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Early prediction of outcome of activities of daily living after stroke: a systematic review

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Stroke. 2011;42(5):1482-1488

ABSTRACT

Background and purpose Knowledge about robust and unbiased factors that predict outcome of activities of daily living (ADL) is paramount in stroke management. This review investigates the methodological quality of prognostic studies in the early poststroke phase for final ADL to identify variables that are predictive or not predictive for outcome of ADL after stroke.

Methods Pubmed, Ebsco/Cinahl, and Embase were systematically searched for prognostic studies in which stroke patients were included ≤2 weeks after onset and final outcome of ADL was determined ≥3 months poststroke. Risk of bias scores were used to distinguish high- and low-quality studies and a qualitative synthesis was performed.

Results Forty-eight of 8425 identified citations were included. The median risk of bias score was 17 out of 27 (range, 6-22) points. Most studies failed to report medical treatment applied, management of missing data, rationale for candidate determinants and outcome cut-offs, results of univariable analysis, and validation and performance of the model, making the predictive value of most determinants indistinct. Six high-quality studies showed strong evidence for baseline neurological status, upper limb paresis, and age as predictors for outcome of ADL. Gender and risk factors such as atrial fibrillation were unrelated with this outcome.

Conclusions Due to insufficient methodological quality of most prognostic studies, the predictive value of many clinical determinants for outcome of ADL remains unclear. Future cohort studies should focus on early prediction using simple models with good clinical performance to enhance application in stroke management and research.

INTRODUCTION

Stroke recovery is heterogeneous in terms of outcome, and it is estimated that 25% to 74% of the 50 million stroke survivors worldwide require some assistance or are fully dependent on caregivers for activities of daily living (ADL) poststroke.[1] In addition to medical management after acute stroke to prevent further cerebral damage, stroke rehabilitation is initiated early with the ultimate goal of achieving better recovery in the first months after stroke and reducing disability during the years that follow.[2] The current trend to shorten the length of stay in hospital stroke units and the increasing demand for efficiency in the continuum of stroke care imply that knowledge about the prognosis for outcome in terms of basic ADL, such as dressing, mobility, and bathing, is crucial to optimize stroke management in the first months. In addition, it guides realistic goal-setting, enables early discharge planning, and correctly informs patients and relatives. This knowledge is also important for adequately designing future trials in stroke rehabilitation. In particular, identifying subgroups of patients that may benefit most from a particular intervention[3] and stratifying patients into prognostically comparable groups[4] will prevent underpowered studies (i.e. type II error), especially because the effects of stroke rehabilitation are relatively small when compared to the prognostic variability across included patients.[5,6]

Unfortunately, prognostic models have not gained much acceptance in clinical practice due to doubts about their predictive accuracy because of issues such as observation bias, problems with generalization of results, and the complexity of algorithms that hamper practical implementation.[7,8] Previous systematic reviews have shown that a high proportion of prognostic studies in stroke are methodologically poor.[7,8] However, the most recent review of this topic dates back to March 2002.[9] Since the last decade, emphasis is given to improve prognostic research by developing guidelines for the reporting of prognostic studies in health care.[10-12]

The purpose of the present systematic review was to investigate the methodological quality of prognostic studies in the early poststroke phase for outcome of ADL and to identify early clinical factors that are predictive or not predictive for outcome of basic ADL beyond 3 months.

MATERIALS AND METHODS

Study identification

The following databases were searched for relevant studies by two researchers (J.V. and J.K.) from inception to October 2010: PubMed (18 Oct), Ebsco/Cinahl (October 12), and Embase (October 19).

The following terms were used (with synonyms and closely related words): "cerebrovascular accident" or "stroke," and "activities of daily living" or "walking" or "gait" or "mobility," and "prognosis"[10-13] or "systematic review" or "meta-analysis." The search strategies in the electronic databases and the full logbook of all the searches are available on request. Studies were included when: (1) they aimed to identify prognostic studies and combined at least 2 separate variables that were used to predict the future outcome in individuals;[3,13] (2) stroke patients aged 18 years or older had been recruited within 2 weeks after onset. In accordance with the World Health Organization, stroke was defined as "rapidly developing clinical symptoms and/or signs of focal, and at times global, loss of cerebral function, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin."[14] Transient ischemic attacks (ICD-10 G45) and subarachnoidal bleeding (ICD-10 I60) were excluded; (3) they were designed as a longitudinal cohort study, which tracks a specific group of people in time from exposure to outcome to identify incidence, natural history, and prognosis of a disease;[15] (4) they had final outcome defined as basic ADL measured at least 3 months after stroke and included the ability to perform basic activities of self-care and mobility. These activities are captured by a combination of codes d510 (washing oneself), d530 (toileting), d550 (eating), d540 (dressing), b5253 (fecal continence) and b6202 (urinary continence), d410 (changing basic body position), d420 (transferring oneself), d450 (walking) from the International Classification of Functioning, disability and health (ICF);[16] and (5) the article was written in English, German, French, or Dutch, because these are the most common languages in peer-reviewed journals.[17] Reference lists were checked for other relevant studies or reviews and personal bibliographies were consulted.

Data abstraction

One reviewer (J.V.) extracted relevant characteristics of each cohort study with respect to numbers recruited, timing of initial and final observations, outcomes used, included and excluded variables for multivariable modeling, and model performance.

Quality appraisal

The methodological quality of reports of prognostic studies was assessed by a developed 27-item checklist which addressed 6 major risks of bias: study participation, study attrition, predictor measurement, outcome measurement, statistical analysis, and clinical performance/validity.[7,8,10,18] As shown in Supplemental Table I (http://stroke.ahajournals.org), each item was graded positive (sufficient information: low risk of bias, 1 point assigned), negative (sufficient information: potential risk of bias, 0 points assigned), or partial/unknown (insufficient information: ? assigned). A total score was obtained by summing all items that were scored as positive. This list was pilot-tested on 3 different prognostic studies that did not meet the study inclusion criteria to reach consensus about each checklist item. A priori, we considered a study to be at low risk for bias when it scored ≥20 points (75% of the maximum score)[8] and a high risk for bias when it scored ≤19 points. Two reviewers (J.V. and M.H.) independently assessed the risk of bias of the included studies. They were not blinded to author names, institutions, or journal of publication. Disagreements were resolved in a consensus meeting.

Analysis

We were unable to perform a quantitative analysis (statistical pooling) of the data because of heterogeneity in terms of study design, moment of inception and follow-up, and the composition and analytical methods of the multivariable models. Consequently, a best-evidence synthesis was performed independently by J.V. and E.W. to summarize the findings of the included studies. Based on the number, quality (i.e. low- or high-risk of bias), and results of these cohort studies, 4 levels of evidence for a particular predictor variable were distinguished: (1) strong evidence: generally consistent findings in multiple (≥2) studies with low risk of bias; (2) moderate evidence: generally consistent findings in 1 study with low risk of bias and ≥1 studies with high risk of bias; (3) limited evidence: only 1 study with low risk of bias is available; (4) insufficient or no evidence: consistent findings in multiple studies with high risk of bias, inconsistent findings in multiple studies, inconsistent findings within 1 study, or no significant result with outcome of interest is present.[19,20] Generally consistent findings means that the number of studies showing evidence was >50% of the total number of studies within the same methodological quality category. Otherwise, insufficient or no evidence was allocated. Subsequently, predictors and nonpredictors were classified according to the ICF, in terms of body structures, body functions, activities and participation, and personal and environmental factors.

RESULTS

Study identification

Figure 2.1 shows that the electronic search resulted in 8425 citations. On the basis of this search and checking their references, a total of 48 studies were included.[21-71] Contacting authors for further information did not result in additional inclusions. A list of excluded studies can be obtained from the corresponding author on request.

Study characteristics

A description of the main characteristics of the included prognostic studies can be found in Supplemental Table II (http://stroke.ahajournals.org). The number of participants in the 48 inception cohorts ranged from 41[34] to 4499,[64] and amounted to a total of 25843 subjects. Forty-two of the 48 studies recruited immediately after hospital admission (i.e. hospital-based).[21-26,29,31,32,34-40,42,44-54,56-59,61,62,64-71] Twenty-one studies included patients with ischemic and hemorrhagic strokes,[21,27a,30,31,33,35,38,39,41,46,49,52,58,62-67,69,70] whereas 13 studies were restricted to first-ever strokes.[22,29-31,37,41,45,48,50,53,64,66] The mean time that had elapsed between stroke onset and initial observation was 5.4 days, ranging from 136.6 minutes[48] to 14 days.[33,38,44,52] All studies defined final outcome of ADL at a fixed moment after onset, with the exception of two.[45,69] Some studies used >1 ADL measurement in their prognostic investigations.[23,42,61] The Barthel Index (BI; K=24)[23,24,26,29,31,32,34,37,41,42,45,46,51-53,58-62,64-66,68] was the most frequently used scale to assess ADL outcome, followed by the modified Rankin Scale (mRS; K=18),[21-23,25,30,35,37,38,42,44,47,49,50,57,67,70,71] the Glasgow Outcome Scale (GOS; K=4),[40,42,56,61] the Functional Independence Measure (FIM; K=2),[38,54]

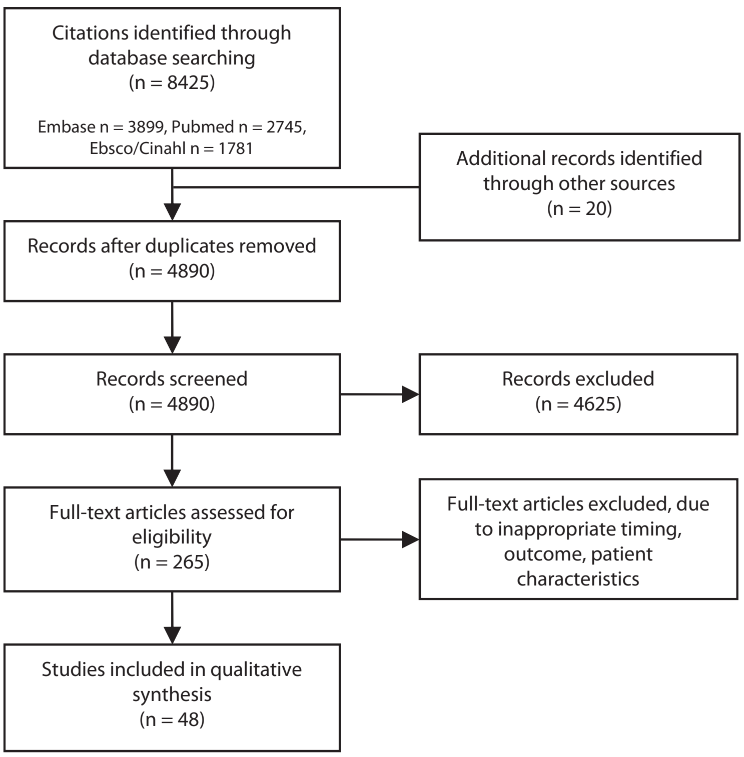

Figure 2.1 Flow diagram of literature search

the Oxford Handicap Scale (OHS; K=1),[27a] the Katz scale (K=1),[63] and other less known ADL assessment instruments (K=2).[39,69] Thirty-six studies dichotomized[21-26,27a,29-33,35-37,40,42-51,53,56,59-62,64,65] or classified[41,58] outcome of ADL, with cut-off scores ranging from 60[23,42] to 95[23,24,26,33,44,45,62] for the 100-point version of the BI, and from 12[59,65] to 19[29] for the 20-point BI version. The mRS cut-off scores varied from 1[23,37,42] to 5.[23]

Quality appraisal

As shown in Supplemental Table III (http://stroke.ahajournals.org), the median risk of bias scores of the included studies was 17 points (range 6[71] to 22[21,22]). Six of the 48 studies were of high methodological quality and scored ≥20 out of 27 available points.[21-26]

Study design

Eighty-three percent of the included studies clearly stated the inclusion and exclusion criteria, and 48% described baseline key characteristics of the study sample. A prospective design was used in 77% of the studies. Twenty-seven percent gave information about the medical or paramedical treatment provided.

Study attrition

The number of loss to follow-up was reported in 77% of the articles, reasons were stated in 67%, and adequate methods of dealing with missing data were described in 33% of the studies.

Predictor measurement

Predictors were well-defined in 92% of the studies, but only 19% reported a clear rationale for the cut-off scores that were used.

Outcome measurement

The outcome was clearly defined in 96% of the studies, and 42% properly defined both cut-off points and rationale.

Statistical analysis

All studies reported whether they used linear or logistic regression techniques; however 38% gave information about variable selection methods and the probability value used for acceptance. Univariable crude estimates and confidence intervals were described in 19% of the studies, whereas 73% reported point estimates with confidence intervals of the multivariable analysis. Finally, 35% did not dichotomize variables of a continuous nature, like age.

Clinical performance/validity

Clinical performance was tested in 56% of the studies using explained variance (K=9),[26,34,38,45,54,57,63,69,71] area under the curve (K=7),[21,23-25,27a,29,42] or c-statistic (K=1),[57] overall accuracy (K=6),[22,26,29,31,39,59] sensitivity and specificity (K=5),[22,32,41,44,59] Hosmer-Lemeshow statistic (K=2),[36,44] calibration (K=1),[23] whereas 1 study just reported the graph of the receiver-operating characteristic curve.[68] The model developed was internally validated in 8% and externally in 21% of the studies.

Identified early poststroke predictors of final outcome

Six studies showed a low risk of bias and 42 studies a high risk of bias. Table 2.1 shows the predictor variables measured early after stroke with their level of evidence, that were predictive for outcome of ADL ≥3 months.

Strong evidence was found for patients' neurological status measured with the National Institutes of Health Stroke Scale (NIHSS) or the Canadian Neurological Scale (CNS), with items relating to lower severity of (upper limb) paresis as strong components for better outcome of ADL. In addition, strong evidence was found for older age as a variable disfavoring outcome of ADL. Supplemental Table IV (http://stroke.ahajournals.org) lists those variables that were found not to be predictive for outcome of ADL ≥3 months. Synthesis resulted in strong evidence that gender and risk factors, such as atrial fibrillation, are unrelated to final outcome of ADL ≥3 months.

DISCUSSION

Prediction plays an important role in evidence-based clinical decision-making after stroke by objectifying, simplifying, and increasing the accuracy of forecasting patients' future functioning.[72] The present research synthesis investigated which early measured variables are predictive or not predictive of basic ADL outcome after stroke. A vital aspect herein is the assessment of

Table 2.1 Best-evidence synthesis of early measured variables predictive for outcome of activities of daily living ≥3 months after stroke, according to the International Classification of Functioning, disability and health (ICF)

Variable	Level of evidence
Body structures	
Stroke classification	IV
Imagine variables	
Stroke volume	IV
Focal computed tomography abnormality	III
Leukoaraiosis	III
Superficial middle cerebral artery	IV
Cortical	IV
Posterolateral extension involving posterior limb of interal capsule	IV
Location (lobar, deep, infratentorial)	IV
Lenticulostriate arteries infarction	III
NIHSS*small vessel occlusion	IV
Days to magnetic resonance imaging	IV
Intima-media thickness	IV
Body functions	
Initial neurological status	I
GCS verbal	IV
Able to talk and oriented	IV
Paresis	IV
Arm	I
Gripstrength*MEP	IV
Tendon reflexes	IV
Able to swallow	IV
Cognitive deficit *	IV
Dysphasia	IV
Complications	
Neurological complications	III
Fever	III
Orpington prognostic score	IV
Allen prognostic score	IV
Activity and participation	
Trunk control test	IV
Gait	
Ability to walk	IV
Able to walk unaided	II
ADL functioning	IV
Change in ADL at days 2-15	IV
Disability	III
Leg function	IV

Table 2.1 continues on next page.

Table 2.1 *Continued*

Variable	Level of evidence
Personal factors	
Age	I
Prestroke independence	II
Prestroke mobility	IV
Comorbidity and riskfactors	
No. of riskfactors	IV
Previous stroke	II
Neurological impairment	IV
Diabetes	IV
Hypetension	IV
Myocardial infarction	IV
Heart failure	IV
Cognitive impairment	IV
Cardiac, blood, and urine variables	
Urea	IV
Depression	IV
CFU-EC increment, week 1	IV
Living alone	IV
Relationship with significant other	IV
Previous Short Form-36 health survey	IV
Prestroke institutionalization	IV
Educational level	IV
Prestroke financial security	IV
Nutrition	
Malnutrition	IV
Undernourished	IV
Undernutrition, week 1	IV
Race	IV
Black*time	IV
Environmental factors	
Time from onset	IV
Time (log function)	IV
Dicharge to nursing home or other institution	IV
Inpatient treatment neurologist	IV
Days to rehabilitation initiation	IV
Black*days to rehabilitation*time	IV
Days to rehabilitation*time	IV
Adequacy home and neighborhood	IV

I, strong evidence: generally consistent findings in multiple (≥2) studies with low risk of bias. II, moderate evidence: generally consistent findings in 1 study with low risk of bias and ≥1 studies with high risk of bias. III, limited evidence: only 1 study with low risk of bias is available. IV, insufficient or no evidence: consistent findings in multiple studies with high risk of bias, inconsistent findings in multiple studies, inconsistent findings within 1 study, or no significant result with outcome of interest is present. ADL, Activities of Daily Living; CFU-EC, Colony-Forming Unit-Endothelial Cell; GCS, Glasgow Coma Scale; NIHSS, National Institutes of Health Stroke Scale. *e.g. neglect, dyspraxia, visuospatial problems.

methodological quality. The large number of studies published in the past decade shows that prognosis in stroke rehabilitation is a growing field of interest. However, prognostic research is complex, acknowledging that the generalization is mostly limited. Because of methodological shortcomings and inadequate reporting, the predictive value of most determinants for outcome of ADL after stroke is indistinct. It should be acknowledged, however, that the development of the methodology of prognostic studies is still in progress[10] and that the guidelines for reporting observational studies according to the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement only recently have been established.[12] Fortunately, our review shows a positive evolution of the methodological quality of prognostic studies because 5 out of the 6 high-quality studies were published in the past decade. This illustrates the growing awareness among investigators that they have to meet the methodological criteria for prediction model development.

Despite the fact that only a small proportion (12.5%) of the included studies were of high quality, we found strong evidence that age and outcomes assessing severity of neurological deficits in the early poststroke phase, such as the NIHSS[23,25,73] and CNS,[22] are highly associated with final basic ADL outcome beyond 3 months after stroke. More specifically, items related to severity of motor impairments seem to be the most important components of these scales for predicting outcome of ADL. These findings are largely confirmed by Counsell et al,[7] who reported these multivariable tested predictors for the outcome in terms of survival in an independent state. In addition, there is strong evidence that gender and the presence of risk factors for stroke, such as atrial fibrillation, do not predict outcome of basic ADL. The present systematic review also shows that the added value of imaging data for the prediction of ADL outcome is limited when compared to the contribution of clinical variables alone.[21,29,74]

Just as in stroke trials, the BI and mRS were the 2 activity-level outcome measures most frequently used in prognostic stroke studies.[75] Both outcomes were dichotomized for regression analysis in many studies, though cut-off points varied. For example, "independent" or "favorable" on the BI was defined as either >60, ≥85, ≥90, >95, or ≥95, hampering a valid comparison across the included studies. The comparability of studies can be improved by using well-established cut-off points.[76] Remarkably, the FIM, which is commonly used to evaluate outcome in terms of ADL dependency after stroke,[77] has hardly been used in inception cohorts started from stroke onset (i.e. within 2 weeks) for the purpose of making predictions beyond 3 months.[38,54]

Unfortunately, prognostic models are not commonly applied in routine care for a number of reasons. First, successful clinical implementation of the investigated models is hampered by the complexity of the algorithms derived from them. Second, opportunities to generalize the probabilities of derived models are limited due to differences in patient characteristics. The cohorts in the prognostic studies included in our review were often mixed but sometimes restricted to, for example, ischemic or hemorrhagic strokes, or anterior circulation or posterior circulation infarcts. Obviously, the selection of a cohort with a common underlying stroke type increases the precision with which the outcome of interest can be predicted but limits its generalization to other stroke types. This finding suggests that transparency is needed concerning the criteria used for patient selection. In addition, case-mix adjustment has to be considered to control for differences in sample recruitment. Third, generalization of the probabilities of existing models based on clinical and imaging variables is hampered by differences in the timing of clinical determinant measurement in the early poststroke phase.[6,73,78] For example, in a recent cohort study we found that the earliest time at which an optimal prediction of ADL independency outcome (i.e. ≥19 points according to the BI) could be made was at day 5 after stroke, whereas day 2 scores resulted in suboptimal prediction due to an underestimation of patients' abilities when they are still bed-ridden.[78] In contrast, the accuracy of the NIHSS in predicting ADL outcome is almost unaffected by the timing of assessment in the first 9 days after stroke, making this instrument more robust for determining patient prognosis.[73] Finally, prediction models still misclassify a certain amount of patients, but most prognostic studies failed to report information about the performance of the model derived and also failed to verify its internal and external validity, which is important since prediction rules are always less accurate when retested in an independent patient cohort.[8,79]

The present review does have some limitations. First, despite a sensitive search, publications may have been missed because of poor indexation of the literature reporting observational studies including prognostic research.[80] Second, data extraction was performed by 1 reviewer.[81] Third, the scoring list for the assessment of methodological quality was based on recent recommendations for prognostic research as well as criteria used in previous scoring lists for assessment of prognostic stroke research.[10,18] However, there may be room for improvement because the development of criteria for assessing methodological quality is still in progress. For example, the used criteria for defining study characteristics such as an inception cohort (i.e. ≤2 weeks) and final outcome (i.e. ≥3 months) are based on purely pragmatic grounds.

A future overview of unbiased predictors of ADL outcome will only be possible when the key methodological criteria for prognosis research are met. Besides, future studies should aim for robust but clinically feasible predictors of ADL outcome. For this, consensus about ICF-linked definitions and standardized measurement of these predictors is conditional. Recently, we found in 3 cohorts of patients with a first-ever hemispheric stroke that the baseline value of the dependent variable for measuring ADL is highly predictive of the final outcome.[5,78,82] However, only a few low-quality studies have investigated this relationship so far.[29,31,46,59,62,66] In addition, Stinear[82] recently suggested that the accuracy of prediction might be increased by combining simple bed-side tests of motor impairment with neuroimaging, genotyping, and neurophysiological assessment of neural plasticity. Furthermore, patients preferably should be tested at fixed moments early after stroke, because clinical determinants are time-dependent and nonlinearly related with stroke recovery.[6] Determining the optimal timing for predictions requires studies with an intensive repeated-measurement design.[83] In the same vein, new statistical methods such as random coefficient analysis[52] allow one to investigate how early neurological improvements may affect the accuracy of predicting final outcome after stroke. In addition, an accurate model is of no benefit if it is not generally applicable and is not implemented in practice.[84] This means that implementation studies are needed to investigate the added value of using prediction rules in daily practice for the accuracy of clinical decision-making, compared to clinical expertise alone.[84] Finally, the present systematic review shows that more attention must be given to a uniform procedure in selecting and dichotomizing determinants to make prognostic models comparable.[75]

Sources of funding

This research project was supported by the Royal Dutch Society for Physical Therapy (KNGF grant number 8091.1).

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