Safety and Efficacy of Oral Anticoagulants for Atrial Fibrillation in Patients After Bariatric Surgery

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Anticoagulation management is challenging in bariatric surgery patients, due to altered gastrointestinal anatomy and potentially reduced absorption. Few studies have evaluated clinical outcomes in this population. The objective of this study was to compare the efficacy and safety of oral anticoagulants in patients with and without a history of bariatric surgery. A retrospective, matched cohort study was conducted, utilizing data from the OptumLabs Data Warehouse. Patients ≥18 years old, with nonvalvular atrial fibrillation (NVAF), and treated with an oral anticoagulant between January 1, 2010 and December 31, 2018 were included. Outcomes were compared between bariatric and nonbariatric surgery patients. Secondary analysis compared warfarin to the direct oral anticoagulants (DOAC) in the bariatric cohort. The primary efficacy outcome was the rate of ischemic stroke and systemic embolism and the primary safety outcome was major bleeding. A total of 1,673 bariatric surgery and 155,619 nonbariatric surgery patients were identified. There was no significant difference in the rate of ischemic stroke or systemic embolism (0.83 vs 1.32 per 100 person years; Hazard ratio [HR] 0.62, 95% confidence interval [CI] 0.31 to 1.22; p = 0.17) or major bleeding (5.30 vs 4.87 per 100 person years; HR 1.05, 95% CI 0.80 to 1.37; p = 0.73) between bariatric and nonbariatric surgery patients. In bariatric surgery patients alone, efficacy and safety were similar with warfarin compared with the DOACs. Results of this study suggest that bariatric surgery patients are not at an increased thrombotic or bleeding risk when using oral anticoagulants for NVAF. DOACs may be a reasonable alternative to warfarin. **(Am J Cardiol 2020;136:76−80)**

Background

Bariatric surgery is a mainstay of treatment for obesity, and results in anatomic changes which may influence pharmacokinetic properties of medications.[1−3] Atrial fibrillation (AF) is a common co-morbidity among the bariatric surgery population as obesity itself increases the risk of developing AF and often requires anticoagulation. To date there is limited evidence describing the efficacy and safety of oral anticoagulants in patients with bariatric surgery, and even less to guide agent selection when therapy is warranted. As compared with the nonbariatric population where direct oral anticoagulants (DOACs) are considered first line for prevention of stroke and transient ischemic attacks in nonvalvular atrial fibrillation (NVAF), warfarin has been considered the drug of choice for postbariatric surgery patients due to availability of laboratory monitoring and established therapeutic ranges.[2] Use of DOACs in a bariatric surgery population presents an opportunity to improve anticoagulation practice, due to a lack of dietary restrictions, fewer drug-drug interactions, and a wide therapeutic window, although evidence is limited to case studies and series with conflicting results.[4−8] This study aims to supplement previous research by evaluating the efficacy and safety of oral anticoagulants in bariatric surgery patients relative to nonbariatric surgery patients and compare warfarin to DOACs amongst a bariatric population.

Methods

This study was a retrospective, matched cohort study of individuals represented in the OptumLabs Data Warehouse, which includes claims data for privately insured and Medicare Advantage enrollees in a large, private, U.S. health plan. Individuals with both medical and pharmacy insurance coverage were included. The study was exempt from institutional board review as it used pre-existing de-identified data. Funding was provided by the Mayo Midwest Pharmacy Research Committee.

Patients 18 years of age or older with NVAF, who filled a prescription for warfarin or a DOAC (rivaroxaban, apixaban, dabigatran, or edoxaban) between January 1, 2010 and

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December 31, 2018 were included. The diagnosis of AF was identified via International Classification of Disease (ICD) billing codes, as was the diagnosis of bariatric surgery (eTable in Supplementary Material). Patients were required to have at least 12 months of continuous enrollment in a medical health plan prior to the index date. The index date was considered the first fill date of the index medication in the study period after patients met the 12 month enrollment requirement, regardless of whether they had been on the medication prior. A 30 day gap in prescription fill was allowed, but after that the patient was no longer considered on treatment. We excluded individuals with valvular heart disease, end-stage chronic kidney disease (CKD) or kidney transplant or dialysis at any time, as identified by procedure, ICD9, and ICD10 codes (eTable in Supplementary Material). Patients who underwent hip or knee replacement surgery within six weeks prior to index date or had a diagnosis of deep vein thrombosis or pulmonary embolism at baseline were also excluded.

For the primary analysis, outcomes were compared between bariatric and non-bariatric surgery patients. Patients were assigned to the bariatric surgery cohort if they had bariatric surgery on or prior to the study index date. In an ancillary analysis, we compared outcomes in patients on warfarin versus DOACs in the bariatric surgery cohort.

The primary efficacy outcome was the rate of ischemic stroke and systemic embolism. The primary safety outcome was major bleeding. Both the safety and efficacy outcomes were determined using procedure, revenue, ICD9, and ICD10 codes (eTable in Supplementary Material). Mortality, included as a secondary outcome, was identified by merging in a list of deceased patients based on OptumLab ID.

In order to conduct the analyses, both cohorts—the full cohort and the bariatric surgery only sub-cohort—were first weighted using 1:1 overlapping weights. This allowed the small count of bariatric surgery patients to be more accurately compared with the large count of nonbariatric surgery patients and for the smaller count of DOAC patients within the bariatric cohort to be compared with the relatively larger count of warfarin patients.

The 3 primary outcomes—stroke or systemic embolism, major bleed, and death—were then set to be survival-time data, allowing the use of a Cox proportional hazards model via maximum likelihood. The secondary analysis was to tabulate rate ratios, producing person years and event rate values for each outcome. Using these 2 analyses, it was determined both (1) how frequently an outcome occurred; and (2) whether or not there was a significant difference in outcome frequency between first, bariatric patients and non-bariatric patients, and second, warfarin patients and DOAC patients within the bariatric patient cohort.

Results

A total of 1,673 bariatric surgery and 155,619 nonbariatric surgery patients were identified. After weighted matching, baseline characteristics were mostly similar between groups (Table 1a). Baseline characteristics were also similar between warfarin and DOAC patients within the bariatric cohort (Table 1b). The mean age of patients included was 72 years and 43% of patients were female. The most common co-morbidities were hypertension (95.1%), diabetes mellitus (50.7%), coronary heart disease (54.2%), and vascular disease (56.3%). Among bariatric surgery patients

Table 1a
Baseline characteristics before and after weighted matching

Variable	Unweighted			Weighted		
	Bariatric (n = 1673)	Nonbariatric (n = 155,619)	Std Diff	Bariatric (n = 1673)	Nonbariatric (n = 155,619)	Std Diff
Age, mean (SD)	72.2 (10.3)	71.6 (10.8)	0.0639	72.2 (10)	72.2 (10)	0.0000
Women	733 (43.8%)	68,314 (43.9%)	0.0017	686 (43.7%)	686 (43.7%)	0.0000
White	1390 (83.1%)	117,262 (75.4%)	0.1915	1297 (82.6%)	1297 (82.6%)	0.0000
Insurance						
Commercial	474 (28.3%)	40,359 (25.9%)	0.0540	441 (28.1%)	441 (28.1%)	0.0000
Medicare	1199 (71.7%)	115,263 (74.1%)	0.0540	1130 (71.9%)	1130 (71.9%)	0.0000
Region						
Northeast	1033 (61.7%)	22,472 (14.4%)	1.1154	940 (59.8%)	940 (59.8%)	0.0000
South	468 (28%)	66,265 (42.6%)	0.3093	461 (29.3%)	461 (29.3%)	0.0000
Midwest	63 (3.8%)	51,196 (32.9%)	0.8127	63 (4%)	63 (4%)	0.0000
West	109 (6.5%)	15,589 (10%)	0.1274	107 (6.8%)	107 (6.8%)	0.0000
Heart failure	679 (40.6%)	58,953 (37.9%)	0.0554	636 (40.5%)	636 (40.5%)	0.0000
Hypertension	1594 (95.3%)	140,749 (90.4%)	0.1886	1494 (95.1%)	1494 (95.1%)	0.0000
Diabetes mellitus	859 (51.3%)	58,345 (37.5%)	0.2816	796 (50.7%)	796 (50.7%)	0.0000
Coronary heart disease	904 (54%)	83,251 (53.5%)	0.0108	852 (54.2%)	852 (54.2%)	0.0000
Vascular disease	938 (56.1%)	87,308 (56.1%)	0.0007	884 (56.3%)	884 (56.3%)	0.0000
Thromboembolism	310 (18.5%)	33,782 (21.7%)	0.0793	292 (18.6%)	292 (18.6%)	0.0000
Chronic kidney disease	237 (14.2%)	23,740 (15.3%)	0.0307	221 (14.1%)	221 (14.1%)	0.0000
CHA_2DS_2-VASc						
0-1	61 (3.6%)	12,626 (8.1%)	0.1908	59 (3.8%)	91 (5.8%)	0.0963
2-3	377 (22.5%)	41,656 (26.8%)	0.0983	356 (22.7%)	395 (29.2%)	0.0586
≥4	1235 (73.8%)	101,340 (65.1%)	0.1898	1155 (73.6%)	1083 (69%)	0.1008
HAS-BLED ≥3	1280 (76.5%)	94,045 (60.4%)	0.3513	1189 (75.7%)	1187 (75.6%)	0.0024

Abbreviation: SD = standard deviation.

Table 1b
Baseline characteristics before and after weighted matching in the bariatric surgery cohort

Variable	Unweighted			Weighted		
	Warfarin (n = 933)	NOAC (n = 740)	Std Diff	Warfarin (n = 282)	NOAC (n = 282)	Std Diff
Age, mean (SD)	73.1 (9.6)	71.1 (11)	0.1956	72.2 (5.7)	72.2 (6.3)	0.0000
Women	429 (46%)	304 (41.1%)	0.0017	123 (43.7%)	123 (43.7%)	0.0000
White	759 (83.3%)	620 (81.7%)	0.0247	229 (82.5%)	229 (82.5%)	0.0000
Insurance						
Commercial	219 (23.5%)	255 (34.5%)	0.2440	82 (29%)	82 (29%)	0.0000
Medicare	714 (76.5%)	485 (65.5%)	0.2440	200 (71%)	200 (71%)	0.0000
Region						
Northeast	642 (68.8%)	391 (52.8%)	0.3317	173 (61.5%)	173 (61.5%)	0.0000
South	210 (22.5%)	258 (34.9%)	0.2758	78 (27.7%)	78 (27.7%)	0.0000
Midwest	31 (3.3%)	32 (4.3%)	0.0523	12 (4.2%)	12 (4.2%)	0.0000
West	50 (5.4%)	59 (8%)	0.1049	19 (6.6%)	19 (6.6%)	0.0000
Heart failure	356 (38.2%)	323 (43.6%)	0.1119	114 (40.5%)	114 (40.5%)	0.0000
Hypertension	890 (95.4%)	704 (95.1%)	0.0121	268 (95.1%)	268 (95.1%)	0.0000
Diabetes mellitus	471 (50.5%)	388 (52.4%)	0.0390	142 (50.4%)	142 (50.4%)	0.0000
Coronary heart disease	479 (51.3%)	425 (57.4%)	0.1226	154 (54.6%)	154 (54.6%)	0.0000
Vascular disease	499 (53.5%)	439 (59.3%)	0.1180	160 (56.8%)	160 (56.8%)	0.0000
Thromboembolism	169 (18.1%)	141 (19.1%)	0.0242	54 (19.1%)	54 (19.1%)	0.0000
Chronic kidney disease	119 (12.8%)	118 (15.9%)	0.0911	38 (13.3%)	38 (13.3%)	0.0000
CHA_2DS_2-VASc						
0-1	22 (2.4%)	39 (5.3%)	0.1525	9 (3.3%)	13 (4.8%)	0.0731
2-3	202 (21.7%)	175 (23.6%)	0.0477	65 (23.1%)	62 (22.2%)	0.0235
≥4	709 (76%)	526 (71.1%)	0.1115	207 (73.5%)	206 (73.1%)	0.0104
HAS-BLED ≥3	731 (78.3%)	549 (74.2%)	0.0979	209 (74.4%)	213 (75.7%)	0.0304

Abbreviation: SD = standard deviation.

Table 2
Frequency of use of individual oral anticoagulants

Generic name	Frequency
Apixaban	53,322 (33.90%)
Dabigatran	12,641 (8.04%)
Edoxaban	172 (0.11%)
Rivaroxaban	34,185 (21.73%)
Warfarin	56,972 (36.22%)

73.6% had a CHA_2DS_2-VASc score ≥4, versus 69% in the nonbariatric surgery cohort, and the majority of patients (75%) had a HAS-BLED score ≥3. Overall warfarin was the most frequently prescribed oral anticoagulant and apixaban use was most common among the DOACs (Table 2).

Outcomes were based on an event rate per 100 patient years. There was no difference in stroke or systemic embolism, which occurred at a rate of 0.83 in the bariatric surgery cohort versus 1.32 in the nonbariatric surgery cohort (Hazard ratio [HR] 0.62, 95% confidence interval [CI] 0.31 to 1.22; p = 0.17). There was also no difference in the rate of major bleeding (5.30 vs 4.87; HR 1.05, 95% CI 0.80 to 1.37; p = 0.73) or mortality (1.81 vs 1.84; HR 0.95, 95% CI 0.61 to 1.49; p = 0.82) between study groups (Table 3).

When considering only bariatric surgery patients, the rate of study outcomes was similar between patients receiving warfarin as compared with the DOACs. There was no difference in the rate of stroke or systemic embolism (1.96 vs 0.68; HR 1.41, 95% CI 0.32 to 6.19; p = 0.65). In addition, there was no difference between warfarin and the DOACs in major bleeding (5.52 vs 6.22; HR 0.84, 95% CI 0.46 to 1.55; p = 0.59) or mortality (1.95 vs 1.5; HR 1.36, 95% CI 0.45 to 4.06; p = 0.59; Table 4).

Table 3
Primary outcomes

Outcome	No. of events	Person years	Event rate	HR (95% CI)	p Value
SSE					
Nonbariatric	16	1209	1.32	Reference	
Bariatric	9	1043	0.83	0.62 (0.31-1.22)	0.17
Bleed					
Nonbariatric	58	1195	4.87	Reference	
Bariatric	54	1018	5.30	1.05 (0.80-1.37)	0.73
Death					
Nonbariatric	22	1219	1.84	Reference	
Bariatric	19	1045	1.81	0.95 (0.61-1.49)	0.82

Abbreviations: HR = hazard ratio; SSE = stroke or systemic embolism.

Table 4
Secondary outcomes

Outcome	No. of events	Person years	Event rate	HR (95% CI)	p Value
SSE					
DOAC	1	177	0.68	Reference	
Warfarin	2	187	1.96	1.41 (0.32-6.19)	0.65
Bleed					
DOAC	11	175	6.22	Reference	
Warfarin	10	182	5.52	0.84 (0.46-1.55)	0.59
Death					
DOAC	3	177.3	1.5	Reference	
Warfarin	4	187.9	1.95	1.36 (0.45-4.06)	0.59

Abbreviations: HR = hazard ratio; SSE = stroke or systemic embolism.

Discussion

Oral anticoagulants are commonly indicated in bariatric surgery patients due to the high prevalence of concomitant AF. The findings of this study suggest that the use of oral anticoagulants in a bariatric population results in similar rates of ischemic stroke or systemic embolism and major bleeding compared with a nonbariatric population. Furthermore, use of a DOAC relative to warfarin resulted in similar efficacy and safety in patients with a history of bariatric surgery and AF.

In light of the obesity epidemic multiple studies have sought to assess the benefit of bariatric surgery on clinical outcomes. It is well established that bariatric surgery provides numerous cardiovascular benefits including improvements in glycemic control and left ventricular ejection fraction, as well as reduced risk of new onset AF.[9−11] In the context of known AF the impact of bariatric surgery on morbidity has been called in to question. Prior data initially suggested that the risk of AF morbidity, including hospitalizations following bariatric surgery may be increased particularly in the first few years following procedure.[12] In contrast, multiple more recent studies have found that bariatric surgery is associated with reduced AF burden and also reduced AF recurrence following ablation relative to nonbariatric surgery patients.[13−15] In the wake of such compelling evidence, the incidence of bariatric surgery in the general population is likely to further increase in the coming years. As such clinicians will face the unique challenge of anticoagulation management in the context of potentially diminished drug absorption, reduced efficacy, and very limited clinical evidence.

Alterations in gastric emptying time, decreased small intestine transit time, and reduced intestinal surface area resulting from bariatric surgery have the potential to influence pharmacokinetic properties of anticoagulants.[1−3] In addition changes in exposure to intestinal CYP3A4 metabolism and P-gp efflux transporters may also impact the oral bioavailability of commonly used anticoagulants, albeit to varying degrees.[2] The results presented here suggest that despite significant changes in gastrointestinal anatomy oral anticoagulants can be used safely and effectively in the bariatric surgery population without an increased risk for adverse events compared with patients without a history of bariatric surgery.

Due to the availability of laboratory monitoring and established therapeutic ranges warfarin has been considered the standard of care for bariatric surgery patients. Previous studies have shown that warfarin requirements are reduced following bariatric surgery, potentially due to vitamin K deficiencies and changes in gastric pH, however, no studies have assessed clinical outcomes amongst patients receiving warfarin.[16,17] Data is further limited when considering the use of DOACs in this population. Patients with a significantly altered gastrointestinal tract were not included in phase II and III studies which limits the extrapolation of their findings to this unique population. A matched cohort study that enrolled bariatric surgery patients receiving dabigatran, rivaroxaban, or apixaban, revealed nonsignificant changes in peak levels with apixaban and dabigatran. Rivaroxaban peak levels, however, were significantly lower in the postbariatric surgery cohort, suggesting impaired absorption.[5] Other smaller studies suggest minimal influence of anatomic changes on rivaroxaban pharmacokinetics, but were notably limited by single dose response assessments and small sample sizes.[6−8] Prior to the current study the clinical significance of past findings was unclear, but it appears based on the results presented here that alterations in anticoagulant pharmacokinetics as a result of bariatric surgery may not impact clinical outcomes.

DOACs are currently the preferred agents for anticoagulation in the general NVAF population based on similar efficacy in reducing the risk of stroke or systemic embolism with a superior safety profile compared with warfarin.[18] Furthermore, their use is associated with fewer dietary restrictions, minimal drug-drug interactions, and standardized dosing. The results of this study showed no difference in outcomes between warfarin and DOACs in the bariatric population and may represent another potential avenue for expanded DOAC use.

This is the largest study to date evaluating clinical outcomes associated with oral anticoagulants in a bariatric surgery population and the first to compare warfarin to the DOACs. There are, however, several limitations to mention. Despite the large sample size, low event rates may have limited the ability to detect a difference between groups. The use of billing codes for identification of comorbidities and clinical outcomes implies the potential for misclassification. In addition, residual confounding between treatment groups cannot be ruled out despite the use of robust propensity matching techniques. The most notable of these is obesity, which is consistently underreported with ICD codes. The time in therapeutic range for patients receiving warfarin was also not available in the OptumLabs Data Warehouse. Finally, the retrospective, observational nature of the study limits the ability to draw conclusions regarding causality.

To conclude, in this study the safety and efficacy of oral anticoagulant use for AF in the bariatric population was similar to that of a nonbariatric surgery population. In addition, DOACs demonstrated similar efficacy and safety

compared with warfarin in bariatric surgery patients and appear to be a reasonable alternative to warfarin.

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Authors Contribution

Abby Hendricks: conceptualization, methodology, investigation, writing – original draft, visualization, project administration; Joseph Zieminski: conceptualization, methodology, investigation, writing – review & editing, supervision; Xiaoxi Yao: methodology, software, resources, data curation shannon dunlay: methodology, writing – review & editing; Lindsey Sangaralingham: methodology, software, formal analysis, data curation; John G. O'Meara: writing –review & editing, supervision; Theocles Herrin: software, formal analysis, data curation, writing – review & editing, visualization; Scott Nei: conceptualization, methodology, investigation, writing – review & editing, supervision, funding acquisition.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2020.09.020.

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