Institutional Review Board approved
• Retrospective cohort study (electronic chart review)
• Timeframe: January 1, 2013 – June 30, 2015
• Patients with atrial fibrillation taking apixaban who experienced a major bleeding event will be assessed for inclusion using the following steps:
  1. Identification of apixaban use through an electronic medical record system search
  2. From the apixaban use list, identification of patients with ICD-9 codes for hemorrhage, atrial fibrillation with or without transfusion (not required for intracranial hemorrhage patients)
  3. Additional cases identified using an internal adverse event reporting system
  4. Identify patients with a major bleed (based on International Society on Thrombosis and Haemostasis criteria) and a temporal relationship to apixaban use
• Systematic data collection will occur on those with a major bleed: patient characteristics, management of bleed, and outcomes will be assessed and reported using descriptive statistics

PRELIMINARY RESULTS*

<table>
<thead>
<tr>
<th>Data Collection Ongoing</th>
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<tbody>
<tr>
<td>Table 1. Patient Demographics</td>
<td>Table 2. Select Patient Characteristics, n = 7</td>
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<tr>
<td>Male, n (%)</td>
<td>Chronic kidney disease 42.9</td>
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<tr>
<td>Age (years), mean ± SD</td>
<td>Acute kidney injury at time of bleed 28.6</td>
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<tr>
<td>Weight, mean ± SD</td>
<td>Hypertension 57.1</td>
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<td>Creatinine clearance (mL/min), mean ± SD</td>
<td>Malignancy 28.6</td>
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<tr>
<td>Heart Valve Replacement, n (%)</td>
<td>Post-bleed ICU length of stay (days), mean ± SD 9.1 ± 2.7</td>
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<td>INR, median (IQR)</td>
<td>Transition to palliative/hospice care, n (%) 2 (2.86)</td>
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</tbody>
</table>
| HEMORR2HAGES, median (IQR) | Anticoagulation held at discharge (out of 5 patients), n (%) 3 (60)
| Mean INR during apixaban use, median (IQR) | In-hospital mortality, n (%) 0 (0) |
| Anticoagulation on hold, n (% | 30-day mortality, n (%) 2 (28.6) |

DISCUSSION

• Seven out of twelve patients screened thus far were included in the study, suggesting an approximate 50% rule-in rate from our screening criteria
• Patients who experienced a major bleed were often male, older, had hypertension, anemia, and moderate bleeding risk scores
• Most patients bled prior to admission
• Gastrointestinal bleeding was the most common bleed site
• Concurrent antiplatelet therapy occurred in more than 50% of patients
• PRBCs were the most commonly used method of bleeding management
• One patient suffered a thrombotic event (bilateral lower extremity deep vein thrombosis) while apixaban was held
• The 30-day mortality was 28.6%

DISCLOSURE

Authors of this presentation do not have any disclosures to report regarding financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter presented.

REFERENCES