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Early hip fracture surgery is safe for patients on direct oral anticoagulants

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Abstract

Objectives: To determine how preoperative direct oral anticoagulant (DOAC) use affects rates of blood transfusion, clinically important blood loss, and 30-day mortality in patients with hip fracture undergoing surgery within 48 hours of presentation to the emergency department.

Design: Retrospective cohort study.

Setting: Academic trauma center.

Patients: A total of 535 patients with hip fracture who underwent open cephalomedullary nail fixation or arthroplasty either taking a direct oral anticoagulant or no form of chemical anticoagulant/antiplatelet agent before presentation (control).

Main Outcome Measures: Demographics, time to surgery, type of surgery, blood transfusion requirement, clinically important blood loss, and 30-day mortality.

Results: Forty-one patients (7.7%) were taking DOACs. DOAC patients were older (81.7 vs. 77 years, $P = 0.02$) and had higher BMI (26.9 vs. 24.2 kg/m^2, $P = 0.01$). Time from admission to surgery was similar between DOAC users (20.1 hours) and the control (18.7 hours, $P > 0.4$). There was no difference in receipt of blood transfusion ($P = 0.4$), major bleeding diagnosis ($P = 0.2$), acute blood loss anemia diagnosis ($P = 0.5$), and 30-day mortality ($P = 1$) between the DOAC and control group. This was true when stratifying by type of surgery as well.

Conclusions: Our results suggest that early surgery may be safe in patients with hip fracture taking DOACs despite theoretical risk of increased bleeding. Because early surgery has previously been associated with decreased morbidity and mortality, we suggest that hip fracture surgery should not be delayed because a patient is taking direct oral anticoagulants.

Level of Evidence: Prognostic Level III.

Keywords: trauma, hip fracture, direct oral anticoagulant, outcomes

1. Introduction

Hip fractures are among the most commonly encountered fractures in orthopaedic practice with over 250,000 occurring in the United States annually.[1] The large volume of these fractures leads to high cost to the health care system. In 2010, total cost of managing hip fractures in the United States was estimated at $17 to $20 billion.[2] This number is expected to increase as the population in the United States ages, making management of these fractures an important consideration from both a patient and broader health care cost perspective.

Current clinical guidelines recommend surgery within 48 hours after intertrochanteric and femoral neck fractures to reduce morbidity and mortality.[2,3] Many patients with hip fracture are older, and their management is complicated by polypharmacy.[4] In particular, a proportion of these patients are taking some form of anticoagulant or antiplatelet medication.[5] Previous studies have focused on the effect of preoperative use of clopidogrel, aspirin, and vitamin K antagonists on patients with hip fracture. Current guidelines from the American Academy of Orthopaedic Surgeons supports that hip fracture surgery should not be delayed for patients taking aspirin or clopidogrel at time of presentation, however recognize that there is limited evidence on this subject.[2] Literature on vitamin K antagonists suggests testing International Normalized Ratio (INR) and proceeding to surgery when INR is less than 1.5, usually requiring a treatment to reverse the anticoagulant until the INR threshold is obtained.[3]

To the best of our knowledge, there is a lack of studies on the safety of early hip fracture surgery in patients taking direct oral anticoagulant (DOAC, ie, rivaroxaban, apixaban, dabigatran, etc.) preoperatively. The only study to shed light on this topic is a retrospective study in 2019 from Israel that discovered patients with hip fracture taking DOAC medications had a longer time till surgery, but no evidence of higher bleeding rates compared with patients taking Coumadin and thus were of the opinion that

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earlier surgery would be indicated in DOAC patients.[5] There are not currently recommendations for timing of urgent orthopaedic surgery for patients on DOACs. However, product guides state that DOAC should be discontinued for minimum of 24 hours before surgery.[6] Anecdotally, surgical timing for patients on DOACs preoperatively requiring urgent surgeries is variable. Our objective was to determine how preoperative DOAC use affects rates of blood transfusion, acute blood loss anemia and/or major bleeding diagnosis, and 30-day mortality in patients with hip fracture undergoing surgery within 48 hours of presentation to the emergency department.

2. Materials and Methods

2.1. Study Cohort

A retrospective chart review of all patients with hip fracture (OTA/AO 31-A, B, C) at a single multicenter institution over a 5-year period (December 2012 to December 2017) was performed using *ICD-9* and *CPT* codes. Patients who underwent hemiarthroplasty, total hip arthroplasty (THA), or cephalomedullary femoral nailing (CMN) for intertrochanteric or femoral neck fracture were included. Patients on antiplatelet agents and/or vitamin K antagonists at admission or who underwent surgery more than 48 hours after presentation were excluded. Patients with concomitant injuries, those who received a spinal or epidural anesthesia, and those treated nonoperatively were excluded from the study. Patients were divided and grouped into 2 cohorts based on DOAC use and nonuse (control) at time of admission.

Standard practice at our institution over this period involved the following: All patients underwent similar preoperative and postoperative blood tests, as well as evaluation by internal medicine providers. Definitive orthopaedic surgery was scheduled as an urgent case. Patients proceeded to surgery when medically stable as determined by surgeon's clinical judgment and assistance of comanaging providers. Type of surgical procedure performed was based on surgeon's clinical judgment after assessing radiographic imaging of the fracture and patient demographic/activity level. Postoperatively, patients on DOACs at time of admission had these drugs restarted while DOAC nonusers were started on deep vein thrombosis prophylaxis based on surgeon preference. Patients were made weight-bearing as tolerated immediately after surgery unless contraindication was present.

2.2. Data Collection

Demographic and medical data were collected retrospectively after the study design was approved by the institutions review board. The time to surgery (TTS) was calculated using the time from hospital presentation to time that surgery started as recorded in the medical chart. The primary end point was clinically important blood loss, determined by receipt of transfusion, acute blood loss anemia diagnosis, and/or major bleeding diagnosis. Receipt of transfusion was defined as transfusion of red blood cell products intraoperatively or during inpatient postoperative stay. Our institutional transfusion threshold at time of study was 7g/dL or in patients with symptomatic anemia (tachycardia, cardiac ischemia, shortness of breath, weakness, fatigue, change in mental status, etc). Acute blood loss anemia diagnosis was determined through medical chart review for diagnosis of acute blood loss anemia in the medical problem list for the patient's admission. Diagnosis of major bleeding was based on the definition for "major bleeding in surgical studies" from the Scientific and Standardization Subcommittee on Control of Anticoagulation,[7] primarily being drop in hemoglobin of $\geq$2g/dL or transfusion of $\geq$2 units of whole or red blood cells. All-cause mortality within 30 days of surgery was also collected. Data on use of incisional wound vac, subsequent incision and drainage for seroma or hematoma, and surgical site infection were recorded. Criteria for the application of incisional wound vac, subsequent incision and drainage, and diagnosis of surgical site infection were determined based on surgeon's clinical judgment.

2.3. Statistical Analysis

Statistical analyses were performed with SPSS 25.0 software package (SPSS, Chicago, IL). Descriptive data included mean and SD for continuous variables and number and frequencies for categorical variables to describe patient baseline characteristics, surgery types, and clinical outcomes. Fisher exact tests and the Student *t*-test were used to compare categorical and continuous data, respectively. Logistic regression was used to control for baseline differences between cohorts. A P value of <0.05 was considered statistically significant.

3. Results

There were 535 patients who met inclusion criteria for this study. Forty-one patients (7.7%) were taking DOACs at the time of presentation to the hospital. Patient data and outcomes are described in Table 1. Patients using DOACs were older (81.7 vs. 77 years, $P = 0.02$) and had higher BMI (26.9 vs. 24.2 kg/m^2, $P = 0.01$). Operative time and time from admission to surgery were similar between DOAC users and the control group (20.1 vs. 18.7 hours, $P = 0.43$). A similar proportion of DOAC users and controls underwent CMN surgery (56.1% [23] vs. 62.1% [307], $P = 0.5$). Patients using DOACs had a lower preoperative hemoglobin (11.2 vs. 11.9, $P = 0.01$) and a smaller change in hemoglobin after surgery (1.0 vs. 1.8, $P < 0.01$) compared with the control group. No difference was found in receipt of blood transfusion (51.2% [21] vs. 43.5% [215], $P = 0.41$), major bleeding diagnosis (46.3% [19] vs. 57.1% [282], $P = 0.2$), acute blood loss anemia diagnosis (41.5% [17] vs. 35.9% [177], $P = 0.5$), and 30-day mortality (4.9% [2] vs. 5.1% [25], $P = 1$) between DOAC and control group.

Subgroup analyses based on surgery type of arthroplasty (including hemiarthroplasty and THA) or CMN was performed. The results are described in Table 2. For patients undergoing arthroplasty, initial preoperative hemoglobin was statistically lower in the DOAC group compared with the control (10.9 vs. 12.4, $P < 0.01$), yet the control group had a significantly larger drop in hemoglobin after surgery compared with the DOAC group (1.6 vs. 0.6, $P = 0.01$). For patients undergoing CMN, there was no difference in preoperative or postoperative hemoglobin levels, but the control group had a larger drop in hemoglobin after surgery compared with the DOAC group (1.9 vs. 1.3, $P = 0.02$). For patients undergoing arthroplasty, no difference in major bleeding diagnosis (33.3% [6] vs. 47.6% [89], $P = 0.3$), acute blood loss anemia diagnosis (33.3% [6] vs. 27.4% [51], $P = 0.5$), and 30-day mortality (5.6% [1] vs. 5.3% [10], $P = 1$) between the DOAC and control group was appreciated. However, receipt of blood transfusion was higher in the DOAC group after undergoing arthroplasty (61.1% [11] vs. 28.9% [54], $P = 0.01$).

TABLE 1

Patient Data and Outcomes

	Direct Oral Anticoagulant (N = 41)	Control (N = 494)	P
Age (years), M (SD)	81.7 (10.4)	77.3 (14.0)	**0.02***
Sex, N (%)			0.17
Male	17 (41.5)	153 (31.0)	
Female	24 (58.5)	341 (69.0)	
BMI (kg/m^2), M (SD)	26.2 (3.1)	24.2 (6.2)	**0.01***
Surgery type, N (%)			0.50
Hemi/THA	18 (43.9)	187 (37.9)	
CMN	23 (56.1)	307 (62.1)	
Time to surgery			
Mean (hours), M (SD)	20.1 (9.7)	18.7 (10.5)	0.43
>24 hours, N (%)	12 (29.3)	103 (20.9)	0.23
>36 hours, N (%)	2 (4.9)	39 (7.9)	0.76
Preoperative Hgb, M (SD)	11.2 (1.6)	11.9 (1.8)	0.01
Postoperative Hgb, M (SD)	10.2 (1.4)	10.1 (1.9)	0.6
Δ Hgb, M (SD)	1.0 (1.2)	1.8 (1.7)	<0.01
Transfusion, N (%)	21 (51.2)	215 (43.5)	0.41
Major bleeding, N (%)	19 (46.3)	282 (57.1)	0.19
Acute blood loss anemia, N (%)	17 (41.5)	177 (35.9)	0.5
30-day mortality, N (%)	2 (4.9)	25 (5.1)	1

Bold entry to highlight statistical significance.
*$P < 0.05$.
BMI, body mass index; Hemi/THA, hemiarthroplasty/total hip arthroplasty; CMN, cephalomedullary nail; Hgb, hemoglobin; Δ, change.

Logistic regression was performed to correct for preoperative hemoglobin differences between DOAC and control groups. When adjusted for preoperative hemoglobin levels, DOAC use was no longer significantly associated with receipt of blood transfusion ($P = 0.3$).

In the CMN subgroup, no difference in receipt of blood transfusion (43.5% [10] vs. 52.4% [161], $P = 0.5$), major bleeding diagnosis (56.5% [13] vs. 62.9% [193], $P = 0.7$), acute blood loss anemia diagnosis (47.8% [11] vs. 41.0% [126], $P = 0.5$), and 30-day mortality (4.3% [1] vs. 4.9% [15], $P = 1$) between the DOAC and control group was evident.

Incisional wound vac use was not significantly higher in the DOAC group (n = 3, 7.3%) compared with 20 patients on no anticoagulants (4.1%). There was no statistically significant difference in patients requiring incision and drainage of seroma or hematoma between DOAC users and nonusers (4.9% [2] vs. 1.8% [9], $P = 0.2$). Similarly, DOAC users did not have a greater deep infection rate compared with nonusers (2.4% [1] vs. 1.4% [7], $P = 0.5$).

4. Discussion

Our investigation suggests that patients taking direct oral anticoagulants who underwent early open hip fracture operative fixation did not experience increased clinically significant blood loss measured by receipt of transfusion, acute blood loss anemia diagnosis, and major bleeding diagnosis. The natural concern for patients taking anticoagulants whom require urgent or emergent surgery is complications related to increased blood loss. To the best of our knowledge, there have been no studies examining clinical outcomes regarding blood loss in patients taking DOACs at the time of hip fracture. Previous studies have focused on patients taking warfarin, clopidogrel, or aspirin at the time of hip fracture. Collinge et al[8] performed a retrospective study on the risk for bleeding complications in 1036 patients with hip fracture taking clopidogrel with or without aspirin, warfarin, aspirin only, or no anticoagulant. They found no significant differences in estimated blood loss, transfusion receipt, final blood count, perioperative complications, or mortality. In their study, approximately 40% of patients were taking anticoagulant medications at

TABLE 2

Subgroup Analyses Based on Surgery Type

	Hemi/THA			CMN		
	Direct Oral Anticoagulant (N = 18)	Control (N = 187)	P	Direct Oral Anticoagulant (N = 23)	Control (N = 307)	P
Preoperative Hgb, M (SD)	10.9 (1.4)	12.4 (1.8)	<0.01*	11.4 (1.7)	11.6 (1.7)	0.54
Postoperative Hgb, M (SD)	10.3 (1.1)	10.7 (1.7)	0.16	10.0 (1.6)	9.7 (1.9)	0.29
Δ Hgb, M (SD)	0.6 (1.3)	1.6 (1.5)	0.01*	1.3 (1.0)	1.9 (1.7)	0.02*
Transfusion, % (N)	61.1 (11)	28.9 (54)	0.01 (0.3*)	43.5 (10)	52.4 (161)	0.5
Major bleeding, % (N)	33.3 (6)	47.6 (89)	0.3	56.5 (13)	62.9 (193)	0.7
Acute blood loss anemia, % (N)	33.3 (6)	27.4 (51)	0.5	47.8 (11)	41.0 (126)	0.5
30-day mortality, % (N)	5.6 (1)	5.6 (10)	1	4.3 (1)	4.9 (15)	1

* After adjusting for preoperative hemoglobin using logistic regression analysis.
*$P < 0.05$.
Hemi/THA, hemiarthroplasty/total hip arthroplasty; CMN, cephalomedullary nail; Hgb, hemoglobin; Δ, change.

the time of presentation, demonstrating the widespread use of these medications in patients with hip fractures. Chechik et al[9] examined perioperative blood loss in patients on antiplatelet drugs, finding increased blood loss in patients taking uninterrupted clopidogrel and combined clopidogrel and aspirin. However, they deemed that early hip fracture surgery is safe in these patients because there was no significant difference in mortality or complications. A recent meta-analysis examining the safety of early hip fracture surgery in patients taking clopidogrel found no difference in overall or 30-day mortality, but there was an increase in odds of receiving blood transfusion.[10] Current guidelines from the American Academy of Orthopaedic Surgeons recommend not delaying surgery in patients taking clopidogrel or aspirin.[2] Notably, there are no recommendations on surgical timing for patients taking DOACs in these guidelines.

The most commonly used direct oral anticoagulants are apixaban, rivaroxaban, and dabigatran. Rivaroxaban and apixaban function through direct inhibition of activated factor X, while dabigatran is a competitive inhibitor of thrombin.[11,12] Half-life of DOACs are quite variable with numerous factors such as age and renal function affecting drug clearance, reported half-life ranges from 5 to 17 hours.[6] Suggestions provided by manufacturers of these drugs recommend a minimum of at least 24 hours, and up to 96 hours or more in patients with high bleeding risk, between the last dose and surgery.[6] The European Heart Rhythm Association recommends deferring urgent procedures for at least 12 and preferably 24 hours after last dose of DOAC and obtaining a full coagulation panel; however, this is not based on any cited scientific studies.[13] These recommendations do not take into account the risk of bleeding or nature of the individual procedure.

The benefits of spinal anesthesia for patients with hip fracture have been well documented, especially for those with pulmonary comorbidities.[14] Data support waiting more than 48 hours before performing spinal anesthesia on patients taking DOACs, which would lead to a longer time till surgery and in turn increase the risk for postoperative complications.[15] Therefore, the type of anesthesia primarily used at our institution was general rather than spinal anesthesia to offset these risks.

In our study, the patients taking DOACs were 7.7% of the total population included in this study which is comparable with the similar study described by Scherrmann et al for which of their cohort, around 5% were DOAC users.[5] This supports the generalizability of the data derived from this study.

Patients using DOAC had a mean time from presentation to surgery of 20.1 hours, which was similar to patients on no anticoagulant. This differed from a recent study by Tran et al[16] examining time to hip fracture surgery in patients on anticoagulants. They found that the median TTS was 66.9 hours. Time to surgery likely varies significantly based on preference of surgical team and medical optimization of the patient; however, our study suggests that DOAC use itself should not affect TTS, which is in agreement with the 2019 study out of Israel.[5]

Blood transfusion is variable but common in patients undergoing hip fracture surgery. In our study, rates of blood transfusion were highest in DOAC users undergoing hemiarthroplasty or THA. The rate of transfusion in this group was 61.1%, which is within the range of 23%–69.7% in all patients with hip fracture reported in the literature.[8,10] Furthermore, blood transfusion has been shown to be associated with increased risk of postoperative infection for THA.[17] However, this was primarily focused on elective THAs rather than trauma, and there was no direct correlation between DOAC use and increased risk of deep infection in this study.

Another theoretical concern for patients on DOACs undergoing surgery is increased drainage and risk of hematoma formation, which could lead to an increased deep infection rate. Our study did not find a significant increase in rate of incisional wound vac use, incision and drainage of seroma or hematoma, or deep infection rate in DOAC users. After hip fracture surgery, superficial surgical site infection rates in literature vary from 0.7% to 7.3% and 1.6%–5.1% for deep infection.[18–23] This correlated with the deep infection rate in the DOAC and control groups for this study, 2.4% and 1.4%, respectively.

This study is not without limitations. Limitations include the retrospective design of the study and relatively small number of patients on DOACs. This led to the inability of stratifying patients by the type of DOAC they were taking. Studies with a larger sample size or a prospective design should be conducted on the clinical impact of DOAC use on patients with hip fracture; particularly when the type of DOAC could be stratified. In addition, the main outcome of this study was clinically important blood loss. Bleeding is difficult to quantify; therefore, we used indirect measures of bleeding that were deemed clinically relevant. The measures used (acute blood loss anemia diagnosis, transfusion required, and major bleeding) are similar to those used in other studies of blood loss in surgical patients.[7,9] Despite these limitations, this study expands the growing body of literature on preoperative anticoagulant use in patients with hip fracture. The findings suggest little to no difference in DOAC users as the rates of bleeding and mortality are consistent with those reported in the literature.[7–10,24] While no significant difference was found between incisional wound vac use, incision and drainage, or deep infection rate, this study was underpowered to detect such differences. However, rates of incision and drainage and deep infection are consistent with those reported in the literature.[18–23]

Previous studies have demonstrated the safety of performing early surgery in patients using vitamin K antagonists and antiplatelet agents despite the theoretical increased bleeding risk.[2,3,5,6] In our study, DOAC users undergoing arthroplasty were approximately twice as likely to receive blood transfusion. However, this difference seems to be due to their lower hemoglobin levels preoperatively because after adjusting for preoperative hemoglobin levels (10.9 for the DOAC group and 12.4 in the control group), DOAC use was no longer significantly associated with receipt of blood transfusion. To the best of our knowledge, this is the first study explicitly examining the impact of preoperative DOAC use on clinically important blood loss in patients with hip fracture undergoing surgery. Our results suggest that early surgery may be safe in patients taking DOACs despite theoretical risk of increased bleeding, but further investigations with larger DOAC patient populations should be completed. In conclusion, as early surgery has previously been associated with decreased morbidity and mortality, we suggest that hip fracture surgery should not be delayed because a patient is taking direct oral anticoagulants.

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