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Validation of two risk-prediction models for recurrent falls in the first year after stroke: a prospective cohort study

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Abstract

Background: several multivariable models have been derived to predict post-stroke falls. These require validation before integration into clinical practice. The aim of this study was to externally validate two prediction models for recurrent falls in the first year post-stroke using an Irish prospective cohort study.

Methodology: stroke patients with planned home-discharges from five hospitals were recruited. Falls were recorded with monthly diaries and interviews 6 and 12 months post-discharge. Predictors for falls included in two risk-prediction models were assessed at discharge. Participants were classified into risk groups using these models. Model 1, incorporating inpatient falls history and balance, had a 6-month outcome. Model 2, incorporating inpatient near-falls history and upper limb function, had a 12-month outcome. Measures of calibration, discrimination (area under the curve (AUC)) and clinical utility (sensitivity/specificity) were calculated.

Results: 128 participants (mean age = 68.6 years, SD = 13.3) were recruited. The fall status of 117 and 110 participants was available at 6 and 12 months, respectively. Seventeen and 28 participants experienced recurrent falls by these respective time points. Model 1 achieved an AUC = 0.56 (95% CI 0.46–0.67), sensitivity = 18.8% and specificity = 93.6%. Model 2 achieved AUC = 0.55 (95% CI 0.44–0.66), sensitivity = 51.9% and specificity = 58.7%. Model 1 showed no significant difference between predicted and observed events (risk ratio (RR) = 0.87, 95% CI 0.16–4.62). In contrast, model 2 significantly over-predicted fall events in the validation cohort (RR = 1.61, 95% CI 1.04–2.48).

Conclusions: both models showed poor discrimination for predicting recurrent falls. A further large prospective cohort study would be required to derive a clinically useful falls-risk prediction model for a similar population.

Keywords: *risk prediction, accidental falls, stroke, older people*

Introduction

Stroke survivors fall at almost twice the rate of healthy peers with 5% sustaining serious fall-related injuries [1, 2]. Falls are associated with slower stroke recovery and poorer psychological outcomes [3]. Accurate identification of those at risk is therefore important. Prognostic risk-prediction models, combining two or more variables, are developed to estimate an individual's risk in order to facilitate clinical decision-making [4]. Before widespread implementation, risk-prediction models should undergo three development stages: (i) derivation: identification of prognostic factors to develop the model; (ii) validation: testing of the model in a similar population (internal validation) and/or in a different population (external validation) (iii) impact analysis: evaluation of the effect on patient outcomes, clinician behaviour or costs [5]. A recent systematic review summarised falls-prediction models derived within the first year after stroke [6]. Five studies derived nine models to predict falls in community-dwellers [7–11]. Three of these studies reported sufficient information to allow for model validation [9–11]. Two studies predicted recurrent falls, an outcome recommended by a consensus group for research on falls prevention among older adults [9, 11, 12]. The third study included single falls in the outcome [10].

Mackintosh *et al.* [9] developed two prediction models for recurrent falls at 6-months post-discharge, combining an impaired balance measure (either Berg Balance Scale (BBS) score <49 or Step Test score <7) and inpatient falls history. Both models achieved sensitivity and specificity values >80%, but this should be interpreted with caution due to the small sample size (n = 55 participants, n = 12 events) [9]. Ashburn *et al.* [11] also derived two models for recurrent falls but with a 12-month follow-up period. Their model combining six variables, achieved an area under the receiver operating characteristic (ROC) curve (AUC) of 0.71, and sensitivity and specificity of 64% and 69%, respectively, suggesting moderate performance [4]. Their second model, combining upper limb function and inpatient 'near-fall' history achieved similar performance [11]. Neither group conducted internal validation of their models but both acknowledged the need for external validation before clinical-practice recommendations could be made [4, 9, 11].

The aim of this study was to externally validate two previously derived risk-prediction models for recurrent falls in the first year post-stroke in a consecutive sample of recently discharged community-dwelling stroke survivors.

Methodology

This validation study was designed as part of the Falls Related EvEnts after StrokE (FREESE) prospective cohort study. Methods are reported according to the TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis) guidelines [4]. Adult patients (aged > 18 years) with a diagnosis of acute stroke and a planned discharge to home were consecutively recruited between November 2013 and August 2014 from five large, acute university teaching hospitals in Ireland. Acute stroke diagnoses included cerebral ischaemic infarction, ischaemic infarction with haemorrhagic transformation and intracerebral haemorrhages. Those discharged to a nursing home or unable to provide informed consent due to cognitive or severe receptive language deficits were excluded. Ethical approval was received from Research Ethics Committees at each hospital. Written informed consent was obtained from all participants.

The outcome of interest was recurrent falls (>1 fall) over the follow-up period. A fall was defined as 'an unexpected event in which the participants come to rest on the ground, floor or lower level' excluding violent blows or seizures [9, 12]. International recommendations for falls ascertainment were followed [12]. Falls were recorded using daily diaries with monthly return. Reminder phone calls were made if necessary. Telephone or face-to-face interviews based on a falls schedule used by Ashburn *et al.* [11] were conducted to rectify missing data and to ascertain falls circumstances at 6 and 12 months post-discharge.

One model with a 6-month and one model with a 12-month follow-up period were chosen for validation. Of the two models derived by Mackintosh *et al.* [9], the model including the BBS was chosen as this measure is commonly included in post-stroke studies investigating falls [6]. The model derived by Ashburn *et al.* [11] combining two predictors was selected, as their study, with 48 events, was underpowered for the derivation of their 6-item model [6, 13].

The four predictors included in the two risk-prediction models were assessed in the validation cohort at baseline. The definitions of balance, inpatient falls and inpatient near-falls were identical in the validation and derivation cohorts [9, 11]. A physiotherapist assessed participants using the BBS (0–56 points) in the hospital or rehabilitation setting within a week pre-discharge [14]. As soon as possible post-discharge, a researcher not involved in physical assessments telephoned participants and asked them to recall any falls or near-falls experienced in hospital. A near-fall was defined as 'an occasion on which an individual felt that they were about to fall, but did not actually fall' [11]. The research physiotherapist remained blind to inpatient falls and near-falls history.

The validation and derivation studies used different definitions of upper limb function. Ashburn *et al.* [11] assessed upper limb function using the Rivermead Motor Assessment (RMA), which ranges from 0 to 15 points [15]. The validation study used the Motor Assessment Scale Upper Limb (MAS-UL) scale, a similar measure commonly used in the Irish setting [16, 17], which ranges from 0 to 18 points. A comparison of RMA and MAS-UL components was conducted and the validation cohort upper limb score was 're-weighted' to a maximum of 15 points. See Supplementary data, Appendix Table I, available in *Age and Ageing* online for further details.

Statistical analysis

Participants with complete outcome data at the time point of interest were included in the validation analysis and classified into risk groups based on each model. Measures of calibration, discrimination and clinical utility were calculated.

Mackintosh *et al.* presented the following model: high-risk if BBS score <49/56 and an inpatient falls history [9]. Therefore, participants in the validation cohort with both risk factors were classified as 'high-risk' of recurrent falling and the remaining participants as 'low-risk'. This will be referred to as the '6-month model'. Ashburn *et al.* [11] presented the following predictive score based on a logistic regression model: 0.293 + 1.29 (if inpatient near-fall)—(0.094) (upper limb score). This value was calculated in the validation cohort using the re-weighted MAS-UL score. Participants of the validation cohort were categorised as 'high-risk' or 'low-risk' of recurrent falling based on the cut-off score of −0.4114 provided by Ashburn *et al.* [11]. This will be referred to as the '12-month model'.

Calibration, the agreement between predicted and observed outcomes, was assessed using a method described by Dimitrov *et al.* [18, 19]. The predicted number of events in the validation cohort was calculated using outcome frequencies across risk groups in the derivation studies [19]. Estimates of 'predicted: observed' risk ratios (RRs) were calculated with 95% confidence intervals (CIs), using a Mantel–Haenszel random-effects analysis [20]. Discrimination, a model's ability to differentiate between individuals with and without the event, was quantified using the area under the ROC curve statistic (AUC). An AUC of 0.5 represents chance, 0.7–0.9 represents moderate discrimination and 1.0 represents perfect discrimination [4]. ROC curves for both binary models were plotted with single operating points [21]. Sensitivity and specificity were calculated to assess clinical utility of the models.

Missing values for each predictor were tabulated. Multiple imputations were conducted for missing values as a sensitivity analysis [4]. Data were analysed using Stata (version 13.1, StataCorp) and Review Manager (version 5.3, Cochrane Collaboration).

Results

A total of 128 participants were assessed at baseline in the validation cohort. Participants had a mean age of 68.6 years (SD = 13.3 years) and a median length of stay of 14 days (interquartile range 7–38 days). The fall status of 117 and 110 participants was available at the 6-month and 12-month follow-up time points, respectively. By 6 months, 30 participants (25.6%) had fallen post-discharge, 17 repeatedly (14.5%). By 12 months, 49 participants (44.5%) had fallen, 28 repeatedly (25.5%). Supplementary data, Appendix Figure I, available in *Age and Ageing* online shows a flow diagram of participants through recruitment and follow-up. Table 1 shows a comparison between the validation cohort and both derivation cohorts [9, 11]. Supplementary data, Appendix Table II, available in *Age and Ageing* online shows additional clinical characteristics of the validation cohort. Complete-case analyses, including 110 and 102 participants for the 6- and 12-month models, respectively, are presented below.

Performance of the 6-month model in validation cohort

Eleven recurrent fallers were predicted and 16 were observed in the validation cohort at 6 months [9]. Figure 1a presents a breakdown across risk groups. No statistically significant difference was found between observed and predicted events for the 6-month model (RR = 0.87, 95% CI 0.16–4.62). Supplementary data, Appendix Figure II, available in *Age and Ageing* online shows the forest plot of this analysis, stratified by risk group. The 6-month model showed poor discrimination in the validation cohort (AUC = 0.56, 95% CI 0.46–0.67). Figure 1b shows the non-parametric ROC curve. The

Table 1. Comparison between derivation and validation cohorts.

	Six-month model derivation cohort [9]	Twelve-month model derivation cohort [11]	Validation cohort
	N = 55	*N* = 115	*N* = 117 at 6 months *N* = 110 at 12 months
Mean age in years (SD)	68.1 (12.8)	70.2 (N/R)	68.5 (13.5)
Male gender	45%	62%	62%
Mean no. of months from stroke onset at baseline	2.3 (SD 1.6)	2.6 (range 0.3–11)	0.8 (SD 1.2, range 0.1–5.4)
Previous stroke (%)	20.0%	16.5%	14.5%
BBS < 49 (%)	47.3%	N/A	47.8% (*m* = 4)[a]
Fall in hospital (%)	41.8%	N/A	11.3% (*m* = 7)[a]
Near-fall in hospital (%)	N/A	26.1%	43.0% (*m* = 3)[b]
Upper limb function assessment measure	N/A	RMA mean: 10.5	Adjusted MAS-UL mean: 12.8 SD 2.6 (*m* = 5)[b]
No. of recurrent fallers at 6 months (% of sample)	12 (21.8%)	N/A	17 (14.5%)
No. of recurrent fallers at 12 months (% of sample)	N/A	48 (41.7%)	28 (25.2%)

[a] *m*, number of participants missing data for predictor out of 117.
[b] *m*, number of participants missing data for predictor out of 110.
N/R, not reported; N/A, not applicable

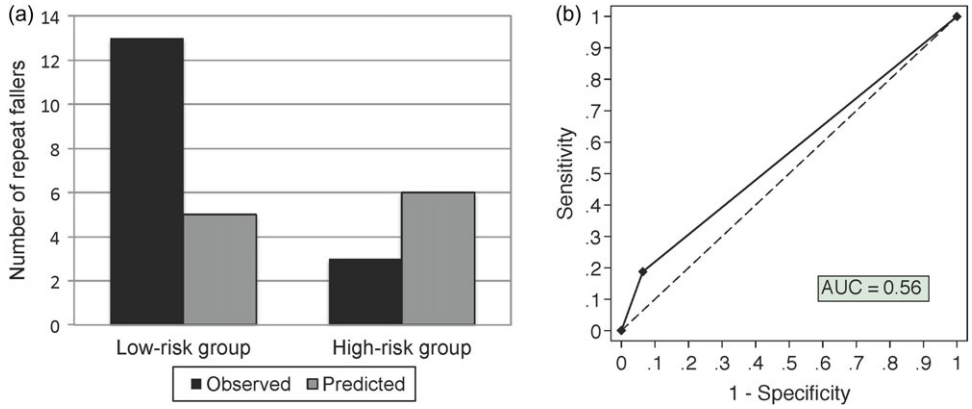

Figure 1. Performance of the 6-month model in validation cohort. (a) Calibration: number of recurrent fallers predicted based on frequencies in derivation cohort versus number of observed fallers in validation cohort. (b) Discrimination: area under ROC curve = 0.56.

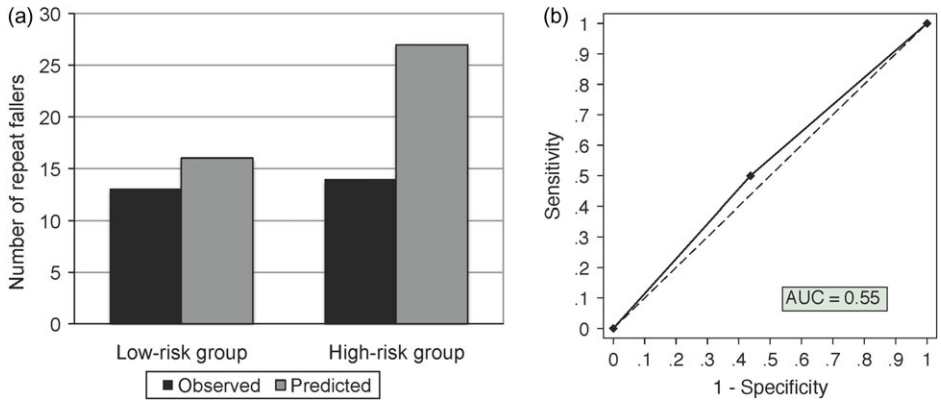

Figure 2. Performance of the 12-month model in validation cohort. (a) Calibration: number of recurrent fallers predicted based on frequencies in derivation cohort versus number of observed fallers in validation cohort. (b) Discrimination: area under ROC curve = 0.55.

model achieved high specificity (93.6%, 95% CI 86.6–97.6) but low sensitivity (18.8%, 95% CI 4.1–45.6).

Performance of the 12-month model in validation cohort

Forty-three recurrent fallers were predicted and 27 were observed in the validation cohort at 12 months [11]. Figure 2a presents a breakdown across risk groups. A statistically significant difference was found between the predicted and observed number of recurrent fallers for the 12-month model (RR = 1.61, 95% CI 1.04–2.48). Supplementary data, Appendix Figure III, available in *Age and Ageing* online shows the forest plot of the analysis, stratified by risk group.

The 12-month model showed poor discrimination in the validation cohort (AUC = 0.55, 95% CI 0.44–0.66). Figure 2b shows the non-parametric ROC curve. The model shows both low sensitivity (51.9%, 95% CI 31.9–71.3) and specificity (58.7%, 95% CI 46.7–69.9%).

There were very few missing values in this study (Table 1). Multiple imputation of missing values did not alter the overall results.

Discussion

This study attempted to externally validate two risk-prediction models for recurrent falls after stroke. Both models poorly discriminated between those with and without recurrent falls and also demonstrated low estimates of sensitivity, implying that they are unsuitable for accurately ruling out fall events. Additionally, the 12-month model showed statistically significant differences between predicted and observed outcomes.

In the original derivation study, the 6-month model achieved high sensitivity and specificity [9]. This performance was not replicated in the current study. Firstly, possibly due to longer inpatient stay duration, the derivation cohort had four times the inpatient falls incidence of the validation cohort [9]. They also had higher falls (45% versus 26%) and recurrent fall rate (22% versus 15%) at 6 months [9]. Secondly, the derivation study had a small sample size (12 events). The original reported adjusted odds ratios (OR) for the model predictors showed wide 95% CIs (fall in hospital OR = 20.5 (2.2–190.6)) and no internal validation techniques were performed [9]. The model was likely over-fitted

to the derivation sample, leading to optimistic performance measures [4].

The 12-month model showed an AUC of 0.69 in the derivation cohort [11], but poorer performance in the current validation cohort. This may be due to a lack of internal validation or differences in duration since stroke, near-fall incidence and upper limb function definition between the validation and derivation cohorts [4, 11]. The difference in duration since stroke may be partly accounted for by recent changes to stroke care, including improved diagnosis, hyper-acute treatment and earlier discharge [22]. Despite a shorter length of stay, our participants reported more near-falls [11]. Participants in the two studies may have interpreted the meaning of 'near-fall' differently [23]. Furthermore, although the definition of upper limb function varied across studies, a conservative method was used for re-weighting [11, 15, 17]. Despite similar recruitment and falls-ascertainment methods, Ashburn *et al.* found a higher falls rate (55% versus 45%) and recurrent falls rate (42% versus 26%) than the validation study at 12 months [11].

Prediction model performance can sometimes be improved by recalibration to the new setting, re-estimation of coefficients or including additional predictors [13]. This was not appropriate in the current study. Firstly, Mackintosh *et al.* presented a dichotomous score rather than the full regression model [9]. Secondly, both models showed poor discrimination. Simple recalibration would not have improved performance [13]. Finally, the original derivation studies had several clinical and statistical limitations, including predictor definitions. Mackintosh *et al.* dichotomised the BBS score prior to modelling [9], thus limiting the ability to investigate any non-linear relationship between balance and falls [4, 24]. A 'near-fall' as defined in the 12-month model derivation study may have been ambiguous for people early post-stroke [23]. Continuous patient-reported assessments including the falls-efficacy scale may have more reliability and power during statistical modelling [4, 25].

Limitations

This study has some limitations. The sample size was relatively small with 17 and 28 events at 6 and 12 months, respectively. While a single 'simulation study' has recommended that 100 outcome events and 100 'non-events' are required for external validation, this principle has not been widely accepted [18, 26]. Although it was not the original study aim, the number of outcome events would have prevented major model updating using the validation data set, should this have been deemed appropriate [13].

Resource limitations, including the number of assessors available, did not allow for full blinding of predictor–predictor and predictor–outcome assessment, resulting in possible sources of bias [4]. Blinding the physiotherapist to fall-related events was prioritised to avoid biasing ongoing recruitment and physical assessments that can require subjective judgement [4]. Despite the prospective study design, there was a small amount of missing predictor data (less than 8% of participants). The treatment of missing values has been reported for transparency [4], and multiple imputations did not significantly alter the results.

Future implications

The models in this study are not suitable for impact analysis or clinical use. A large derivation study would be required to develop a falls-risk prediction model for this population with acceptable performance and generalisability. As falls are complex, risk-prediction models should include more predictors [27]. The most common falls predictors entered into multivariable models in post-stroke cohort studies are measures of neglect, gait speed, cognition, depression, falls efficacy, the BBS and the Timed Up and Go test [6]. A derivation study with 7 candidate predictors would require 70 events (an estimated sample size of approximately 400 participants based on the current study) for sufficient power to predict recurrent fall events [13]. Researchers should model variables continuously where possible, conduct internal validation and adhere to TRIPOD reporting guidelines to facilitate external model validation [4, 13, 24]. Specifically, the full final regression formula needs to be presented to allow for recalibration to other settings [4].

Our study indicates that it is not currently possible to accurately predict recurrent community falls after stroke at the point of discharge. Ashburn *et al.* [11] recommended that in the absence of conclusive evidence, all people with stroke returning home should be considered at risk of falls. This is supported by the current study and the up-to-date NICE guidelines for falls prevention in older adults [28]. Deeming all stroke survivors to be at risk would have implications for service provision. For this reason and because multifactorial post-stroke falls-prevention interventions have not yet shown effectiveness [29], further research is required to identify falls-management strategies applicable to a broad post-stroke population. This could include the design of a complex intervention informed by qualitative research with survivors of stroke [30].

Key points

- Accurate identification of stroke patients at risk of falling is important for planning rehabilitation services on discharge.
- Two previously derived risk-prediction models for recurrent falls post-stroke have performed poorly in this validation study.
- A further large prospective cohort study is required to derive a useful falls-risk prediction model for this population.
- Future derivation studies should conduct internal validation and adhere to TRIPOD guidelines to facilitate external validation.

Conflicts of interest

None declared.

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Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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