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 [1]. 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 [2].

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY). Data distribution of data was evaluated using histograms and Q-Q plots. Categorical variables were presented as numbers and percentages, while continuous variables were presented as mean with standard deviation for normally distributed data and as median with interquartile ranges for non-normally distributed data. For comparisons between groups, the Chi-squared test was used for categorical variables, and the Mann–Whitney U test was applied for numerical variables. The threshold for statistical significance was established at $p < 0.05$.

Patients with variables documented as "unclear," including head trauma, loss of consciousness, amnesia, or disorientation, were conservatively coded as positive in the analysis to ensure comprehensive assessment. All patients were successfully followed for 42 days, with no patients lost throughout the follow-up interval. Patients who died during follow-up and whose cause of death could not be definitively determined were classified as may have experienced CIIB, as it could not be definitively ruled out, and were considered to have required a head CT. The diagnostic accuracy of the Falls Decision Rule was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio, and negative likelihood ratio, each accompanied with 95% CI. These metrics were employed the evaluate the rule's effectiveness in identifying CIIB while minimizing unnecessary CT imaging.

References

[1] de Wit K, Mercuri M, Clayton N, Mercier É, Morris J, Jeanmonod R, et al. Derivation of the Falls Decision Rule to exclude intracranial bleeding without head CT in older adults who have fallen. CMAJ. 2023;195(47):E1614-e21. https://doi.org/10.1503/cmaj.230634.

[2] Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39(2):175-91. https://doi.org/10.3758/bf03193146.