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Traditional and machine learning models for predicting haemorrhagic transformation in ischaemic stroke: a systematic review and meta-analysis

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Abstract

Background Haemorrhagic transformation (HT) is a severe complication after ischaemic stroke, but identifying patients at high risks remains challenging. Although numerous prediction models have been developed for HT following thrombolysis, thrombectomy, or spontaneous occurrence, a comprehensive summary is lacking. This study aimed to review and compare traditional and machine learning-based HT prediction models, focusing on their development, validation, and diagnostic accuracy.

Methods PubMed and Ovid-Embase were searched for observational studies or randomised controlled trials related to traditional or machine learning-based models. Data were extracted according to Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS) checklist and risk of bias was assessed using the Prediction model Risk Of Bias ASsessment Tool (PROBAST). Performance data for prediction models that were externally validated at least twice and showed low risk of bias were meta-analysed.

Results A total of 100 studies were included, with 67 focusing on model development and 33 on model validation. Among 67 model development studies, 44 were traditional model studies involving 47 prediction models (with National Institutes of Health Stroke Scale score being the most frequently used predictor in 35 models), and 23 studies focused on machine learning prediction models (with support vector machines being the most common algorithm, used in 10 models). The 33 validation studies externally validated 34 traditional prediction models. Regarding study quality, 26 studies were assessed as having a low risk of bias, 11 as unclear, and 63 as high risk of bias. Meta-analysis of 15 studies validating eight models showed a pooled area under the receiver operating characteristic curve of approximately 0.70 for predicting HT.

Conclusion While significant progress has been made in developing HT prediction models, both traditional and machine learning-based models still have limitations in methodological rigour, predictive accuracy, and clinical applicability. Future models should undergo more rigorous validation, adhere to standardised reporting frameworks,

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and prioritise predictors that are both statistically significant and clinically meaningful. Collaborative efforts across research groups are essential for validating these models in diverse populations and improving their broader applicability in clinical practice.

Systematic review registration International Prospective Register of Systematic Reviews (CRD42022332816).

Keywords Ischaemic stroke, Haemorrhagic transformation, Prediction model

Background

Stroke is the leading cause of death and disability in the world [1] and haemorrhagic transformation (HT) is a potentially devastating complication after acute ischaemic stroke [2]. HT may occur spontaneously during acute phase of stroke, or as a complication of interventions such as thrombectomy, thrombolysis, dual antiplatelet, and anticoagulation [3]. HT is associated with poor outcome after ischaemic stroke and contributes to the underutilisation of reperfusion therapies [4]. Identifying patients at high risk of HT has so far proved challenging [5]. Numerous prediction models have been developed to predict HT after thrombolysis [6], after thrombectomy, or spontaneously, but none has yet to be incorporated into consensus clinical guidelines because of their less than satisfactory performance [7]. With advancement in technology and medical informatics in recent decades, a large volume of ischaemic stroke data has been generated and stored in structured electronic formats worldwide, facilitating the use of artificial intelligence approaches such as machine learning for developing prediction models [8]. It is not immediately clear how these prediction models have been developed, whether they have been validated, or how they compare to each other. Given the emerging evidence, we aimed to perform a systematic review and meta-analysis to identify all traditional and machine learning models for predicting HT, describe their development and validation, and compare their diagnostic accuracies.

Methods

We reported this systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA) [9]. The study protocol was registered with PROSPERO International Prospective Register of Systematic Reviews under registration number CRD42022332816.

Literature searching

We systematically searched PubMed and Ovid-Embase for potentially eligible studies from database inception through March 1, 2022. This search was subsequently updated on October 16, 2023 and again October 31, 2024. Search terms included ischemic stroke, ischaemic stroke, haemorrhagic transformation, haemorrhagic transformation, intracerebral haemorrhage, intracerebral haemorrhage, prediction, predicting, predictive, score, and model. The reference lists of potentially eligible studies were manually checked to identify additional studies. Full search strategies were available in Supplement 1.

Eligibility criteria

We included observational studies or randomised controlled trials in Chinese or English that reported new models or validation of existing models to predict HT after ischaemic stroke, regardless of thrombolysis or thrombectomy. We excluded reviews, case studies, editorials, letters, and meeting abstracts. We also excluded original research studies if they only explored predictors of HT without constructing a formal model.

Study selection and quality assessment

Two reviewers (Zengyi Zhang and Zhimeng Zhang) independently screened the databases for eligible studies based on titles and abstracts, followed by reading of the full text. Disagreements about study inclusion were resolved through discussion with a third investigator (Yanan Wang or Junfeng Liu). The quality of included studies was assessed using the Prediction model Risk Of Bias ASsessment Tool (PROBAST) [10]. The risk of bias was assessed across four domains of PROBAST (participants, predictors, outcome, and analysis), while applicability was evaluated across three domains (participants, predictors, and outcome).

Data extraction

Two reviewers (Zengyi Zhang and Zhimeng Zhang) independently extracted data using a predefined form based on the Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS) checklist [11], which included information about study characteristics, predictors, and model development and validation, as follows: (1) Study characteristics: first author, publication year, study country, study population, study type, number of centres, source of data, outcome measure, and events. (2)

Predictors: predictors were categorised into various domains, including demographics, clinical characteristics, laboratory examination, imaging findings, and genes. (3) Model development and validation: model name, modelling methods, calibration, discrimination, model validation, and prediction format. Modelling methods included logistic regression, literature review, and machine learning, etc. Calibration of models was conducted by Hosmer-Lemeshow goodness-of-fit test or calibration plots. Discrimination of models was evaluated using the area under the receiver operating characteristic curve (AUC). Model validation included internal and external validation. Presentations of models included risk scores, nomogram, and classifier-based framework, etc.

Outcome measure

The primary outcome measure was any HT, defined as the presence of haemorrhage within the infarct territory or as parenchymal haemorrhage outside the infarct zone. This haemorrhage was not visible on the initial CT or MRI scan after ischaemic stroke but was detected on follow-up imaging. Secondary outcome measures included radiological and clinical subtypes of HT. Radiological subtypes, classified according to criteria of European-Australian Cooperative Acute Stroke Study (ECASS) II, included haemorrhagic infarction (HI) and parenchymal haematoma (PH) [7]. Clinical subtypes consisted of symptomatic intracerebral haemorrhage (sICH) and asymptomatic intracerebral haemorrhage (aICH). The classification criteria for sICH included the criteria of National Institutes of Neurological Diseases and Stroke (NINDS), Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST), ECASS II, ECASS III, the Third International Stroke Trial (IST-3), and Heidelberg Bleeding Classification (HBC) [12].

Statistical analysis

Qualitative data synthesis of prediction models

We categorised the included studies into two types: model development studies (which establish and validate prediction models) and validation studies (which conduct external validation of existing models). A descriptive analysis was then performed for each type. For model development studies, we summarised study population characteristics, types of predictors, types of outcome measures, model development methods, and presentation formats. For studies that use machine learning to develop prediction models, we summarised the machine learning algorithms. We also evaluated model performance, including discrimination and calibration. For validation studies, we focused on summarising study population characteristics, types of outcome measures, and model performance evaluation (including discrimination and calibration). Additionally, we conducted separate qualitative analyses of the risk of bias and applicability for each study type.

Quantitative analysis and comparison of the performance of prediction models

For validation studies, we conducted meta-analyses based on the type of prediction model and type of HT. However, three conditions must be met simultaneously: (1) The model has at least two external validation studies; (2) Risk of bias was assessed as low risk; (3) AUC and 95% confidence interval (CI) were provided. AUC values are interpreted as follows: values less than 0.6 indicate poor performance, 0.6–0.69 suggest moderate performance, 0.7–0.79 reflect good performance, 0.8–0.89 indicate very good performance, and values greater than 0.9 demonstrate excellent performance [13]. We calculated the pooled effect size using the random effects model and evaluated the heterogeneity using the I^2 statistic, with thresholds of 25%, 50%, or 75% indicating low, moderate, or high heterogeneity, respectively. Publication bias was assessed through visual inspection of funnel plots. The impact of potential publication bias on pooled estimates was analysed using the 'trim-and-fill' method [14]. Data were analysed using Stata 18.0 (Stata Corp, College Station, TX, USA). $P<0.05$ was considered statistically significant.

Results

We identified 12,335 articles in our initial database search in March 2022 and included 62 of these in our study. An additional 28 articles were included from an updated search in October 2023, and a final update on October 31, 2024, identified 10 articles for inclusion. Finally, 100 studies were included: 67 focused on model development [15–81] and 33 on model validation [82–114] (Fig. 1).

Model development studies

Among the 67 model development studies, 44 studies developed 47 traditional prediction models, whereas 23 studies developed machine learning models. A total of 61 studies included both derivation and internal validation stages, while six studies focused exclusively on derivation. The study populations varied, with ischaemic stroke patients treated with thrombolysis comprising the largest group ($n=35$), followed by those undergoing thrombectomy ($n=14$), general ischaemic stroke patients ($n=11$), without thrombolysis or thrombectomy ($n=5$), and with thrombolysis or thrombectomy ($n=2$). Centre settings included 38 multicentre studies, 27 single-centre studies, and two studies that did not specify centre status. Most

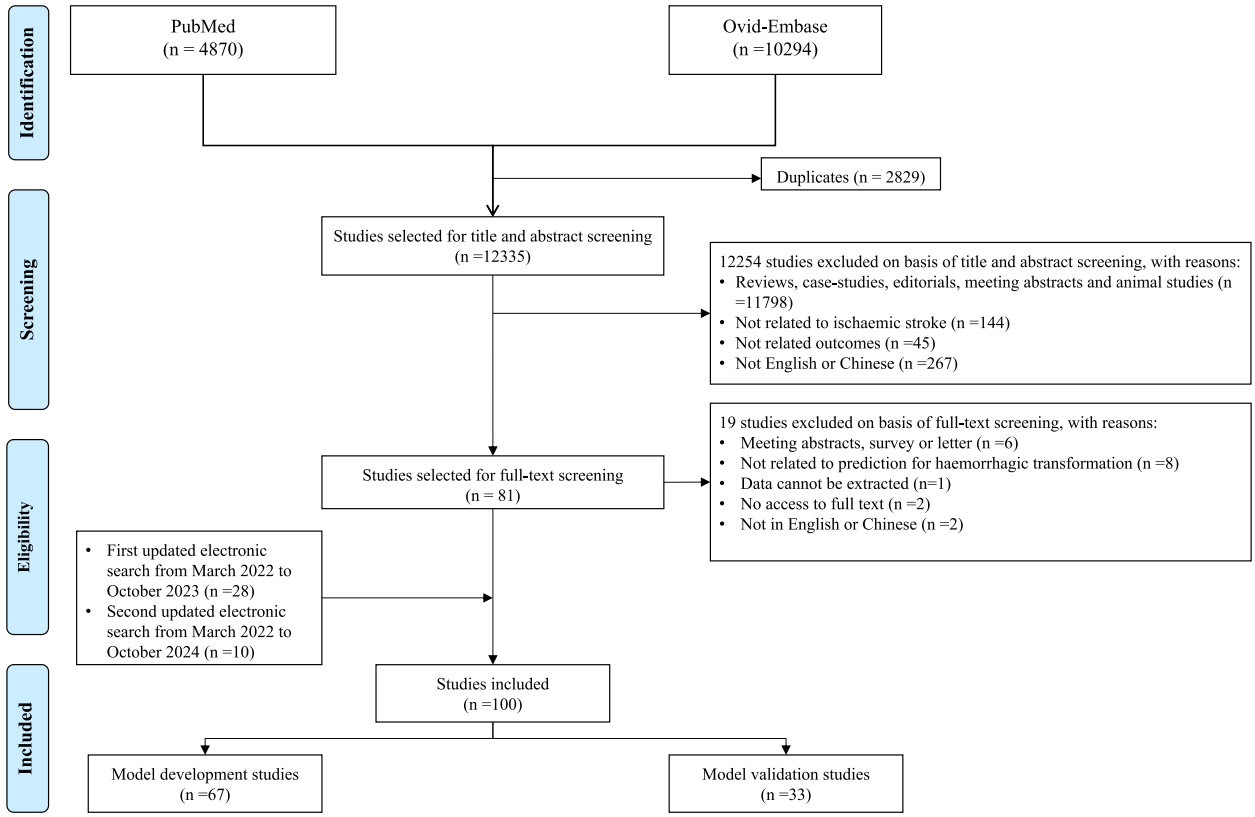

Fig. 1 Flowchart of study selection

studies assessed any HT ($n=39$) as the outcome measure, with additional radiological subtypes, such as HI ($n=2$) and PH ($n=6$), and clinical subtypes of sICH ($n=37$). Criteria for sICH classification included NINDS ($n=13$), ECASS II ($n=16$), and ECASS III ($n=5$) (Table 1 and Supplemental Table 1).

Of the 44 traditional prediction model studies, logistic regression was the predominant method (40 studies), while three studies derived models from literature reviews, and one study did not specify the model development method (Supplemental Table 1). Among the 23 machine learning model studies, support vector machines were the most common algorithm ($n=10$), followed by logistic regression ($n=8$) and random forest ($n=7$) (Supplemental Table 2).

The most frequent predictors in traditional models included the National Institutes of Health Stroke Scale score (NIHSS; $n=35$), blood glucose ($n=23$), age ($n=18$), Alberta Stroke Program Early Computerised Tomography Score ($n=15$), atrial fibrillation ($n=12$), and systolic blood pressure ($n=11$) (Fig. 2 and Supplemental Table 3). Presentation methods for traditional prediction models primarily included risk scores ($n=24$) and nomograms ($n=17$). All studies reported AUC for model discrimination, with 38 studies also reporting calibration results using the Hosmer–Lemeshow test ($n=13$), calibration plots ($n=14$), or both ($n=11$) (Supplemental Table 1).

Risk of bias was assessed across the 67 studies, with 56 rated as high risk, 10 as unclear, and only one as low risk. Bias was primarily concentrated in the analysis domain, with 53 studies exhibiting high risk due to issues such as inadequate sample sizes, dichotomisation of continuous variables, improper handling of missing data, and reliance on univariate analysis for predictor selection. In the participant domain, 19 studies were rated as high risk, primarily due to reliance on retrospective data sources. All 67 studies demonstrated a low risk of bias in the predictor domain, and 66 showed a low risk of bias in the outcome domain. Applicability was generally favourable across participants, predictors, and outcomes (Supplemental Table 4).

Model validation studies

All 33 studies focused exclusively on external validation of traditional prediction models; no machine learning models were included. The primary study population was ischaemic stroke patients treated with thrombolysis

Table 1 Summary of baseline characteristics of included studies

	Model development studies ($n = 67$)	Model validation studies ($n = 33$)
Publication year		
2008–2013	9	6
2014–2019	13	20
2020–2024	45	7
Type of study		
Derivation	6	0
Derivation and validation	61	0
Validation	0	33
Type of prediction model		
Traditional model	44	33
Machine learning model	23	0
Study population		
General ischaemic stroke	11	5
Ischaemic stroke with an indication for anticoagulation	0	1
Ischaemic stroke with thrombectomy	14	4
Ischaemic stroke with thrombolysis	35	23
Ischaemic stroke with thrombolysis or thrombectomy	2	
Ischaemic stroke without thrombolysis or thrombectomy	5	0
Multicentre		
Yes	38	20
No	27	13
Not reported	2	
Type of haemorrhagic transformation		
Any haemorrhagic transformation	39	11
Radiological category		
Haemorrhagic infarction	2	0
Parenchymal haemorrhage	6	1
Clinical category		
aICH	2	2
sICH	37	29
NINDS	13	15
SITS-MOST	3	12
ECASS II	16	16
ECASS III	5	2
IST-3	1	0
HBC	4	1

Abbreviations: *aICH* Asymptomatic intracerebral haemorrhage, *sICH* Symptomatic intracerebral haemorrhage, *NINDS* National Institutes of Neurological Diseases and Stroke, *SITS-MOST* Safe Implementation of Thrombolysis in Stroke-Monitoring Study, *ECASS II* European-Australian Cooperative Acute Stroke Study II, *ECASS III* European-Australian Cooperative Acute Stroke Study III, *IST-3* The Third International Stroke Trial, *HBC* Heidelberg Bleeding Classification

($n=23$), with additional groups including general ischaemic stroke patients ($n=5$), patients treated with thrombectomy ($n=4$), and a small group with specific indications for anticoagulation ($n=1$). Centre settings included 20 multicentre and 13 single-centre studies. The most frequently reported outcome measure was sICH ($n=29$). Criteria for sICH classification included NINDS ($n=15$), ECASS II ($n=16$), and SITS-MOST ($n=12$) (Table 1. and Supplemental Table 1). AUC for discrimination was reported in 31 studies, and calibration was reported in 11 studies, with eight using the Hosmer–Lemeshow test, two using calibration plots or curves, and one study using both (Supplemental Table 1).

Of the 33 validation studies, 25 were rated as low risk of bias, one as unclear, and seven as high risk. In the participant domain, three studies were rated as high risk, mainly due to reliance on retrospective data sources. All studies showed low risk of bias in the predictor and outcome domains. In the analysis domain, five studies were rated as high risk, with two studies having inadequate

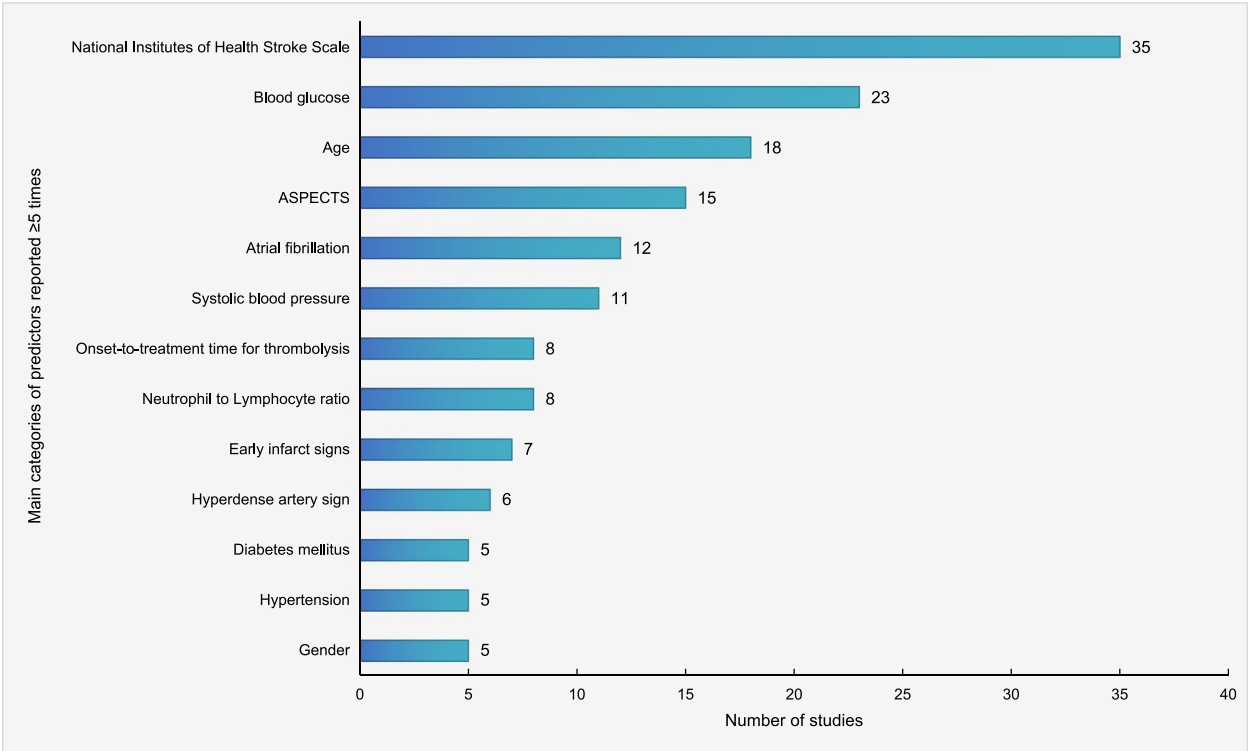

Fig. 2 Main categories of predictors reported ≥ 5 times in traditional model development studies. ASPECTS, Alberta Stroke Program Early Computerised Tomography Score

sample sizes ($n < 100$) and four not fully evaluating prediction model performance. Applicability was generally favourable across participants, predictors, and outcomes (Supplemental Table 4).

Meta-analysis of prediction model performance

A total of 15 studies [87, 89–91, 94, 96, 98, 99, 101, 103, 105, 107, 112–114] were included in the meta-analysis, encompassing the external validation of eight models. For predicting any HT, three studies that validated seven models identified the 'Sugar-Early infarct signs-Dense artery sign-Age-NIHSS' (SEDAN) score as having the highest discrimination (AUC 0.70, 95% CI 0.67–0.73; $I^2 = 0.06\%$; Fig. 3A). For predicting sICH per NINDS criteria, nine studies validating seven models showed that the 'Haemorrhage After Thrombolysis' (HAT) score and the 'Glucose-Race-Age-Sex-Pressure-Stroke severity' (GRASPS) achieved the best discrimination (AUC 0.69 Fig. 3B). For predicting sICH per SITS-MOST criteria, seven studies validating seven models found similar AUCs (around 0.68) for the HAT (Haemorrhage after Thrombolysis), GRASPS, Multicentre Stroke Survey (MSS), and Safe Implementation of Treatments in Stroke Symptomatic Intracerebral Haemorrhage Risk (SITS-SICH) scores (Fig. 3C). For predicting sICH ECASS II criteria, ten studies validating seven models demonstrated that the HAT and MSS score had the best discrimination (AUC 0.69 Fig. 3D). No publication bias was detected (Supplemental Fig. 1).

Discussion

This systematic review and meta-analysis identified 47 traditional and 23 machine learning-based prediction models for HT after ischaemic stroke. Traditional models predominantly employed logistic regression, with key predictors such as NIHSS, blood glucose, and age being most commonly included. Among these traditional models, 34 were externally validated, and eight were validated at least twice in low-risk studies, achieving pooled AUCs of approximately 0.70. In contrast, machine learning models exhibited substantial variability in performance, with AUCs ranging from 0.42 to 0.99. Regarding study quality, 26 studies were assessed as having a low risk of bias, 11 as unclear, and 63 as high risk of bias.

Despite the promise of these models, the selection of predictors remains a critical challenge. Most traditional models rely heavily on statistical methods for predictor selection, often without considering clinical relevance, which may introduce selection bias [115]. Only a small subset of studies reviewed the literature to identify

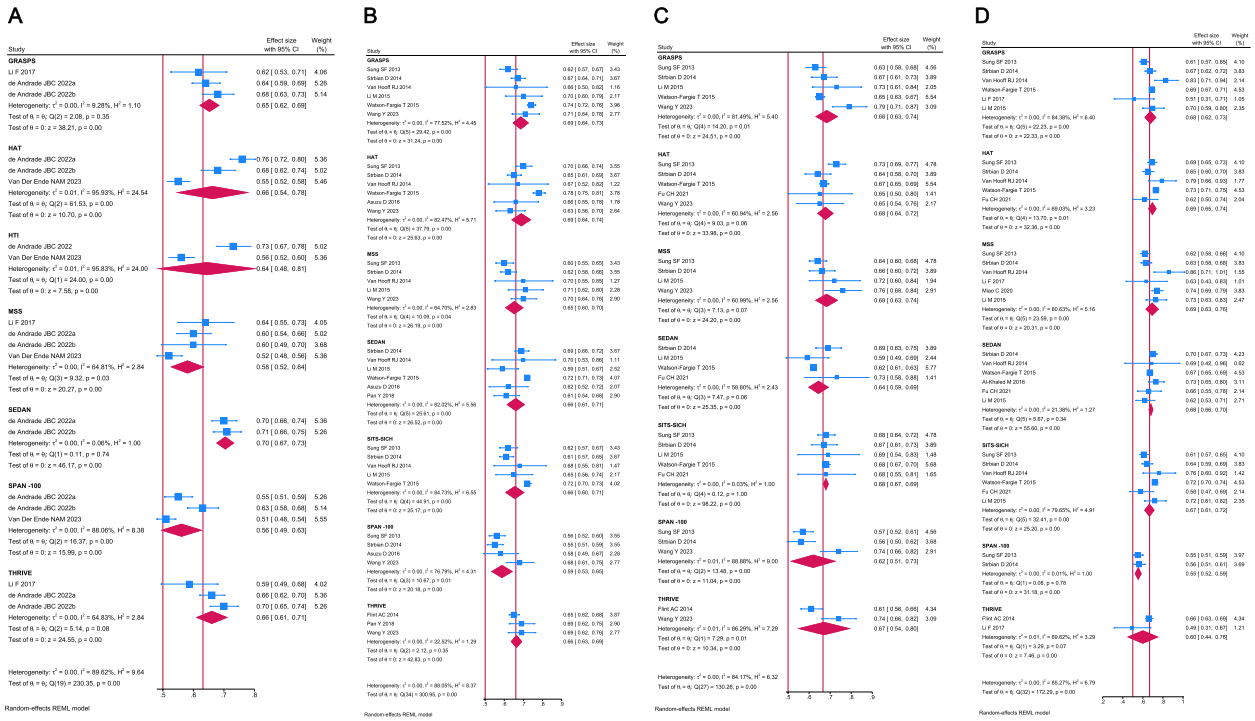

Fig. 3 Meta-analysis of the area under the receiver operating characteristic curve of different models for predicting haemorrhagic transformation after acute ischaemic stroke, where such outcome was defined as any type of haemorrhagic transformation (**A**) or as symptomatic intracerebral haemorrhage diagnosed according to the criteria of the National Institutes of Neurological Diseases and Stroke (**B**), Safe Implementation of Thrombolysis in Stroke-Monitoring Study (**C**), or European-Australian Cooperative Acute Stroke Study II (**D**)

predictors that were both statistically and clinically significant [16, 22, 70]. Among the frequently used predictors in traditional models were NIHSS, blood glucose, and age, all of which have robust support in the literature for their association with HT risk [3, 7, 116–118]. Systolic blood pressure was another commonly included predictor and has shown a consistent relationship with HT risk [119–122]. Stroke type, such as those based on the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification and Oxfordshire community stroke project (OCSP) classification, was also frequently used [35, 45, 50, 63]; however, the accurate determination of stroke type shortly after admission remains challenging and limits their utility in clinical practice. Additionally, genetic and imaging predictors, including single-nucleotide polymorphisms [17, 110] and the Alberta Stroke Program Early Computerised Tomography Score, show promise, but are often impractical in the acute phase of stroke due to time and resource constraints. These challenges highlight the need for consensus on a core set of reliable and feasible predictors that can be standardised across models to enhance clinical utility.

Regarding the AUC performance of the models, traditional models showed an AUC around 0.70, indicating that these models have a moderate or good ability to predict HT. While this suggests that they offer reliable predictions for identifying high-risk patients, there is significant room for improvement in terms of predictive accuracy and clinical utility. In contrast, machine learning models exhibited a wide range of AUC values (0.42–0.99), reflecting substantial variability in performance. Some models demonstrated excellent performance (AUC > 0.9), while others had poor predictive value (AUC < 0.5). This variation could be attributed to differences in model type, the quality of data used, and the selection of predictors.

Although machine learning models have the potential to improve prediction accuracy, they still face challenges related to their clinical feasibility and generalisability, especially when incorporating complex data such as radiomic and other imaging data [18, 23, 24, 32, 44, 54, 55, 66, 68, 72, 73, 75–77, 80, 81]. The reliance on these data types introduces practical challenges, as the collection and processing of radiomic data can be time-consuming and resource-intensive. These factors limit the implementation of such models in acute stroke care. Therefore, future machine learning models should focus on simplifying input requirements without sacrificing predictive accuracy. Additionally, integrating diverse data sources—such as clinical, imaging, and laboratory

variables—may improve model comprehensiveness but also presents challenges related to data harmonisation and standardisation.

Methodological weaknesses were evident across many of the included studies. A substantial proportion relied on retrospective data, which is associated with a higher risk of bias. Small sample sizes were also common, with many studies failing to meet the recommended sample size ratio for predictor-to-outcome events. The dichotomisation of continuous variables often led to the loss of valuable information, further increasing the risk of bias. Furthermore, many studies inadequately addressed missing data, either by excluding patients with incomplete data or using inappropriate imputation methods. Calibration assessments were often insufficient, with 51 studies failing to assess calibration altogether, and many that did used the Hosmer-Lemeshow test, which may not be suitable for complex models involving multiple predictors [123]. These methodological issues raise concerns about the reliability and generalisability of the models, while the PROBAST tool published in 2019 [10] has improved bias assessment, its inconsistent application in studies published after 2019 highlights the need for broader adoption of standardised reporting frameworks. Moreover, future studies should prioritise external validation cohorts to ensure that prediction models are robust and applicable across diverse clinical settings.

Future research should focus on addressing the methodological limitations identified in this review. Specifically, studies should prioritise prospective, multicentre studies with larger, more diverse sample sizes to improve generalisability. External validation cohorts should be used to ensure the reliability of prediction models across various clinical settings. Additionally, the selection and definition of key predictors, particularly stroke classification and imaging biomarkers, should be more consistent across studies. Simplifying prediction models, while maintaining predictive power, will be critical for enhancing their utility in acute stroke care. Furthermore, it is essential that future studies not only assess the accuracy of models but also their clinical feasibility, ensuring that models can be easily implemented in routine practice without requiring significant resources or specialised expertise.

There are several limitations to this systematic review and meta-analysis. First, in addition to AUC, other metrics like the net reclassification index, integrated discrimination index, net benefit, and decision curve analysis [124] can also assess model performance. However, these metrics were reported in only a few studies, so we did not conduct a pooled analysis for them. Second, there was significant heterogeneity in the meta-analysis results. This variability, due to differences in study populations, treatment protocols, and outcome definitions, limited the ability to perform meaningful subgroup analyses. Third, the variability in the predictors used in machine learning models and the lack of external validation for these models prevented their inclusion in the meta-analysis. Finally, we included only studies published in English and Chinese, which may have introduced language bias.

Conclusion

In conclusion, while substantial progress has been made in developing HT prediction models, both traditional and machine learning-based models still face significant limitations, particularly in terms of methodological rigour, predictive performance, and clinical applicability. To enhance their clinical utility, future models must undergo more rigorous validation, adhere to standardised reporting frameworks, and incorporate predictors that are both statistically significant and clinically meaningful. Collaborative efforts across research groups are essential to validate these models in diverse patient populations, ultimately improving their broader applicability in clinical practice.

Abbreviations

aICH	Asymptomatic intracerebral haemorrhage
AUC	Area under the receiver operating characteristic curve
CHARMS	Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies
CI	Confidence interval
ECASS	European-Australian Cooperative Acute Stroke Study
GRASPS	Glucose-Race-Age-Sex-Pressure-Stroke severity
HAT	Haemorrhage After Thrombolysis
HBC	Heidelberg Bleeding Classification
HI	Haemorrhagic infarction
HT	Haemorrhagic transformation
IST-3	The Third International Stroke Trial
MSS	Multicentre Stroke Survey
NIHSS	National Institutes of Health Stroke Scale
NINDS	National Institutes of Neurological Diseases and Stroke
OCSP	Oxfordshire community stroke project
PH	Parenchymal haematoma
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement
PROBAST	Prediction model Risk Of Bias ASsessment Tool
SEDAN	Sugar-Early infarct signs-Dense artery sign-Age-NIHSS
sICH	Symptomatic intracerebral haemorrhage
SITS-MOST	Safe Implementation of Thrombolysis in Stroke-Monitoring Study
SITS-SICH	Safe Implementation of Treatments in Stroke Symptomatic Intracerebral Haemorrhage Risk
TOAST	Trial of ORG 10172 in Acute Stroke Treatment

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
JL and ML researched literature and conceived the study. YW, ZZ, ZZ, XC, and JL were involved in protocol development, literature search data extraction, and data analysis. YW and JL wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
As no individual patient-level data were used, institutional review board approval and informed consent were not required.

Consent for publication
Not applicable.

Competing interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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