Derivation of the Falls Decision Rule to exclude intracranial bleeding without head CT in older adults who have fallen

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Abstract

Background: Ground-level falls are common among older adults and are the most frequent cause of traumatic intracranial bleeding. The aim of this study was to derive a clinical decision rule that safely excludes clinically important intracranial bleeding in older adults who present to the emergency department after a fall, without the need for a computed tomography (CT) scan of the head.

Methods: This prospective cohort study in 11 emergency departments in Canada and the United States enrolled patients aged 65 years or older who presented after falling from standing on level ground, off a chair or toilet seat, or out of bed. We collected data on 17 potential predictor variables. The primary outcome was the diagnosis of clinically important intracranial bleeding within 42 days of the index emergency department visit. An independent adjudication committee, blinded to baseline data, determined the primary outcome. We derived a clinical decision rule using logistic regression.

Results: The cohort included 4308 participants, with a median age of 83 years; 2770 (64%) were female, 1119 (26%) took anticoagulant medication and 1567 (36%) took antiplatelet medication. Of the participants, 139 (3.2%) received a diagnosis of clinically important intracranial bleeding. We developed a decision rule indicating that no head CT is required if there is no history of head injury on falling; no amnesia of the fall; no new abnormality on neurologic examination; and the Clinical Frailty Scale score is less than 5. Rule sensitivity was 98.6% (95% confidence interval [CI] 94.9%–99.6%), specificity was 20.3% (95% CI 19.1%–21.5%) and negative predictive value was 99.8% (95% CI 99.2%–99.9%).

Interpretation: We derived a Falls Decision Rule, which requires external validation, followed by clinical impact assessment. **Trial registration:** ClinicalTrials.gov, no. NCT03745755.

As populations age, emergency departments are managing a growing number of older adults who fall.[1–3] Falling on level ground is the most common cause of traumatic intracranial bleeding.[4–6] Diagnosis of fall-related intracranial bleeding is an important part of assessment for patients in the emergency department. Identification of intracranial bleeding by computed tomography (CT) scan of the head can lead to timely and necessary intervention, such as reversal of anticoagulation therapy and neurosurgery, and may facilitate shared decision-making about next steps in care with patients and families.

Ordering a head CT scan on every older adult who has fallen is inefficient and costly because most do not have intracranial bleeding (studies estimate the rate of bleeding to be about 5%).[7] Overuse of CT in this population prolongs the emergency department visit, which has been shown to increase the rate of delirium[8] while also diverting resources from other emergency patients. Furthermore, not all emergency departments have 24-hour on-site CT scanning facilities, meaning that some of these patients may be transferred to another centre.

The Canadian CT Head rule[9–12] determines the need for head CT in patients with head injuries, but applies to patients who

have experienced disorientation, amnesia or loss of consciousness. No research exists to guide neuroimaging use for older adults who hit their head on falling but do not experience these symptoms. Additionally, guidance from the literature is lacking for older adults who have fallen but cannot recount what happened or did not hit their head. Our aim was to derive a clinical decision rule that applies to all older adults presenting to the emergency department after a fall, and identifies patients who can have clinically important intracranial bleeding ruled out without ordering a head CT.

Methods

Study design

We conducted a prospective cohort study that followed the methodological standards for clinical decision rules in emergency medicine[11] and the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) guidelines.[13] The study coordinating centre was at McMaster University.

Study population

Eleven academic hospitals in Canada and the United States enrolled patients aged 65 years or older who presented to the emergency department within 48 hours of having a fall. The study protocol has been published previously.[14] Patients were eligible if they fell from standing on level ground, off a chair or toilet seat, or out of bed. Patients were included regardless of whether they had hit their head on falling. For patients to be included, the treating emergency physician had to have documented the history and examination findings on a standardized study form at the time of assessment. We excluded patients who were previously enrolled, who lived outside the hospital catchment area, who were transferred from another hospital or who left before completion of their medical assessment. We excluded patients from the study if more than 2 variables were left undocumented on the physician study form. Missed-eligible cases were recorded throughout the study at the 2 primary McMaster University recruitment sites, and during a 60-day recruitment period at all 9 additional sites.

Patient assessment and follow-up

An emergency physician assessed each patient at their index emergency department visit. The decision to order a head CT during the index visit was at the discretion of the treating emergency physician. All patients were then followed for 42 days. The follow-up period was set after surveying 23 emergency, neurology, neurosurgery, geriatric and internal medicine physician experts in Canada, the US, France and the United Kingdom. The experts would follow an older adult with a head injury for delayed intracranial bleeding for a median of 7 days (interquartile range 2–28 days). Follow-up in this study was extended to 42 days to ensure we captured all delayed intracranial bleeds. Enrolment was restricted to patients who resided within the respective hospital catchment area, because patients were followed locally through a standardized medical record review by trained research assistants. We did not conduct in-person or telephone follow-up because patient-reported intracranial bleeding has poor sensitivity (37%, 95% confidence interval [CI] 21%–56%).[15] To ensure quality, all chart data were independently validated by the coordinating centre using de-identified source documentation.

Outcome definition and measurement

The primary outcome was "clinically important intracranial bleeding" diagnosed within 42 days of the index presentation to the emergency department. We defined clinically important intracranial bleeding as bleeding within the cranial vault that subsequently received medical or surgical treatment within 90 days, or that led to death within 90 days of the intracranial bleed. We defined "medical treatment" as any of the following: temporary or permanent discontinuation of anticoagulant or antiplatelet medication, administration of an antifibrinolytic drug, reversal of anticoagulation, admission to hospital or neurosurgical intervention. All head CT scans reporting to show intracranial bleeding were reviewed by a centralized independent adjudication committee (consisting of a study neurologist, neurosurgeon, trauma surgeon and radiologist), blinded to the baseline history and clinical findings.

Predictor variables

We assessed potential predictor variables in a precursor study of 1753 older patients who had fallen and presented to the emergency department.[16] We selected 17 candidate predictor variables, which were considered biologically plausible and related to the outcome of intracranial bleeding: age; sex; head impact on falling; loss of consciousness; amnesia; history of previous major bleed (International Society of Thrombosis and Hemostasis criteria[17]); cirrhosis; previous ischemic stroke; chronic renal impairment; Glasgow Coma Scale reduced from baseline; bruise or laceration on the head; new abnormality on neurologic examination; hemoglobin < 10 g/L; platelet count < 80×10^9/L; anticoagulant therapy; antiplatelet therapy; and Clinical Frailty Scale ≥ 5; i.e., being dependent on others for high-order instrumental activities of daily living.[18]

The treating physician completed a standardized data collection form (Appendix 1, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.230634/tab-related-content) at the time of initial patient assessment, and before the results of the head CT were available (the physician was therefore blinded to the outcome). Additional data were collected by trained on-site research assistants following standardized validation procedures for all data from charts.

Statistical analysis

We excluded variables with more than 20% missing data as we believed these variables would be missing in clinical practice. For the purposes of decision rule derivation, when head injury, loss of consciousness, amnesia or disorientation were categorized as "unclear," we recategorized these responses as positive responses. We performed variable selection for the rule using 1000 bootstrap samples from all the data, where the procedure randomly selects patients with replacement from the

original data set. Within each bootstrap sample, we developed logistic regression models with clinically important intracranial bleeding as the outcome and the candidate variables as the independent variables. To obtain a parsimonious model, we reduced each model by means of fast backward elimination using the Akaike Information Criterion. We ranked the variables according to the percentage of the 1000 bootstrap models in which they were included, and selected the final variables in rank order. The rule included the minimum number of predictor variables required to achieve a sensitivity of more than 98%.

We developed a decision rule indicating that intracranial bleeding was ruled out if none of the risk factors were present. If 1 or more risk factors were present, the decision rule would indicate the need for a CT scan. Performance was expressed as sensitivity, specificity, negative predictive value and utility (the proportion of all patients who were classified by the decision rule as having had bleed excluded). We reported diagnostic accuracy among home-dwelling patients and those who lived in retirement, long-term care or nursing homes. We calculated the 95% CIs for estimates using the Wilson score method. We performed analyses using the rms package in R 4.03.

Sample size

According to the rule of thumb widely adopted at the time of protocol development, we estimated that we would require at least 10 events per included variable.[19,20] We anticipated that 5% of patients would receive a diagnosis of clinically important intracranial bleeding,[7] and we assumed that our initial model would consist of 17 candidate variables. Based on this assumption, a sample size of 4080 should have included 200 patients with intracranial bleeding (12 events per variable).

Ethics approval

We obtained research ethics approval from the local research ethics board of each enrolling site.

Results

We recruited patients between Jan. 30, 2019, and Nov. 15, 2020 (see Appendix 2 for recruitment per study site, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.230634/tab-related-content). In total, 5056 patients were assessed for eligibility, 748 were excluded (exclusion reasons outlined in Figure 1) and 4308 were

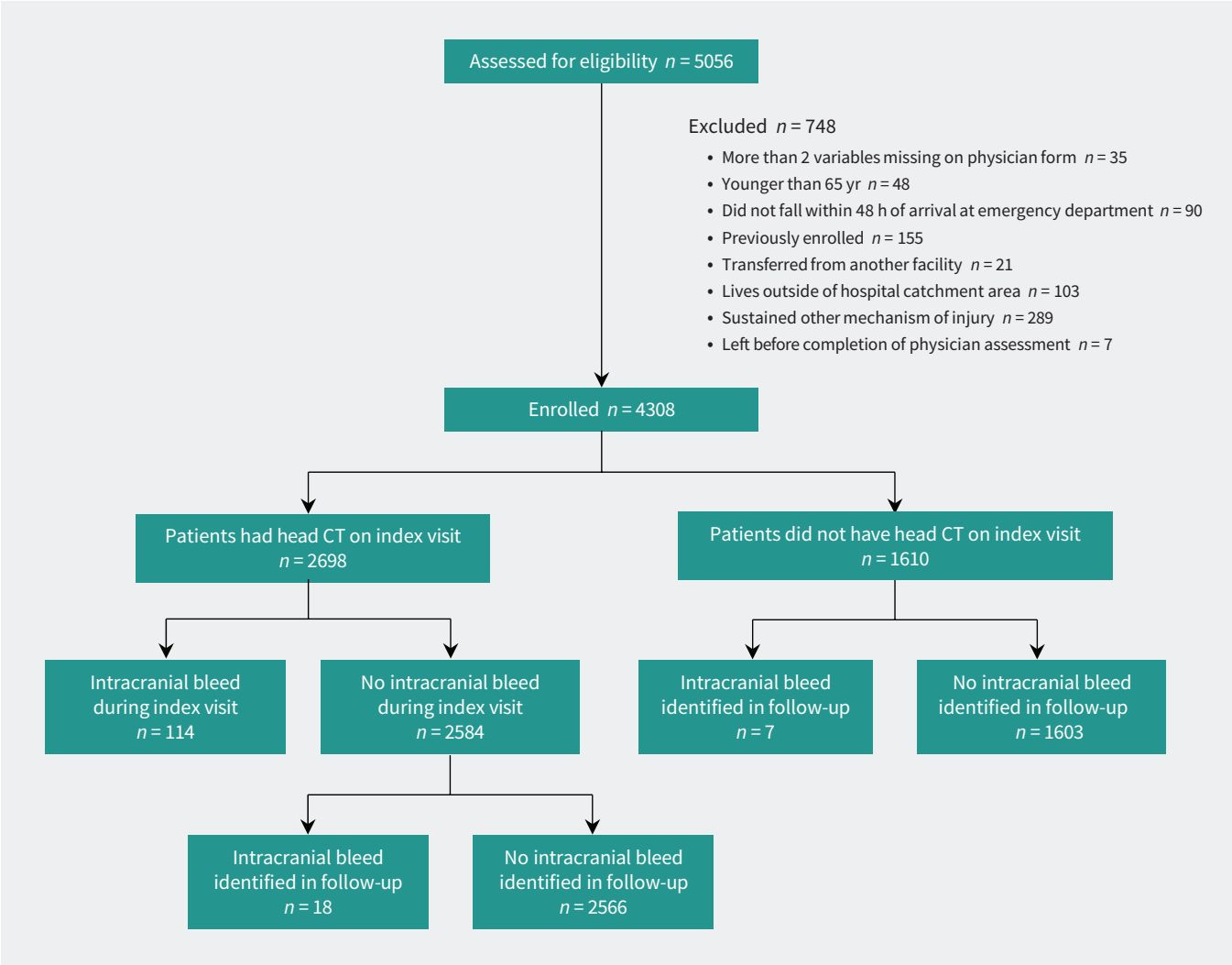

Figure 1: Flow chart for diagnosis of intracranial bleeding study. Note: CT = computed tomography.

Table 1 (part 1 of 2): Demographics of the study cohort and examination findings*

Variable	No. (%)† of patients *n* = 4308
Predictor variables‡	
Median age, yr (IQR)	83 (75–89)
Female	2770 (64)
Clear history of head injury	2161 (50)
Unclear history of head injury	502 (12)
Clear history of loss of consciousness	325 (8)
Unclear history of loss of consciousness	852 (20)
Clear history of new amnesia about events of fall	611 (14)
Unclear history of amnesia	697 (16)
History of previous major bleed	87 (2)
Previous stroke or transient ischemic attack	761 (18)
Renal impairment	832 (19)
Cirrhosis	60 (1)
Takes anticoagulation medication	1119 (26)
Warfarin	203 (5)
Rivaroxaban	223 (5)
Apixaban	544 (13)
Dabigatran	59 (1)
Edoxaban	7 (< 1)
Dalteparin	13 (< 1)
Tinzaparin	2 (< 1)
Enoxaparin	14 (< 1)
Fondaparinux	1 (< 1)
Heparin	4 (< 1)
Anticoagulant name not documented	49 (1)
Takes antiplatelet medication	1567 (36)
ASA	1104 (26)
Clopidogrel	153 (4)
Ticagrelor	1 (< 1)
ASA and clopidogrel	78 (2)
ASA and ticagrelor	3 (< 1)
Antiplatelet name not documented	228 (5)
Clinical Frailty Scale score	
1 Very fit	230 (5)
2 Well	468 (11)
3 Managing	894 (21)
4 Very mild frailty	589 (14)
5 Mildly frail	711 (17)
6 Moderately frail	929 (22)
7–8 Severely frail or very severely frail	457 (11)
9 Terminally ill	21 (< 1)
Not documented	9 (< 1)

Table 1 (part 2 of 2): Demographics of the study cohort and examination findings*

Variable	No. (%)† of patients *n* = 4308
Bruise or laceration on the head	1662 (39)
Reduced Glasgow Coma Scale score from baseline	229 (5)
New abnormality on neurologic examination	237 (6)
Median hemoglobin, g/L (IQR)	124 (112–134)
Median platelet count × 10^9/L (IQR)	215 (171–264)
Other variables	
Retrograde amnesia for > 30 min	134 (3)
Vomited	157 (4)
Once	86 (2)
More than once	71 (2)
Diabetes	1209 (28)
Hypertension	3120 (72)
Active cancer	402 (9)
Cognitive impairment	1316 (31)
History of frequent falls	1100 (26)
Congestive heart failure	510 (12)
Living circumstances	
Living at home	2454 (57)
Living in a retirement community	767 (18)
Living in a nursing home or long-term care facility	719 (17)
Not documented	368 (9)
Median weight, kg, as documented in chart (IQR)	70 (59–82)
Median Glasgow Coma Scale score at time of physician assessment (IQR)	15 (15–15)
Signs of basal skull fracture	70 (2)
Suspected open or depressed skull fracture	11 (< 1)
Median creatinine, μmol/L (IQR)	84 (25–111)
Median international normalized ratio (IQR)	1.1 (1.0–1.2)
Admitted from emergency department into hospital	1536 (36)

Note: ASA = acetylsalicylic acid, IQR = interquartile range.
*Summary of missing data: amnesia of event missing for 4 patients, Clinical Frailty Scale score missing for 9, bruise or laceration missing for 6, reduced Glasgow Coma Scale score from baseline missing for 6, new abnormality on neurologic examination missing for 5, hemoglobin missing for 1255, platelet count missing for 1268, retrograde amnesia missing for 11, vomited more than once missing for 5, weight missing for 1555, Glasgow Coma Scale score missing for 6, signs of basal skull fracture missing for 1, creatinine missing for 1277, international normalized ratio missing for 2496.
†Unless otherwise specified.
‡These variables were used to derive the decision rule.

enrolled. The missed-eligible rate was 43% (Appendix 2). Missed-eligible patients were similar in age (median age 82 yr) and sex (61% female) to those recruited with a similar rate of intracranial bleeding (3.4%). The adjudication committee determined that there were 173 patients with intracranial bleeding, of whom 34 received no treatment and no hospital admission, leaving 139 classified as

having clinically important intracranial bleeds (114 receiving diagnoses on the index visit and 25 during the 42-day follow-up). At the end of the 42-day follow-up period, 3498 of 4308 enrolled patients (81%) were known to be alive and 185 (4%) had died. At study completion, 625 (15%) had no record of hospital visits after the 42-day follow-up period and we could not confirm their vital status.

Patient demographics are shown in Table 1. The median age was 83 years, with 64% of the cohort being female. Half of the cohort hit their head when they fell, 26% took anticoagulant medication and 35% antiplatelet medication. Table 2 describes patients who received a diagnosis of clinically important intracranial bleeding, 21% of whom died within 90 days.

Hemoglobin level was missing for 1255 patients and platelet count was missing for 1268; therefore, we excluded these predictor variables from further analysis. The frequency of inclusion of each variable in the bootstrap models is shown in Appendix 3 (available at www.cmaj.ca/lookup/doi/10.1503/cmaj.230634/tab-related-content). After further consideration, we excluded sex, as we sought a rule that applied to all sexes. Appendix 3 includes the diagnostic accuracy of the decision rule, as each variable is added sequentially.

The final Falls Decision Rule is outlined in Figure 2. The rule indicates very low benefit of a head CT scan for diagnosing intracranial bleed if there is definitely no history of head injury, the patient can confirm they have no amnesia of the fall, there is no new abnormality on neurologic examination, and the Clinical Frailty Scale score is less than 5. When the history of head injury or amnesia is unclear, the patient requires neuroimaging.

Rule sensitivity for clinically important intracranial bleeding was 98.6% (95% CI 94.95%–99.6%), specificity 20.3% (95% CI 19.1%–21.5%) and negative predictive value 99.8% (95% CI 99.2%–99.9%). Application of the rule would have avoided CT scanning in 19.9% (95% CI 18.8%–21.1%) of the study population. For all adjudicated intracranial bleeding (both clinically important and clinically unimportant), the sensitivity was 98.8% (95% CI 95.9%–99.7%) and specificity 20.7% (95% CI 19.5%–22.0%).

Given the relatively low specificity of the Falls Decision Rule, post hoc, we created a Focused Falls Decision Rule: no head CT if definitely no history of head injury, and no new abnormality on neurologic examination. This focused version had a lower sensitivity of 95.0% (95% CI 90.0%–97.0%), but a higher specificity of 38.0% (95% CI 36.6%–39.5%). We report the sensitivity and specificity of the Falls Decision Rule and the Focused Falls Decision Rule by living circumstances in Table 3.

Table 2 (part 1 of 2): Clinically important variables and outcomes*

Variable	No. (%)† of patients *n* = 139
Predictor variables	
Median age, yr (IQR)	83 (76–89)
Female	74 (53)
Clear history of head injury	103 (74)
Unclear history of head injury	23 (17)
Clear history of loss of consciousness	29 (21)
Unclear history of loss of consciousness	53 (38)
Clear history of new amnesia about events of fall	42 (30)
Unclear history of amnesia	46 (33)
History of previous major bleed	3 (2)
Previous stroke or transient ischemic attack	30 (22)
Renal impairment	30 (22)
Cirrhosis	1 (1)
Takes anticoagulation medication	38 (27)
Warfarin	6 (4)
Rivaroxaban	8 (6)
Apixaban	19 (14)
Dabigatran	2 (1)
Enoxaparin	1 (1)
Anticoagulant name not documented	2 (1)
Takes antiplatelet medication	58 (42)
ASA	38 (27)
Clopidogrel	6 (4)
ASA and clopidogrel	6 (4)
Antiplatelet name not documented	8 (6)
Clinical Frailty Scale score	
1 Very fit	2 (1)
2 Well	11 (8)
3 Managing	30 (22)
4 Very mild frailty	23 (17)
5 Mildly frail	22 (16)
6 Moderately frail	29 (21)
7–8 Severely or very severely frail	19 (14)
9 Terminally ill	3 (2)
Reduced Glasgow Coma Scale score from baseline	32 (23)
Bruise or laceration on the head	84 (60)
New abnormality on neurologic examination	35 (25)
Median hemoglobin, g/L (IQR)	125 (113–139)
Median platelet count × 10^9/L (IQR)	215 (166–257)

Interpretation

Using data that are readily available to physicians working in emergency departments (routine history and examination findings), we developed a simple clinical decision rule for older patients who present to the emergency department after a fall (the "Falls Decision Rule"). The rule identifies patients for whom neuroimaging for intracranial bleeding would have very low yield. Application of the Falls Decision

Rule would avoid head CT scans in 20% of the study population. Although the prevalence of clinically important intracranial bleeding in this study was low, participants receiving a diagnosis of intracranial bleeding had a poor prognosis, with 29 of 139 (21%) patients dying within 90 days, so correct identification of these patients is important.

Our suggestion that all older patients who have experienced a head injury should receive neuroimaging concurs with the Canadian CT Head Rule.[9–12] Additionally, our rule guides physicians to obtain head CT for the 12% of patients in whom head impact is unknown. Our findings build on our previous work, reporting that intracranial bleeding was independently associated with reduced Glasgow Coma Scale-

Table 2 (part 2 of 2): Clinically important variables and outcomes*

Variable	No. (%)† of patients *n* = 139
Outcomes	
Bleed site	
Epidural bleed	1 (1)
Subdural bleed	44 (32)
Subarachnoid bleed	17 (12)
Intraparenchymal bleed	20 (14)
Intraventricular bleed	5 (4)
Multicompartment bleed	52 (37)
Neurosurgical intervention	8 (6)
Intensive care admission	12 (9)
Median hospital length of stay, days (IQR)	3 (1–12)
90-day mortality	29 (21)

Note: ASA = acetylsalicylic acid, IQR = interquartile range.
*Summary of missing data: reduced Glasgow Coma Scale score from baseline missing for 1 patient, hemoglobin missing for 8, platelet count missing for 8, hospital length of stay missing for 12.
†Unless otherwise specified.

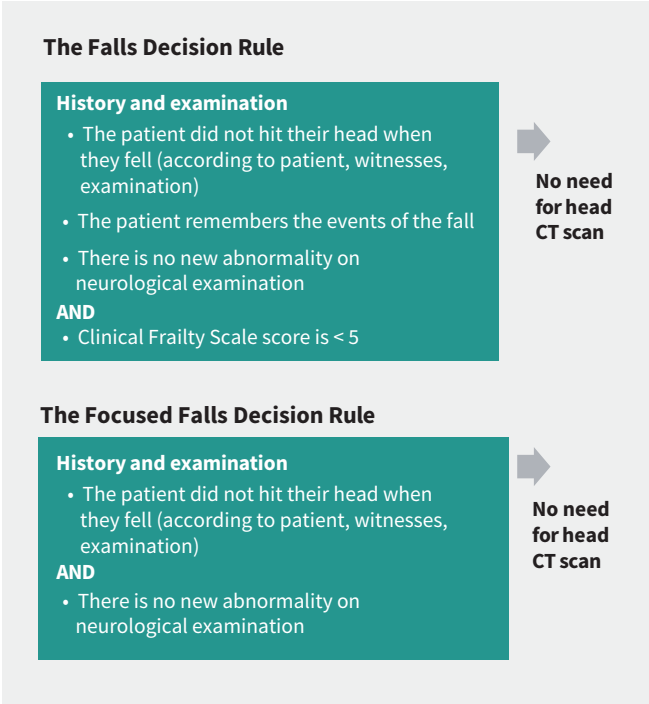

Figure 2: The Falls Clinical Decision Rules. The Falls Decision Rule has a sensitivity of 98.6% (95% confidence interval [CI] 94.9%–99.6%) and specificity of 20.3% (95% CI 19.1%–21.5%) for clinically important intracranial bleeding. The Focused Falls Decision Rule has a sensitivity of 95.0% (95% CI 90.0%–97.5%) and specificity of 38.0% (95% CI 36.6%–39.5%) for clinically important intracranial bleeding. Note: CT = computed tomography.

Table 3: Diagnostic accuracy of decision rules reported by living circumstances*

Decision rule	Living circumstances	Sensitivity (95% CI)	Specificity (95% CI)
Falls Decision Rule	All patients	137/139	856/4169
		98.60 (94.9–99.6)	20.30 (19.1–21.5)
	Home	79/79	629/2375
		100.00 (95.4–100.0)	26.50 (24.8–28.3)
	Retirement, long-term care or nursing home	47/49	107/1437
		95.90 (86.3–98.9)	7.50 (6.2–8.9)
Focused Falls Decision Rule	All patients	132/139	1585/4169
		95.00 (90.0–97.5)	38.00 (36.6–39.5)
	Home	77/79	961/2375
		97.50 (91.1–99.3)	40.50 (38.5–42.5)
	Retirement, long-term care or nursing home	44/49	465/1437
		89.80 (78.2–95.6)	32.30 (30.0–34.8)

Note: CI = confidence interval.
*Place or residence was unknown in 368 patients.

score , new abnormality on neurologic examination and bruise or laceration on the head.[16] Our findings concord with 2 smaller prospective studies, both of which found that intracranial bleeding was associated with loss of consciousness and signs of head trauma in this population.[21,22]

Our findings have several clinical implications. Neither anticoagulation nor antiplatelet medication is included in our decision rule that determines the need for head CT scan. This is consistent with all previous published research in older adults presenting with a fall to the emergency department.[16,21–24] Taken together, these findings mean that emergency physicians should not consider anticoagulant or antiplatelet use when determining the need for head CT. The benefits of the Falls Decision Rule implementation include improved sensitivity for intracranial bleeds compared with usual practice and standardization of assessment. However, implementing the Falls Decision Rule across our study sites would likely increase the proportion of patients undergoing scanning. Implementing our alternative Focused Falls Decision Rule may be more appealing in emergency departments without on-site CT scanning facilities, if scanning resources are overwhelmed, or in patients who are receiving palliative care.

Limitations

The limitations of our study design included that emergency physicians chose whether to perform a head CT, which could have inflated the strength of association between predictor variables that are commonly used to make this decision and the diagnosis of intracranial bleeding. The missed-eligible rates varied across sites. Follow-up length was informed by expert opinion and was conducted by review of the institutional electronic medical record. In our previous study, which used direct follow-up with the patient, all intracranial bleeds reported by patients were also identified on record review.[16] In the current study, we restricted enrolment to patients who resided within the hospital catchment area, and most sites had access to records from regional neurosurgical centres. Although patients were advised to return if they developed neurologic symptoms, it is possible intracranial bleeding could have led to recovery or death without being diagnosed. The impact of COVID-19 on this study is unknown.

Decision rules perform best in derivation studies. The Falls Decision Rule and Focused Falls Decision Rule require external validation to ensure their safety, reliably and acceptability for excluding intracranial bleeding in this emergency department population.

Conclusion

We prospectively developed the Falls Decision Rule, which identifies a group of older adults who have fallen and who do not require a head CT in the emergency department to rule out intracranial bleeding. The rule can be applied to all older adults who have fallen, regardless of whether they sustained a head injury or can recount the events of the fall. The rule has the potential to standardize patient testing.

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Competing interests: Ashkan Shoamanesh reports receiving a grant from the Canadian Institutes of Health Research (CIHR), outside the submitted work. Ian Buchanan reports receiving honoraria from Pfizer Inc. for participating in a scientific planning committee on anaphylaxis care in 2018 and 2021. Paul Engels reports serving as a board member of the Trauma Association of Canada (unpaid position). Andrew Worster reports holding a patent for the Clinical Chemistry Score. Alexandra Papaioannou reports participating on advisory boards and in speakers' bureaus and has received honoraria from Amgen Canada. Judy Morris reports serving as a board member of the Association des médecins d'urgence du Québec and the Canadian Association of Emergency Physicians. No other competing interests were declared.

This article has been peer reviewed.

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