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Risk of Traumatic Intracranial Hemorrhage in Patients with Head Injury and Preinjury Warfarin or Clopidogrel Use

Daniel K. Nishijima, MD, MAS, Steven R. Offerman, MD, Dustin W. Ballard, MD, David R. Vinson, MD, Uli K. Chettipally, MD, MPH, Adina S. Rauchwerger, MPH, Mary E. Reed, DrPH, James F. Holmes, MD, MPH, and for the Clinical Research in Emergency Services and Treatment (CREST) Network

Department of Emergency Medicine, UC Davis School of Medicine, (DKN, JFH) Sacramento, CA; Kaiser Permanente South Sacramento Medical Center, (SRO) Sacramento, CA; Kaiser Permanente San Rafael Medical Center and Medical Offices, (DWB) San Rafael, CA; Kaiser Permanente Sacramento Medical Center and Medical Offices, (DRV) Sacramento, CA; Kaiser Permanente South San Francisco Medical Center and Medical Offices, (UKC) San Francisco, CA; Kaiser Permanente Division of Research, (ASR, MER) Oakland, CA

Abstract

Objectives—Appropriate use of cranial computed tomography (CT) scanning in patients with mild blunt head trauma and pre-injury anticoagulant or antiplatelet use is unknown. The objectives of this study were: 1) to identify risk factors for immediate traumatic intracranial hemorrhage (tICH) in patients with mild head trauma and preinjury warfarin or clopidogrel use, and 2) to derive a clinical prediction rule to identify patients at low risk for immediate tICH.

Methods—This was a prospective, observational study at two trauma centers and four community hospitals that enrolled adult emergency department (ED) patients with mild blunt head trauma (initial ED Glasgow Coma Scale score 13 to 15) and pre-injury warfarin or clopidogrel use. The primary outcome measure was immediate tICH, defined as the presence of ICH or contusion on the initial cranial CT. Risk for immediate tICH was analyzed in eleven independent predictor variables. Clinical prediction rules were derived with both binary recursive partitioning and multivariable logistic regression.

Results—A total of 982 patients with a mean age of 75.4 years (SD $\pm$ 12.6 years) were included in the analysis. Sixty patients (6.1%; 95% CI = 4.7% to 7.8%) had immediate tICH. History of vomiting (relative risk [RR] 3.53; 95% CI = 1.80 to 6.94), abnormal mental status (RR 2.85; 95% CI = 1.65 to 4.92), clopidogrel use (RR 2.52; 95% CI = 1.55 to 4.10), and headache (RR 1.81; 95% CI = 1.11 to 2.96) were associated with an increased risk for immediate tICH. Both binary recursive partitioning and multivariable logistic regression were unable to derive a clinical prediction model that identified a subset of patients at low risk for immediate tICH.

Conclusions—While several risk factors for immediate tICH were identified, the authors were unable to identify a subset of patients with mild head trauma and pre-injury warfarin or clopidogrel use who are at low risk for immediate tICH. Thus, the recommendation is for urgent and liberal cranial CT imaging in this patient population, even in the absence of clinical findings.

Corresponding Author: Daniel Nishijima, MD, MAS, University of California, Davis Medical Center, 4150 V. St. PSSB, 2100, Sacramento, CA 95817, TEL (916) 734.1376; FAX (916) 734.7950; daniel.nishijima@ucdmc.ucdavis.edu.

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INTRODUCTION

Each year, traumatic brain injury (TBI) accounts for an estimated 1.4 million emergency department (ED) visits, 275,000 hospitalizations, and 52,000 deaths in the United States, at an estimated cost of 60 billion dollars.¹ With an aging population, older adults with pre-injury anticoagulant or antiplatelet use represent an increasing proportion of TBI patients evaluated in the ED.² These patients could be well-appearing and have low-impact mechanisms of injury, such as ground level falls,^{3,4} yet frequently have life-threatening traumatic intracranial hemorrhage (tICH) requiring neurosurgical interventions and specialized critical care.^{5,6}

Thus, emergency physicians (EPs) are challenged with identifying which patients with head trauma and pre-injury anticoagulant or antiplatelet use are at high risk for acute tICH and require immediate cranial computed tomography (CT) imaging. Clinical prediction rules based on large, prospective studies accurately identify patients with mild TBI who are at very low risk for tICH (sensitivity range 83% to 100%) and neurosurgical lesions (sensitivity 100%).⁷⁻⁹ These studies, however, excluded or had very few patients with pre-injury anticoagulant or antiplatelet use.

Current mild TBI guidelines for patients with pre-injury anticoagulant or antiplatelet use are largely based on small, retrospective studies that suggest an increased risk for tICH following blunt head trauma.¹⁰⁻¹² For patients with pre-injury anticoagulant use and head trauma, guidelines vary from liberal imaging (cranial CT regardless of loss of consciousness [LOC] or amnesia)¹³ to more limited imaging (cranial CT provided the patient sustain LOC or amnesia).¹⁴ For patients with pre-injury antiplatelet use and head trauma, current guidelines do not list antiplatelet medications as a risk factor for tICH.^{13,15} Thus, confusion exists regarding the appropriate utilization of cranial CT in patients with blunt head trauma and anticoagulant or antiplatelet use.

The objective of this study was to prospectively derive a clinical prediction rule to identify adult patients with mild head injury and pre-injury warfarin or clopidogrel use at low risk for tICH. This study represents a secondary aim of a larger prospective study evaluating the prevalence and incidence of immediate and delayed tICH in this patient population.¹⁶

METHODS

Study Design

This was a prospective, observational, multicenter study conducted at two trauma centers and four community hospitals in northern California. The study was approved by the institutional review boards at all sites with an alteration of informed consent. The sponsors of the study had no role in study design, data collection and analysis, or manuscript preparation. The corresponding author had full access to all the data and had final responsibility for the decision to submit for publication.

Study Setting and Population

Consecutive adult (>18 years old) ED patients with pre-injury warfarin or clopidogrel use (within the prior seven days) and mild blunt head trauma (initial ED Glasgow Coma Scale [GCS] score 13 to 15) were enrolled. We defined blunt head trauma as any blunt head injury regardless of LOC or amnesia. Patients who did not receive cranial CT scans during the index ED visit were excluded from the primary analysis. We also excluded patients with known injuries transferred from outside facilities.

Study Protocol

The treating ED faculty physicians completed standardized questionnaires prior to cranial CT imaging. All physicians participating in the study received an explanation of the questionnaire with definitions of each criterion. Items in the questionnaire were based on a review of the literature on minor head trauma, and included age, mechanism of injury (ground level fall versus non-ground level fall), warfarin use, clopidogrel use, concomitant aspirin use, headache, vomiting, LOC or amnesia, drug or alcohol intoxication, physical evidence of trauma above the clavicles, and abnormal mental status. A ground level fall was defined as a fall from standing height or less. Headache was defined as the presence of any head pain after injury. Vomiting was defined as any post-injury emesis. LOC or amnesia was defined as witnessed LOC or failure of the patient to recall the events of the injury. Drug or alcohol intoxication was defined as clinician impression of intoxication based on history, physical exam, or laboratory testing. Physical evidence of trauma above the clavicles was defined as any external injury to the face, neck, or scalp, and included abrasions, lacerations, contusions and hematomas, or fractures. An abnormal mental status was defined as an initial ED GCS score less than 15. Patients with a GCS score less than 15 but not differing from baseline (e.g., history of dementia) were not considered to have an abnormal mental status.

Cranial CT imaging and hospital admission were at the discretion of the patients' treating physicians. Electronic medical records were reviewed in a standardized fashion by research coordinators and site investigators to assess CT scan results, ED disposition, and hospital course.

At each site, approximately 10% of patients (non-randomly selected) had a separate, independent faculty physician assessment that was masked to and completed within 60 minutes of the initial assessment to evaluate the reliability of pre-selected clinical variables. Data on patients eligible but not enrolled during ED evaluation were abstracted from their medical records to assess for enrollment bias.

Outcomes

The primary outcome measure was the presence of immediate tICH (defined as any ICH or contusion) as interpreted by the staff neuroradiologist on initial ED cranial CT. The patient was considered to have tICH if the radiology report was consistent with tICH. Patients with delayed tICH (initial normal CT but with a repeat CT consistent with tICH) were not considered to meet the primary outcome measure. The secondary outcome measure was the presence of neurosurgical intervention, which was defined as the use of intracranial pressure monitor or brain tissue oxygen probe, placement of burr hole, craniotomy/craniectomy, intraventricular catheter, subdural drain, or the use of mannitol or hypertonic saline.

Data Analysis

Data were compared using STATA for Windows, Rel. 11.0 (STATA Corp., College Station, TX). Normally distributed continuous data were reported as the mean with standard deviations ($\pm$ SDs), and ordinal or non-normally distributed continuous data described as the median with interquartile (25% to 75%) ranges (IQR). Proportions and relative risks are presented with 95% confidence intervals (CI).

Eleven independent predictor variables (age 65 years or older, warfarin use, clopidogrel use, concomitant aspirin use, non-ground level fall mechanism of injury, headache, vomiting, LOC or amnesia, drug or alcohol intoxication, evidence of trauma above the clavicles, abnormal mental status), defined a priori, underwent bivariate testing with chi-square or Fisher's exact test (in instances of small cell size). We used a standard model building

approach as candidate variables predicting immediate tICH (threshold $p < 0.20$) were entered into a multivariable analysis using both binary recursive partitioning and logistic regression. Binary recursive partitioning was conducted with Classification and Regression Trees (CART) software (Salford systems, San Diego, CA). We used the Gini splitting function in CART and set the misclassification costs for missing a tICH at 100:1 (relative cost of 100 for misclassifying one patient with immediate tICH to that of misclassifying one patient without tICH). Logistic regression was conducted with a random-effects model to account for random variation. Model fit was tested using the Hosmer-Lemeshow goodness-of-fit test.¹⁷ Adjusted variables that were significant in the regression model ($p < 0.05$) were included in the clinical prediction rule. Derived prediction rules were validated using internal cross validation for the recursive partitioning model and bootstrap validation for the logistic regression model. We calculated the sensitivity, specificity, and positive and negative predictive values (PPV and NPV) with 95% CIs for both derived models. Inter-rater reliability of independent variables recorded by initial and second physicians are reported as the kappa coefficient and percent agreement.

RESULTS

Between April 2009 and January 2011, 1101 patients were enrolled (83.3% of all eligible patients) (Figure 1). Comparison of patients enrolled and those eligible but not enrolled demonstrated similar characteristics (age, sex, medication use, ED cranial CT, and hospital admission) and outcomes (immediate tICH, neurosurgical intervention, and in-hospital mortality). Overall, 119 patients were excluded from analysis (25 transferred patients, 29 patients with non-mild head trauma, and 65 patients without cranial CT imaging at index ED visit), leaving 982 patients for data analysis.

The mean age in the included cohort was 75.4 years ($SD \pm 12.6$ years) and 464 patients (47.3%) were male. The majority of patients sustained ground level falls (83.6%), were taking warfarin (72.7%), did not sustain LOC or amnesia (81.0%), had evidence of trauma above the clavicles (70.9%), and had normal mental status (89.5%). See Table 1 for additional characteristics of the study population.

There were 60 patients (6.1%; 95% CI = 4.7% to 7.8%) with the primary outcome of immediate tICH diagnosed on initial ED cranial CT. None of the 65 patients who did not receive initial ED cranial CT scans were later diagnosed with immediate tICH, although two patients were lost to follow-up.

Of the 60 patients diagnosed with immediate tICH, there were 12 patients (20.0%; 95% CI = 10.8% to 32.3%) who received neurosurgical interventions. These are listed in Table 2 and most frequently involved craniotomy/craniectomy (7 patients, 11.7%) and mannitol administration (5 patients, 8.3%). Ten of the 60 patients (16.7%; 95% CI = 8.3% to 28.5%) with immediate tICH died during hospitalization.

Clopidogrel use, headache, vomiting, drug or alcohol intoxication, and abnormal mental status were associated with an increased risk for immediate tICH on bivariate analysis ($p < 0.20$) (Table 3). Binary recursive partitioning was unable to derive a prediction rule that reliably identified a subset of patients at low risk for tICH.

Multivariable logistic regression identified vomiting (adjusted odds ratio [aOR] 3.68; 95% CI = 1.55 to 8.76) and abnormal mental status (aOR 3.08; 95% CI = 1.60 to 5.94) as associated with immediate tICH (Table 4). The Hosmer-Lemeshow goodness of fit test had a p value of 0.004, suggesting poor calibration of the model. Test characteristics of the clinical prediction rule consisting solely of these two variables were poor (sensitivity 37%,

specificity 87%, PPV 16%, NPV 95%). All clinical variables measured for inter-rater reliability had substantial agreement (range 91% to 97%) (Table 5).¹⁸

DISCUSSION

We were unable to derive a clinical prediction rule to accurately identify the presence of immediate tICH on cranial CT in patients with mild blunt head trauma and pre-injury warfarin or clopidogrel use. Two clinical variables, vomiting and abnormal mental status, were significantly associated with increased risk for immediate tICH on multivariable logistic regression. These two variables, however, were absent in a substantial number of our cohort of patients with tICH.

To our knowledge this is the first prospective study to evaluate risk factors for immediate tICH in patients with mild head injury and pre-injury anticoagulant or antiplatelet use. Prior retrospective studies were also unable to identify a number of clinical predictors for immediate tICH in this patient population. Li et al. were unable to identify any clinical predictors for abnormal cranial CT scans in patients with head injury and pre-injury warfarin use.¹⁰ Brewer et al found only LOC to be significantly associated with immediate tICH in trauma registry patients with pre-injury warfarin or clopidogrel use and a GCS of 15.³

The results of this study have a number of clinical implications. First, this study suggests that it is difficult to identify a low-risk group of patients with pre-injury warfarin or clopidogrel use and blunt head trauma who may be safely managed without cranial CT imaging. The inability to derive a clinical prediction rule is likely the result of the relative lack of differentiating clinical characteristics between patients with immediate tICH and those without. Patients in our study were relatively well-appearing and homogenous; they were 65 years and older with ground level falls, normal mental status, and few clinical symptoms. However, despite being well-appearing, these patients were still at risk for immediate tICH. Seven of the 60 patients (12%) with immediate tICH had low mechanisms of injury (ground level fall), no clinical symptoms (no history of LOC or amnesia, headache, vomiting), and normal clinical exams (no intoxication, normal mental status, and no evidence of trauma above the clavicles). Second, current National Institute for Health and Clinical Excellence head injury guidelines (updated 2007) recommend urgent (< 1 hour) CT imaging in patients with head injury and pre-injury warfarin use, *provided* they sustain loss of consciousness (LOC) or amnesia.¹⁴ However 45 of 60 (75%) of patients with immediate tICH in our study did not sustain LOC or amnesia. We thus recommend liberal cranial CT imaging for these patients, even those with minimal head trauma who do not sustain LOC or amnesia. Finally, patients with immediate tICH have high morbidity and mortality; 20% required neurosurgical intervention and 17% died during hospitalization. This emphasizes the importance of rapid diagnosis of tICH with cranial CT imaging to determine the need for reversal of anticoagulant or antiplatelet effects with medications and blood products. Patients with delayed reversal of anticoagulation have increased morbidity and mortality.¹⁹ Furthermore, in patients who require immediate neurosurgical intervention, rapid and efficacious reversal to an appropriate international normalized ratio (INR) level is essential; patients with INR levels >1.25 have increased postoperative mortality.^{20,22}

LIMITATIONS

Our results should be interpreted in the context of several limitations. There were relatively few patients who met the primary outcome of immediate tICH (60 patients). However, there were enough outcomes for the accepted ratio of 10 outcomes of interest for every variable entered into the regression model.²³ Furthermore, including more patients with tICH would not resolve the fact that many patients with immediate tICH appeared to have no risk factors

for tICH beyond age and anticoagulant use. The relatively few outcomes also limited our ability to conduct subgroup analyses by type of medication use (warfarin or clopidogrel) or by INR level.

As this was an observational study, CT scans were not obtained on all patients, and ethical considerations prevented CT scanning solely for study purposes. Some patients not undergoing CT scans during their initial ED visits potentially had undiagnosed tICH. However, none were identified in clinical follow-up, which is a reasonable method to evaluate for clinically important outcomes when the definitive test is not ethical or feasible.²⁴

CONCLUSIONS

While we identified several risk factors for immediate traumatic intracranial hemorrhage, we were unable to identify a subset of patients with mild head trauma and pre-injury warfarin or clopidogrel use who are at low risk for immediate traumatic intracranial hemorrhage. We thus recommend urgent and liberal cranial computed tomography imaging in this patient population, even in the absence of clinical findings.

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Figure 1.

Flow of Patients in the Study

CT = computed tomography; tICH = traumatic intracranial hemorrhage

Table 1

Patient Characteristics

Characteristic	n (%) (N=982)
Demographics	
Age, mean (SD), y	75.4 (12.6)
Male sex	464 (47.3)
Mechanism of injury	
Ground level fall	821 (83.6)
Fall from height	36 (3.7)
MVC, < 35 miles per hour	15 (1.5)
MVC, ≥ 35 miles per hour	23 (2.3)
MVC, unknown speed	8 (0.8)
Pedestrian struck by automobile	4 (0.4)
Bicyclist struck by automobile	4 (0.4)
Direct blow	51 (5.2)
Unknown mechanism	15 (1.5)
Other mechanism	5 (0.5)
Medication use *	
Warfarin use	714 (72.7)
Clopidogrel use	279 (28.4)
Concomitant aspirin use	45 (4.6)
Clinical history	
Vomiting	41 (4.2)
Headache	349 (35.5)
Loss of consciousness or amnesia	187 (19.0)
Physical exam	
Alcohol intoxication	34 (3.5)
Any evidence of trauma above the clavicles	696 (70.9)
Trauma to face	367 (37.4)
Trauma to neck	33 (3.4)
Basilar skull fracture	2 (0.2)
Scalp abrasion	149 (15.2)
Scalp contusion	292 (29.5)
Scalp laceration	170 (17.3)
Normal mental status (GCS 15)	879 (89.5)
ED course	
Admitted to hospital	346 (33.1)

SD = standard deviation; MVC = motor vehicle collision; GCS = Glasgow Coma Scale

* 11 patients with concomitant warfarin and clopidogrel use

Table 2

Neurosurgical interventions

Intervention	No. (%) of patients (n=60)
Intracranial pressure monitor or oxygen probe	0
Burr hole	3 (5.0)
Craniotomy/craniectomy	7 (11.7)
Intraventricular catheter placement	2 (3.3)
Subdural drain	2 (3.3)
Mannitol use	5 (8.3)
Hypertonic saline use	0
Total patients with neurosurgical interventions	12 (20.0)

Table 3

Relative risk ratios for the clinical variables for traumatic intracranial hemorrhage (tICH) (bivariate analysis)

Clinical variable	tICH present n/N (%)	tICH absent n/N (%)	Relative risk (95% CI)
Age 65 years and older	50/60 (83.3)	750/922 (81.3)	1.14 (0.59–2.20)
Warfarin use	31/60 (51.7)	683/922 (74.1)	0.40 (0.25–0.65)
Clopidogrel use	30/60 (50.0)	249/922 (27.0)	2.52 (1.55–4.10)
Concomitant aspirin use	4/60 (6.7)	41/922 (4.4)	1.49 (0.56–3.92)
Non-ground level fall mechanism	10/60 (16.7)	151/922 (16.4)	1.02 (0.53–1.97)
Headache	30/60 (50.0)	319/922 (34.6)	1.81 (1.11–2.96)
Vomiting	8/60 (13.3)	33/922 (3.6)	3.53 (1.80–6.94)
Loss of consciousness or amnesia	15/60 (25.0)	172/922 (18.7)	1.42 (0.81–2.49)
Drug or alcohol intoxication	4/60 (6.7)	30/922 (3.3)	1.99 (0.77–5.18)
Trauma above the clavicles	41/60 (68.3)	655/922 (71.0)	0.89 (0.52–1.50)
Abnormal mental status	15/60 (25.0)	88/922 (9.5)	2.85 (1.65–4.92)

Table 4

Adjusted risk for traumatic intracranial hemorrhage (multivariable analysis)

Variable	Adjusted Odds Ratio (95% CI)
Warfarin use	0.62 (0.70–5.49)
Clopidogrel use	1.68 (0.19–14.72)
Vomiting	3.68 (1.55–8.76)
Headache	1.60 (0.93–2.77)
Drug or alcohol intoxication	1.61 (0.50–5.16)
Abnormal mental status	3.08 (1.60–5.94)

Table 5

Inter-rater reliability of clinical variables

Variable	Kappa (95% CI)	% agreement (95% CI)
Glasgow Coma Scale score	0.65 (0.58–0.70)	90.8 (84.9–96.2)
Evidence of trauma above clavicles	0.93 (0.86–1.0)	97.3 (92.2–99.4)
Vomiting	0.65 (0.33–0.97)	96.3 (90.9–99.0)
Headache	0.80 (0.67–0.92)	91.7 (84.9–96.2)
Loss of consciousness or amnesia	0.84 (0.71–0.97)	95.4 (89.6–98.5)
Drug or alcohol intoxication	0.56 (0.00–0.71)	97.3 (92.2–99.4)