1. Methods

Study design and settings

This prospective cohort study was conducted at a single center, Marmara University Pendik Training and Research Hospital, a Level 1 trauma center with an annual ED visit frequency approximating 200,000. Marmara University Clinical Research Ethics Committee approved the study protocol (protocol number: 09.2024.48, date 12.01.2024]), and the research was carried out in accordance with the ethical principles delineated in the Declaration of Helsinki.

In reporting the study, the Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines were followed, and the corresponding flow diagram was utilized to ensure clarity and transparency in the presentation of diagnostic accuracy results [1].

Study participants

The study prospectively enrolled all consecutive geriatric patients (aged >65 years) who presented to the emergency department of XXX (blinded) Hospital within 48 hours following a ground-level fall. In alignment with the derivation study, this encompassed patients who had fallen from a standing position as well as those who had fallen from a toilet, chair, or bed. Patient enrollment commenced on January 20, 2024, and persisted until the required sample size was attained on October 1, 2024. Exclusions were made for patients who had previously enrolled in the study, those who left the hospital against medical advice prior to the completion of the diagnostic and treatment protocols, individuals with incomplete data, those transferred from another facility, and foreign patients not registered in the national database (as they could not be monitored for long-term outcomes).

Patient assesment and data collection

This observational study was conducted devoid of any external intervention. Each patient included in the investigation was managed and treated by their primary emergency physician, who autonomously determined the necessity for a head CT at the time of presentation.

Demographic information (e.g., age, sex), history of antiplatelet or anticoagulant utilization, particulars of the fall, and clinical frailty scores were gathered by the research personnel through self-reports from patients, their relatives, and/or from patient medical records after obtaining consent to participate in the study [2]. In instances where the treating physician mandated laboratory testing, results such as hemoglobin and platelet levels were

documented. The determination to perform a head CT and the subsequent results were also recorded. Outcomes including the requirement for surgical intervention, and mortality were tracked.

Patients were observed for delayed intracranial bleeding over a period of 42 days, adhering to the protocol established by the derivation study [3]. During this follow-up interval, any subsequent hospital visits were identified via the national healthcare system (e-pulse), and those who presented again were assessed for evidents of intracranial bleeding.

Outcome definition and test methods

Since this is an external validation study, the outcome definitions used in the validation study were applied exactly as originally defined. The definition of clinically important intracranial bleeding (CIIB) was defined to include any intracranial bleeding requiring medical or surgical intervention within follow-up period or resulting in death within temporal scope. Medical intervention was defined as either the temporary or permanent cessation of antiplatelet or anticoagulant therapy, administration of antifibrinolytics, reversal of anticoagulation, hospital admission, or surgical procedures [3].

An ED Specialist and a radiologist were evaluated all head CT scans independently and blindedly to the demographic and clinical particulars of the patients. In case of disagreement, a third reviewer (radiologist) assessed the images to achieve consensus.

Patients were followed for 42 days after their ED visit. If they sought care at another healthcare facility during this period, their clinical status and test results were reviewed to evaluate for intracranial bleeding. In alignment with the derivation study, patients who did not develop symptoms warranting a hospital visit and did not die during the follow-up period were considered negative for CIIB. Given that previous studies have demonstrated the poor sensitivity (37%, 95% confidence interval [CI] 21-56%) of patient-reported intracranial bleeding, patients who neither revisited the hospital nor died were not actively contacted, adhering to the original derivation protocol [3, 4]. In the event of patient death, the cause of death was determined through follow-up with family members via telephone and a review of medical records. Death reports and related documentation were also examined. All available clinical data were collectively reviewed by the research team, and final CIIB classification was determined by consensus.

Index test (The Falls Decision Rule and The Focused Falls Decision Rule)

This study assessed two clinical decision instruments: the Falls Decision Rule and the Focused Falls Decision Rule, both conceived by de Wit and colleagues. According to the Falls Decision Rule, a head CT scan is deemed

unnecessary if all of the subsequent criteria are satisfied: (1) the patient did not hit their head during the fall, as determined through patient history or witness accounts; (2) no novel abnormalities detected on neurological examination; (3) the patient retains memory of the events surrounding the fall; and (4) the Clinical Frailty Scale score is below 5.

The Focused Falls Decision Rule, a simplified variant of the original tool, includes only the first two criteria: the absence of head impact during the fall and no new neurological abnormalities upon examination.

Sample size

The sample size for this diagnostic accuracy study was calculated to validate the Falls Decision Rule. Based on the incidence, sensitivity, and specificity values reported by the de Wit et al., the minimum required sample size was determined to be 663 participants, assuming 80% power and a 0.05 margin of error [3]. To account for potential data loss and measurement errors, the target sample size was increased by 15%, resulting in a minimum of 763 participants. The sample size calculation was performed utilizing G*Power version 3.1.9.2 [5].

References

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