Assessment and comparison of the max-ICH score and ICH score by external validation

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Abstract

Objective
We tested the hypothesis that the maximally treated intracerebral hemorrhage (max-ICH) score is superior to the ICH score for characterizing mortality and functional outcome prognosis in patients with ICH, particularly those who receive maximal treatment.

Methods
Patients presenting with spontaneous ICH were enrolled in a prospective observational study that collected demographic and clinical data. Mortality and functional outcomes were measured by using the modified Rankin Scale at 3 months. The ICH score and max-ICH score incorporate measures of symptom severity, age, hematoma volume, hematoma location, and intraventricular hemorrhage, with the max-ICH score also including a term for oral anticoagulation and having 16 score categories vs 11 for the ICH score. We compared the area under the receiver operating characteristic curve (AUC) for the ICH score and max-ICH score for both mortality and poor functional outcome, defined as modified Rankin Scale scores 4–6.

Results
We analyzed outcomes for 372 patients, including 71 patients (19%) in whom care limitation/withdrawal of life support was instituted. Both the ICH score and max-ICH score showed good prognostic performance for 3-month mortality and poor functional outcomes in the full group as well as the subgroup with maximal treatment (i.e., no care limitations; AUC range 0.80–0.86), with no significant difference in AUC between the scores for either endpoint in either group.

Conclusions
External validation with direct comparison of the ICH score and max-ICH score shows that their prognostic performance is not meaningfully different. Alternatives to simple scores are likely needed to improve prognostic estimates for patient care decisions.

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Glossary

AUC = area under the receiver operating characteristic curve; **FOS** = functional outcome score; **GCS** = Glasgow Coma Scale; **ICH** = intracerebral hemorrhage; **mRS** = modified Rankin Scale; **NIHSS** = NIH Stroke Scale; **ROC** = receiver operating characteristic; **TRIPOD** = Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis.

Accurate prognostication is essential for guiding the care of patients with intracerebral hemorrhage (ICH), but prognostication models for ICH outcome have proven unreliable. One issue is the inability of common prognostic scores to account for the effects of early complications, which strongly influence outcomes.[1] Separately, "self-fulfilling prophesies" based on initial impressions may lead to care limitations in cases with severe initial symptoms, perhaps inappropriately.[2] Providing full intensive treatment, i.e., "maximal treatment," and avoiding new do-not-resuscitate orders during the first 5 days after ICH has been found to reduce observed mortality compared to predictions based on historical controls using the ICH score.[3] A new prognostic score for patients with ICH, the max-ICH score, has recently been proposed as superior to the ICH score, particularly for patients who receive maximal treatment and whose risk of poor outcomes may be inflated by ICH score prognosis.[4] Expert consensus stipulates that unvalidated models should not be used in clinical practice because derivation studies typically overestimate the accuracy of newly fitted models, and recommends external validation of newly derived models (a type 4 analysis by the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis [TRIPOD] Statement rubric).[5–7] Moreover, at least 10 prognostic scores for ICH outcome have been proposed, with several, including the ICH functional outcome score (ICH-FOS) and Essen-ICH score, showing superior performance to the ICH score, but none have displaced the ICH score in routine use.[8] Thus, we sought to confirm the hypothesis that the max-ICH score is meaningfully superior to the ICH score for characterizing mortality and functional outcome prognosis in patients with ICH, particularly those who receive maximal treatment, by external validation.

Methods

Patients presenting to Northwestern Memorial Hospital with spontaneous ICH between January 2010 and March 2017 were prospectively enrolled in an observational study, as previously reported in detail.[1] Briefly, all patients were diagnosed by a board-certified neurointensivist. Patients with ICH attributed to trauma, hemorrhagic conversion of ischemic stroke, structural lesions, or vascular malformations were excluded. All patients were admitted to and managed in a neuro-intensive care unit. The Glasgow Coma Scale (GCS) score and NIH Stroke Scale (NIHSS) score were prospectively recorded at the time of initial evaluation by a trained neurologist and/or neurosurgeon. Demographic information, medical history, medication history, standardized clinical instruments (GCS, pre-ICH modified Rankin Scale [mRS]), pretreatment blood pressure, laboratory data, imaging data including hematoma volumes using Analyze software (Mayo Clinic, Rochester, MN) by a semiautomated process, medical management variables, surgical interventions, and medical complications were prospectively recorded, along with the mRS score at 3 months obtained by a validated interview, as we have recently reported in detail.[1]

Maximal treatment was defined as the absence of early care limitations within the intensive care stay, including withdrawal of life support or palliative withholding of life-sustaining treatments in favor of comfort-based end-of-life care, which was recorded contemporaneously in this prospective group. The ICH score and max-ICH score were calculated as specified in prior studies (table 1).[4,9] Both incorporate measures of clinical symptom severity, patient age, hematoma volume, hematoma location, and presence of intraventricular hemorrhage, with the max-ICH score also including a term for oral anticoagulation and having 16 score categories vs 11 for the ICH score. We constructed receiver operating characteristic (ROC) curves for mortality and poor functional outcome, defined as mRS scores 4–6, at 3 months. We assessed the predictive accuracy of the prognostic scores by calculating the area under the curve (AUC) of the ROC curves using the nonparametric method in the full group of patients with ICH as well as the "maximally treated" patients, identical to the methods of the derivation study.[4] The differences in the AUC of the ROC curves for the ICH score and max-ICH score were compared for significance as described by Hanley and McNeil, identical to the method used in the max-ICH score derivation study.[4]

Standard protocol approvals, registrations, and patient consents

The study was approved by the institutional review board. Written informed consent was obtained from the patient or their legally authorized representative. The institutional review board approved a waiver of consent for patients who died during initial hospitalization, or who were incapacitated and for whom a legal representative could not be located.

Data availability

Anonymized data not published within this article will be shared by request from any qualified investigator for the purpose of replicating the results.

Results

Among 558 patients, we were unable to obtain 3-month follow-up in 186, yielding 372 patients (mean 67 ± 14 years old, 51% female, 55% white) with requisite data for analysis. There was no difference in initial clinical severity by ICH

ICH score variable	Points	Max-ICH score variable	Points
Glasgow Coma Scale		NIH Stroke Scale	
3–4	2	≥21	3
5–12	1	14–20	2
13–15	0	7–13	1
		0–6	0
Age, y		Age, y	
≥80	1	≥80	3
<80	0	75–79	2
		70–74	1
		≤69	0
Hematoma volume, mL		Hematoma volume, mL	
≥30	1	Lobar ≥30	1
<30	0	Lobar <30	0
		Nonlobar ≥10	1
		Nonlobar <10	0
Intraventricular hemorrhage		Intraventricular hemorrhage	
Yes	1	Yes	1
No	0	No	0
Infratentorial hemorrhage		Oral anticoagulation	
Yes	1	Yes	1
No	0	No	0

Abbreviation: ICH = intracerebral hemorrhage.

score between surviving patients lost to follow-up and those in whom follow-up was obtained either in the full cohort ($p = 0.28$) or the maximally treated group ($p = 0.51$) or in patient age ($p = 0.35$ and $p = 0.24$, respectively). Consent was not obtained in 4% of eligible patients presenting to our medical center. There were 71 patients (19%) in whom early care limitation/withdrawal of life support was instituted, with the remaining 301 patients receiving maximal treatment. The demographic and clinical characteristics of the patients are summarized in table 2. We prospectively recorded transfer status and found no association between outcome and transfer status either on univariate tests or in a model that corrects for ICH score (transfer status $p = 0.992$).

Figure 1 shows observed mortality and poor outcome rates for each rank of the ICH score and max-ICH score in the maximally treated group. The Spearman correlation coefficient for the ICH score and max-ICH score in the full group was 0.81 ($p < 0.0001$) and 0.79 ($p < 0.0001$) in the

maximally treated subgroup. In the full group, both the ICH score and max-ICH score showed good prognostic performance (all ROC AUC >0.8 with asymptotic p values <0.001) for 3-month mortality and poor functional outcomes with no significant difference in AUC between the 2 scores. Similarly, in the maximally treated subgroup, the ICH score and max-ICH score showed good prognostic performance (all ROC AUC >0.8, 95% confidence intervals ranged ±0.03–0.05, all p < 0.001) for mortality and poor functional outcomes with no significant difference in AUC between the 2 scores. The ROC analyses are summarized in table 3 and shown graphically in figure 2. The overall predictive performance of the models was confirmed by the likelihood ratio χ^2 test (all $p < 0.001$) with no significant issues with model calibration detected (unweighted sum of squared errors test for goodness of fit all nonsignificant; table 4).

Discussion

In this observational study of patients with spontaneous ICH selected by the same criteria as the max-ICH derivation study, we found that the ICH score and max-ICH score are both good predictors of 3-month mortality and functional outcomes, but the performance of the max-ICH score is not demonstrably superior to the ICH score in either the full group of patients or in patients who receive maximal treatment. The similar performance of the 2 scores is likely explained by their similar composition. The ICH score and max-ICH score comprise a strongly correlated clinical severity score (GCS and NIHSS, respectively) along with terms to adjust for hematoma volume and location, age, and intraventricular hemorrhage, with the only distinct variable being oral anticoagulation exposure in the max-ICH score.[4,9] The size of this validation set is approximately the size of the derivation and validation sample sizes of the ICH score combined, and well within the recommended ideal size (minimum n = 100, ideal n ≥ 200) for a prognostic score validation sample.[7] Any nonidentical scores can be shown to have different accuracies given a sufficiently large sample. The conclusion here is not that the null hypothesis has been proven, but that, based on the confidence intervals of our AUC point estimates, we infer that any observable difference in predictive performance between these 2 scores is small and unlikely to be clinically meaningful.

External validation of prognostic scores is imperative and often neglected, although performance in derivation cohorts usually exaggerates a model's predictive accuracy due to overfitting, unique characteristics of the derivation cohort, and other factors.[5,10] Although many thousands of papers are published per year reporting new prognostic scores or clinical prediction rules (e.g., 15,662 in 2005), a very small number undergo validation and are found sufficiently superior to enter clinical use and influence physician behavior or patient outcomes.[11] For example, the publication of the ICH-FOS score, which included large derivation and

Table 2 Patient characteristics

|	Maximally treated	Early care limitations	*p* Value
No. of patients	301	71	
Age, y	65.1 ± 14.1	72.6 ± 13.8	<0.001
Sex, F	148 (49)	40 (56)	0.34
Race			0.51
Unknown/other	2 (<1)	0 (0)	
American Indian/Native Alaskan	2 (<1)	0 (0)	
Asian	4 (1)	0 (0)	
Black or African American	128 (43)	24 (34)	
Native Pacific Islander	6 (2)	2 (3)	
White	159 (53)	45 (63)	
Hispanic ethnicity	25 (8)	5 (7)	0.99
Admission GCS score	13 (8–15)	6 (4–11.5)	<0.001
Admission NIHSS score	10 (4–20)	23.5 (15.25–28)	<0.001
Initial hematoma volume, mL	12.2 (5–30)	35.5 (15–74.2)	<0.001
Intraventricular hemorrhage on presentation	142 (47)	52 (73)	<0.001
Lobar location	120 (40)	36 (51)	0.13
Infratentorial location	37 (12)	12 (17)	0.33
Oral anticoagulant use	40 (13)	13 (18)	0.37
Admission systolic blood pressure, mm Hg	179 ± 42	180 ± 43	0.98
max-ICH score	3 (1–5)	5 (4–7)	<0.001
ICH score	1 (0–3)	3 (2–4)	<0.001
Hospital length of stay, d	9 (5–18)	4.5 (2–10)	<0.001
Died in hospital	53 (10.3)	58 (78.4)	<0.001
Poor functional outcome (modified Rankin Scale score 4–6) at 3 mo	165 (55)	71 (100)	<0.001
Dead at 3 mo	82 (27)	71 (100)	<0.001

Abbreviations: GCS = Glasgow Coma Scale; ICH = intracerebral hemorrhage; NIHSS = NIH Stroke Scale.
Data are provided as n (%), mean ± SD, or median (interquartile range).

validation samples, compared its performance to 8 other published ICH severity scales, and despite reporting modestly superior accuracy of the ICH-FOS and Essen-ICH scores compared to the ICH score, a shift to their use has not been observed.[8] Other studies comparing the ICH score to other novel or modified scores have yielded similarly findings.[12,13] Most recently, in fact, 7 ICH prognostic scores including the max-ICH score were compared for prediction of functional outcomes and death in a registry of 2,851 Chinese patients (or 2,581 patients per the abstract) representing a mixture of maximally treated and nonmaximally treated patients.[14] There was no difference between the accuracy of the ICH score and max-ICH score for predicting death (AUC 0.81 for both scores, *p* = 0.85), but the max-ICH score was found to be inferior to both the ICH-FOS

and Essen-ICH scores (AUC 0.83, *p* < 0.001, and AUC 0.83, *p* = 0.005, respectively). For functional outcomes, while the performance of the max-ICH score was superior to the ICH score (AUC 0.83 vs 0.77, *p* = 0.003), it was similar to ICH-FOS (AUC 0.85, *p* = 0.36) and inferior to Essen-ICH (AUC 0.84, *p* < 0.001). There was no separate analysis of maximally treated patients.[14] The results of this validation study suggest that the superior performance of the max-ICH score compared to the ICH score in the max-ICH derivation study may be associated with relative overfitting.

While several severity metrics have been proposed to assess patients with ICH, the ICH score has been formally externally validated, is the most widely used risk adjustment score in clinical ICH research, and is now the standardized core

Figure 1 Mortality and poor outcome by ICH score and max-ICH score rank
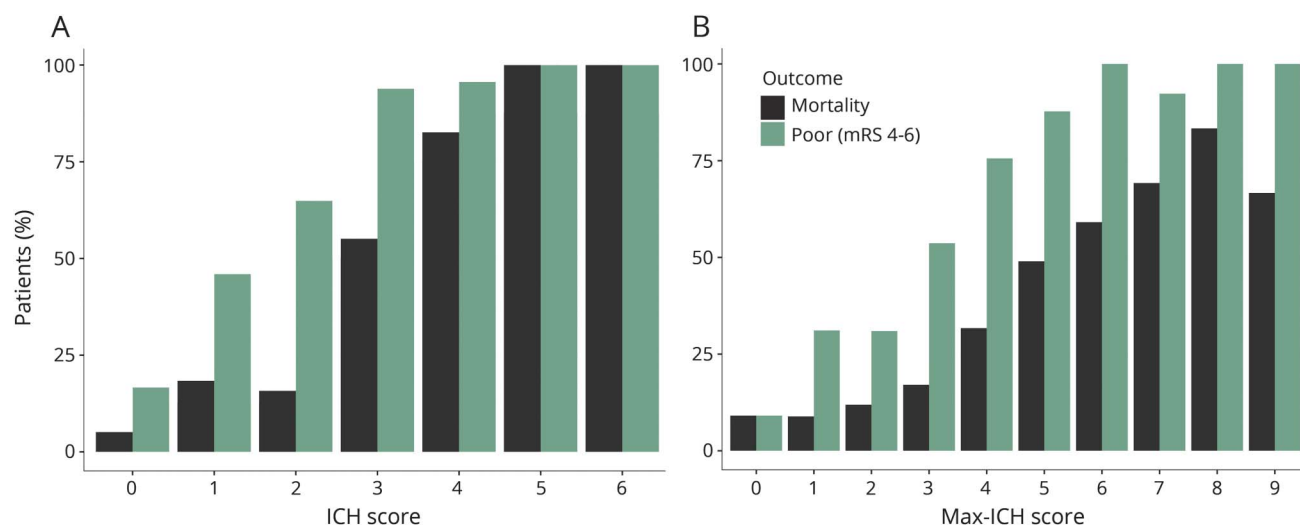
Observed mortality (black) and poor outcome (green) rates are shown for the ICH score (A) and max-ICH score (B) for each score rank in the maximally treated group. ICH = intracerebral hemorrhage; mRS = modified Rankin Scale.

measure (CSTK-03) required to be collected for every ICH admission to comprehensive stroke centers accredited by the Joint Commission.[9] Replacing the well-entrenched ICH score would require a compellingly improved system, and marginal improvements in prognostication based on initial findings may be an unfruitful pathway. At least 10 ICH severity scales have been derived and published without any emerging as sufficiently superior to the ICH score to supplant it. Only so much about the future is truly knowable at the time of admission, which limits the performance of prognostic scores based on admission data, yet other approaches may be useful. Delayed reassessment is a promising alternative. The majority of neurologic changes, both improvement and deterioration, occur early, and early reassessment can capture and incorporate those useful data to yield a more informative prognostic picture.[1] Moreover, a prospective study has confirmed that delaying goals of care decision making in ICH reduces overall mortality.[3] Finally, experienced practitioners discern prognosis better than

simple prognostic scores in patients with ICH, incorporating knowledge about comorbidities and other factors not considered in score formulas.[15,16]

The characteristics of the study participants are similar to the derivation study. Although noncategorical variables cannot be statistically compared, patients were generally near 70 years old, and about 5 years older in the care limitations group. ICH scores were 3 and 1 in the early care limitation and maximally treated groups here compared to 4 and 1 in the derivation study, and NIHSS scores were 23.5 and 10 in the current study vs 29 and 11 in the original. Large differences in intraventricular hemorrhage and hematoma volume were present between the care limitation and maximal care groups in both studies, as expected.
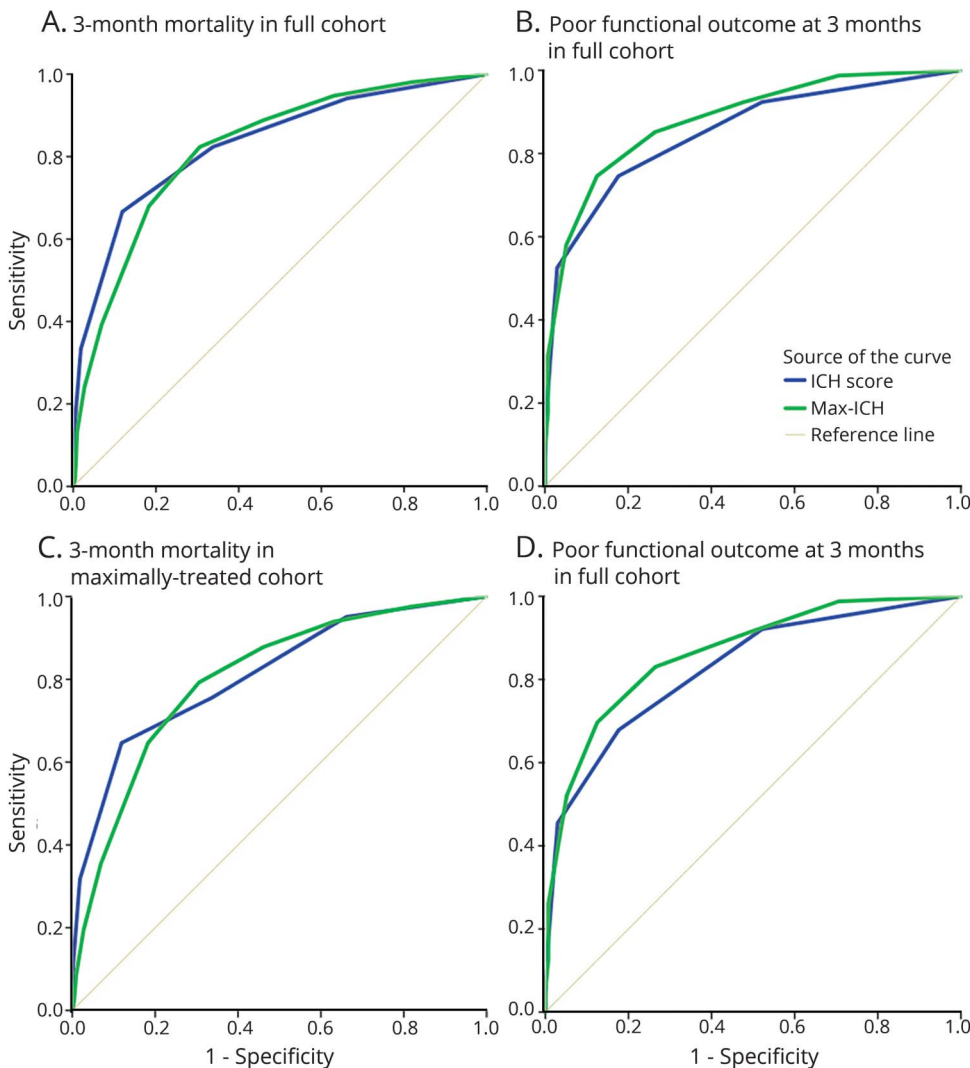
Although this study conforms to recommendations of the TRIPOD Statement, there are limitations because of differences

Table 3 Receiver operating characteristic curve analyses

| Group and outcome | Score model | | | | |
| | ICH score | | max-ICH score | | |
	AUC (95% CI)	p	AUC (95% CI)	p	p for AUC difference
Mortality in full group	0.83 (0.79–0.88)	<0.001	0.82 (0.78–0.86)	<0.001	0.69
Poor functional outcomes in full group	0.85 (0.81–0.89)	<0.001	0.88 (0.85–0.92)	<0.001	0.34
Mortality in maximal treatment subgroup	0.81 (0.76–0.87)	<0.001	0.80 (0.75–0.86)	<0.001	0.80
Poor functional outcomes in maximal treatment subgroup	0.83 (0.78–0.87)	<0.001	0.86 (0.82–0.90)	<0.001	0.28

Abbreviations: AUC = area under the receiver operating characteristic curve; CI = confidence interval; ICH = intracerebral hemorrhage.
p: asymptotic p value for AUC and Hanley and McNeil p value for AUC comparison.

A. 3-month mortality in full cohort

B. Poor functional outcome at 3 months in full cohort

C. 3-month mortality in maximally-treated cohort

D. Poor functional outcome at 3 months in full cohort

Source of the curve
ICH score
Max-ICH
Reference line

ROC curves are shown for the ICH score and max-ICH score for prediction of mortality and poor functional outcomes at 3 months in the full group (n = 372, panels A and B) and the maximal treatment subgroup (n = 301, panels C and D). ICH = intracerebral hemorrhage; ROC = receiver operating characteristic.

between the derivation study and this study. Maximal treatment was defined in the max-ICH score derivation study by excluding patients with care limitations instituted within the first 24 hours, as determined retrospectively. We excluded patients with care limitations occurring anytime within their intensive care stay as prospectively recorded in our database. The inclusion of patients with later intensive care unit care limitations may account for some of the difference in prognostic score performance between the original study and this validation study. Our broader definition of care limitations may capture more instances of self-fulfilling poor outcome due to later care withdrawal and nonmaximal treatment, but the influence of different definitions of maximal treatment is not known. Moreover, it remains possible that customary care practices and ethnographic factors differ between North American and European centers in that the effects of early care limitations differ in groups like the German derivation sample of the max-ICH score in such a way that the max-ICH score may demonstrate superiority. Similarly, this is a single-center study in which some institutional practices may

not generalize. We were unable to obtain functional outcomes in approximately one-third of patients treated in our center. The initial clinical severity and ages were not different between the analyzed patients and patients missing follow-up data, either in the maximally treated or full groups. Because the components of these 2 scores are similar, a pattern of missing data influencing one much greater than the other is unlikely, but we cannot exclude the possibility that a biased pattern of missing data influenced our results. There were differences in the way functional outcomes were measured. The max-ICH derivation study used 12-month mRS as the primary outcome measure, which they primarily obtained by responses on a mailed questionnaire, and used a propensity score matching technique to estimate theoretical outcomes that may have been observed in patients who had early care limitations.[4] This study used 3-month mRS as the primary outcome. We may have missed measuring late improvements in some patients. Other studies have shown that functional improvements after ICH happen mostly within the first 3 months, and that improvements between 3 and 12 months

Table 4 Model performance and calibration characteristics

| | Score model | | | |
| | ICH score | | max-ICH score | |
Group and outcome	Likelihood ratio χ^2	Unweighted sum of squared errors	Likelihood ratio χ^2	Unweighted sum of squared errors
Mortality in full group	$\chi^2 = 145.2$, $p < 0.001$	$z = -0.77$, $p = 0.44$	$\chi^2 = 109.8$, $p < 0.001$	$z = -1.59$, $p = 0.11$
Poor functional outcomes in full group	$\chi^2 = 156.5$, $p < 0.001$	$z = 0.95$, $p = 0.34$	$\chi^2 = 168.9$, $p < 0.001$	$z = 1.03$, $p = 0.30$
Mortality in maximal treatment subgroup	$\chi^2 = 89.9$, $p < 0.001$	$z = -1.24$, $p = 0.21$	$\chi^2 = 64.4$, $p < 0.001$	$z = -0.96$, $p = 0.34$
Poor functional outcomes in maximal treatment subgroup	$\chi^2 = 116.5$, $p < 0.001$	$z = 0.78$, $p = 0.43$	$\chi^2 = 132.8$, $p < 0.001$	$z = 0.51$, $p = 0.61$

Abbreviation: ICH = intracerebral hemorrhage.

are too slight to measure by mRS.[17,18] Not having measured late improvements in functional outcomes would affect the results of this study if the max-ICH score were uniquely more sensitive to predicting late changes between 3 and 12 months. Moreover, we used a structured interview technique to ascertain the mRS score, which has been validated as reliable.[1] Finally, the sample size of the maximally treated subgroup (301 patients) is not large enough to validate a small difference between the ICH score and max-ICH score. A much larger cohort of maximally treated patients with ICH could be used to confirm a small magnitude of superiority of one prognostic scoring system over others, just as the Essen-ICH score was confirmed to be modestly superior to the max-ICH score and ICH score in unselected patients.[8,14] Citing the 10 related publications, the summary of this topic in the American Heart Association Guidelines for the Management of Spontaneous Intracerebral Hemorrhage appears to have held true over time: "Numerous grading scales exist specifically for ICH. Although the optimal severity scale is not yet clear, the most widely used and externally validated is the ICH score. These severity scales should not be used as a singular indicator of prognosis."[19]

Author contributions

Dr. Schmidt: interpretation of the data and revising the manuscript for intellectual content. Dr. Liotta: acquisition of data, interpretation of the data, and revising the manuscript for intellectual content. Dr. Prabhakaran: interpretation of the data and revising the manuscript for intellectual content. Dr. Naidech: design of the study, acquisition of data, interpretation of the data, and revising the manuscript for intellectual content. Dr. Maas: design and conceptualization of the study, acquisition of data, analysis and interpretation of the data, drafting the manuscript, and revising the manuscript for intellectual content.

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Disclosure

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