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Effect of preinjury warfarin use on outcomes after head trauma in Medicare beneficiaries

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Abstract

Background—Elderly Americans are at increased risk of head trauma, particularly fall related. The effect of warfarin on head trauma outcomes remains controversial.

Methods—Medicare beneficiaries with head injuries from 2009 to 2011 were identified by International Classification of Diseases (ICD)-9 code. Preinjury warfarin use was determined using Part D claims. Multiple logistic regression models determined the association of preinjury warfarin on need for hospitalization, intensive care unit care, and occurrence of intracranial hemorrhage. Association between warfarin and in-hospital mortality was assessed using a Cox proportional hazard model.

Results—Of 11,078 head injured patients, 5.2% were injured while on warfarin. Preinjury warfarin increased the odds of intracranial hemorrhage by 40% and doubled the risk of 30-day in-hospital mortality after adjusting for demographic and clinical factors.

Conclusions—Warfarin at the time of head injury increases the risk of adverse outcomes in Medicare beneficiaries with head injuries. Caution should be used when initiating anticoagulation in elderly Americans at risk for trauma.

Keywords

Elderly; Trauma; Warfarin; Coumadin; Intracranial hemorrhage; Head injury

Over 2 million Americans, many of them elderly, are started on warfarin annually, for various indications.¹ The rapid aging of the American population suggests that the number of chronically anticoagulated elderly patients will continue to grow in the coming years.² Older individuals are at unique risk of injury because of age-related deconditioning that predisposes them to injury, particularly because of falls.³ Furthermore, frailty and comorbidities predispose older patients to worse outcomes after injury compared with younger patients.⁴ Warfarin use at the time of injury may exacerbate outcomes, in particular after head injury where there is a risk of catastrophic intracranial hemorrhage (ICH).⁵

Multiple studies have examined the effect of warfarin on outcomes after head injury. While some have shown that warfarin increases the risk of mortality,^{5–9} others have found

equivalent outcomes for warfarin users compared with patients who are not on warfarin^{10–12}. However, the majority of these studies have been single center or locoregional studies and have focused on ICH alone. To date, there is little national data on the impact of warfarin on the incidence of ICH after head injury and associated outcomes despite widespread use of warfarin in the growing US elderly population. Additionally, existing studies have struggled to correctly identify warfarin users, something that is often not accurately recorded in inpatient records.

Therefore, we used prescription drug claims of elderly beneficiaries who were on warfarin in the weeks before sustaining head injury. We sought to determine the effect of preinjury warfarin use on postinjury outcomes. We hypothesized that warfarin use at the time of injury would increase the incidence of ICH and result in more adverse outcomes including hospital admission, intensive care unit (ICU) care, and 30-day in-hospital mortality.

Methods

Data source and subject selection

Inpatient, limited outpatient (Medicare Provider and Analysis Review) and Part D (prescription drug use) event files (2009 to 2011) were queried for a 5% random national sample of Medicare beneficiaries. Inclusion in the study was limited to patients who were aged 65 or older on January 1, 2009 and had at least 1 year of continuous Part A and B coverage as well as 12 months of continuous Part D enrollment without health maintenance organization (Part C) for any year to assure completeness of data ($n = 864,604$).

Medicare Provider and Analysis Review was used to obtain variables related to initial presentation after head injury and subsequent hospitalization including diagnoses (up to 10), procedures (up to 10), need for ICU care, hospital length of stay (LOS), ICU–LOS, and to calculate each patient's Elixhauser comorbidity index.¹³ Similarly, outpatient claims files were used to determine patient diagnoses (up to 20) and Elixhauser index for patients who were treated and released after visits to the emergency room after head injury. Demographic factors (age, race, sex) were obtained from Medicare denominator files. Part D claims were used to obtain medication name, strength, date of prescription, and date of prescription fill. Injury severity scores (ISS) were calculated using ICDMAP-90 software (Johns Hopkins University, Baltimore, MD).

Case identification

We identified head-injured patients by encounters in the emergency room or admission to the hospital with an ICD-9 code indicating any injury at or above the brow line anteriorly and skull base posteriorly (concussion, skull fracture with or without ICH, and/or ICH alone; Appendix I). The presence of concomitant long bone fractures and torso injuries were also noted (Appendix II). A 2-month wash in period was allowed to measure exposure to drugs of interest.

Patients were considered warfarin users if they had 2 or more Part D claims (prescription fills) for warfarin/Coumadin in the 60 days before their head injury encounter as long as those prescriptions were filled on different dates. Our definition of preinjury warfarin use

ensures that our study patients were prescribed warfarin, which they took with enough regularity to refill it at least once in the immediate preinjury period. We also used Part D claims to identify the use of antiplatelet drugs (Appendix III) before injury using the same method used for warfarin use.

Outcomes of interest

Patients were considered to have sustained ICH as a result of head injury if one or more of their diagnosis codes included subdural, extradural, subarachnoid, and unspecified ICHs because of injury and/or cerebral lacerations and contusions (Appendix I). We first examined ICH incidence and need for hospitalization after head injury based on warfarin exposure. We then compared subsequent outcomes (need for ICU care, hospital LOS, ICU-LOS, 30-day in-hospital mortality) between warfarin users and nonusers who required hospitalization. In-hospital mortality was measured at 30 days based on the a priori assumption that deaths after more prolonged hospitalizations would be unlikely to be clinically attributable to warfarin use at the time of head injury.

Statistical analysis

Demographic (age, sex, race), clinical (Elixhauser comorbidity index), injury characteristics (concomitant long bone fracture, torso injury, ISS), and outcomes of warfarin users were compared with nonusers with univariate tests of association. Chi-square tests were used for categorical variables, Wilcoxon rank-sum tests for non-normally distributed continuous variables, and *t* tests for normally distributed continuous variables.

Multiple logistic regression analyses were used to examine the association of warfarin use with the occurrence of ICH and need for hospitalization in all head-injured patients while controlling for demographic, clinical, and presence of long bone fractures and/or torso injuries. Factors with univariate comparison ($P \leq .2$) or clinical importance were included in both models. The final model for odds of hospitalization also included ICH. Subgroup analyses were then performed to measure the independent effect of warfarin use on outcomes for patients hospitalized after head injury using a multiple logistic regression model for need for ICU care and a Cox proportional hazards model for 30-day in-hospital mortality. These analyses controlled for demographic and clinical factors considered in the hospital admission model described above. For the mortality model, the need for ICU care and ISS were also considered as covariates.

This study was deemed exempt by the University of Massachusetts Medical School institutional review board and was approved by the Center for Medicare and Medicaid Services via RESDAC. Analyses were performed using SAS 9.2 (SAS Institute, Cary NC, 2013).

Results

Of the 864,604 patients meeting eligibility criteria, 11,078 (1.3%) suffered head injury between March 2009 and December 2011 (Fig. 1). Head-injured patients were mostly white (85%) women (69%) with greater than or equal to 3 Elixhauser comorbidities (53%), and a mean age of 80 (standard deviation 8.4) years. A majority of head-injured patients ($n =$

9791, 88%) had isolated head injury with few having torso ($n = 664$, 6.0%) or long bone ($n = 742$, 6.7%) trauma. Five hundred seventy-two patients (5.2%) were exposed to warfarin before head trauma according to our criteria. Warfarin users were more likely to be female, older, and have higher Elixhauser and ISS scores than nonusers (Table 1). Antiplatelet drug use at the time of head injury was also lower among patients using warfarin. Warfarin users had lower rates of concomitant torso trauma while rates of long bone fracture were similar across both groups.

Warfarin users were more likely to sustain ICH and to require hospitalization but had no difference in ICU utilization once hospitalized (Table 2). Among those who were hospitalized and survived to discharge (or to 30 days), hospital LOS and ICU LOS were similar among warfarin users and nonusers. However, 30-day in-hospital mortality was nearly twice as high for warfarin users compared with nonusers (12% vs 6.8%, $P < .01$).

In multivariable analysis, preinjury warfarin use was an independent predictor of sustaining ICH after head injury (adjusted odds ratio [AOR] 1.4, 95% confidence interval [CI] 1.2 to 1.6) but was not a predictor of requiring hospitalization (AOR 1.2, 95% CI .99 to 1.5) (Fig. 2). Age 75 to 84 (AOR 1.7, 95% CI 1.5 to 1.8), age greater than or equal to 85 (AOR 2.0, 95% CI 1.8 to 2.2), male sex (AOR 1.5, 95% CI 1.4 to 1.7), Asian race (AOR 1.5, 95% CI 1.2 to 1.9), Elixhauser index greater than or equal to 3 (AOR 1.2, 95% CI 1.1 to 1.3), concomitant torso injury (AOR 1.6, 95% CI 1.4 to 1.9), concomitant long bone fracture (AOR 1.3, 95% CI 1.1 to 1.5), and antiplatelet medication use (AOR 1.2, 95% CI 1.0 to 1.4) were also independent predictors of ICH. Similarly, age 75 to 84 (AOR 1.2, 95% CI 1.1 to 1.4), age greater than or equal to 85 (AOR 1.3, 95% CI 1.1 to 1.4), male sex (AOR 1.3, 95% CI 1.1 to 1.4), Elixhauser index greater than or equal to 3 (AOR 1.1, 95% CI 1.0 to 1.3), concomitant long bone fracture (AOR 3.2, 95% CI 2.6 to 4.0), concomitant torso trauma (AOR 5.8, 95% CI 4.4 to 7.5) and ICH (AOR 13, 95% CI 11 to 14) were all independent predictors of requiring hospitalization after head injury.

Among hospitalized patients ($n = 6,734$), there was no difference in odds of requiring ICU care between warfarin users and nonusers (AOR 1.2, 95% CI .95 to 1.5). ICH conferred more than 3 times the odds of needing ICU care (AOR 3.5, 95% CI 3.1 to 4.0). Hispanic race (AOR 1.4, 95% CI 1.1 to 1.7) and the presence of torso injury (AOR 1.8, 95% CI 1.5 to 2.1) were also significant predictors of needing ICU care. Preinjury warfarin use doubled the risk of 30-day in-hospital mortality (AHR 2.0, 95% CI 1.5 to 2.6). Age greater than or equal to 85 years (AHR 1.3, 95% CI 1.0 to 1.7), ICH (AHR 2.2, 95% CI 1.5 to 3.4), and ISS per 1 unit (AHR 1.06, 95% CI 1.05 to 1.07) were also significant predictors of mortality. Elixhauser index and antiplatelet use were not independent predictors of in-hospital mortality.

Comments

This was a retrospective review of a national sample of Medicare beneficiaries evaluated for head injury. We used Part D prescription drug claims to more accurately identify preinjury warfarin use and determine the anticoagulant's effect on injury outcomes. Just over 1% of our national cohort was admitted for a head injury during our data period. If we were to

extrapolate to the entire US Medicare population, an estimated 73,000 Medicare beneficiaries are expected to be admitted for head injury annually.

Overall, 5.2% of patients in our national sample were taking warfarin before sustaining head injury and warfarin use increased with age, from 3.2% in 65- to 75-year-olds to 6.2% in 85- to 104-year-olds. This is slightly lower than rates reported in other studies (7.3% to 19%) likely because of our strict criteria for identifying warfarin use.^{5-8,10,14} Based on anticipated aging of the US population and high prevalence of anticoagulation among elderly Americans,^{1,2,15} our nation's healthcare system will be flooded with elderly patients who suffer head injury while anticoagulated in the near future. Thus, our finding that preinjury warfarin use among Medicare beneficiaries increased the risk of ICH and mortality after sustaining head injury, even after adjusting for potential confounders including injury severity and antiplatelet medication use, is concerning.

The risk of injury because of increasing frailty and decreasing cognition increases with age.¹⁶ Once injured, elderly patients are at increased risk of poor outcomes after trauma, in particular after head injury.^{17,18} Meanwhile, warfarin is commonly prescribed for atrial fibrillation and other comorbidities, which are also more prevalent with advancing age.¹⁹

While the current literature demonstrates a dramatic decrease in atrial fibrillation-related strokes^{20,21} and venous thromboembolism because of the use of anticoagulants,²² studies regarding the safety of these medications have shown an increased risk of bleeding complications including ICH particularly for elderly patients.^{23,24} Importantly, many of these studies do not include traumatic ICH as an outcome, meaning that they could be overlooking serious effects of anticoagulation in the injury-prone elderly. As the process of aging progresses, the benefits of chronic anticoagulation may no longer outweigh the risks. Considering these risks is particularly important given the influx of newer anticoagulants that are being aggressively marketed to older American's with publically financed prescription drug coverage.

Our study indicates that warfarin use increases a patients' risk of incurring ICH in the setting of head injury by 40%. Antiplatelet use also conferred a slight increase in this risk of ICH, but the effect was less impressive. Our claims data did not contain exact mechanism of injury and physiologic markers of injury severity; thus, it was difficult to determine if the difference in the occurrence of ICH between the warfarin users and nonusers is attributable solely to warfarin exposure. However, even after adjusting for the presence of other injuries such as torso injuries and long bone fractures (which may serve as markers for polytrauma), the effect of warfarin on the odds of ICH remained significant. Thus, our findings support previous recommendations to automatically admit elderly patients on warfarin even in the face of normal examinations and imaging because of risk of potentially catastrophic, late-appearing head bleeds.^{25,26}

We found that patients on warfarin at the time of injury had 2 times the risk of 30-day in-hospital mortality compared with those not on warfarin. Others have also reported increased mortality in anticoagulated traumapatients.⁵⁻⁷ However, some have suggested that higher mortality in anticoagulated elderly trauma patients is attributable more to the effects of age

and comorbidities than the effects of warfarin exposure.^{10,25} Studies comparing the effect of therapeutic and supratherapeutic International normalized ratio (INRs) to normal INRs have found worse head injury outcomes, including 5 times the odds of dying, among those with elevated INRs.¹⁴ This would indicate that the driving force behind the elevated mortality risk in warfarin users is because of the anticoagulant effect itself rather than the presence of comorbidities that may be present in warfarin users. When we controlled for both age and comorbidities in our cohort, the effect of warfarin use on mortality after head injury remained significant.

There are several limitations to this study. As with all administrative data, we did not have access to some clinical information such as the exact mechanism of injury, laboratory values measuring the effectiveness of warfarin exposure, radiologic findings documenting exact severity of head injury, and methods, if any, for coagulopathy reversal. While we measured the effect of prescription antiplatelet agents on outcomes, Aspirin which is the most commonly used antiplatelet agent is available over the counter and are not reflected in Part D data.

Despite these important limitations to our knowledge, ours is one of the few national studies on the impact of warfarin on head injury outcomes. In comparison, previous research has largely been limited to locoregional studies that relied on reported use of warfarin at the time of presentation.^{6,8,14,25} Additionally, our use of prescription drug claims with a strict definition for warfarin exposure more accurately describes the impact of warfarin on head injury outcomes than other studies attempting to answer the same question using institutional databases and chart review.

We found that warfarin use at the time of head injury among Medicare beneficiaries aged greater than or equal to 65 years confers an increased risk of ICH and mortality even when accounting for age, comorbidities, injury severity, and prescription antiplatelet agents. As the US population continues to age and the anticoagulated elderly population continues to grow, physicians will need to carefully balance the benefits of anticoagulation with the risks of potentially catastrophic bleeding complications.

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Appendix I

ICD-9 codes used to determine occurrence of head injury

Injury site	ICD-9 code
Skull fracture codes	
Fracture vault of skull	800.xx

Injury site	ICD-9 code
Fracture base of skull	801.xx
Other skull fracture	803.xx
Multiple skull fractures	804.xx
Concussion	850.xx
Intracranial hemorrhage codes	
Intracranial hemorrhage following injury	852.xx
Other intracranial hemorrhage following injury	853.xx
Intracranial injury following injury NOS	854.xx
Skull fracture, vault of skull with intracranial hemorrhage	800.1x–800.4x; 800.6x–800.9x
Fracture, base of skull with intracranial hemorrhage	801.1x–801.4x; 801.6x–801.9x
Other skull fractures with intracranial hemorrhage	803.1x–803.4x; 803.6x–803.9x
Multiple skull fractures with intracranial hemorrhage	804.1x–804.4x; 804.6x–804.9x
Cerebral laceration	851.xx
Subarachnoid hemorrhage following injury	852.0x–852.1x
Subdural hemorrhage following injury	852.2x–852.3x
Extra dural hemorrhage following injury	852.4x–852.5x
Other intracranial hemorrhage following injury	853.xx
Intracranial injury NOS	854.xx

NOS = Not otherwise specified.

Appendix II

ICD-9 codes indicating the presence of torso injury and long bone fractures

Site	ICD-9 code
Thoracic injury	860.xx, 861.xx, 862.xx, 901.xx, 807.xx
Rib fractures	807.0–807.4
Hemo/pneumothorax	860.0–860.5
Pulmonary contusion	861.31
Thoracic vascular injury	901.xx
Abdominal injury	863.xx, 864.xx, 865.xx, 866.xx, 868.xx, 869.xx, 902.xx
Liver injury	864.xx
Splenic injury	865.xx
Renal injury	866.xx
Small bowel injury	863.2–863.3
Large bowel injury	863.4–863.5
Intra-abdominal great vessel injury	902.xx
Pancreatic injury	863.81–863.84; 863.91–863.94
Other	868.xx, 869.xx
Pelvic injury	867.xx, 808.xx
Pelvic fracture	808.xx

Site	ICD-9 code
Urological injury	867.0–867.3
Gynecological injury	867.4–867.5
Humerus fracture	812.xx
Radius/ulna fracture	813.xx
Femur fracture-neck	820.xx
Femur fracture-shaft	821.xx
Patella fracture	822.xx
Tib/fib fracture	823.xx
Ankle fracture	824.xx

Appendix III

Medications classified as antiplatelet drugs available to outpatients by prescription

Generic	Brand
Adenosine diphosphate receptor inhibitors	
ogrel	Plavix
Prasugrel	Effient
Ticagrelor	Brilinta
Ticlopidine	Ticlid
Phosphodiesterase inhibitors	
Cilostazol	Pletal
Adenosine reuptake inhibitors	
Dipyridamole	Persantine

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Figure 1.

Patient selection. ⁺Warfarin use defined as 2 or more prescriptions for warfarin filled on 2 different dates within 60 days before head trauma. *Includes subdural, epidural, subarachnoid hemorrhages, intracranial hemorrhage NOS, and cerebral laceration/contusion. **Includes skull fracture and concussion without mention of intracranial hemorrhage.

Figure 2.

Adjusted odds ratios for head injury outcomes for warfarin[§] users compared with those not on warfarin at the time of injury (Medicare beneficiaries ≥ 65, 2009 to 2011). *Odds of ICH ($n = 11,078$) c-statistic = .60, Hosmer–Lemeshow goodness-of-fit test, $P = .19$. Controlled for age, sex, race, Elixhauser score, concomitant torso trauma, concomitant long bone fracture, and use of antiplatelet agents. **Odds of requiring hospitalization after head injury ($n = 11,078$) c-statistic = .81, Hosmer–Lemeshow goodness-of-fit test, $P < .01$. Controlled for age, sex, Elixhauser score, concomitant torso injury, concomitant long bone fracture, and ICH. ***Odds of requiring ICU care among those hospitalized for head injury ($n = 6,734$) c-statistic = .65 and Hosmer–Lemeshow goodness-of-fit test, $P = .17$. Controlled for age, sex, race, Elixhauser score, concomitant torso injury, and ICH. ****Hazard ratio for in-hospital death within 30 days of admission for head injury controlled for ISS, age, sex, race, ICH ($n = 6039$, 463 events) c-index = .72, Hosmer–May goodness-of-fit test, $P < .01$. Controlled for age, sex, race, ICH, and ISS. ^See Appendix I. §Two or more prescriptions for warfarin as measured by Part D claims in the 60 days before head injury.

Table 1

Comparison of demographic and clinical characteristics of Medicare beneficiaries 65 years (March 2009 and December 2011) who were and were not on warfarin at the time of head injury* (*n* = 11,078)

	Preinjury warfarin [†] (<i>n</i> = 572)	No preinjury warfarin (<i>n</i> = 10,506)	<i>P</i> value [‡]
Demographic characteristics			
Female	418 (73)	7,189 (68)	.02
Race/ethnicity			.08
White, not Hispanic	507 (89)	8,873 (84)	
African American	24 (4.2)	599 (5.7)	
Hispanic	28 (4.9)	613 (5.8)	
Asian/Pacific Islander/Other	13 (2.3)	421 (4.0)	
Age groups			<.01
65–74	102 (18)	3,077 (29)	
75–84	239 (42)	3,925 (37)	
85–104	231 (40)	3,504 (33)	
Clinical characteristics			
Elixhauser index			<.01
0	57 (10)	2,212 (21)	
1	48 (8.4)	1,363 (13)	
2	60 (10)	1,412 (13)	
3	407 (71)	5,519 (53)	
Antiplatelet agent [§]	23 (4.0)	760 (7.2)	<.01
ISS			<.01
Minor (1–9)	165 (33)	3,718 (41)	
Moderate (10–15)	41 (8.2)	774 (8.6)	
Severe (16–24)	259 (52)	3,954 (44)	
Critical (25+)	33 (6.6)	553 (6.2)	
Isolated trauma to the head	519 (91)	9,272 (88)	.07
Long bone fracture(s) present	40 (7.0)	702 (6.7)	.77
Torso injury present	19 (3.3)	645 (6.1)	.01

Data are expressed as number (percent).

ISS = injury severity score.

* See Appendix I.

[†]Two or more prescriptions for warfarin as measured by Part D claims in the 60 days before head injury.

[‡]Chi-square test of association.

[§]Two or more prescriptions for an antiplatelet agent as measured by Part D claims in the 60 days before head injury.

Table 2
Comparison of outcomes between Medicare beneficiaries 65 years (March 2009 and December 2011) who were and were not on warfarin at the time of head Injury* (n = 11,078)

	Preinjury warfarin [†] (n = 572)	No preinjury warfarin (n = 10,506)	P value [‡]
All head injury patients			
Development of ICH	373 (65)	5,944 (57)	<.01
Need for hospital admission	390 (68)	6,344 (60)	<.01
Hospitalized head injury patients (n = 376)		(n = 6,231)	
Hospital LOS [§]	5 (3–8)	4 (2–8)	.22
Need for ICU care	214 (57)	3,370 (54)	.28
ICU LOS [§]	3 (2–5)	3 (1–5)	.64
Died within 30 days of injury	45 (12)	421 (6.8)	<.01

Data are expressed as number (percentage) or median (interquartile range).

ICH = intracranial hemorrhage; ICU = intensive care unit; LOS = length of stay.

* See Appendix I.

[†] Two or more prescriptions for warfarin as measured by Part D claims in the 60 days before head injury.

[‡] Chi-square test of association for categorical variables; Wilcoxon rank-sum test (non-normally distributed data).

[§] Among those who survived to discharge or 30 days, whichever came sooner.