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Xiaowen Kong

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Mona Ali

See next page for additional authors

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ADVERSE EVENTS IN LOW VERSUS NORMAL BODY WEIGHT PATIENTS PRESCRIBED APIXABAN OR RIVAROXABAN FOR ATRIAL FIBRILLATION.

Deborah DeCamillo¹, Brian Haymart¹, Xiaowen Kong¹, Scott Kaatz², Mona Ali³, Geoffrey Barnes¹, Scott Kaatz⁴

¹University of Michigan Ann Arbor, MI, USA, ²Henry Ford Health System Detroit, MI, USA, ³Beaumont Health Royal Oak, MI, USA, ⁴Hurley Medical Center Flint, MI, USA

Title: Adverse Events in Low versus Normal Body Weight Patients Prescribed Apixaban or Rivaroxaban for Atrial Fibrillation.

Background: Clinical trials comparing direct oral anticoagulants (DOACs) to warfarin included only a small number of patients that weighed less than 60 kilograms (kg). The safety and efficacy of DOACs in low weight adult patients with atrial fibrillation (AF) is still unclear. Published data is not only sparse but have mixed outcomes. Therapy with DOACs may increase bleeding and/or clotting risk with uncertain antithrombotic benefit in low weight patients. **Objective:** To assess bleeding and thrombotic event rates for patients with AF that are prescribed a DOAC and have a low body weight (less than 60 kg) versus patients that have a normal body weight (60 to 100 kg). **Methods:** Within the Michigan Anticoagulation Quality Improvement Initiative (MAQI²), we analyzed data for patients with AF prescribed apixaban or rivaroxaban from 2017 through 2021 who had at least 12 months of follow-up. Patients were excluded if they were prescribed dosing different from package insert instructions. Patients were divided by weight into low (less than 60 kg) and normal (60 to 100 kg) cohorts. Assessments included rates of thrombotic events, major bleeding events (International Society on Thrombosis and Haemostasis [ISTH]), and non-major bleeding events requiring an Emergency Department (ED) visit. Patient characteristics were compared using Chi-square and t-test. Bleeding event rates were adjusted for age, gender, and diabetes mellitus and thrombotic event rates were adjusted by CHA₂DS₂-VASc score. Poisson regression was used to estimate adjusted adverse event rates to control for potentially confounding covariates (apixaban only due to few patients prescribed rivaroxaban). **Results:** A total of 616 patients met the inclusion criteria: 83 (13.5%) low weight and 533 (86.5%) normal weight. Most patients were prescribed apixaban (88.5%) with the low weight cohort more often prescribed the lower dose of apixaban (55% versus 6.2%, p<0.0001). The low weight cohort had a higher mean age (78.9% versus 74.4%, p<0.0002), proportion of females (94% versus 54%, p<0.0001) and CHA₂DS₂-VASc score (4.4 (1.6) versus 3.9 (1.6)), but a lower proportion of patients with diabetes mellitus (9.6% versus 25.1%, p<0.0018) [Table 1]. In the unadjusted analysis of patients prescribed apixaban, non-major bleeding events requiring an ED visit (10.8 per 100 patient-years versus 7.4 per 100 patient-years, p<0.0001), occurred more often in the low versus normal weight patient cohort [Table 2]. However, adjusted analysis found no statistically significant difference in events in low and normal weight cohorts prescribed apixaban [Table 2]. Comparisons within patients prescribed rivaroxaban could not be made due to a small sample size of low weight patients. **Conclusions:** Among low weight patients with AF the use of apixaban was not associated with bleeding (major and non-major) or thrombotic events after adjusting for potential confounding covariates. Larger studies may offer further insight into the overall safety and efficacy of DOAC therapy in these patients.

Table 1. Patient characteristics

	Low weight patients (< 60 kg) N= 83	Normal weight patients (60-100 kg) N= 533	p-value
Age mean (sd)	78.9 (10)	74.4 (10.1)	0.0002
Gender (female) (%)	78 (94%)	289 (54.2%)	<0.0001
Race (%):			
White	68 (81.9%)	451 (84.6%)	0.53
Black	9 (10.8%)	57 (10.7%)	0.97
Other	6 (7.2%)	25 (4.7%)	0.29
DOAC prescribed (%):			
Apixaban	78 (94%)	467 (87.6%)	0.092
Apixaban 2.5 mg BID	43 (55.1%)	29 (6.2%)	<0.0001
Rivaroxaban	5 (6%)	66 (12.4%)	0.092
Rivaroxaban 15 mg QD	2 (40.0%)	8 (12.0%)	0.14
Overall low dose DOAC prescribed (%)	45 (54.2%)	37 (6.9%)	<0.0001
CHA ₂ DS ₂ -VASc score (sd)	4.4 (1.6)	3.9 (1.6)	0.0026
Modified HAS-BLED at Enrollment mean (sd)	2.8 (1.3)	2.8 (1.2)	0.78
Prior bleeding history (%)	32 (38.6%)	205 (38.5%)	0.99
Serum creatinine mean (sd)	0.9 (0.6)	1.1 (0.8)	0.18
Chronic kidney disease (%)	9 (10.8%)	91 (17.1%)	0.33
Diabetes mellitus (%)	8 (9.6%)	134 (25.1%)	0.0018
Hypertension (%)	65 (78.3%)	434 (81.4%)	0.50
Cirrhosis (%)	0	0	/

Abbreviations: DOAC= direct oral anticoagulant, sd= standard deviation, mg= milligram, BID= twice a day, QD= every day, CHA₂DS₂-VASc=congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category, modified HAS-BLED= hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, elderly (age>65), drug or alcohol use

Table 2. Adverse events: unadjusted and adjusted

	Low weight patients (< 60 kg) N= 83	Normal weight patients (60-100 kg) N= 533	p-value
Apixaban # (%)	78 (94)	467 (87.6)	0.092
Number of years of follow-up, median (IQR)	2 (1.5)	2 (0.5)	0.95
Adverse events (unadjusted)			
Bleeding events # (number per 100 pt-yr)			
Major:	5 (3.0)	26 (2.8)	0.80
Intracranial	0 (/)	2 (0.2)	/
GI	3 (1.8)	11 (1.2)	0.46
Other	2 (1.2)	13 (1.4)	1
Non-major bleeds requiring ED visit	18 (10.8)	69 (7.4)	<0.0001
Thrombotic events # (number per 100 pt-yr)			
CVA	3 (1.8)	6 (0.6)	0.14
TIA	1 (0.6)	2 (0.2)	0.39
Adverse events (adjusted)			
Bleeding events (number per 100 pt-yr) (95%CI) *			
Major	3.0 (2.0, 4.3)	2.8 (1.9, 4.0)	0.97
GI	1.8 (1.1, 2.8)	1.2 (0.6, 2.1)	0.45
Other	1.2 (0.6, 2.1)	1.4 (0.8, 2.3)	0.58
Non-major bleeds requiring ED visit	10.8 (8.9, 13.0)	7.4 (5.8, 9.3)	0.60
Thrombotic events (number per 100 pt-yr) (95%CI) †			
CVA	3.0 (2.0, 4.3)	1.9 (1.1, 3.0)	0.66
TIA	1.8 (1.1, 2.8)	0.6 (0.2, 1.3)	0.33
	0.6 (0.2, 1.3)	0.2 (0.02, 0.7)	0.40
Rivaroxaban # (%)	5 (6)	66 (12.4)	0.092
Number of years of follow-up, median (IQR)	1.5 (0.5)	2.5 (2)	0.17
Adverse events (unadjusted)			
Bleeding events # (number per 100 pt-yr)			
Major:	0 (/)	3 (1.8)	/
Intracranial	0 (/)	1 (0.6)	/
GI	0 (/)	1 (0.6)	/
Other	0 (/)	1 (0.6)	/
Non-major bleeds requiring ED visit	0 (/)	15 (9.1)	/
Thrombotic events # (number per 100 pt-yr)			
CVA	0 (/)	2 (1.2)	/
TIA	0 (/)	1 (0.6)	/

Abbreviations: IQR= interquartile range, GI= gastrointestinal, CVA= cardiovascular accident, TIA= transient ischemic attack, CI= confidence interval
 *Adjusted for age, gender, and diabetes mellitus
 †Adjusted for CHA₂DS₂-VASc score

ASSOCIATION OF HYPONATREMIA WITH CLINICAL OUTCOMES IN PATIENTS ADMITTED WITH ACUTE PULMONARY EMBOLISM: ANALYSIS OF THE NATIONAL INPATIENT SAMPLE

VAISHALI DEENADAYALAN MD, DENNIS DANSO KUMI MD, BIRJU PATEL MD
 John H Stroger Jr Hospital of Cook County Chicago, IL, USA

Background: Acute Pulmonary Embolism (PE) is associated with significant morbidity and mortality and is the third most common cause of cardiovascular death worldwide. Hyponatremia is associated with a negative prognosis in several conditions like Congestive heart

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